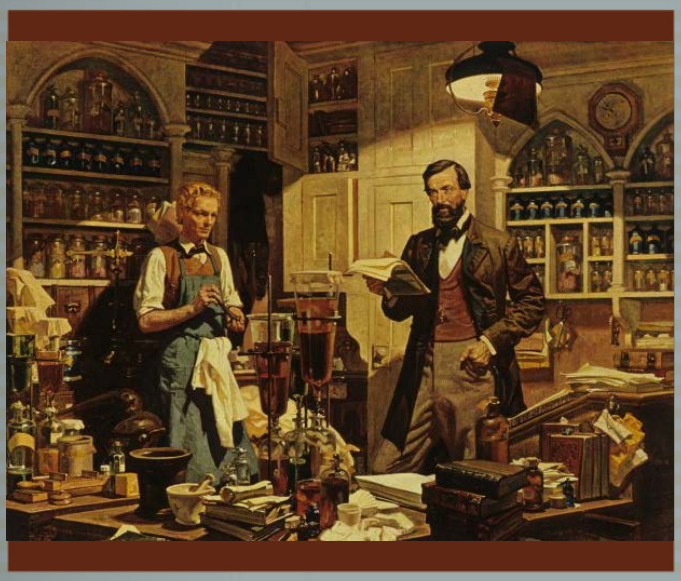
Syllabus for Pharmacy Courses

(B. Pharm & M. Pharm.)



Dr. Babasaheb Ambedkar Marathwada University, Aurangabad

DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY

CIRCULAR NO.ACAD/NP/B.Pharm & M.Pharm./Syllabus/21/ 2013

It is hereby notified for the information of all concerned that, on the recommendation of the Dean, Faculty of Engineering and Technology, the Hon'ble Vice-Chancellor has accepted the ***"Revised Syllabi and Course Structure of B.Pharmacy and M.Pharmacy, under the Faculty of Engineering and Technology"*** on behalf of the Academic Council Under Section-14(7) of the Maharashtra Universities Act, 1994 as appended herewith.

This is effective from the Academic Year 2013-2014 and onwards.

All concerned are requested to note the contents of this circular and bring the notice to the students, teachers and staff for their information and necessary action.

University Campus,
Aurangabad-431 004.
REF.NO. ACAD/NPB.& M.PHARM./
SYLLABI / 2013/ 29437-52

Date:- 08-08-2013.

★★★★★★★

Director,
Board of College and
University Development.

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Copy forwarded with compliments to :-

1] The Principals, affiliated concerned Colleges,
Dr. Babasaheb Ambedkar Marathwada University.

2] The Director, University Network & Information Centre, UNIC, with **a request to upload the syllabi on University Website.**

Copy to :-

1] The Controller of Examinations,

2] The Superintendent, [Engineering Unit],

3] The Programmer [Computer Unit-1] Examinations,

4] The Programmer [Computer Unit-2] Examinations,

5] The Superintendent, [Eligibility Unit] ,

6] The Director, [E-Suvidha Kendra], in-front of Registrar's Quarter,
Dr. Babasaheb Ambedkar Marathwada University,

7] The Record Keeper,
Dr. Babasaheb Ambedkar Marathwada University.

-=**=-

S/150613/-*

Syllabus of Pharmacy Course

(B. Pharm and M. Pharm)

Including amended Regulations, Structure,
Scheme of Examination and Equivalence in Subjects

Dr. Babasaheb Ambedkar
Marathwada University, Aurangabad

All India Council for Technical Education, New Delhi

Dr. Babasaheb Ambedkar Marathwada University, Aurangabad

Industry Institute Partnership Cell Govt. College of Pharmacy, Aurangabad

AICTE,
New Delhi

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TABLE OF CONTENT:

PART - A

B. Pharm. Syllabus

Dr. BabasahebAmbedkarMarathwada University, Aurangabad

Bachelor of Pharmacy (B. Pharm.)

0.527 There shall be eight semester examinations leading to the Degree of Bachelor of Pharmacy (B. Pharm.) namely:

1. The First semester B. Pharm.: Examination at the end of First semester B. Pharm.
2. The Second semester B. Pharm.: Examination at the end of Second semester B.Pharm.
3. The Third semester B. Pharm.: Examination at the end of Third semester B. Pharm.
4. The Fourth semester B. Pharm.: Examination at the end of Fourth semester B. Pharm.
5. The Fifth semester B. Pharm.: Examination at the end of Fifth semester B. Pharm.
6. The Sixth semester B. Pharm.: Examination at the end of Sixth semester B. Pharm.
7. The Seventh semester B. Pharm.: Examination at the end of Seventh semester B. Pharm.
8. The Eighth semester B. Pharm.: Examination at the end of Eighth semester B. Pharm.

0.528 Each semester will be of six months/ 90 working days duration. The examination specified above shall be once per semester at such places and on such dates as may be notified by the University

0.529 An applicant for the admission to the examination specified in ordinance shall complete a regular course of the study in the course prescribed for examination concerned not less than one academic semester (six month) in the college of Pharmacy / Pharmaceutical Sciences recognized by the Dr. BabasahebAmbedkarMarathwada University, Aurangabad.

0.530 A candidate shall be admitted to the first semester B. Pharm. if he / she has:

- Passed the HSC (Std XII) examination of Maharashtra Board of Secondary and Higher Secondary Education or its equivalent examination with
  - English as one of the subject
  - Both subjects mentioned in Group I
  - Any one of the subjects mentioned in Group II

    Group I 1 Physics 2. Chemistry

    Group II: 1. Mathematics 2. Biology
- Secured minimum 45% marks (40% for backward class candidates for Maharashtra State only) in the subject Physics, Chemistry and the subject of maximum marks amongst the subject mentioned in group II of above added together.
- Appeared for Common entrance test conducted by competent authority of Govt. of Maharashtra or Govt. of India, for that academic year and secured non-zero score in that common entrance test.

  The above and further eligibility criteria may be subjected to change from time to time depending upon the rules and regulations of Govt. of Maharashtra.
- If admitted candidate has not appeared for the subject Mathematics / Biology in his HSC (Std. XII) examination then he has to pass this subject from University

examination (Remedial Mathematics / Remedial Biology) or Maharashtra Board of Secondary and Higher Secondary Education examination with minimum passing marks.

0.531

- A candidate shall be admitted to the Second semester B. Pharm. if he/she has passed the First semester B. Pharm. examination.
- A candidate shall be admitted to the Third semester B. Pharm. if he/she has passed the Second semester B. Pharm. examination.
- A candidate shall be admitted to the Fourth semester B. Pharm. if he/she has passed the Third semester B. Pharm. examination.
- A candidate shall be admitted to the Fifth semester B. Pharm. if he/she has passed the fourth semester B. Pharm. examination.
- A candidate shall be admitted to the Sixth semester B. Pharm. if he/she has passed the Fifth semester B. Pharm. examination.
- A candidate shall be admitted to the Seventh semester B. Pharm. if he/she has passed the Sixth semester B. Pharm. examination.
- A candidate shall be admitted to the Eighth semester B. Pharm. if he/she has passed the Seventh semester B. Pharm. examination.
- No candidate shall be admitted to the Fifth semester B. Pharm., unless he / she pass examination of all the subjects (including theory, practical) of First and second semester B. Pharm. examination.
- No candidate shall be admitted to the Seventh semester B. Pharm, unless he / she passes examination of all the subjects (including theory, practical) of First, Second, Third and Fourth semester B. Pharm.
- No candidate shall be admitted to the Fifth semester B. Pharm. unless he / she pass the subject Mathematics / Biology of Maharashtra Board of Secondary and Higher Secondary Education or Remedial Mathematics/ Remedial Biology of University.
- No candidate (Directly admitted candidate to Third semester B. Pharm.) shall be admitted to the Seventh semester B. Pharm. unless he / she pass the subject Mathematics/ Biology of Maharashtra Board of Secondary and Higher Secondary Education or Remedial Mathematics / Remedial Biology of University.
- No candidate shall be allowed to admit for the examination,if he / she does not fulfill the attendance criteria as per the university norms. A candidate shall have minimum 75 % attendance at theory hours as well as practical sessions. The Head / Principal / Director of the department / college / institute shall establish a suitable method for monitoring the attendance of admitted candidates like daily attendance sheet for each subject, thumb impression attendance machine etc.

0.532 An applicant for admission to an examination shall satisfy the Head / Principal / Director of the Department / College / Institute in the terminal and other tests conducted during the respective semester regarding his / her suitability to take the examination.

0.533 Every candidate shall require to undergo at least one month practical training (continuous or in part) at any time after the end of sixth semester B. Pharm. examination in the recognized pharmaceutical manufacturing concern or in an analytical laboratory or pharmaceutical research organization or hospital failing which he / she will not be eligible for conferment of degree of the University.The candidate has to submit a project completion report based on his/ her practical training.The Principal of College / Institute shall issue a certificate regarding successful completion of his training.

0.534 No candidate shall be admitted to any of the examination if he/she has already passed the same examination or equivalent examination of any other statutory university / board.

R.646 The structure of B. Pharm. course, scheme of examination including maximum marks allotted to the sessional examination in each paper, the written part and practical part for each of the four examinations, shall be as indicated in **(Annexure A).**

R.647 The scope of the subjects shall be as indicated in the syllabus**(Annexure A)**.

R.648 The head / Principal / Director of the Department / College / Institute shall maintain a complete record of the marks obtained by the candidates in the sessional examinations.

R.649 The head / Principal / Director shall send sessional examination marks secured by the candidate to the registrar / Controller of examination of the university in the sealed cover not less than 15 days before the commencement of semester examination.

R.650 In order to pass examination, candidate must have obtained

- At least 40% of marks in theory examination (excluding sessional examination marks) and 45 % marks in practical (excluding sessional examination marks) separately in each subject theory and practical and
- Must obtain at least 50% of the total marks assigned to that examination.

R.651
- There shall not be classification of successful examiners at the First, Second, Third, Fourth, Fifth, sixth and seventh semester B. Pharm. examinations.
- The rank in order of merit of first five students shall be declared on the basis of aggregate marks obtained at the Fifth, Sixth, Seventh and Eighth semester B. Pharm. examination combined together.

R.652 The division of successful examinee at the B. Pharm. examination shall be declared on the basis of the aggregate marks obtained at the Fifth, Sixth, Seventh and Eighth semester B. Pharm. examination taken together.

R.653 The following shall be the mode of Awards of the class at an examination

- Candidate obtaining 75% or more marks of grant total
  : First class with distinction
- Candidate obtaining 60% or more but less than 75% marks of grant total
  : First class
- Candidate obtaining 50% or more but less than 60% marks of grant total
  : Second class

R.654
- An examinee who is successful at an examination and obtained not less than 75% marks

of the total marks prescribed in a subject shall be declared to have passed the examination with Distinction in that subject

Explanation: Distinction in a subject will be awarded at the fifth, sixth, seventh and eighth semester B. Pharm examination separately.

- Only those candidates who have passed an examination in one attempt will be eligible for any award, scholarship, to be awarded for that examination.

R.655 A candidate at First, Third, Fifth, Seventh semester B. Pharm. examination, who fail to secure the prescribed minimum marks in all theory papers and practical examinations may at his/her option, be admitted to a subsequent examination in that paper or practical only on payment of fresh fee. An examinee under this provision shall be allowed to keep term in the next higher class. He/She may take both examinations simultaneously, but his/her result at the higher examination shall not be declared unless he / she is declared successful at the lower examination.

A candidate at First and Second, Third and Fourth, Fifth and Sixth semester B. Pharm. examination (taken together), who fail to secure the prescribed minimum marks in not more than two theory papers and not more than two practical examinations (taken together as First and Second, Third and Fourth, Fifth and Sixth semester) may at his/her option, be admitted to a subsequent examination in that theory paper or practical only on payment of fresh fee. An examinee under this provision shall be allowed to keep term in the next higher class (Third, Fifth, Seventh semester). He/She may take both examinations simultaneously, but his/her result at the higher examination shall not be declared unless he / she is declared successful at the lower examination.

R.656 An examinee failing in all theory papers and all practical at the First, Third, Fifth and Seventh semester examination may at his / her reappear as ex-student at subsequent examination in the subject in which he / she has failed, on payment of fresh fee. Such candidates will be allowed to keep the term in next higher class.

An examinee failing in more than two theory papers and / or more than two practical examination at First and Second, Third and Fourth, Fifth and Sixth semester B. Pharm. examination (taken together), may at his / her appear as ex-student at subsequent examination in the subject in which he / she has failed, on payment of fresh fee. Such candidates will not be allowed to keep the term in next higher class at Third, Fifth and Seventh semester.

R657
- At least, one sessional examinationswill be held by the teaching institute every semester for the purpose of theory internal assessment. The sessional examination marks will be calculated as the average of the best of two performances (If more than one sessional examination conducted) of these examinations.
- There shall not be sessional examination for practical internal assessment. The evaluation of candidates shall be carried out for practical internal marks as per **Annexure A**provided in this document.

- A candidate failing in any of the university examination may, at the discretion of the Head / Principal / Director of the department / institute / College be permitted, for such period as the head / Principal / Director consider necessary to attend the course instruction on the paper or practical in which he / she has failed as the case may be, in such case the Head / Principal/ Director shall award him / her fresh sessional examination marks on the basis of his / her fresh performance.
- A separate Improvement sessional shall be conducted for assessment of such performance on the complete syllabus of the particular subject. One improvement examinations shall be conducted by the department / institute / college every semester. Separate time table shall be declared after application of candidate for such examination.
- Provision of ordinance related to condition of deficiency of marks for passing an examination shall apply to the examination under the concerned ordinance implemented time to time.
- This new curriculum (including regulation, structure and syllabus) will be for the academic year 2013-14 onward for First and Second semester B. Pharm., for academic year 2014-15 onwards for Third and Fourth semester B. Pharm., for academic year 2015-16 onwards for Fifth and Sixth semester B. Pharm., and for academic year 2016-17 onwards for Seventh and Eighth semester B. Pharm.

  The candidate failing in an examination with old course (All previous courses) will have to clear that examination as per the equivalence given in the **Annexure B**given in this document.
- All the candidates of with previous course will have to take the subsequent higher examinations as per the carry on rule decided by the University time to time.

Annexure A

Structure of Syllabus

Abbreviations: TH: Theory, **PR:** Practical, **SC:** Subject Code, **INT:** Internal, **EXT:** External

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HR.		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR.	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
I	110	1	Physical Pharmacy I	4	6	3	4	80	20	80	20	100	100	4	4
I	120	2	Pharmacognosy – I	4	3	3	4	80	20	40	10	100	50	4	2
I	130	3	Human Anatomy & Physiology	4	6	3	4	80	20	80	20	100	100	4	4
I	140	4	Functional English & Communication Skills	3	--	3	--	80	20	--	--	100	--	4	--
I	150	5	Remedial Mathematics / HSC Mathematics OR Remedial Biology / HSC Biology	3 *	--	3	--	80 *	20 *	--	--	100 *	--	--	--
			SEM TOTAL	**15**	**15**			**320**	**80**	**200**	**50**	**400**	**250**	**16**	**10**
II	210	1	Computers & Statistics	2	3	2	3	40	10	40	10	50	50	2	2
II	220	2	Pharmaceutics-I	4	6	3	4	80	20	80	20	100	100	4	4
II	230	3	Pharmaceutical Organic Chemistry – I	4	6	3	4	80	20	80	20	100	100	4	4
II	240	4	Pharmaceutical Inorganic Chemistry	4	--	3	--	80	10	--	--	50	--	2	--
II	250	5	Environmental science	2	--	2	--	40	10	--	--	50	--	2	--
			SEM TOTAL	**16**	**15**			**320**	**70**	**200**	**50**	**350**	**250**	**14**	**10**
III	310	1	Physical Pharmacy II	4	6	3	4	80	20	80	20	100	100	4	4
III	320	2	Pharmaceutical Organic Chemistry – II	4	6	3	4	80	20	80	20	100	100	4	4
III	330	3	Pharmaceutical Microbiology	4	6	3	4	80	20	80	20	100	100	4	4
III	340	4	Pathophysiology	4	--	3	--	80	20	--	--	100	--	4	--
			SEM TOTAL	**16**	**18**			**320**	**80**	**240**	**60**	**400**	**300**	**16**	**12**
IV	410	1	Pharmaceutics – II	4	6	3	4	80	20	80	20	100	100	4	4
IV	420	2	Pharmaceutical Medicinal Chemistry - I	4	--	3	--	80	20	--	--	100	--	4	--
IV	430	3	Pharmaceutical Analysis - I	4	6	3	4	80	20	80	20	100	100	4	4
IV	440	4	Pharmacognosy – II	4	--	3	--	80	20	--	--	100	--	4	--
			SEM TOTAL	**16**	**12**			**320**	**80**	**160**	**40**	**400**	**200**	**16**	**8**

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HR.		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR.	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
V	510	1	Pharmaceutical Engineering	4	--	3	--	80	20	--	--	100	--	4	
V	520	2	Pharmaceutical Medicinal Chemistry – II	4	--	3	--	80	20	--	--	100	--	4	--
V	530	3	Medicinal Natural Products	4	6	3	4	80	20	80	20	100	100	4	4
V	540	4	Pharmacology – I	4	--	3	--	80	20	--	--	100	--	4	--
V	550	5	Biochemistry	4	6	3	4	80	20	80	20	100	100	4	4
			SEM TOTAL	**20**	**12**			**400**	**100**	**160**	**40**	**500**	**200**	**20**	**8**
VI	610	1	Hospital & Dispensing Pharmacy	4	6	3	4	80	20	80	20	100	100	4	4
VI	620	2	Pharmacology – II	4	6	3	4	80	20	80	20	100	100	4	4
VI	630	3	Pharmaceutical Analysis - II	4	6	3	4	80	20	80	20	100	100	4	4
VI	640	4	Pharmaceutical Jurisprudence	4	--	3	--	80	20	--	--	100	--	4	--
			SEM TOTAL	**16**	**18**			**320**	**80**	**240**	**60**	**400**	**300**	**16**	**12**
VII	710	1	Pharmaceutics – III	4	6	3	4	80	20	80	20	100	100	4	4
VII	720	2	Pharmaceutical Medicinal Chemistry - III	4	6	3	4	80	20	80	20	100	100	4	4
VII	730	3	Clinical Pharmacy and Therapeutics	4	--	3	--	80	20	--	--	100	--	4	--
VII	740	4	Pharmaceutical Analysis III	4	--	3	--	80	20	--	--	100	--	4	--
VII	750	5	Project Work	--	3	--	2	--	--	50	--	--	50	--	2
			SEM TOTAL	**16**	**15**			**320**	**80**	**200**	**50**	**400**	**250**	**16**	**10**
VIII	810	1	Biopharmaceutics& Pharmacokinetics	4	--	3	--	80	20	--	--	100	--	4	--
VIII	820	2	Biotechnology	4	6	3	4	80	20	80	20	100	100	4	4
VIII	830	3	Industrial Natural Products	4	6	3	4	80	20	80	20	100	100	4	4
VIII	840	4	Pharmaceutical Management	4	--	3	--	80	20	--	--	100	--	4	--
			SEM TOTAL	**16**	**12**			**320**	**80**	**160**	**40**	**400**	**200**	**16**	**8**
			TOTAL	***131***	***117***			***2640***	***650***	***1560***	***390***	***3250***	***1950***	***130***	***78***

* Not as a regular University examination of First semester B. Pharm.

Guideline for Evaluation of candidates in practical

- The evaluation of candidates for their performance in practical shall be done on day to day basis
- The marks out of 10 shall be allotted for each practical conducted. For absent candidate zero marks shall be allotted.
- The distribution for marks out of 10 shall be as follows
    - Attendance : out of 02
    - Conduct of experiment : out of 04
    - Result and interpretation : out of 02
    - Journal writing and other : out of 02
- A viva voce shall be conducted during each practical for regular monitoring of progress of candidate.
- At the end of semester (during sessional examination) the average marks of all the experiments shall be computed and double of the computed marks shall be allotted as sessional practical examination marks.
- The journal / record book assessment of the candidates shall be done on day to day basis. So that the progress of candidate can be monitored.

Annexure B

EQUIVALENCE IN SUBJECTS

Equivalence in the subject from previous syllabus (from academic year 2012-13 known as revised syllabus) to this syllabus shall be given as per following table.

Sr. No	Previous syllabus subject			Equivalent Subject		
	Sub. Code	**Class**	**Subject**	**Sub. Code**	**Semester**	**Subject**
1.	1.1	First B. Pharm.	Pharmaceutics-I	220	II	Pharmaceutics – I
2.	1.2	First B. Pharm.	Biochemistry	210	IV	Biochemistry
3.	1.3	First B. Pharm.	Anatomy Physiology & Health Education	130	I	Human Anatomy and Physiology
4.	1.4	First B. Pharm.	Pharmaceutical Inorganic Chemistry	240	II	Pharmaceutical Inorganic Chemistry
5.	1.5	First B. Pharm.	Dispensing of Medication & Hospital Pharmacy	610	VI	Hospital and Dispensing Pharmacy
6.	1.6	First B. Pharm.	Pharmaceutical Mathematics	No equivalent subject (candidate has to appear for original subject)		
7.	1.7	First B. Pharm.	Computer Applications	210	II	Computer and Statistics
8.	1.8	First B. Pharm.	Pharmaceutical Organic Chemistry-I	230	II	Pharmaceutical Organic Chemistry I
9.	2.1	Second B. Pharm.	Pharmaceutics-II (Physical Pharmacy)	310	III	Physical Pharmacy II
10.	2.2	Second B. Pharm.	Pharmaceutical Microbiology	330	III	Pharmaceutical Microbiology
11.	2.3	Second B. Pharm.	Pharmaceutical Organic Chemistry-II	320	III	Pharmaceutical Organic Chemistry II
12.	2.4	Second B. Pharm.	Pharmacognosy – I	120	I	Pharmacognosy – I
13.	2.5	Second B. Pharm.	Pathophysiology and Clinical Biochemistry	340	III	Pathophysiology

Sr. No	Previous syllabus subject			Equivalent Subject		
	Sub. Code	Class	Subject	Sub. Code	Semester	Subject
14.	2.6	Second B. Pharm.	Pharmaceutical Analysis-I	430	IV	Pharmaceutical Analysis – I
15.	2.7	Second B. Pharm.	Pharmaceutical Engineering	510	V	Pharmaceutical Engineering
16.	3.1	Third B Pharm.	Pharmaceutical Cosmetic Technology	410	IV	Pharmaceutics – II
17.	3.2	Third B Pharm.	Pharmacognosy-II	440	IV	Pharmacognosy – II
18.	3.3	Third B Pharm.	Medicinal Chemistry-I	420	IV	Pharmaceutical Medicinal Chemistry – I
19.	3.4	Third B Pharm.	Pharmacology and Toxicology	540	V	Pharmacology – I
20.	3.5	Third B Pharm.	Biopharmaceutics and Pharmacokinetics	810	VIII	Biopharmaceutics and Pharmacokinetics
21.	3.6	Third B Pharm.	Pharmaceutical Analysis-II	530	V	Pharmaceutical Analysis-II
22.	3.7	Third B Pharm.	Biotechnology	820	VIII	Biotechnology
23.	4.1	Final B. Pharm	Dosage Form Design	710	VII	Pharmaceutics – III
24.	4.2	Final B. Pharm	Pharmacognosy and Phytochemistry	830	VIII	Industrial Natural Products
25.	4.3	Final B. Pharm	Medicinal Chemistry-II	720	VII	Pharmaceutical Medicinal Chemistry – II
26.	4.4	Final B. Pharm	Pharmacology and Bioassay	620	VI	Pharmacology – II
27.	4.5	Final B. Pharm	Pharmaceutical Management	840	VIII	Pharmaceutical Management
28.	4.6	Final B. Pharm	Quality Assurance Techniques	530 & 740	V & VII	Pharmaceutical Analysis-II and Pharmaceutical Analysis-III
29.	4.7	Final B. Pharm	Pharm.Jurisp.& Intellectual property Rights.	640	VI	Pharmaceutical Jurisprudence

Syllabus for First Semester B. Pharmacy

Class: First semester B. Pharm. **Subject Code:** 110
Subject: Physical Pharmacy I (Theory) **Allotted Hrs.:** 3

OBJECTIVE:

- To acquaint the students with the fundamental principles & their applications with reference to Pharmacy.
- To study the physical, colligative and thermodynamic properties of matter.
- To study physico-chemical properties of solutions like phase rule, refractive index, electro-chemistry etc.
- To study ionic equilibrium, kinetics and absorption phenomenon.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Composition & physical states of matter** Intermolecular forces & their impact on state of the matter. Various physical properties of matter, dipole moment, dielectric constant, Van Derwaal's equation & critical phenomenon, liquefaction of gases, aerosols.	4
2	**Colligative Properties** The liquid state, vapor pressure, ideal & realsolutions. Raoult's law, elevation of boiling point, depression of freezing point, osmotic pressure, determination of molecular weight based on colligative properties.	6
3	**Thermodynamics** First, second & third law of thermodynamics. Thermochemical laws, isothermic & adiabetic processes, reversible processes, work of expansion, heat content, enthalpy, heat capacity. Gibb's & Helmoltz equation & chemical potential.	10
4	ChemicalEquillibria	5
5	**Phase rule** One, two, & three component systems along with their applications. Solid- solid, solid - liquid, & liquid-liquid systems. Distillation of binary systems, azeotropic mixtures, steam, vacuum, & fractional distillation.	7
	SECTION B	
6	**Refractive index** Refractive index, specificrefractivity, molar refractivity, refractometers.	2
7	**Solutions** Solubility, factorsa ffecting solubility, solubility curves. Types of solutions, effect of co-solvancy, pH & other factors on solubility. Solubility of gases in liquids, liquids in liquids, & solids in liquids, critical solution temperature, law of partitioning & it sapplications. Solute solvent interactions. Expression of concentration of pharmaceutical solutions & calculations. Molarity, molality, mole fraction & percentage expressions.	8
8	**Electrochemistry** Properties of electrolyte solutions, electrolysis. Faraday's law of electrolysis, electron transport, electrical cell, single electrode potential, concentration cells, half-cells & half-cell potential, type sof half cells, sign convention, Nerst equation, salt bridge, electro motive series, standard potential, SHE. Measuring the relative voltage of half cells , Calculation of standard potential. Reference & Indicator electrodes. Standard oxidation-reduction potential.	6
9	**Ionic equilibrium** Theory of conductivity, equivalent conductance, mobility of ions, specific conductance.	6
10	**Kinetics** Order of reactions, derivation & internal form of rate laws, molarity of reaction, derivation of rate constants.	6
	TOTAL	**60**

Reference Books:
• Glasstone, Samuel, Text Book of Physical Chemistry, Mc Milan Publishers
• Carstensen, J.T., Advanced Pharmaceutical Solids, Marce lDekker
• Connors, K.A., Chemical Stability Of Pharmaceuticals, WileyJ.
• Martin, Alfred, Physical Pharmacy, Waverley Publishers
• Conners,K.A., Thermodynamics Of Pharmaceutical Systems, WileyJ.
• Raymond, Chang, Physical Chemistry with Applications to BiologicalS ystem, CollierMcMilan InternationalEd.

Class: First Semester B. Pharm. **Subject Code:** 110
Subject: Physical Pharmacy I(Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To train students on safe handling of chemicals, glassware, & instruments /equipments.
- To give students training o nuse of correct technique/s, methodology insetting up the experiment/s.
- To familiarize the students about use of various instruments, including proper handling, precautions during use, & appropriate maintenance techniques.

Sr.No.	Laboratory Experiments
1.	Introduction to apparatus, equipment, & instruments.
2.	Determination of specificgravity of liquid solutions.
3.	Determination of critical solution temperature of phenol-water system.
4.	Determination of critical solution temperature of triethylamine-water system.
5.	Determination of partition coefficient of benzoic acid [or anyother simple molecule] intoluene- water.
6.	Determination of partitioncoefficient of iodinein CCI4–water.
7.	Determination of specifi refractivity & molar refractivity using refractometer.
8.	Determination of molecular weight by Rast's camphor method.
9.	Determination of heat of solubilization of benzoic acid in water.
10.	Determination of buffer capacity of asolution of aweak acid & it's salt.
11.	Study of mutual solubility of ternary system:benzene-acetone-water.
12.	Study of mutual solubility of ternary system:toluene-acetone-water.
13.	Determination of order of reaction for hydrolysis of ester.
14.	Determination of molecular weightof a macro molecule like [albumin/gelatin/peptoneetc.] by osmotic pressure.
15.	Determination of half-cell potential of Cu-Cu.
16.	Determination of half-cell potential of Zn-Zn.
17.	Determination of half cell potential of concentration cells.
18.	Multiple experiments from the above list can be given depending on their significance in pharmacy.

Class: First Semester B. Pharm. **Subject Code:** 120
Subject: Pharmacognosy – I (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To create the awareness regarding importance of Pharmacognosy
- To provide knowledge regarding relationship of Pharmacognosy and taxonomy
- To provide knowledge regarding study of different families and their field identification
- To provide the idea regarding cultivation, collection, standardization and storage of crude drugs

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Definition, History, Scope and Development of Pharmacognosy, importance of taxonomy and chemotaxonomy in evolution of Pharmacognosy	4
2	Study of plant cell and tissue system in plant	3
3	Plant taxonomy: Introduction of taxonomy, History and Development , principle of classification of plant, systems of nomenclature, diagnostic features and medicinal significance of algae, fungi, bryophyta and pteridophyta	4
4	Diagnostic features and medicinal significance of gymnosperm families, (Ginkgoaceae, Pinaceae, Ephedraceae,) and Angiosperm including the families Apocynaceae, Solanaceae, Rutaceae, Umbillifereae, Leguminoseae, Rubiaceae, Liliaceae, Graminea, Labiatae.	14
5	General Evolutionary trends in flowering plants	3
	Plant Identification characters, Conventional and unconventional keys for plant identification. Role of medicinal garden in plant identification	3
	SECTION B	
6	Modern trends in Plant Taxonomy relating to external morphology, vegetative anatomy, floweral anatomy and chemistry in relation to taxonomy (Chemotaxonomy)	3
7	Sources of crude drug: Biological, marine, Mineral and plant tissue culture as source of crude drug.	3
8	Classification of crude drug: Alphabetical, Morphological, Taxonomical, chemotaxonomical, Chemical and Pharmacological classification of crude drug.	4
9	Cultivation collection processing and storage of crude drug, factors influencing quality of crude drug, types of fertilizers, pest management and pest control, plant hormones and their application	6
10	Preparation of herbarium sheets and their importance in authentication of plants.	2
11	Natural Mineral: sources, chemical constituents, adulterants and uses of: Talc, Bentonite, Kaolin, Asbestos, Kieselguhr, and Calamine.	3
12	Study of Natural fibres (Cotton, Silk, Jute and Wool)	3
13	Biological sources, chemical constituents, adulterants and uses with method of preparation of Carbohydrates and derived products: agar, guar gum acacia, Honey, Isabgol, pectin, Starch, sterculia and Tragacanth	3
14	Natural pesticides: Tobacco, Pyrethrum, Neem	2
	TOTAL	**60**

Reference Books:

- Craker L., Herbs, Spices And Medicinal Plants, CBS Publishers
- V. V. Sivarajan, Introduction to the Principles of Plant Taxonomy, Syndicate of university of Cambridge
- O P. Sharma, Plant Taxonomy, Tata McGraw-Hill Education
- Trease and Evans, Pharmacognosy, W. B. Saunders, New York
- V. E. Tylor, L. R. Brady and S. B. Robbers, Pharmacognosy, K. M. Varghese Co. Bombay.

Class: First Semester B. Pharm. **Subject Code:** 120
Subject: Pharmacognosy – I (Practical) **Allotted Hrs. :** 3

Sr.No.	Laboratory Experiments
1.	Study of microscope
2.	Techniques in microscopy, camera Lucida, details of mountants, clearing agents, micro-chemical reagents
3.	Identification of mineral drug by morphological characters and chemical characteristics- Agar, Tragacanth, Talc, Bentonite, Kaolin, Asbestos, Kieselguhr, Calamine.
4.	Micrometers and measurement of microscopic characters (Size of starch grains/calcium oxalate crystal/fibers)
5.	Study of morphological and microscopical characters of crude drugs of monocot and dicot stem, leaves roots, bark fruits and seeds.
6.	Morphological study of plants under various families mentioned in theory (any two plant from each family) in local area.
7.	Preparation of herbarium sheet and visit to Botany Department in Herbarium section
8.	Field visit-Study of Medicinal plants

Class: First Semester B. Pharm. **Subject Code:** 130
Subject: Human Anatomy and Physiology (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To impart fundamental knowledgeof the structure and functions of the human body
- To understand homeostasis mechanisms and its relation with various body systems.
- To develop knowledge regarding various tissues and organs of different systems of human body
- The knowledge imparted should help the students to understand the pharmacology of drugs

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Cell physiology** Cell, Cell junctions, transport mechanisms, homeostasis, ion channels, secondary messengers	3
2	**The Blood** Composition and functions of blood, RBC, WBC, platelets. Hemostasis, blood groups, mechanism of clotting. Introduction to disorders of blood	6
3	**Gastrointestinal tract** Structure of the gastrointestinal tract, functions of its different parts including those of liver, pancreas and gall bladder, various gastrointestinal structures and their role in the digestion and absorption of food	4
4	**Respiratory System** Structure of respiratory organs, functions of respiration mechanism and regulation of respiration, respiratory volumes and vital capacity	3
5	**Autonomic nervous system** Physiology and functions of the autonomic nervous system. Mechanism of neurohumoral transmission in ANS	6
6	**Sense organs** Structure and physiology of eye (vision), ear (hearing), taste buds, nose (smell) and skin.	4
7	**Skeletal System** Structure and function of skeleton. Articulation and movement. Disorders of bones and joints. Skeletal muscle sliding mechanism.	3
	SECTION B	
8	**Central Nervous system** Structure and Functions of different parts of brain and spinal cord. Neurohumoral transmission in the central nervous system, reflexaction ,electroencephalogram, specialized functions of the brain, cranial nerves and their functions	6
9	**Urinary System** Various parts Structure and functions of the kidney and urinary tract. Physiology of urine formation and acid base balance. Brief Introduction to disorders of kidney	5
10	**Endocrine Glands** Basic anatomy and physiology of pituitary, thyroid, parathyroid, adrenal glands and pancreas. Local hormones. Brief introduction to disorders of various endocrine glands	6
11	**Reproductive System** Structure and functions of male and female reproductive system. Sex hormones, physiology of menstrual cycle, and various stages of pregnancy and parturition	5
12	**Cardiovascular system** Anatomy of heart and blood vessels, physiology of blood circulation, cardiac cycle, conducting system of heart, heart sound, electrocardiogram, blood pressure and its regulation	7
13	**Lymphatic system** Composition, formation and circulation of lymph. Spleen and its functions	2
	TOTAL	60

Reference Books:
• Vander, Sherman, Luciano, Human Physiology: The Mechanism Of Body Function, McGraw Hill International
• JohnB.West, Best And Taylor's Physiological Basis Of Medical Practice, Williams &Wilkins
• GerardJ. Tortora & Bryan Derikson, Principles of Anatomy and Physiology, JohnWileyand Sons,Inc
• Arthur C.Guyton And John E.Hall, Text Book Of Medical Physiology, ElsevierIndia
• Anne Waugh Allison Grant, Rossand Wilson Anatomy and Physiology in Health and Illness, Churchill Livingstone Elsevier

Class: First Semester B. Pharm. **Subject Code:** 130
Subject: Human Anatomy and Physiology (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To impart fundamental knowledge on the structure and functions of the human body.
- To understand homeostasis mechanisms and its relation with various body systems.
- To develop the knowledge regarding various tissues & organs of different systems of human body.
- The knowledge imparted should help the students to understand the pharmacology of drugs.

Sr.No.	Laboratory Experiments
1.	Study of compound microscope.
2.	Microscopic study of different tissues.
3.	Identification of bones and points of identification.
4.	Study of different systems with the help of charts and models.
5.	Blood experiments: General techniques inHaemocytometry. a. Enumeration of Red Blood Corpuscles (RBC). b. Determination of White Blood Corpuscles (WBC). c. Estimation of Hemoglobin. d. Estimation of different LeukocyteCount (DLC). e. Estimation of Erythrocyte Sedimentation Rate (ESR). f. Determination of Blood groups. g. Determination of Bleeding & Clotting time.
6.	To record human heart rate and pulse rate.
7.	To study the effect of posture and exercise on blood pressure.
8.	Recording of human body temperature.
9.	Determination of tidal volume & vital capacity.

Class: First Semester B. Pharm. **Subject Code:** 140
Subject: Functional English & Communication Skills **Allotted Hrs.:** 3

OBJECTIVE:

- To develop the ability to speak and write grammatically corrects English.
- To develop skill in listening comprehension
- To develop the ability to read, understand and express in English language

Sr. No.	Unit and Contents	Hrs.
1	**Applied Grammar** Remedial study of grammar, review of grammar an dvocabulary. Effective use of dictionary, phonetics	11
2	**Reading Comprehension** To read and comprehend selected materials, articles, magazines, journals related to Pharmacy	10
3	**Forms of Composition** Letter writing, note taking, precise writing, essay writing, anecdotal records, diary writing, reports, resume/curriculum vitae and the likes	10
4	**Communication Skill** Oral report, discussion, lecture/seminar, debate ,telephonic conversation	6
5	**Listening Comprehension** Media, audio, video, speeches and the likes	8
	TOTAL	**45**

Reference Books:

- Lesiker,Raymond.V and MaireEHatley, Basic Business Communication NewYork, TataMcGraw Hill
- Hamplyons Liz& Ben Heasley, Study writing,Cambridge, Cambridge University Press
- Beaumont Digtyand Colin Granger, English Grammar, An International reference practice book, London,Heinmann
- ElisonJohn, Theright word at the right time Aguide to the English, The Reader's Digest

Class: First Semester B. Pharm. **Subject Code:** 150
Subject: Remedial Mathematics **Allotted Hrs.:** 3

OBJECTIVE:

- To give broad understanding of mathematical aspects having usefulness in understanding expressions encountered in various subjects during the course
- To provide basic ideas of matrices, determinants, & fundamentals of calculus
- To develop the ability to solve simple to moderate problems with reference to Sr. no.2
- To establish a bridge between mathematics and applications to Pharmacy

Sr. No.	Unit and Contents	Hrs.
Unit – 1	**Significant figure** Fraction, exponents, power and roots, Ratio & proportions logarithms.	04
Unit – 2	Matrixes and determinants	05
Unit – 3	**Graphs and Equation** Solving simple equations using graphs. Solving simultaneous and quadratic equations.	05
Unit – 4	**Relations and Functions** Concept of proportions, introduction to functions, exponential and log functions, meaning of log and linear forms.	04
Unit – 5	Fundamentals of trigonometry and geometry	04
Unit -6	**Sequences and series** Patternsandformulae,arithmeticprogressions,geometric progression, partial fractions.	06
Unit -7	**Binomial series** Binomial series for positive whole number and applications of binomial series and selections.	06
Unit -8	**Calculus** Functions and limits, Derivatives, Integral calculus, introductory aspects of Laplace transformation.	05
Unit-9	**Integral calculus** Integration by decomposition, by substitution, by parts and by successive reduction, integration of algebraic rational function, integration of trigonometric function	06
	Total	**45**

Reference Books:

- GrewalB.S., Numerical Methods, Khanna Publishers
- Steve Dobbs & Jane Miller, Advanced Level Mathematics Statistics, Cambridge University Press
- Adams Dany Spencer, Laboratory Mathematics, Carrol & Graphs
- Jenny Olive, Maths. A Students Survival Guide, Cambridge University Press
- James R Barrante, Applied Math ematics for Physical Chemistry (II ED.), Prentice Hall Incorporations.

Class: First Semester B. Pharm. **Subject Code:** 150
Subject: Remedial Biology **Allotted Hrs.:** 3

OBJECTIVE:

- To underst and the nature of biological population
- To provide general knowledge of environmental effects and behavior
- To introduce learner towards the organizational and functional aspects of lower animals
- To introduce student towards the structural and functional aspects of plants kingdom

Sr. No.	Unit and Contents	Hrs.
Unit – 1	**Plant Cell** It's structure and living and non-living inclusions. Plant cell division. Different types of plant tissues and their functions.	04
Unit – 2	Morphology and Histology of plant parts; Root, stem, bark, wood, leaf, flower, fruit and seed. Modifications of roots and stems.	04
Unit – 3	**Plant Taxonomy** Classification, study of the following families with special reference to Medicinally important plants: Apocynaceae, Solanaceae, Umbelliferae, Abiatae, Leguminosae, and Liliaceae.	05
Unit – 4	**Animal cell** Structure, living and non-living inclusions. Animal cell division. Different types of cells and tissues, their functions.	04
Unit – 5	Study of comparative anatomy of different vertebrates – fish, amphibians, reptiles, aves and mammals.	04
Unit -6	Basic study of the following systems of frog GI, nervous, cardiovascular: genitourinary, musculo-skeletal, respiratory systems.	05
Unit -7	Fundamentals of parasitology Life cycles of some animal parasites that cause human disease - Malarial and filarial parasites and tape worm.	04
	Total	30

Reference Books:

- DuttaA.C., Botanyfor Degreestudents, Oxford
- Marshall&Williams, TextBookof Zoology, CBSPublishers&Distributors
- A.Fahn, Plant Anatomy, AdityaBooks PrivateLimited
- Weiz PaulB, LaboratoryManualin Scienceof Biology, McGraw-Hill book company

Syllabus for Second Semester B. Pharmacy

Class: Second semester B. Pharm. **Subject Code:** 210
Subject: Computer and Statistics (Theory) **Allotted Hrs.:** 2

OBJECTIVE:

- To provide the overview of development of computers
- To enable students to work in MS Window environment
- To impart the knowledge in performing general calculations involved in various disciplines of Pharmacy using spread sheet
- To provide the information in designing reports using word processing software
- To provide the basis of creating scientific presentations
- To enable students in utilizing computers for chemical structure drawing, viewing, and editing using free tools on internet along with the ability of performing literature survey

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	**Basic Statistics** Basic concepts of statistics: Data, data graphics, frequency distribution. Measure of central tendency (mean, median, mode, harmonic mean, geometric mean), application in LAL tests, scattering of data (range, mean, deviation, standard deviation, RSD and SEM etc.).	05
Unit – 2	**Correlation, regression** Correlation analysis, correlation coefficient, Spearman's rank correlation coefficient. Linear regression analysis (applications in Beer Lambert's curve, stability study). Introduction to curve fitting techniques.	08
Unit – 3	**Introduction to probabilities** Binomial and normal probabilities distribution.	04
Unit – 4	**Sample and sampling method** Size and its significance. Sampling techniques and their application in pharmacy. Hypothesis testing [t-statistics (application in dissolution testing of solid dosage form), chi-square test].	04
Unit – 5	**Analysis of variance** Introduction and application of the test in pharmacokinetic study.	04
	SECTION B	
Unit – 6	**Introduction** Introduction to computers- introduction to I/O devices, binary conversion computer classification. Application of computers in pharmacy.	04
Unit – 7	**Languages** Common languages in computers. Types of languages elementary programming in BASIC language, algorithm flow chart, solution of problems based on biostatistics and other simple problems of pharmaceutical interest.	05
Unit – 8	**MS Word** Typing of text with stress on the following features: typing of text with different fonts and different sizes, indentation, superscripts, subscript, Greek terms such as alpha, betas etc., spell checking, use of thesaurus, cut paste and other features of edit. Preparation of tables for practical of pharmaceutical chemistry, pharmaceutical technology, pharmacology and / or pharmacognosy.	05
Unit – 9	**MS Excel** Calculation in EXCEL. Preparation of templates for application in pharmaceutical chemistry,pharmaceuticaltechnology, pharmacologyandpharmacognosyforexample statistical treatment of data for Beer Lambert's curve, solution of problems based on physical chemistry, pharmaceutical engineering, stability study, area under the curve, bio-assay, bioequivalence study, extraction,$R_f$valueand other elementary problemsof pharmaceutical importance. Special attention must be given to arithmetic expression. Hierarchy of operations, library functions such as logarithm, square root, standard deviation, sum average, t-test, ANOVA etc. Drawing graphs in EXCEL – line graph, histogram, pie chart. At least one graph for each discipline of chemistry, pharmaceutical technology, pharmacology and pharmacognosy. Editing chart features such as annotation, labeling of axis, changing legends etc.	05

Unit – 10	**MS PowerPoint** Typing of text with stress on the following features: Typing of text with different fonts and different sizes, indentation, superscripts, subscript, Greek terms such as alpha, betas etc., spell checking, use of thesaurus, cut paste and other features of edit. Preparation of power point presentation & use of multimedia techniques for advance level presentation. Preparation of tables for practical of pharmaceuticalchemistry, pharmaceutical technology, pharmacology and / or pharmacognosy.	05
Unit – 11	**E -mail and internet** Introduction to E-mail and internet demonstration of sites of pharmaceuticalinterest suchashttp://www.fda.gov, http://www.phyarmpro.com,http://www.pharmacy.org, www.pubmed.com, etc. Search engines. Introduction to sites for patent search and literature search.	05
Unit-12	ISIS	02
Unit-13	RASMOL	02
Unit -14	CHEMSKETCH	02
	Total	**60**

Reference Books:
• S.Bolton, Pharmaceutical Statistics, Marcel Dekker
• Dromey R.G., How To Solve It by Computer, P B Books
• Korth Henry F, Database System Concept, Mc Graw Hill
• Stephen Sagman, Microsoft Office For Windows, TataMcGraw Hill
• T.J.O' Leary ,L.I.O'Leary, MS Office, Tata Mc Graw Hill

Class: Second semester B. Pharm. **Subject Code:** 210
Subject: Computer and Statistics (Practical) **Allotted Hrs. :** 3

OBJECTIVE:

- To train students in use of different software.
- To train students in drawing chemical structure susing appropriate method.
- To impart training on use of internet & it sadvantages.
- To give training in preparation of seminar/presentation material in powerpoint.

Sr.No.	Laboratory Experiments
1	Computer Operating System Like DOS and Windows.
2	Windows, Managing Windows, Working with Disk , Folders and files
3	MS-Office (MS Word, MS Power point, MS Excel, MS Access)
4	Internet Features (E- mail, Browser etc.)
5	Practical based on the topics covered in theory MS-EXCEL, stress must be given to topics of pharmaceutical interest only (e.g. statistical analysis of pharmaceutical data, stability study, area under the curve, calculation of molecular weight, calculation of solubility, buffers, filtration, acid-base titration, oxidation - reduction, physical pharmaceutics, pharmaceutical engineering etc.). The equation will be provided at the time of examinations.
6	Practical based on biometrics: Pharmaceutical application of students and paired test SD- SEM, chi-square test – ANNOVA , regression analysis (application to stability testing) – ANNOVA (application in pharmacokinetics).
7	Assignments: Computerization of any two practicals taught (text, tables, figures, calculation, steps etc).

Class: Second Semester B. Pharm. **Subject Code:** 220
Subject: Pharmaceutics – I (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To provide the overview of Pharmacy discipline and its development
- To introduce students to wards various dosage forms, systems of medicine and their therapeutic importance
- To expose learner to the formulation methodology of galanicals

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit - 1	**Pharmacy Profession:** Pharmacy as a career, evaluation of Pharmacy, earlier period middle to modernages	2
Unit - 2	**Introduction to Pharmaceutics** Definition, importance of pharmaceutics, areas concerned, scope of Pharmaceutics, history and development of profession of Pharmacy and Pharmaceutical industry in India. A brief review of present Indian Pharma. Industrying global perspective	2
Unit – 3	**Introduction to dosage form** Definition of drug. New drug and dosage form. The desirable properties of a dosage form, the need of dosage form. Ideas about available type of dosage forms and new drug delivery system.	03
Unit – 4	**Route of administration** Route of administration with respect to dosage form design, physiological consideration for various routes of administration.	04
Unit – 5	**ADME** Scheme of fate of dosage form after its administration. Definition and introduction to concept of absorption, distribution, biotransformation and elimination of drug. Introduction to bioavailability and various equivalence referring plasma time profile of drug.	04
Unit – 6	**Sources of drug information** Introduction to Pharmacopoeia with reference to IP, BP, USP and International Pharmacopeia. Study of structure / features (index) general notice and compartment of monographs of excipients, drug and drug product. Other sources. textbooks, journals, internet (drug information system, online database, patient/ consumer information and non- print material. Classification of information, primary, secondary and tertiary. Nomenclature of drug.	04
Unit – 7	**Allopathic dosage form** Merits / demerits, importance, formulation development – vehicles / excipients with examples for the dosage form : liquid dosage form: monophasic liquid dosage form. Aromatic waters, syrup, elixir, linctus, lotion,liniment, glycerites, solutions, spirits, ENTpreparations,mixtures,paints, mouthwash.	10
Unit – 8	**Crude extract** Infusion, decoction, maceration, percolation, tincture and extract. Methods of preparations of dry, soft and liquid extract.	05
	SECTION B	
Unit – 9	**Allergenic extract** Types of allergens, preparation of extract, testing and standardization of extracts.	04
Unit – 10	**Ayurvedic system of medicine** Theory, basic concept, diagnosis, various branches of treatment in ayurveda, types of drug formulation in Ayurveda and important Ayurvedic drugs and their uses, formulation of asavas, arishtas, watika, churna, tailas, ghruta, lep.	05
Unit – 11	**Homeopathic system of medicine** Theory, basic concept, diagnosis, treatment, source of homeopathic medicines and important homeopathic drugs and their uses.	03
Unit – 12	**Biological products** Absorbable and non-absorbable material types, sutures and ligatures, processing. manufacturing, sterilization, packing, QC tests of materials like catgut and nylon	03
Unit – 13	**GMP** Introduction to GMP, QC and QA	04
	Total	**60**

Reference Books:
• Ansel's, Introduction to Pharmaceutical dosage forms & Drug Delivery Systems, B.I.WarlyPvt.Ltd.
• M. E. Aulton, Pharmaceutics the Science of dosage form Design, Churchill Livingstone
• Ginnaro A.R., Remington' sPharmaceutical Sciences, MarkPublications
• Govt. of India, Indian Pharmacopoeia, The Controller of Publication, NewDelhi
• B.P. Commission, British Pharmacopoeia, H.M.S.O.London
• WalterLund, British Pharmaceutica lCodex, The Pharma London
• USGovt., United States Pharmacopoeia, U.S.Govt.,
• National Formulary, RoyalLondon
• Shivarajan V.V., Ayurvedic Drugs And Their Plant Sources, Oxfordand IBH
• MandalP.P, Text Book of Homeopathic Pharmacy, New Central Book Agency

Class: Second Semester B. Pharm. **Subject Code:** 220
Subject: Pharmaceutics – I (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To train students in preparation of simple dosage forms.
- To train students on dose calculations of some of the dosage forms.
- To make students familiar with different packaging materials used in dosage forms packaging.

Sr. No.	Laboratory Experiments
1.	To study mono graph from latest edition of Indian Pharmacopoeia (Chemical/Rawmaterial /Formulation). One form of each category (at least)
2.	Preparationof Followingclassesof products involvingthemetrology calculation 1.Aromaticwater (minimum 2) 2. Solution a) Aqueous iodine solution I.P. b) Strong iodine solution I.P. c) Strong ammonium acetate solution I.P. d) Cresol with soap solution I.P. e) Surgical soda solution I.P. 3. Spirits 4. Glycerin 5. Syrup 6. Elixirs 7. Lotion 8. Liniment 9. Ear drops 10. Nasal drops 11. Tinctures
3	Determination of bulk and tap density of Pharmaceutical solids
4.	Calculationof displacementvalueand preparationof suppository (of each base min. one)
5	Determination of particle size by optical method
6	Determination of particle size by sieving method
7	Evaluation of material using Pharmaceutical packaging
8.	Study oflabelsof differentformulations (minimum 25 types)

Class: Second Semester B. Pharm. **Subject Code:** 230
Subject: Pharmaceutical Organic Chemistry (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To impart a review of structural aspects of organic compounds & learn arrow based reaction mechanisms.
- To develop understanding of scientific nomenclature of organic compounds.
- To develop the ability to understand chemical reactions related to various functional groups of carbon, oxygen, nitrogen and halogens**.**

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**General principles** A brief review of classification & sources of organic compounds, atomic orbitals, Hybridization, sigma & pi-bonds, intermolecular forces, inductive, resonance and steric effects, conjugation, bond length, bondangles & bondenergies along with their significance in reactions. Different theories of acidity & basicity should be covered briefly. Ease of formation & order of stabilities of carbocation and carbanions along with the reasons for the same should be covered. Relationships between energy content, stability, reactivity & their importance in chemical reactions should be covered. Calculations for determining empirical & molecular formula should becovered.	8
2	**Different classes of aliphatic compounds** The following classes of compounds should be taught in detail with respect to their IUPAC / systematic nomenclature, industrial [wherever applicable] & laboratory methods o fpreparations, physical properties, chemical reactions, uses with emphasis on reaction mechanisms [arrow based] & stereochemistry [wherever applicable]. • Alkanes [including cyclic compounds] • Alkenes [including cyclic compounds] • Alkynes [only open chain compounds] • Aliphatic hydroxyl compounds • Alkyl halides • Aldehydes & ketones • Carboxylic acids • All functional derivatives of carboxylic acids	 3 3 3 3 4 4 4 4
	SECTION B	
3	**Free radicals** Concept of hemolytic & heterolytic bond fission. Free radicals; their stability, methods of generations and important reactions including named reactions	3
4	**Aromaticity & aromatic chemistry** Concept of aromaticity, Huckel's rule &its use in determining thearomatic/non-aromatic character of a compound. A brief coverage of structure of benzene and related electophilic & nucleophilic aromatic substitution reactions along with reactivity & orientation in these reactions. Mechanism, orientation, stereochemical implications of substitution reactions (SN1, SN2, SNi) and elimination reactions (E1, E2, E1cb)	9
5	**Different aromatic classes of compounds** The following classes of compounds should be taught in detail with respect to their IUPAC/ systematic nomenclature, industrial [wherever applicable] & laboratory methods of preparations, physical properties, chemical reactions and uses with emphasis on reaction mechanisms [arrowbased] & stereochemistry [wherever applicable]. • Aromatic hydrocarbons. • Aromatic & aliphaticamines.	2 2 2

	• Diazonium salts • Aromaticnitro-compounds, arylhalides, & ethers	3 1
	TOTAL	60

Reference Books:

- MorrisonR.T.&Boyd R.M., Organic Chemistry, Prentice Hall Of India, NewDelhi-110001
- HendricksonJ.B.,Cram D.J.,and HammondG. S, Organic Chemistry, Mc GrawHill, Kogakusha Ltd., NewDelhi
- Finar I.L., OrganicChemistry (Vol.I andII), Longman Group Ltd., England, ELBS Series
- NormanR.O., Principles of Organic Synthesis, Chapman& Hall
- CareyF.A., Organic Chemistry, TheMcGraw Hill CompaniesLtd., New
- Cleyten, Warren,Worruther, Organi Chemistry

Class: Second Semester B. Pharm. **Subject Code:** 230
Subject: Pharmaceutical Organic Chemistry (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To impresss up on students the importance of various safety issues involved in a chemical laboratory & first aid to be given in case of an chemical accident
- To train students in determining various physicochemical constants of a compound
- To train students in using different purification techniques necessary in a chemistry

Sr.No.	Laboratory Experiments
1.	Safety in laboratories. Precautions inhandling chemicals, fire hazards with solvents, hair, etc. First aid in all such unfortunate accidents
2.	Determination of physical constants like melting points, boiling points, etc
3.	Demonstration of filtration techniques, sodium fusion test
4.	Experiments on different purification techniques like a]useof charcoal, b]recrystallization [including criteria for selection of various solvents], c]simple distillation, d]demonstration of vacuum & steam distillations, fractional distillation if feasible, e]sublimation
5.	Qualitative analysis of organic compounds which includes element detection [N,S,X except F], detection of various functional groups, preparation of different derivatives & their significance
6.	Acetylation and benzoylation (recommended preparation: acetanilide, beta-naphthyl benzoate, Aspirin)
7.	Oxidations using"Cr"salts & alkaline KMnO4(anyone).
8.	Nitration (recommended preparation: nitration of acetanilide and likewise)

Class: Second Semester B. Pharm. **Subject Code:** 240
Subject: Pharmaceutical Inorganic Chemistry (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To emphasize the importance of inorganic entities inPharmaceuticals.
- To provide knowledge about importantin organic Pharmaceuticals inPharmacopoeia regarding their preparation, quality standard and Pharmaceutical uses
- To highlight the domain of radiopharmaceuticals used in the diagnostics and therapy
- To describe typical therapeutic classes and inorganic agents associated with them

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Pharmaceutical Impurities** Impurities in pharmaceutical substances, sources, types & effects of impurities. Limit tests for chloride, sulphate & heavy metals like lead, iron, arsenic, mercury Asper IndianPharmacopoeia [I.P.]	10
2	**Monographs** Monograph & its importance, various tests included in monographs as per I. P. A study of the following compounds with respect to their methods of preparation, assay, & pharmaceutical uses: sodium citrate, calcium carbonate, copper sulphate, light & heavy kaolin, ammonium chloride & ferrous gluconate	7
3	**Isotopes** Isotopes- stable & radioactive, mode & rate of decay. Types & measurement of radioactivity. Radiopharmaceuticals & their diagnostic & therapeutic applications in pharmacy & medicine such as 125I, 32P, 51Cr, 60Co, 59Fe, 99Tc-M. Radiocontrast media, use of BaSO4 in medicine	8
	SECTION B	
4	**Therapeutic classes of drugs** The following topics should be dealt with covering nomenclature [including stereochemical aspects], biological activity [including side & toxic effects], mode of action, structure activity relationship [where ever applicable] & syntheses of reasonable molecules. 1. Dentifrices, desensitizing agents, & anticaris agents. 2. General anesthetics. 3. Local anesthetics. 4. Antiseptics, disinfectants, sterilants, & astringents. 5. Purgatives, laxatives & antidiarrhoeal agents. 6. Diagnostic agents. 7. Coagulants, anticoagulants & plasma expanders	35
	TOTAL	60

Reference Books:

- Foye,W.O., PrinciplesOf Medicinal Chemistry, Varghese&Company, Mumbai,India
- Wilson,C.,Gisvold,O.,&Doerge,J.B., Text Book Of Organic Medicinal & Pharmaceutical Chemistry
- Lippincot Company, Toronto,Canada
- Block,J.H.,Roche,F.B., Soine,T.I.&Wilson,C.O., Inorganic Medicinal & Pharmaceutical Chemistry
- Varghese Publishing, House,Mumbai, India
- Atherden,L.M., Bentley And Drivers Textbook Of Pharmaceutical Chemistry, Oxford Medical Publications.
- Govt. of India, Indian Pharmacopoeia, (Vol.I &II), Controller of Publisher, Govt. of India.

Class: Second Semester B. Pharm. **Subject Code:** 250
Subject: Environmental Science **Allotted Hrs.:** 2

OBJECTIVE:

- To study the importance of environmental science and environmental studies
- To know the importance of key to the future of mankind.
- To study continuing problems of pollution loss of forest, solid waste disposal, degradationof Environment, issues like economic productivity and national security.
- Study of Global warming, the depletion of ozone layer and loss of biodiversity, & its impact on environmental issues.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Multidisciplinarynatureof environmentalstudies** Definition, scope and importance. Need for public awareness	4
2	**NaturalResources** Renewable and non-renewable resources : Natural resources and associated problems. 1) Forest resources: Use and over-exploitation, deforestation, case studies. 2) Timber extraction, mining, dams and their effects on forest and tribal people. 3) Water resources : Use and over-utilization of surface and ground water, 4) Floods, drought, conflicts over water, dams-benefits and problems. 5) Mineral resources: Use and exploitation, environmental effects of extracting and using mineral resources, case studies. 6) Food resources: World food problems, changes caused by agriculture and overgrazing, effects of modern agriculture, fertilizer-pesticide problems, water logging, salinity, case studies. 7) Energy resources: Growing energy needs, renewable and non renewable energy sources, use of alternate energy sources. Case studies. 8) Land resources: Land as a resource, land degradation, man induced landslides, soil erosion and desertification. a. Role of an individual in conservation of natural resources. b. Equitable use of resources for sustainable lifestyles	10
3	**Ecosystems** Concept of an ecosystem. 1. Structure and function of an ecosystem. 2. Producers, consumers and decomposers 3. Energy flow in the ecosystem. 4. Ecological succession. 5. Food chains, food webs and ecological pyramids. 6. Introduction, types, characteristic features, structure and function of the following ecosystems:- a. Forest ecosystem. b. Grassland ecosystem. c. Desert ecosystem. d. Aquatic ecosystems (ponds, streams, lakes, rivers, oceans, estuaries).	8
4	**Biodiversity and its conservation** 1. Introduction: – Definition: genetic, species and ecosystem diversity. 2. Biogeographical classification of India 3. Value of biodiversity :consumptive use, productive use, social, ethical, aesthetic and option values 4. Biodiversity at global, National and local levels. 5. India as a mega-diversity nation 6. Hot-spots of biodiversity. 7. Threats to biodiversity: habitat loss, poaching of wildlife, man-wildlife conflict 8. Endangered and endemic species of India. 9. Conservation of biodiversity: In-situ and Ex-situ conservation of biodiversity	8

	SECTION B	
5	**Environmental Pollution** Definition 1. Causes, effects and control measures of : a. Air pollution. b. Water pollution. c. Soil pollution. d. Marine pollution. e. Noise pollution. f. Thermal pollution & Nuclear hazards. 2. Solid waste management:- Causes, effects and control measures of urban and Industrial wastes. 3. Role of an individual in prevention of pollution. Case studies. 4. Disaster management:- Floods, earthquakes, cyclones and landslides	9
6	**Social Issues and the Environment** From Unsustainable to sustainable development 1. Urban problems related to energy 2. Water conservation, rain water harvesting, watershed management 3. Resettlement & rehabilitation of people, its problems & concerns. Case Studies. 4. Environmental ethics: Issues and possible solutions. 5. Climate change, global warming, acid rain, ozone layer depletion, nuclear accidents and holocaust. Case Studies. 6. Wasteland reclamation. 7. Consumerism and waste products. 8. Environment Protection Act. 9. Air (Prevention and Control of Pollution) Act. 10. Water (Prevention and control of Pollution) Act 11. Wildlife Protection Act 12. Forest Conservation Act 13. Issues involved in enforcement of environmental legislation. Public awareness	9
7	**Human Population and the Environment** Population growth, variation among nations. 1. Population explosion – Family Welfare Programmes 2. Environment and human health. 3. Human Rights. 4. Value Education. 5. HIV/AIDS. 6. Women and Child Welfare. 7. Role of Information Technology in Environment and human health. Case Studies	6
8	**Fieldwork** 1. Visit to a local area to document environmental assets,/river /forest / grassland/hill/mountain. 2. Visit to a local polluted site-Urban/Rural/Industrial/Agricultural. 3. Study of common plants, insects, birds. 4. Study of simple ecosystems-pond, river, hill slopes, etc	6
	TOTAL	60

Reference Books:

- Brunner R. C., Hazardous Waste Incineration, Mc Graw HillInc.
- Gleick H.P, Water incrisis, Pacific Institute., for Studies in Dev., Environment & Security. Stockholm Env.Institute, Oxford Univ. Press
- HawkinsR.E., Encyclopedia of Indian Natural History, Bombay Natural History Society, Bomba
- Heywood V.H & Waston R. T., Global Biodiversity Assessment., Cambridge Univ. Press
- MckinneyM.L. & School R.M., Environmental Science systems & Solutions, Webenhanced edition.
- OdumE.P., Fundamentals of Ecology, W.B. Saunders Co.USA,

Syllabus for Third Semester B. Pharmacy

Class: Third Semester B. Pharm. **Subject Code:** 310
Subject: Physical Pharmacy – II (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To establish relationship between chemical nature and physical properties of the molecules.
- To understand importance of physicochemical properties of materials in pharmaceutical discipline.
- To develop the concepts of applying knowledge of physicochemical properties of material in development of stable and effective dosage form.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Matter,propertiesof matter:** States of matter, change in the state of matter, latent heat and vapor pressure, sublimation-critical point, eutectic mixtures, gases, aerosols- inhalers, relative humidity, liquid complexes, liquid crystals, glasses state, solid crystalline and amorphous polymorphism.	7
2	**Micromeriticsandpowder rheology:** Particle size and distribution, average particle size number and weight distribution, particle number, method of determining particle size and volume, optical microscopy, sieving, sedimentation, determining surface areas, permeability, adsorption, derived properties of powders, porosity, packing arrangement densities, bulkiness and flow properties.	8
3	**Surfaceandinterfacialphenomenon:** Liquid interface, surface and interfacial tensions, surface free energy, measurement of surface and interfacial tension, spreading coefficient, adsorption and liquid interfaces, surface active agents, HLB classification, solubilization, detergency, absorption at solid interfaces, solid gas and solid liquid interfaces, complex films, electrical properties of interfaces.	9
4	**Viscosityandrheology:** Newtonian systems, law of flow, kinematics viscosity, effect of temperature, non Newtonian systems, pseudoplastics, dilatant, plastic, thixotropy in formulations, determination of viscosity and thixotropy by capillary, falling ball, rotational viscometer, application of theology in pharmacy.	7
	SECTION B	
5	**Dispersionsystems:** **a.** Colloidal dispersions: Definition, types, properties of colloids, protective colloids, application of colloids in pharmacy. **b.** Suspensions and emulsions: Interfacial properties of suspended particles settling in suspension, theory of sedimentation, effect of Brownian movement, sedimentation of flocculated particles, sedimentation parameters, wetting of particles, significance of electrical properties in dispersions, controlled flocculation, flocculation in structured vehicles, rheological considerations, emulsions: types, theories, physical stability	9
6	**Complexation:** Classification of complexes, methods of preparations and analysis, applications.	6
7	**Buffers:** Buffer equations and buffer capacity in general. Buffers in pharmaceutical systems, preparations and stability, buffered isotonic solutions. Measurements of tonicity calculations and methods of adjusting isotonicity.	5
8	**Solubility:** **a.** Miscibility-influenceofforeign substances-three component systems-dielectric constant and solubility, solubilityof solidsinliquids-ideal andnon-ideal solutionssolvation and association in solutions-solubility of salts in water-solubility of slightly soluble and weak electrolyte-calculating solubility of weak electrolytes as influenced by pH, influence of solvents on the solubility of drugs-combined effect of pH and solvents, distribution of solutes between immiscible solvents, effect of ionic dissociation and molecular association on partition, extraction, preservatives action of weak acids in emulsions, drug action and	9

	distribution co-efficient. **b.** Concepts of dissolution and diffusion.	
	TOTAL	60

Reference Books:

- Kim CherhgJu, Advance Pharmaceutical Physicochemical Principles, CRC Press
- M. E.Aulton, Pharmaceutics: The Science of Dosage Form Design, Churchill Livingstone
- MartinAlfred, Physical Pharmacy, Lippincott
- MooreW.J., Physical Chemistry
- RaymondChang, Physical Chemistry for Biosciences, University Sciences Books
- GinnaroA.R., "Remington: Thescience and Practice of Pharmacy", Mack Publishingcompany.

Class: Third Semester B. Pharm. **Subject Code:** 310
Subject: Physical Pharmacy – II (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To train students about different techniques used in getting some of the important physical constants of a compound.
- To train students on use of methods used to find physical parameters of physiological importance.
- To introduce students to some of the chemical & instrumental methods of analysis.

Sr.No.	Laboratory Experiments (Minimum 2 experiments)
1.	To determine molecular weight of (anthracene/ phenanthrene) by Beckman's thermometer method
2.	To determine molecular weight of nitrobenzene/toluene/aniline by steam distillation.
3.	To determine the upper convolute temperature and composition of phenol -water system
4.	To construct the ternary phase diagram of water chloroform acetic acid system
5.	To determine the heat of neutralization of strong acid and strong base
6.	To determine the refractive index and refrachor of given sample having molecular weight
7.	To determine the wavelength of maximum absorption of given dye using visible spectrophotometer
8.	To determine the molecular weight of given sample using Lands Berger apparatus
9.	To determine the molecular weight of given sample by Rast's camphor method
10.	To determine the pKa of (benzoic acid/salicylic acid / any solid amine) by acid base titration
11.	To determine partition coefficient of benzoic acid / salicylic acid / iodine in chloroform / benzene water system
12.	To determine the effect of potassium iodide on the solubility of iodine
13.	To study the diffusion profile of brilliant green through cellophane membrane
14.	To study the hydrogen peroxide degradation by volumetric measurement of oxygen
15.	To determine the energy of activation of methyl / ethyl acetate hydrolysis
16.	To determine the surface tension and parachore of given sample using stalagmometer
17.	To determine the specific surface of charcoal using acetic acid adsorption
18.	To determine critical micellar concentration (CMC) of given ionic surfactant by conductometric measurement
19.	To determine the effect of surfactant (tween 80) on solubility of salicylic acid
20.	To determine the effect of electrolyte on sedimentation of calamine suspension
21.	To determine the particle size distribution of an emulsion using optical microscopy
22.	To determine the particle size distribution using sieve analysis
23.	To study the effect of lubricant on flow property of given powder
24.	To determine the various densities and porosity of given powder system
25.	To determine the viscosity and rheogram of given sample of liquid
26.	To determine the molecular weight of PVP / PVA using Oswald's viscometer
27.	To determine the optical rotation of given substance
28.	To demonstrate viscosity measurement using Brookfield's viscometer
29.	To determine density/specific gravity of liquids

Class: Third Semester B. Pharm. **Subject Code:** 320
Subject: Pharmaceutical Organic Chemistry II (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To provide advanced synthetic conversions of organic functional groups
- To emphasize the importance of carbonyl group in synthesis of diversified molecules.
- To expose the students towards heterocyclic compounds & their chemistry
- To facilitate the concept of stereochemistry in organic compounds with respect to molecules of biological importance like carbohydrates and aminoacids along with their chemistry

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Polycyclic aromatic hydrocarbons** Syntheses & reactions with mechanisms of bi- & tricyclic fused carbocyclic rings like naphthalene, anthracene, & phenanthrene	4
2	**Carbonylchemistry** Carbonyl chemistry involving group conversions & their reaction mechanisms along with stereochemistry wherever applicable. A. Wolf-Kishner reduction & Huang-Minlong modification. B. Reduction of arylsulfonyl hydrazine / hydrazones to alkanes. C. Bamford Steven reaction. D. DCC Oxidation of alcohol. E. Michael addition / 1,4-addition / conjugate addition. F. Mannich condensation / reaction. G. Robinson annulation. h. Stobbe condensation. H. Darzen's glysidic ester synthesis. I. Beckmann rearrangement. J. Baeyer villiger rearrangement. K. Curtius, Wolff, & Lossen rearrangements. L. Willgerodt rearrangement. M. Pinacol-pinacolone rearrangement. N. Use of diazomethane& sulphurylides inthe same. O. Methylene transfer reactions. Use of diazomethane & sulphur ylides in the same. P. Mono- & dialkylations in 1,3-dicarbonyl compounds. Q. Formation & use of enol ethers, enol acetates & enamines as protective groups & in regiospecific alkylations.	15
3	**HeterocyclicChemistry** IUPAC Nomenclature of heterocyclic rings [3-10 membered] containing O, S, & N atoms. Nomenclature of above rings containingmono-,di-, & multiple [same or different] heteroatoms should also be covered. Nomenclature of 2 & 3 fused rings containing mono-, di-, & multiple heteroatoms [same or different] should also be covered. Syntheses & reactions of three to six membered rings be studied in detail. Syntheses of five & six membered rings containing mono- or any di- heteroatoms [O, S, & N] should be covered. Syntheses of quinoline, isoquinoline, benzoxole, benzthiole, & benzazole, benzdiazole, benzoxazole, & benzthiazole should be studied	16
	SECTION B	
4	**Bridgedrings** Bridged ring systems & their nomenclature	2
5	**Oxidation and Reductions** Use of reagents such as (oxidations) potassium dichromate, potassium permanganate, hydrogen peroxide, manganese dioxide, trolofsulfonation,enolateanionformation& (reductions), hydrogenation catalysts, using palladium, platinium, Lithium aluminium hydride, sodium borohydride, hydrazine hydrate	3

6	**Stereochemistry** Stereochemistry. Chirality & asymmetry [introduction of the same to S, P, & N]. Definition & classification [different types of isomerisms]. Enantiomers, diastereomers. Enantiomerism & diastereomerism. Meso compounds & their optical activity. Stereochemistry in acyclic compounds. Newman projection formulae & their significance. Conformational analysis of n- butane. Absolute & relative configuration. Assigning R & S configuration based on Cahn Ingold & Prelog system. Racemic mixtureits definition & resolution. Definitions of terms stereoselective, stereospecific, enantiomericexcess& distereomeric excess. Stereochemistryincyclicsystems. Conformations of cyclohexane. Cis – trans relationship in cyclohehane. Prediction of stability of different conformations of 1, 2- 1,3- & 1,4- disubstituted cyclohexanes. Effect of multiple substitutions on the stability of cyclohexane conformations. Chair conformationations of cis-,trans-decalins, perhydrophenanthrenes, & a tetracyclic steroidal nucleus. An introduction to atropisomerism	13
7	**Organometalic chemistry** Organo metallic chemistry [preparation & few reactions (recommended: for Cu, Mg, boron)	2
8	**Pericyclicreactions** Pericyclic reactions. Concept of HOMO & LUMO. Drawing of HOMO & LUMO of 1, 3-butadiene, allylic cation, radical & anion, & 1, 3, 5-hexatriene. Meaning of conrotatory & disrotatory. Allowed & disallowed thermal & photochemical reactions. Introduction to sigmatropic, electrocyclic & (4n + 2) cycloaddition reactions. Cope, oxy-cope [Claisen rearrangement], Diel's-Alder & retro Diel's Alder reaction	5
	TOTAL	60

Reference Books:

- MorrisonR.T. andBoyd R.M., Organic Chemistry, Prentice Hall Of India Ltd.,New Delhi-110 001.
- Finar I.L., Organic Chemistry(Vol.I and II) Longman Group Ltd., London. Elbs Series.
- HouseH.O., Modern Synthetic Reactions, W.A.Benjamin,London
- CareyF.A., Organic Chemistry, TheMc Graw HillCompanies.
- PineS.H., Organic Chemistry, Tata Mc Graw Hill Publishing Company.

Class: Third Semester B. Pharm. **Subject Code:** 320
Subject: Pharmaceutical Organic Chemistry II (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To train students on purification of different solvents used in chemical reactions.
- To separate a binary mixture based on their acidic, basic properties.
- To give synthesis experiments for preparation of different compounds/drug molecules & their characterization.

Sr.No.	Laboratory Experiments
1.	Drying of solvents (recommended: ether, THF, CH_2Cl_2, $CHCl_3$, C_6H_6, hexane).
2.	Separation of binary mixtures of different types based on their functional groups.
	Combination of acids, bases & neutral compounds (solid-liquid combinations, liquid-liquid combinations and based on water soluble-water insoluble type)
	Students are expected to do only the separation of the mixture and identification of any one by qualitative organic analysis.
3.	Quantitative determination of reactive groups: nitro, hydroxyl, primary and secondary amines, carboxyl, esters, amides.
4.	Diazotization & coupling reactions.
5.	Electrophilic substitution reactions for polycyclic organic compounds (naphthalene, anthracene)
6.	Synthesis related to molecular rearrangements (recommended: Benzilic acid, Aldol, Cannizarro's , Pinacol-pinacolone, Beckmann)..
7.	Synthesis of heterocyclic compounds

Class: Third Semester B. Pharm. **Subject Code:** 330
Subject: Pharmaceutical Microbiology (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To emphasize microbiological aspects of Pharmaceutica limportance.
- To deal with various aspects of microorganisms,their classification cultivation, identification etc.
- To provide the thorough knowledge of disinfection and sterilization methods.
- To give an idearegarding immunological aspects, their significance.
- To outline the importance of subject in useful diagnostic tests.
- To provide the knowledge about the use of microbiological techniques in quantification /standardization of selected Pharmaceuticals.
- To help in providing idea about infectious diseases diagnosis and their control

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Introduction to Microbiology** Scope and application to pharmacy field. Whittaker's Five Kingdom concept, historical development – biogenesis vs. a biogenesis, Germ theory of fermentation, Germ theory of disease, contribution of Leeuwenhoek, Robert Koch, Jenner, Louis Pasteur and Ehrlich	2
2	**Microscopy and staining technique** Principle, ray diagram, construction, working and applications of light compound, dark field, phase contrast, Fluorescence & electronmicroscope.Concept of resolving power, Magnification power, numerical aperture and angular aperture and working distance. Principle application of oil immersion microscopy. Theory of staining, principle and technique of staining procedure – Monochrome, Gram, acid fast, negative, capsule, endospore.	5
3	**Biology of Microorganisms** Cultural characteristics, pure culture techniques a) Bacteria – Morphology and fine structure of bacteria, Nutritional requirement and type of culture media, growth and growth curve of bacteria, physical condition for growth, measurement of bacterial growth (Counting Methods), Reproduction in bacteria, genetic exchange – transformation, conjugation, and transduction, development of drug resistance by recombination and mutation, preservation of bacterial culture. Biochemical properties (sugar fermentation and IMVIC test). Pathogenesis of staphylococcus, Mycobacterium. Salmonella Introductory study of disease causing rickettsia, importance of actinomycetes in antibiotic production	7
4	**Fungi and Viruses** b) Fungi :- Introduction, general characteristics, morphology, industrial and medical significance of Saccharomyces Cerevisae, Penicillium and Aspergillus, Candida Albicans, Epidermophyton and trichophyta. c) Viruses:- Introduction, structure and general properties Bacteriophages – Lytic and Lysogenic cycle, Epidemiological uses of Bacteriophages, human viruses – Cultivation and Multiplication virus host cell interaction, Pathogensis of HIV and Prions, types of Tumor viruses	5
5	**Aseptic Technique** Omnipresence of microoganisms, importance of asepsis, sources of contamination and methods of prevention, Principle, construction & working of laminar air flow bench	3
6	**Sterilization & Disinfection** a) Concept & classification, principle & methods of sterilization, Mechanisms of cell injury. b) Construction working & applications of moist heat & dry heat sterilizer, gamma radiation sterilizer, filtration sterilizer. indicators of sterilization, microbial death, kinetic terms-D value, z value c) Terminology of chemical antimicrobial Agents, Chemical classification of different disinfectants, characteristics of idealdisinfectants, factors affecting action, evaluation methods (RW Coeff), Kelsey Sykes test, Chick Martin test.	6

	SECTION B	
	Microbial spoilage Types of spoilage, factors affecting spoilage of pharmaceutical products	2
	Immunology and health a) Host parasite Relationship :- normal microbial flora of human body, infection vs. disease, Pathogenicity vs. Virulence, Koch & Rivers Postulates, Reservoir of infectionsources of infection, Portals of Entry, Portals of exit, vectors of infection, communicability of disease, recognized symptoms of microbial disease, classification of immunity • External defense mechanism of host: Skin, Mucus membrane, chemical Secretions, Naturally occurring microbial flora • Internal defense Mechanism : Inflammation, fever, naturalkiller Cells, Phagocytic Cells,Soluble mediators-complement Lymphokines, Interferons b) Immune response : • Specific immunity & immune response • Humoral immunity antibody response, mediators ofHumoralimmunity, basic structure of antibody,antibodyclasses& functions, maturation of immune response, immunologic memory • Antigens : specificity & Immunogenicity, Natural vs.artificialAntigens,Soluble cellular antigens, thymus independent antigen, adjuvant. • hypersensitivity : o Immediate-type or anaphylaxis (type I) o Compliment mediated or cytolytic hypersensitivity (type II) o Immune complexorarthrus hypersensitivity (type III) o Delayed orcellmediated hypersensitivity (type IV) o Cellular immunity o Transplantation immunity o Cellular immunity to viruses o Implications of T-cell response • Acquisition of specific immunity : natural vs. Passive acquisition c) Practical aspects of immunity • Measurement of humoral immunity (antibodies) - Precipitation tests Agglutination tests, RIA, ELISA, immune fluorescence • Production of monoclonal antibodies • Measurementof cellmediatedimmunity - Intradermaltests,testsformigration, mixed lymphocyte reaction (MLR), Cell mediated toxicity (CMT)	22
	Vaccines & Sera Manufacturing (seed lot system) and quality control of bacterial vaccines & Toxoids (Tetanus, TAB, Cholera, BCG, DPT), Viral vaccine (Polio- Salk Sabin, Rabies, MMR, Hepatitis, Chickenpox,influenza),Antisera(diphtheria, tetanus), antiviral Antisera (rabies). preparation of allergenic extracts & diagnostics	6
	Microbial Assay Importance, general methods of assay of antibiotics (Cup & plate method, paper disc method, turbidometry, dilution method), methods for fungicidal & antiviral compounds, assay, microbial limit tests	2
	TOTAL	**60**

Reference Books:

- Martin Frobisher, Fundamentals of Microbiology, WB Saunders Co.
- SchlegelH.G., General Microbiology, Cambridge University Press
- PelczarM.J.& ChanE.C., Microbiology, TataMcGrawHill
- TortoraG.J., Microbiology: A nIntroduction, BenjaminCumming Corp.
- StephenP.Denyer, Hugo and Russes'sPharmaceutical Microbiology, WilleyBlackwell

Class: Third Semester B. Pharm. **Subject Code:** 330
Subject: Pharmaceutical Microbiology (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To make students underst and the omnipresence of microorganisms.
- To study different properties of some of the microorganisms.
- To train students on various methods fo rgrowing bacteria.
- Toa cquaint students with different techniques used for maintaining sterility.

Sr.No.	Laboratory Experiments
1.	To demonstrate the omnipresence of microorganisms.
2.	To study the principle and working of microscope and other laboratory equipments.
3.	To study the principle and working of laminar airflow.
4.	To Study cultural characteristics of microorganisms.
5.	To identify isolated bacteria by simple, negative, gram staining and spore staining. Study of Aspergillus and Penicillium with respect to morphology (Wet mount techniques.)
6.	To observe motility of bacteria by hanging drop techniques.
7.	To prepare and sterilize nutrient broth, nutrient agar, slants, stabs and plates.
8.	To study different techniques of Inoculation of culture on different types of media.
9.	To isolate pure culture by streak plate technique.
10.	To study growth of Fungi on Sabroud's agar and Czepodox agar medium.
11.	To determine microbial count of air by any suitable method.
12.	To determine thermal death temperature and time.
13.	To determine phenol coefficient of disinfectant by P.W. coefficient.
14.	To study growth of Fungi on Sabroud's agar and Czepodox agar medium.
15.	To study sterility testing of following as per. I.P. : a) Water for injection. b) Ophthalmic preparations.
16.	To carry out antibiotic assays of penicillin & streptomycin or some suitable antibiotic.
17.	To carry out vitamin B12 bioassay.
18.	To determine MIC (Minimum Inhibitory concentration) of an antibacterial agent.
19.	To study a) antibacterial b) antifungal activity of any medicinal plant.
20.	To study microbial limits of the following as per I.P. procedure. a) Aluminum hydroxide gel. b) Starch. C) Talc
21.	To study microbial limits of the following as per I.P. procedure.

Class: Third Semester B. Pharm. **Subject Code:** 340
Subject: Pathophysiology (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To impart a thorough knowledge of pathological aspects of various conditions
- To generate the ability to describe etiology and pathogenesis of important diseases states
- To develop the abilityof naming the sign and symptoms of diseases
- To develop the ability to describe complications of diseases

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Basic principles of cell injury and adaptation** Causes, pathogenesis and morphology of cell injury. Abnormalities in lipoproteinemia, glycogen infiltration and glycogen storage disease	5
2	**Basic mechanisms of inflammation and repair** Pathogeneses of inflammation. Chemical mediators in inflammation. athogenesis of chronic inflammation. Repair of wounds in the skin, factors influencing healing of wounds	6
3	**Hypersensitivity** Hypersensitivity type I, II, III, IV. Biological significance of hypersensitivity. Allergy due to food, chemicals and drugs	4
4	**Auto-immunity & diseases of immunity** Mechanism of autoimmunity. Classification of autoimmune diseases in man. Transplantation and allograft reactions, mechanism of rejection of allograft. Acquired Immune Deficiency Syndrome (AIDS). Amylodosis	6
5	**Neoplastic diseases** Disturbances of growth of cells. General biology of tumors, differences between benign and malignant tumors. Classification of tumors. Historical diagnosis of malignancy. Etiology and pathogenesis of cancer. Invasions, metastasis, patterns of spread of cancer. Environmental carcinogenesis	8
	SECTION B	
6	**Shock** Types, mechanisms, stages and management	2
7	**Biological effects of radiation** Nuclear radiation, UV, X-ray and other radiations	1
8	**Protein calorie malnutrition, vitamins, obesity, starvation** Deficiency of vitamins, study of various syndromes due to obesity and starvation	4
9	**Pathophysiology of common diseases** Parkinsonism. Schizophrenia. Depression and mania. Stroke (ischemic and hemorrhage). Hypertension. Angina. Myocardial infarction, CCF. Atherosclerosis. Diabetes mellitus. Peptic ulcer and inflammatory bowel disease. Cirrhosis and alcoholic liver diseases. Acute and chronic renal failure. Asthma and chronic obstructive airway diseases.	14
10	**Infectious diseases** Hepatitis – Infective hepatitis. Sexually transmitted diseases (syphilis, gonorrhea, HIV). Pneumonia, typhoid, urinary tract infections. Tuberculosis. Leprosy.Malaria. Dysentery (Bacterial and amoebic). Viral oncogenesis	10
	TOTAL	**60**

Reference Books:

- Robins CotranKumar, Text Book Of Robins Pathology Basis Of Disease, PrismIndian Edition
- DevlinT.M., Text Book Of Biochemistry with Clinical Correlations, McGraw Hills
- HomesN.H., Clinical Laboratory Test, Springer Publications
- NajihA.Naser, Clinical Chemistry-A Laboratory Manual, Mosby
- RussellJ.G.,HarrisN.D, Pathology & Therapeutics for Pharmacy, Pharmaceutical Press

Syllabus for Fourth Semester B. Pharmacy

Class: Fourth Semester B. Pharm. **Subject Code:** 410
Subject: Pharmaceutics II (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To develop the basis for plant design for the production of Pharmaceuticals.
- To imbibe the concept of industrial Pharmacy.
- To impart the knowledge regarding production methodologyof non-sterile and sterile dosage Form.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Pharmaceutical Plant, location, layout** Plant location and lay out of an industry. Various factors affecting locational aspects of chemical and pharmaceutical plants. Layout of plant building and importance of flow sheet, difference between scientific process and technological process, layout of various departments, equipments, product lay out v/s process layout	5
2	**Dosage Form Necessities and Additives** Antioxidants, preservatives, coloring agents, flavoring agents and diluting agents, emulsifying agents, suspending agents, ointment bases, solvents, and others	5
3	**Powders** Advantages and limitations as dosage form, manufacturing procedure and equipments, special care and problems in manufacturing powders, powders of IP, effervescent granules and salts	6
4	**Capsules** Hard gelatin capsules, shell formulation and manufacturing, capsule sizes, storage, filing, cleaning process general formulation contents and evaluation. Soft gelatin capsules, shell formulation, formulation contents, filing, sealing and storage. Microencapsulation, advantages, encapsulation materials, methods of microencapsulation, I.P. formulations	8
5	**Tablets** Types,ideal requirement,classification, granulation methods, general formulation, compression machines, different types of toolings, difficulties in tableting, trouble shooting aspects, evaluation, sugar coating, compression coating, film coating, problems in tablet coatings and their trouble shooting aspects. IP formulations	8
	SECTION B	
6	**Parenterals - product requiring sterile packaging** Definition, types advantages and limitations, general formulation, vehicles, production procedure, production facilities, controls, tests, selected IP injections, sterile powders, implants, emulsions, suspensions formulation of calcium gluconate injection.	10
7	**Suspensions** Formulation of deflocculated and flocculated suspension, manufacturing procedure, evaluation methods, IP suspensions (2-3 examples)	3
8	**Emulsions** Types,emulsifying agents,generalformulation, manufacturing procedure, evaluation methods, IP emulsions (2-3 examples)	3
9	**Suppositories** (2-3 examples) Idealrequirements,bases,manufacturing procedure, evaluation methods, IP products	2
10	**Semisolids (Ointments, pastes, creams and jellies)** Definitions, bases, general formulation, manufacturing procedure, evaluation methods, IP products.	4
11	**Pharmaceutical Aerosols** Definition, propellants, general formulation, manufacturing and packaging methods, pharmaceutical applications. Impacts of propellants on environment. Metered aerosol	4
12	**Ophthalmic preparations** Requirement, formulation, methods ofpreparation, containers, evaluation, IP products.	2
	TOTAL	**60**

Reference Books:
• Govt. of India, Indian Pharmacopoeia, TheControllerof Publication
• B.P.Comission, British Pharmacopoeia, H.M.S.O.London
• LeonLachman, Leiberman, Pharmaceutical Dosage Form: Table, ChurchillLivingston
• LeonLachman, Leiberman, Pharmaceutical Dosage Form: DisperseSystem, ChurchillLivingston
• AlfonsaGennara, Remingtons,The Science Practice of Pharmacy, Lippincott
• Bankar Gilbert, Cristofer T.Rhods, Modern Pharmaceutics, MarcelDekker

Class: Fourth Semester B. Pharm. **Subject Code:** 410
Subject: Pharmaceutics II (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To train students on preparation of som edosage forms not covered earlier.
- To impart training for analysis of various dosage forms prepared by them

Sr.No.	Laboratory Experiments
1.	To prepare and evaluate the salicylic acid ointment (20 gm).
2.	To prepare aspirin tablet by dry granulation method.
3.	To prepare and evaluate dispersible tablet.
4.	To prepare acetyl salicylic acid tablet by wet granulation.
5.	To evaluate the marketed uncoated and coated tablet formulations.
6.	Quality control of marketed formulations.
7.	To study film coating.
8.	To study sugar coating.
9.	Demonstration of microencapsulation.
10.	To study entry procedures in aseptic area.
11.	Microbial count of aseptic area in filling zone.
12.	To study pyrogen test for sterile product.
13.	Preservative sorption of rubber closure.
14.	To prepare and evaluate calcium gluconate injection I.P.
15.	Preparation and evaluation of ascorbic acid injection I.P.
16.	To prepare water for injection and study sealing of ampoules.
17.	To prepare tablet by direct compression.
18.	To prepare capsule formulations of any one drug.
19.	To prepare basic ophthalmic eye drop.
20.	To prepare glycerol gelatin suppository.
21.	To prepare PEG suppository.
22.	To design layout of Pharmaceutical plant for tablet, parenterals.
23.	To prepare effervescent granules with iron.

Class: Fourth Semester B. Pharm. **Subject Code:** 420
Subject: Pharmaceutical Medicinal Chemistry I (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To develop the linkage between organic chemicals and their transformation to the drug molecule.
- To develop the ability for nomenclature of drugs having various structural features.
- To expose students towards different chemical classes of compounds and their relationships According to their biological activity.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Theoretical aspects of drug action:** Ferguson principle,, relation of physicochemical parameters with biological activity (solubility, partition coefficient, pKa, surface activity, stereochemistry), structural modification strategies for improving permeability, (metabolic, plasma, solution, plasma protein) stabilities, blood brain barrier penetration.	7
2	**Drug metabolism** I Introduction to drug metabolism based on the functional groups. types, factors affecting metabolism	5
3	**Variousclassesof therapeutic agents** A detailed study of the following classes with respect to drug nomenclature, classification, physicochemical properties, mode of action [MOA], structure activity relationships [SAR], wherever applicable, synthesis of simple & prototype molecules, drug metabolism, therapeutic uses & side effects, drug resistance, wherever applicable, should be covered in respective classes of drugs. A. Antibiotics. Penicillins, cephalosporins & other beta-lactam antibiotics like imipenam & aztreonam. Beta-lactamase inhibitors such as clavulanic acid & sulbactum. Chloramphenicol, Tetracyclines, Aminoglycoside antibiotics, Macrolide antibiotics, Lincomycins, Polypeptide antibiotics **SECTION B** B. Antibacterialsulphadrugs[only]. C. Quinolone antibacterials. D. Antiviral agents includinganti-HIVdrugs. E. Thyroid&anti-thyroid drugs. F. Anticancer / anti-neoplastic agents G. Antihistaminics H. Antiulceragents&ProtonPumpInhibitors. I. Antimalarials.	12 5 4 4 4 5 5 3 6
	Note:Synthesis of following drugs should be studied: Chloroquine, primaquine, amodiaquin, pyrimethamine, trimethoprim, ampicillin, cephalexin, chloramphenicol, ciprofloxacin, mepacrine, sulphanilamide, sulphacetamide, sulphathiazole, sulphamethoxazole, sulphadiazine, sulphafurazole, amantadine, zidovudine, acyclovir, 6-mercaptopurine, methotrexate, chlorambucil, cyclophosphamide, thiotepa, ondansetron, omeprazole, chlorpheniramine, diphenhydramine, pyrilamine, antazoline	
	TOTAL	**60**

Reference Books:

- FoyeW.O., PrinciplesOf MedicinalChemistry, K., E.,Varghese&Company
- Wilson C.GisvoldO.,&Doerge.J.B., TextBookOf OrganicMedicinal& PharmaceuticalChemistry, B.LippincotCompany,
- D.J.AbrahamEd., Burger'sMedicinalChemistry&Drug Discovery, JohnWiley& SonsInc.,NewYork.
- Lednicer Daniel, OrganicChemistryOfDrug Synthesis (Vol.I andII), Wiley-Interscience, USA
- PatricG.L., AIntroductiontoMedicinal Chemistry, Abingdon, Oxfordshire,UK

Class: Fourth Semester B. Pharm. **Subject Code:** 430
Subject: Pharmaceutical Analysis I (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To emphasize the importance of quality in drugs & pharmaceuticals.
- To establish the fundamental conventional methods of drug analysis used in laboratories.
- To provide the knowledge regarding the principles of titrimetry and gravimetric techniques.
- To give the basic principles of other analytical techniques used in analytical chemistry.
- To teach applications of these analytical methods to drugs & pharmaceuticals.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Introduction** to Pharmaceutical analysis and quality control, Classification of analytical methods, Importance of quality control in pharmacy	5
2	**Acid-base titrations** Definitions of acids & bases according to Arrhenius & Lewis theory.Definitions of normality, molarity, molality, & equivalent weight. Primary &Secondary standards with examples, & differences between them. Standardization of strong acids & bases using primary & secondary standards.Preparation of standard solutions of & calculations of equivalent weights ofoxalic acid, potassium acid phthalate, calcium chloride dihydrate, & sodium carbonate. Calculation of factors involved in standardization of sodium hydroxide, hydrochloric acid, & oxalic acid. Direct, back & differential titrations. Application of direct & back titrations to preparations like boric acid & borax in a mixture, ammoniated mercury, milk of magnesia, & zinc oxide ointment. Law of mass action, acid-base equillibria, pH scale, pH & hydronium ion concentrations in aqueous systems, calculations of pH for weak acids & weak bases. Use & applications of pH meter. Hydrolysis of salts. Strengths of acids & bases, dissociation constant. Theory of acid –base indicators. Neutralization [titration] curves. Definition, different types of buffers [chemical & biological], & their composition. Buffer capacity, buffered isotonic solutions. Calculations involving preparation of various buffer capacity solutions. Biological & pharmaceutical applications of buffers.	12
3	**Non-aqueous titrations** Need & theory behind it. Acid-base definitions according to Lowry-Bronsted, Lewis & Arrhenius concept. Factors affecting strengths of acids & bases. Intrinsic structure & surrounding environment. Protophilic, protogenic, amphiprotic & aprotic solvents. Acid-base equillibria in nonaqueous media. Titrants & indicators used for assay of acidic & basic substances. Preparation of perchloric acid, formation of onium ion. Assay of 1o, 2o, 3o amines & amine hydrochlorides using perchloric acid & the reactions involved in it. Standardization of sodium ethoxide solution. Assay of phenols & phenobarbitone. General applications of non-aqueous titrations.	8
	SECTION B	
4	**Oxidation- reduction titrations** Definition of oxidation, reduction, oxidizing & reducing agent. Equivalent weight , concept of half reactions. Systematic balancing of half reactions with respect to: a. Oxalic acid-KMnO4, b. FeSO4-ceric nitrate, & c. I_2-sodium thiosulphate solution titrations. A)Calculation of equivalent weight of oxalic acid, KMnO4, FeSO4, permangnate & I_2 from half reactions. Calculation of factors for titrations mentioned in a, b & c. titrations, KMnO4 as self-indicator, it's preparation, standardization, & use in the assay of ferrous gluconate tablets, H2O2, & NaNO2 solution. B) Iodimetric & iodometric titrations. Definitions & difference between iodimetry & iodometry. Preparation, standardization of iodine solution. Assay of ascorbic acid & sulphur ointment by iodimetry. Assay of copper sulphate & ferric chloride by iodometry. Bromometric titrations. Iodate titrations. Definition. Preparation, standardization & use of KIO3 in the assay of ascorbic	10

	acid & KI. C) Cerimetric titrations. Preparation, standardization & use of ceric solutions in the assay of paracetamol tablets. It's advantages over permanganate solutions. D) Bromine titrations. Preparation, standardization & use of bromine solution in the assay of phenol & isoniazide tablets. E) Potassium dichromate titrations. Preparation, standardization & use of potassium dichromate solution in the assay of ferrous ammonium sulphate	
5	**Precipitation titrations** Principle of solubility product & sparingly soluble salts. Titrants & indicators used in Mohr's, Volhard's, & Fajan's methods. Preparation & standardization of silver nitrate & ammonium thiocyanate solutions. Assay of sodium chloride by Mohr's method, use of nitrobenzene in the assay of halides, ammonium chloride, & thiourea by Volhard's method. Calculation of factors in argentimetric titrations. Titration curve method. General applications of precipitation titrations.	6
6	**Complexometric titrations** Difference between double salts & co-ordinate compounds. Definitions of co-ordination number of metal ions, ligands- uni-, bi-, & multidentate. Complexing, chelating, & sequestering agents with respective examples. Structure of complexes of platinum with ammonia. Ethylene diamine tetraacetate [EDTA] as a multidentate ligand in complexometry. Co- ordinate compounds of EDTA with bi-, tri-, & tetravalent metal ions. Stability of complexes & factors affecting it, use of buffers in EDTA titrations. Selective analysis of ions based on pH adjustments, use of masking & demasking agents, pM or metal ion indicators. Standardization of EDTA solution, titration curves, examples of assays carried out by direct & back titrations & by replacement of one complex by the other. Applications of complexometry in the assays of calcium gluconate, milk of magnesia, zinc undecenoate ointment, & aluminium hydroxide gel. Assay of NaF by indirect titration.	8
7	**Gravimetry** Principles of gravimetry. Factors affecting precipitation, formation, & properties of precipitate. Colloidal state. Impurities in precipitate, conditions of precipitation. Precipitation from homogenous solutions, washing, drying, & ignition of precipitate. Experimental techniques of drying & ignition. Applications of gravimetry in pharmacy	3
8	**Extraction techniques** Liquid-liquid extraction, separation of mixtures by extraction. Distribution law. Successive & multiple extraction [Craig method], continuous countercurrent extraction. Effect of temperature & pH on extraction. Inert solute, associate ion pair formation, emulsion problem in extractions. Applications in pharmacy.	4
9	**Miscellaneous methods of analysis** Diazotization titrations. kjeldahl nitrogen estimation. Karl Fisher titrations. Determination of alcohol content in liquid gelenicals. Oxygen flask combustion method.	4
	TOTAL	60

Reference Books:

- Vogel's Text Book of Quantitative Chemical Analysis, 6th Edition, 2004.
- Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th Edition.
- K.A Connors : Text Book of Pharmaceutical Analysis, 3rd Edition, Wiley- inter Science Publication, 1999, New York.
- Indian Pharmacopoeia, 2011, the Controller of Publications, Government of India.
- John H. Kennedy, Principles of Analytical Chemistry, 2nd Edition, Saunders College Publishing, 1990, New York.
- J. W. Munson, Pharmaceutical Analysis – Modern Methods, Part – A & B, 2001.
- Kolthoff 1 M and Stenger V A, Volumetric Analysis, Vol. II Titration Methods, Interscience Publishers, Inc., New York.

Class: Fourth Semester B. Pharm. **Subject Code:** 430
Subject: Pharmaceutical Analysis I (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To familiarize students with the concept of calibration & validation of various items used in analysis.
- To give training to students in carrying out different experiments having different techniques in analysis of raw materials & finished products.
- To impart training to students in determining percent purity of some phamacopoeal substances / pharmaceuticals / drugs.

Sr.No.	Laboratory Experiments
1.	Calibration of weights & glassware.
2.	Preparation & standardization of 0.1 N NaOH & 0.1 N H_2SO_4. (Acid base titration)
3.	Determination of % purity of at least two or more of the following: sodium benzoate, borax & ZnO. Aspirin & tolbutamide content in tablets. (Acid base titration)
4.	Preparation & standardization of $KMnO_4$. Determination of % purity of $NaNO_2$ using $KMnO_4$. (Red-ox titration)
5.	Determination of % purity offerrous fumarate by cerimetry. (Red-ox titration)
6.	Preparation & standardization of I_2 solution. Determination of % purity of ascorbic acid by iodimetry. (Red-ox titration)
7.	Preparation & standardization of sodium thiosulphate and Determination of % purity of $CuSO_4$ by iodometry. (Red-ox titration)
8.	Preparation & standardization of EDTA solution.(Complexometric titration)
9.	Determination of % purity of calcium gluconate injection, magnesium sulphate, aluminium sulphate. (Complexometric titration)
10.	Preparation & standardization of silver nitrate solution Determination of % purity of sodium chloride, ammonium chloride (argentometric titration.)
11.	Preparation and standardization of perchloric acid and Determination of % purity of ephedrine hydrochloride or any drug from IP (non-aqueous titration).
12.	Demonstration of water estimation by KF-titration.
13.	Diazotization titrations of sulpha drugs
14.	Limit tests for Chloride, sulphate, heavy metals like lead, iron, arsenic, mercury as per Indian Pharmacopoeia [I. P.].

Class: Fourth Semester B. Pharm. **Subject Code:** 440
Subject: Pharmacognosy II (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To develop the knowledge of our alternative system of medicine.
- To develop knowledge of different traditional drugs.
- To develop the knowledge base regarding source, active constituents and uses of crude drugs.
- To develop the ability about the understanding of performing chemical tests the identity and quality of natural products.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Alternative various systems of medicine practiced in India viz: Ayurveda, Unani, Homeopathic and Siddha.	2
2	The holistic concept of drug administration in traditional systems of medicine. Introduction to Ayurvedic preparations like Arishtas, Asvas, Gutikas, Tailas, Chumas, Lehyas and Bhasmas.	3
3	Studies of traditional drugs, common vernacular names, botanical sources, morphology, chemical nature of chief constituents, pharmacology, categories and common uses and marketed formulations of following indigenous drugs: Amla, Kantkari, Satavari, Tylophora, Bhilawa, Kalijiri, Bach, Rasna, Punamava, Chitrack, Apamarg, Gokhru, Shankhapushpi, Brahmi, Ashoka, Methi, Lahsun, Palash, Guggal, Gymnema, Shilajit, Nagarmotha, Neem, Manjistha, Gulvel, Pippali and Chirata.	8
4	An introduction to Primary and Secondary metabolites	3
5	A detailed study of various methods of extraction and isolation of phytopharmaceuticals namely infusion, decoction, digestion, maceration, percolation, successive solvent extraction, supercritical fluid extraction, steam distillation, had space techniques, sepbox, selection of suitable extraction process	3
6	Phytochemical Screening: Screening of alkaloids, saponins, cardenolides and bufadienolides, flavonoids and leucoanthocyanidins, tannins and polyphenols, anthraquinones, cynogenetic glycosides, amino acids in plant extracts	2
7	Application different methods of chromatography and spectroscopy in plant drug analysis	5
8	Quality control of herbal drugs as per WHO, AYUSH and Pharmacopoeial guidelines-Extractive values, ash values. Determination of heavy metals, insecticides, pesticides and microbial load in herbal preparations.	2
9	Quantitative microscopy: Definition and determination of stomatal index, stomatal number, palisade ratio, vein islet number, vein termination number, lycopodium spore method.	4
	SECTION B	
10	**Glycosides:** Definition, Classification, General properties, General method of isolation of Glycosides. Study of Source, Morphology, chemical constituents, chemical test, adultrants, sustituents and uses of following drugs a. cardiac glycosides: Digitalis, strophanthus, squill. b. anthracene glycosides: Senna, Aloe, Rhubarb, Cascara c. Saponin glycosides: Dioscorea, asparagus, safed musali, liquorice, Brahmi, Ginseng. d. cyanogenetic glycosides: Bitter almond e. Isothiocyanates glycosides: Black mustard f. Coumarin glycosides: Psroalea, g. Flavonoid glycosides: Silymarin. h. Others: Ashwanghandha, kalmegh, picrorhiza	10
11	Proteins & Enzymes: Biological sources, preparation, characters and uses of: Gelatin, Collagen, diastase, papain bromalain, pancreatin, urokinase, pepsin, trypsin, pencillinase, hyaluronidase and stryptokinase	4
12	Lipids: Bees wax, Castor oil, Cocoa butter, Cod~liver oil, Hydnocarpus oil, Kokum butter, Lard, Linseed oil, Rice, Bran oil, Shark liver oil and Wool fat.	4

13	Animal products: Biological sources, chemical constituents, adulterants and uses of: Shellac, cochineal, cantherides, honey, and musk.	4
14	Natural toxins: Study of allergens, hallucinogens, narcotics, toxic mushrooms and afalotoxin	2
15	Marine Drugs: Introduction, importance, classification of following class of drugs: Cytotoxic and antineoplastic agents, Cardiovascular drugs, Marine toxins, Antimicrobial drugs, and Antibiotic substances.	4
	TOTAL	60

Reference Books:

- Wallis T. E., Textbook of Pharmacognosy, CBS, Delhi
- Jean Bruneton., Pharmacognosy and Phytochemistry, Lavosier Publisher U.K.
- Wagner and Bladt, Plant Drug analysis, Springer U.K.
- V. E. Tylor, L. R. Brady and S. B. Robbers, Pharmacognosy, K.M. Varghese Co.Bombay.
- Indian Herbal Pharmacopoiea, K. M. Varghese Co.Bombay.

Syllabus for Fifth Semester B. Pharmacy

Class: Fifth Semester B. Pharm. **Subject Code:** 510
Subject: Pharmaceutical Engineering (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To create awarenesss regarding the unit operations involved inPharmaceutical industry.
- To provide over viewof Pharmaceutical machineries.
- To enable students in selecting proper equipment for material processing in Pharma. Industry
- To educate learners about hazards and safety aspects in industrial environment.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Fluid flow** Type of flow, Reynold's number, viscosity, concept of boundary layer, basic equation of fluid flow, study of valves, flow meters, manometers and measurement of flow and pressure (mathematical problems included).	4
2	**Heat transfer** Source of heat, mechanism of heat transfer, the laws of heat transfer, steam and electricity as heating media, determination of requirement of amount of steam /electrical energy , steam pressure, boiler capacity, mathematical problems on heat transfer, steam traps and reducing valve, lagging etc	5
3	**Evaporation** Basic concept of phase equilibrium, factors affecting evaporation, evaporators, film evaporators, single effect and multiple effect evaporators, mathematical problems on evaporation	3
4	**Distillation** Rault's law, phase diagram, volatility: simple steam and flash distillation, principles of rectification, Mc-Cabe Thiele method for calculations of number of theoretical plates, azeotropic and extractive distillation, mathematical problems on distillation	6
5	**Drying** Moisture content and mechanism of drying, rate of drying and time of drying calculations, classifications and types of dryers, dryers used in pharmaceutical industries and special drying methods like freeze drying and lyophilization, mathematical problems in drying	6
6	**Size reduction and size separation** Definition, objectives of size reduction, factors affecting size reduction, laws governing in energy & power requirement of a mill, types of mills including ball mill, hammer mill, fluid energy mill , micronizer, quadro co-mil, multimill etc	7
	SECTION B	
7	**Extraction** Theory of extraction, extraction methods, equipment for various types of extraction process	5
8	**Mixing** Theory of mixing, solid-solid, solid-liquid and liquid-liquid mixing equipment	5
9	**Crystallization** Characteristics of crystals like purity, size, shape, geometry, habit, forms, size and factors affecting them. Solubility curves and calculation curves and calculations of heat balance around S Swanson's Walker crystallizer , super saturation theory and its limitations, Nucleation mechanism, crystal growth, study of various types of crystallizers, tanks, agitated batch, Swensons Walker, single vacuums, circulating magma and crystal crystallizers, cacking of crystals and its prevention. Numerical problems on yields. Introduction to polymorphism	5
10	**Filtration and Centrifugation** Theory of filtrations, filter aids, filter media, industrial filters, including filter press, rotary filter, edge filters, filter leaf and laboratory filtration equipments etc., Factors affecting filtration, mathematical problems on filtrations, optimum cleaning cycle in batch filters. Principles of centrifugation, industrial centrifugal filters and centrifugal sedimentars	4

	Dehumidification and humidity control Basic concept and definition, wet bulb and adiabatic saturation temperatures, psychometric count and measurement of humidity, application of humidity measurement in pharmacy, equipments for humidification and dehumidification operations	2
	Refrigeration and air conditioning Principles and applications of refrigeration and air conditioning	2
	Material of constructions General study of composition, corrosion, resistance, properties and applications of the materials of construction with special reference to stainless steel, glass, ferrous metals, cast iron, non ferrous metals, copper and alloys, aluminum and alloys, lead, tin, silver, nickel and alloys, chromium and non metals, stone, slate, brick, asbestos, plastics, rubber, timber, concrete. Corrosion and its prevention with reference to commonly used material in pharmaceutical plants	2
	Automated process control systems Process variable, temperature, pressure, flow, level and vacuum and their measurement. Elements of automatic process control and introduction to automatic process control. Elements of computer aided manufacturing(CAM).	2
	Industrial hazards & safety precautions Mechanical, chemical, electrical, fire, dust, noise hazards, Industrial dermatitis, accident, records, safety requirements/equipments etc	2
	TOTAL	**60**

Reference Books:

- Badger W.L.&BancheroJ.T., Introduction To Chemical Engineering, Mc Graw Hill,NY
- BrownGeorgeG., Unit Operations, CBSPublication
- Cooper&Gunn, Tutorial Pharmacy, CBSPublication
- PerryR.H., Perry's ChemicalEngineersHand Book, TataMcGrawHill
- RichardsonJ.F.&CoulsonJ.M., ChemicalEngineering, AsianBooksDelhi

Class: Fifth Semester B. Pharm. **Subject Code:** 520
Subject: Pharm. Medicinal Chemistry II (Theory) **Allotted Hrs.:** 2

OBJECTIVE:

- To develop the linkage between organic molecules and their transformation to the drug molecule
- To develop the ability to name drugs having various structural features
- To expose students towards different chemical classes of compounds and their relationships according to their biological activity

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Different classes of therapeutic drugs** A detailed study of the following classes with respect to drug nomenclature, classification, physicochemical properties, mode of action [MOA], structure activity relationships [SAR], wherever applicable, synthesis of simple & prototype molecules, drug metabolism, therapeutic uses & side effects. Drug resistance, wherever applicable, should be covered in respective classes of drugs. A. Sedative-hypnotics B. Antiepileptic agents. C. Neuroleptics D. Anti-anxiety drugs E. Diuretics F. Antiamoebic agents G. Anthelminticagents H. Antimycobacterialdrugs I. Antifungal agents **SECTION B** J. Hypoglycemic agents K. Oxytocics L. Anti-coagulants M. Local and general anaesthetics N. Steroids. Corticosteroids [gluco- &mineralocorticoids] &anti- inflammatory steroids, Sex hormones and their synthetic analogs (Male & female contraceptive Agents, anti-fertility agents), Anabolic steroids	4 4 3 3 4 4 3 4 4 3 3 3 3 15
	Note: Synthesis of following drugs should be studied: Chlorothiazide, benzthiazide, acetazolamide, furosemide, ethacrynic acid, phenobarbitone, amylobarbitone, methohexital, dapsone, isoniazid, para-amino salicylic acid, pyrazinamide, ethambutol, ethionamide, metronidazole, tinidazole, diloxanide furoate, niclosamide, diethyl carbamazine citrate, albendazole, miconazole, clotrimazole, ketoconazole, warfarin, dicoumarol, lignocaine, procaine, benzocaine, ketamine, halothane, thiopentone sodium, nitrazepam, gluthetimide, diazepam, meprobamate, ethosuximide, diphenyl hydantoin, trimethadione, carbamazepine, chlorpromazine, haloperidol, doxepine, fluoxetine, imipramine, amitryptiline, 17 beta estradiol, prednisolone, diethyl stilbestrol, dienestrol, progesterone, triamcinolone, phenytoin.	
	TOTAL	60

Reference Books:

- Foye,W.O, PrinciplesOfMedicinalChemistry, K., E.,Varghese&Company
- Wilson,C.,Gisvold,O.,&Doerge.,J.,B., TextBookOf OrganicMedicinal& PharmaceuticalChemistry
- J.B.LippincotCompany, Toronto,Canada
- Wolff Manfred E., Burger's Medicinal Chemistry &DrugDiscovery, John Wiley &Sons Inc.,
- NewYork.
- LednicerDaniel, Organic Chemistry Of Drug Synthesis (Vol.I andII), Wiley-Interscience
- Patric G. L., A Introduction to Medicinal Chemistry, Abingdon, Oxfordshire UK

Class: Fifth Semester B. Pharm. **Subject Code:** 530
Subject: Medicinal Natural Products (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To study the generation of biodrugs in plants as a result of metabolism.
- To impart knowledge about important chemical classes of compounds having bio activity.
- To impart knowledge about important chemical constituent.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	General techniques of biosynthetic studies	2
2	Biogenetic pathways: Formation of primary and secondary metabolites. Study of Calvin cycle, TCA cycle, Shikimic acid pathway, Embden-Mayerh off pathway, acetate hypothesis, isoprenoid pathway.	4
3	Alkaloids: Systematic study of source, cultivation, collection, processing, commercial varieties, chemical constituents, substitutes, adulterants, uses, diagnostic macroscopic and microscopic features and specific chemical tests of following alkaloid containing drugs: a) Pyridine - piperidine: Tobacco, areca and lobelia. b) Tropane: Belladonna, Hyoscyamus, Datura, Coca. c) Quinoline and isoquinoline : Cinchona, ipecac, opium. d) Indole : Ergot, Rauwolfia, Nux-vomica and Vinca e) Imidazole: Pilocarpus f) Steroidal: Veratrum and Kurchi g) Alkaloidal amine: Ephedra and Colchicum. h) Glycoalkaloid: Solanum. i) Purines: Coffee, and tea	10
4	Resins: Study of Drugs Containing Resins and Resin Combination like Colophony, podophyllum, Capsicum, asafoetida, balsam of tolu, balsam of peru, Guggul, Turmeric, Ginger.	4
5	Volatile Oils and Terpenoids: General methods of obtaining volatile oils from plants, Study of macroscopy, chemical constituents, varieties and adultrants of drugs containing volatile oils of Mentha, Coriander, Cinnamon, Orange peel, Citronella, Caraway, Dill, Clove, Fennel, Nutmeg, Eucalyptus, Cardamom, Gaultheria, Sandal wood. Sestquiterpenoids containing drugs: Artemisia and Diterpenoids: Taxus	9
	SECTION B	
6	Tannins: Biological sources, morphology, chemical constituents, chemical test and uses of: Pale catechu, black catechu, Amla, Ashoka, Myrobalan, Arjuna	3
7	Biosynthesi of Terpenoids. Chemistry of Aretmisinin, Taxol, Citronellol, Geraniol, Menthol, and Citral.	7
8	Biosynthesis and Chemistry, of Anthraquinone glycosides, Cardiac glycosides (digitoxin, digoxin) and of diosgenin	6
9	Biosynthesis, and Chemistry, of Alkaloids, atropine, quinine reserpine, morphine, ephedrine, ergot alkaloids and vinca alkaloids.	7
10	Chemistry and biogenesis of medicinally important lignans, quassanoids, flavonoids and anthocynin.	6
11	Carotenoids: β-carotenes and Xanthophylls	2
	TOTAL	60

Reference Books:

- Jean Bruneton., Pharmacognosy and Phytochemistry, Lavosier Publisher U.K.
- P.K.Mukherjee, Quality control herbal drugs, Buisness horizons pharmaceutical publication.
- Wagner and Bladt, Plant Drug analysis, Springer U.K.
- P.M Dewick, Biosynthetic approach, Willy publication

Class: Fifth Semester B. Pharm. **Subject Code:** 530
Subject: Medicinal Natural Products (Practical) **Allotted Hrs. :** 6

Sr.No.	Laboratory Experiments
1.	Demonstration of Microwave extraction, Percolation and Hot continuous extraction technique(Soxhlate Apparatus)
2.	Identification of unorganized drug by morphological characters and chemical characteristics-Agar, Arachis oil, castor oil, Tragacanth, Acacia, Starch, Wool fat, Bess wax, Honey, Gelatin, Cotton, Jute, Silk, Wool.
3.	Qualitative and Quantitative microscopy (Stomatal no, Stomatal index, vein islet and termination no., palisalide ratio)
4.	Determination of Ash value, Foreign Organic matter, Moisture content, Extractive value, Loss on Drying
5.	Morphological and microscopical description of Senna, Isabgul, Fennel, Ginger, Rauwolfia, Datura, Vinca, Nux-vomica, Cinchona, Turmeric.
6.	Microscopical examination of following powder drugs and their mixture-Senna, Datura, Rauwolfia, Glycerrhiza, Cinchona, Cinnamon, Fennel, Coriander, Ginger.
7.	Analysis of fixed oil by Acid value, Saponification value and Iodine value

Class: Fifth Semester B. Pharm. **Subject Code:** 540
Subject: Pharmacology – I (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To underst and pharmacokinetic and pharmaco dynamic principles involved in the use of drugs.
- To understand and identify the various factors that can affect the action of drugs
- To know the various routes of drug administration
- To know the effectof drugs on different systemso f thebody
- To know the drugs used in systemic illness
- To under stand the methods in experimental pharmacology to correlate drug effect swith receptors

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**General Pharmacology** Introduction to Pharmacology- Definition, scope and source of drugs, dosage form and routes of drug administration. Pharmacodynamics-Mechanism of drug action, Receptors, classification and drug receptors interaction, combined effect of drugs, factors modifying drug action. Pharmacokinetics-Mechanism and principle of Absorption, Distribution, Metabolism and Excretion of drugs. Principles of basic and clinical pharmacokinetics. Pharmacogenetics. Adverse drug reactions	12
2	Discovery and development of new drugs-Preclinical and clinical studies	4
3	**Pharmacology of peripheral nervous system** Neurohumoral transmission (Autonomic and somatic). Parasympathomimetics, Parasympatholytics, Sympathomimetics, Sympatholytics, Ganglionic stimulants and blockers. Neuromuscular blocking agents and skeletal muscle relaxants (peripheral). Local anesthetic agents. Drugs used in Myasthenia Gravis	10
	SECTION B	
4	**Pharmacology of cardiovascular system** Introduction of haemodynamics and Electrophysiology of heart. Anti-hypertensive drugs, Anti-anginal agents, Anti-arrhythmic drugs. Drugs used in congestive heart failure. Anti-hyperlipidemic drugs. Drugs used in the therapy of shock. Haematinics, anticoagulants and haemostatic agents Fibrinolytics and antiplatelet drugs. Blood and plasma volume expanders	10
5	**Drugs acting on urinary system** Diuretics and anti-diuretics	4
6	**Drugs acting on Respiratory system** Anti-asthmatic drugs, Mucolytics and nasal decongestants, Anti-tussives and expectorants. Respiratory stimulants	4
7	**Pharmacology of central nervous System** Neurohumoral transmission in the C.N.S with special emphasis on Pharmacology of various neurotransmitters. General anesthetics. Alcohols and disulfiram. Sedatives, hypnotics and centrally acting muscle relaxants Psychopharmacological agents: Antipsychotics, antidepressants, antianxiety agents, anti-manics and hallucinogens. Anti-epileptic drugs. Anti-parkinsonism drugs. Nootropics.	12
8	Narcotic analgesics, Drug addiction, drug abuse, tolerance and dependence	4
	TOTAL	**60**

Reference Books:

- Barar F.S.K., A Text Book Of Pharmacology, Mehta Publications
- KatzungB.G., Basic And Clinical Pharmacology, Lange Medical Publications
- VogelH.G., Drug Discovery And Evaluation, Springer House
- Barar F.S.K., Essentials Of Pharmacotherapeutics, S.Chand & Co.Pvt.Ltd.,
- Rang.M.P.,DaleM.M.,RiterJ. M./4th ed, Pharmacology, Churchill,Livingstone

Class: Fifth Semester B. Pharm. **Subject Code:** 550
Subject: Biochemistry (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To impart broad understanding of molecular level of chemical process associated with living cells
- To develop the knowledge eregarding enzymes and it srelated issues
- To provide idea about metabolic processes involved in illnesses

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Cell** Revision of ultra structure of cell, functions of various cellular constituents. Applications of biochemical principles to pharmacy	2
2	**Carbohydrates** Carbohydrates. Definition and classification D & L nomenclature in sugar. Different ways of drawing / representing sugar molecules. Types of carbohydrates, their functions, digestion, & absorption. Aerobic & anaerobic oxidation with energetics. Glycogenesis, glycogenolysis, & gluconeogenesis. Hexose monophosphate shunt [HMP shunt].Diseases associated with carbohydrate metabolism	9
3	**Proteins** Amino acids and proteins. Definition, classification. Natural essential and non-essential amino acids. Denaturation, strecker, Gabriel pthalamide method for the preparation of amino acid. Peptide bond and its formation. Two protective groups each for – NH_2 and – COOH during protein synthesis. Sequencing of a protein by chemical and enzymatic methods. Different types of proteins. Their functions, digestion & absorption. Denaturation & its effect on biological activity. Renaturation of proteins. Urea formation, urea cycle, creatinine formation. Transamination & deamination. Proteins as enzymes	9
4	**Lipids** Different types of lipids. Their functions, digestion, absorption & metabolism. β-Oxidation of fatty acids with energetics. Biosynthesis of cholesterol [from acetate], adrenocorticoids, androgens, progesterone, estrogens, & bile acids / salts. Ketone bodies, their formation & biochemical significance. Diseases associated with lipid metabolism	8
	SECTION B	
5	**Vitamins** Definition. Classification, structures [except B12] biochemical role, sources, daily requirements, & deficiency symptoms. Vitamins as co-factors in biochemical reactions	6
6	**Biological oxidations & reductions** Oxidation reduction systems in the body. Electron transport chain. Cytochromes & their role. Oxidative phosphorylation & inhibitors of the same	5
7	**Enzymes** Classification & their various roles. Enzyme co-factors. Enzyme kinetics. Michaelis-Menton equation along with its transformations. Double reciprocal plot. Factors affecting enzyme action. Enzyme inhibition, competitive & noncompetitive, & kinetics	6
8	**Nucleic acids** Different types of nucleic acids [NAs] & their composition. Purine & pyrimidine bases, sugars, & phosphoric acid. Nucleosides & nucleotides. Formation of NAs & their back bone. Different ways of representing DNA & RNA molecules. Physico-chemical properties of NAs. Their stability in acidic & basic solutions. Isolation, purification & identification, buoyant density, sedimentation coefficient, & Svedberg constant of NAs. De-novo biosynthesis of NAs. DNA & the Watson-Crick model & its features. DNA as the bearer of genetic information. Central dogma of molecular genetics & the processes defined in the same. Replication of DNA. Different types of RNAs with	12

	their special features & functions. Minor or rare bases. Transcription & translation. Different post translational modifications of proteins. Triplet codon & the codon dictionary. Mutations. An introduction to different types of mutations. Their nature & repair	
	TOTAL	60

Reference Books:

- DavidL.Nelson, Lehninger's Principles of Biochemistry, W.H.FreemanAndCompany
- DebA.C., Fundamentals of Biochemistry, NewCentralBookAgency Kolkata 1996
- MurrayR.K, Harper's Biochemistry,
- PattabIraman, Principles of Biochemistry, GajananBangalore
- ChampeP., Lippincot's Illustrated Reviews Biochemistry, William andWillkins

Class: Fifth Semester B. Pharm. **Subject Code:** 550
Subject: Biochemistry (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To train students in performing experiments involving determination of different bio- constituents in biological fluids.
- To train students in isolation/purification of biologically important macromolecules.
- To train the students in characterization & estimation of biomolecules.

Sr.No.	Laboratory Experiments
1.	Qualitative tests for carbohydrates.
2.	Qualitative tests for amino acids & proteins.
3.	Estimation of creatinine.
4.	Estimation of SGPT & SGOT.
5.	Isolation of different enzymes.
6.	Purification of enzymes.
7.	Effect of temperature, pH, & ions on enzyme activity.
8.	Estimation of salivary amylase & β-amylase.
9.	Demonstration of separation of proteins by electrophoresis.
10.	Preparation of sucrose &/or cesium chloride[CsCl]gradient.
11.	Isolationof DNA/ RNA from plants or non-pathogenic microorganisms.
12.	Purification of DNA/RNA.
13.	Identification of DNA/RNA by chromatographic or spectral methods.
14.	Measurement of buoyant densityof DNA/RNAinsucrose/CsCl gradient.
15.	Estimation of DNA/ RNA.

Syllabus for Sixth Semester B. Pharmacy

Class: Sixth Semester B. Pharm. **Subject Code:** 610
Subject: Hospital and Dispensing Pharmacy (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To train students in different aspects of dispensing medication.
- To impart training on proper use of weighing with different balances.
- To give training on dose calculations for children older patients.
- To give experience in preparation of various dosage forms for dispensing.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Introduction to dispensing, Compounding and Hospital pharmacy.	2
2	Prescription: Definition, Parts, Stages in handling, method for pricing, Ideal prescription.	4
3	Weight and measures system: Imperial and metric system, Their inter-conversion, common household measures.	2
4	Pharmaceutical Calculations: Percentage Calculation, Allegation method, Proof sprit, isotonic solution, dosage calculation (including factor affecting dosage calculations), Dilutions, reducing and enlargement of formula, PPM.	6
5	Fundamental operation in compounding: Weighing and measuring techniques, different types of balances, measurement apparatus, Mixing, Dissolution, Size reduction, Filtration, Size separation (only for dispensing).	2
6	Labeling techniques for dispensing: Requirement for labelling of dispensed medication, Labels for different types of dosage forms with specific direction, caution or advice, Storage condition, definitions of various terms of storage	2
6	Containers and closers for dispensing.: Definitions of primary, secondary, and tertiary packaging, Ideal package, Different types of glass and glass containers for dispensing, plastic and aluminium packaging materials, Unit dose and multidose dispensing.	3
7	Incompatibility: Definitions, types with example and correction (from Cooper and Gun's Dispensing Pharmacy)	3
8	Compounding and dispensing of following dosage forms.	
9	Solutions: Definitions, formulations and compounding, solution for oral use, dilution of solution, solution to be instilled in to body cavity, solution for external use with examples, containers, storage, shelf life.	2
10	Emulsion and creams: Definitions, types, identification, Emulsifying agent classification with example, choice of emulsifying agent for oral and internal use. HLB value its use and calculation, preparation of emulsion by Dry gum, wet gum and bottle method. Emulsion for oral use (acacia emulsion), Emulsion for external use (liniments, lotions, applications), Definition of cream, general method for preparation of cream.	4
	SECTION B	
11	Suspension: Definition, Advantages, and limitations, types, suspending agents, desirable properties of suspension, compounding of suspension containing diffusible substances and indiffusible substances, poorly wettable solids, suspension containing precipitate forming liquid and volatile oil for inhalations. Shelf life, containers, labelling, direction for use.	3
12	Ointments / pastes: Definitions, ointment bases with properties, advantages, limitations and examples, additives in the ointments, method of preparation, Containers and packing, direction and storage.	3

13	Plasters and Poultice: Definitions, different types of plasters and their uses, Kaolin poultice.	2
14	Gels: Definitions, different types, Method of preparation, different gelling agent used. Containers and packing, direction and storage.	2
15	Powders: Definitions, Advantages and limitations, Classification, characteristics of powders, Method of preparation for compound bulk powder, its packing, powders for external use dusting powders, dentifrices, insufflations, douches, wrapping techniques, double wrapping, Definition of granules, general method of preparation, Effervescent granules its composition, preparation, and packing.	3
16	Suppositories and passaries: Definitions, advantages and limitations, different types of bases used with advantages, limitations and examples, concept and calculation of displacement value, description of mould, mould calibration, mould lubrication, method of preparation with coca butter and glycerol-gelatine bases, Containers and packing, directions.	4
17	Capsules: Definitions, different types, sizes of hard gelatine capsules, method of preparation, manual method, hand operated capsule filling machine, simple capsule filling apparatus. Containers and packing, directions, storage.	2
18	Tablets triturates & tablets: Dispensing & compounding of tablet triturates, dispensing from bulk containers and packing, directions.	1
19	Pills: Definitions, advantages and limitations, major ingredients, method of preparations, containers and packing, direction and storage.	1
20	Lozenges and Pastilles: Definitions, comparison, major ingredients, method of preparation, containers and packing, directions and storage.	1
21	Introduction to Hospital: Definition, types, function, layout of hospital organization (No details of each Dept.)	2
22	Introduction to Hospital pharmacy: Definition, history and development, layout and manpower requirement, objectives and scope.	1
23	Functions and responsibilities of Hospital: For inpatient (for patient care areas, Direct patient care, central dispensing areas and general), Out / ambulatory patients.	1
24	Patient counselling and communication: Need for counseling, areas for counseling to the patient. Counselling for inpatient, out patient and while discharge of patient. Assumption and expectations in communications, techniques for effective communications, barriers problems in the communications (only related to patient counselling)	2
25	Pharmacy and therapeutic: Definition, objectives, compositions, working, functions, role in drug safety, adverse drug monitoring and developing emergency	2
26	Hospital formulary: Definition, objectives, advantages and limitations, method and rules for preparation and contents	1
27	Dispensing procedures and drug distribution: For in patients, out patients, controlled medications, for wards and emergency situations.	3
28	Central sterile services dept.: Definitions, objective, functions, advantages, management, location, layout, flow of materials, staff required.	1

29	Sterilization in hospital pharmacy: Introduction to diff. method of sterilization (no detail of equipment and workings.), sterilization method for powders, rubber, gloves, syringes, needles, catheters, surgical materials.	2
30	Medical gases: Definitions, different example, color-coding, accessories required for gas therapy. Therapeutic applications	2
31	Surgical instruments and health accessories: Surgical instruments, wheel chairs, canes, crutches, bed pans, vaporisers, syringes, needles, thermometers, first aid, hot water bottles (no diagrams) only with respect to prescriptions dispensing and patient counselling	2
32	Hospital pharmacy and global scenario including national health scheme: Hospital pharmacy and global scenario including national health scheme (NHS)	1
33	Use of computers in hospital pharmacy: Application of computers in hospital pharmacy.	1
34	Surgical dressings: Surgical dressings ,properties, absorbant dressings, wound dressings, bandages, Surgical adhesive tapes, protectives, plasters, standard for dressing and packaging.	2
	TOTAL	60

Reference Books:

- Remington's pharmaceutical sciences, A.H. Gennaro (Mack publication)
- Pharmaceutical practice, Collet and Aulton (Churchill Livingstone)
- Dispensing of medications, Hoover (Mack Publication)
- Prescription Pharmacy, Sprowls Lipincotts
- Pharmaceutical dispensing for pharmacy student, Cooper and Gunn
- USP, Official
- IP ,BP, USP NF, NFI, and the pharmaceutical codex, Official
- Martindale extra pharmacopoeia, Official
- Introduction to pharmaceutical, J.A. Rees & B Smith (Pharmaceutical press)
- Pharmacy Practice, P. Stones and S J Curtis (Pharmaceutical press)
- Pharmacy Practice, A.J. Winfield, R.M.E. Richards (Churchill Livingstone)
- Hospital and clinical pharmacy, H.P. Tipinis, M.S. Nagarsenkar (Nirali)

Class: Sixth Semester B. Pharm. **Subject Code:** 610
Subject: Hospital and Dispensing Pharmacy (Practical) **Allotted Hrs. :** 6

Sr.No.	Laboratory Experiments
1.	Introduction to laboratory equipments, weighing methodology, handling of prescriptions, labeling instructions for dispensed products.
2.	Preparations based on percolation process.
3.	Preparations based on maceration process.
4.	Study of difference between marketed and dispensed products of different dosage forms(minimum 10 types of dosage forms).
5.	a. Posological calculations involved in calculation of dosage for infants. Enlarging and reducing formula, displacement value. b. Preparations of formulations involving allegation, alcohol dilution, isotonic solution
6.	Compounding and dispensing of following prescriptions (minimum 20 prescriptions). a. Antihypertensive drug b. Antiamoebic drugs c. Anti histaminic drugs d. Anti emetic drugs e. Antacids and ulcer healing drugs Ointments / Paste f. Anti diarrheals and laxatives g Respiratory drugs h. Antibiotics i. Analgesics and antipyretic drugs
7.	Compounding and dispensing of following prescriptions (minimum 20 prescriptions). a. Mixtures b. Solutions c. Emulsions d. Lotions (External preparations) e. Liniments (External preparations) f. Powder g. Granules h. Suppositories i. Ointments / Paste j. Cream k. Incompatibility: Prescription based on physical, chemical and therapeutic incompatibility (2 each) l. Tablets m. Inhalations
8.	Reading and counseling of minimum 20 prescriptions from the clinical practice.
9.	Designing from mock Pharmacy: Layout and structure of retail Pharmacy, compounding, dispensing, storing, labeling, pricing, recording and counseling of prescription.
10.	Procurement of information for the given drug for drug information services.

Class: Sixth Semester B. Pharm. **Subject Code:** 620
Subject: Pharmacology – II (Theory) **Allotted Hrs.:** 3

OBJECTIVE:

- To make student understand drug development and concepts of drug action
- To know the drugs used in infections and chemotherapy with mechanism of action and pharmacokinetics uses, side-effects
- To know peptides as drugs and role of antocoids in various process and drugs acting on them

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Pharmacology of Endocrine system** Basic concepts in endocrine pharmacology. Hypothalamic and pituitary hormones. Thyroid hormones and ant thyroid drugs, Parathormone, Calcitonin and vitamin-D. Insulin, oral hypoglycemic agents and glucagon. ACTH and corticosteroids. Androgens and anabolic steroids. Estrogens, progesterone and oral contraceptives. Drugs acting on the uterus.	8
2	**Chemotherapy** General principals of chemotherapy. Sulphonamides and co-trimoxazole. Antibiotics- Penicillins, cephalosporins, chloramphenicol, Macrolides, uinolines and fluoroquinolins, quinolones. Tetracyclines. Aminoglycosides and miscellaneous antibiotics. Chemotherapy of tuberculosis, leprosy, fungal diseases, viral diseases, AIDS, protozoal diseases, worm infections, urinary tract infections and sexually transmitted diseases. Chemotherapy of malignancy	14
3	**Autacoids and their Antagonists** Histamine, 5-HT and their antagonists. Prostaglandins, thromboxanes and leukotrienes. pentagastrin, cholecystokinin, angiotensin, bradykinin and substance P. Analgesic, anti-pyretic, anti-inflammatory and anti-gout drugs.	8
	SECTION B	
4	**Pharmacology of drug acting on the gastrointestinal tract** Antacids, anti-secretary and antiulcer drugs. Laxatives and antidiarrheal drugs. Appetite stimulants and suppressants. Digestants and carminatives. Emetics and antiemetics	4
5	**Chronopharmacology** Definition of rhythm and cycles. Biological clock and their significance leading to Chronotherapy	2
6	**Immnopharmacology** Immunostimulants and immunosuppressants	3
7	**Chemotherapy of malignant diseases** Basic principal of chemotherapy. Drugs used in cancer chemotherapy	4
8	**Peptides and proteins as mediators** General Principal of peptide pharmacology Biosynthesis and regulation of peptides Peptide antagonists. Protein and peptide as drugs	4
9	**Nitric oxide** Biosynthesis of nitric oxide and its physiological role. Therapeutic use of nitric oxide and nitric oxide donors. Clinical condition in which nitric oxide may play a part	3
10	**Vitamins & Minerals** Vitamin deficiency diseases and their management. Role of minerals in health & diseases	4
11	**Principles of toxicology** Definition of poison. General principles of treatment of Poisoning. Treatment of poisoning due toHeavy metals,insecticides,opiods and other addict forming drugs. Study of acute, sub acute and chronic toxicity as per OECD guidelines. Genotoxicity, Carcinogenicity, teratogenicity and mutagenicity studies	6
	TOTAL	**60**

Reference Books:
• Barar F.S.K., AText Book Of Pharmacology, Mehta Publications
• KatzungB.G., Basic And Clinical Pharmacology, LangeMedical Publications
• Rang.M.P.,DaleM.M.,RiterJ. M./4thed, Pharmacology, Churchill,Livingstone
• C.R Craig & Stitzel, Modern Pharmacology, Little Brown& Co
• Finkel, Richard; Clark, Michelle A, Lippincott's Illustrated Reviews: Pharmacology, Lippincott Williams & Wilkins
• RPS, British National Formulary, Royal Pharmaceutical Society

Class: Sixth Semester B. Pharm. **Subject Code:** 620
Subject: Pharmacology – II (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To teach students how to handle laboratory animals.
- To conduct some simple animal experiments to understand drug action.

Sr.No.	Laboratory Experiments
1.	Commonly used instruments in experimental pharmacology.
2.	Common laboratory animals and anesthetics used for animal studies.
3.	Some common and standard techniques. Bleeding and intravenous injection, intra-gastric administration, procedures for rendering animal unconscious and chemical euthanasia.
4.	Study of different routes of drugs administration in mice/rats.
5.	To Study the effect of hepatic microsomal enzyme inhibitors and inducers on the phenobarbitone sleeping time in mice.
6.	Effect of various agonists and antagonists and their characterization using isolated ileum of rat/guinea pig/rabbit.
7.	Bioassay of acetyl choline on rat ileum by interpolation method.
8.	Experiments on Central nervous system: Recording of spontaneous motor activity, stereotype activity, anti-catatonic activity, analgesic activity, anticonvulsant activity.
9.	Anti-inflammatory activity and skeletal muscle relaxant activity of drugs.
10.	Local anesthetic activity screening by suitable animal model.
11.	Effect of autonomic drugs on rabbit's eye.
12.	Experiments based on computer models like Expharm.
13.	Statistical calculations in experimental pharmacology. a. Student-t-test b. ANOVA

Class: Sixth Semester B. Pharm. **Subject Code:** 630
Subject: Pharmaceutical Analysis II (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To provide the sound basis of analytical techniques based upon electromagnetic radiations.
- To develop the ability to solve simple spectroscopic problems involving UV, IR, NMR and Mass Spectrometry.
- To generate the foundation of electrochemical analytical technique relevant to Pharmaceutical analysis.
- To emphasize the concept techniques and Pharmaceutical importance of chromatography

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Calibration** : Calibration of instruments.	**01**
2	**General principles of spectroscopy** Wave-particle duality, wave properties, particulate properties. Line & band spectrum. Electromagnetic spectrum. Absorption & emission spectroscopy. Understanding of terms such as absorbance, transmittance, absorptivities, molar absorptivity, A 1cm 1%, λmax, effect of solvent & pH on λmax. Law of absorption spectroscopy. Beer-Lambert law, its derivation, deviations in Beer's law.	06
3	**Ultraviolet-visible Spectrometry** Different electronic transitions. Auxochromes & their effects, auxochromic, bathochromic& hypsochromic shifts [red & blue shifts]. Single & double beam spectrophotometers covering sources of radiations, different monochromators, detectors such as barrier cell, photocell, photomultiplier tube. Photodiode array detector. Applications of this technique in qualitative & quantitative estimations giving emphasis on problem solving. Fieser-Woodward rules for calculations of theoretical λmax values.	06
4	**Spectrofluorimetry** Principle, definitions & types of luminescence. Mechanism of fluorescence & phosphorescence. Singlet & triplet states & intersystem crossing. Fluorescence yield& factors affecting it. Quenching of fluorescence & fluorescence quenchers. Structure & fluorescence. Brief discussion of instrumentation. Applications of fluorimetry in pharmacy.	05
5	**Flame photometry & atomic absorption spectrometry** Principle & instrumentation with emphasis on working & importance of different components. Temperature, flame absorption & emission profiles. Interferences & their avoidance. Quantitative estimations & applications.	06
6	**Infrared spectrometry** Infrared region in EM spectrum. Principle, different stretching & bending vibrations. Components [& their working] of a dispersive instrument. Fourier transform [FT] technique, FT instruments & their comparison with dispersive instruments. Sample handling techniques. Functional group & finger print regions in the spectrum. Functional groups identification & their use in characterization of compounds. Problems on identification of functional groups from spectra of unknown compounds.	06
	SECTION B	
7	**Potentiometry and pH metery** Theory, ion selective electrodes, measurement of potential, red-ox titration curve, pH measurement, relation of pH to potential. Types of electrodes used, potentiometric titrations Applications in pharmacy.	05
8	**Conductometry and High frequency titration:** Theory, definitions, Instrumentation, conductivity cell, Application of direct Conductometry, TOC analysis, conduction metric titrations Applications in pharmacy.	03
9	**Polarography.** Principle & instrumentation. Ilkovich equation [no derivation] & its importance. Dropping mercury electrode [DME], saturated calomel electrode. Liquid-liquid	04

	junction potential, polarographic cell. Explanation of origin of S-shaped C-V curve. Applications of this technique. Amperometric titrations, principles, instrumentation, & applications.	
10	**Nephelometry & Turbidimetry** Principles, Tyndall effect. Duboscq turbidimeter. Eeel's nephelometer. Applications.	02
11	**Basic Chromatography.** Introduction to chromatography as an analytical tool. Chromatographic separation methods, Classification, Concepts for selection of Mobile Phase and Stationary Phase. Retention time, Retention volume, resolution. **Paper Chromatography:** Introduction, Principle, Migration Parameters, Types of paper Chromatography, Development techniques in paper chromatography, Steps involved in Paper Chromatography, Pharmaceutical and other Applications **Thin Layer Chromatography** Introduction, Principle, Coating Materials, pre-coated plates, Preparation of TLC Plates, Experimental details for TLC, Mobile phase selection. Advantages and limitations, preparative TLC. Pharmaceutical and other Applications. **Column chromatography.**Introduction, Principle, Migration Parameters, adsorbents, applications. **Ion exchange chromatography** Principle, types applications	14
12	**Miscellaneous** An introduction to electrophoresis.An introduction to lasers & masers.	03
	TOTAL	60

Reference Books:

- Morrison R., T. and Boyd R., M., Organic Chemistry Prentice Hall Of India Ltd., New Delhi-110 001.
- Skoog & West, Pharmaceutical Analysis Lippincott
- Christian, G Analytical Chemistry John Wiley
- Silverstein R. M., G. C. Bassler Spectrometric Identification Of Organic Compounds John Wiley & Sons, New York.
- Dyer J. R., Applications Of Absorption Spectroscopy Of Organic Compounds Englewood, U S A.
- United State Pharmacopoea U. S. Govt.
- B. P. Commission British Pharmacopoea H. M. S. O. London
- Govt. of India Indian Pharmacopoea The Controller of Publications Delhi
- Walter Lund British Pharmaceutical Codex The Pharm London
- National Formulary Royal Londons

Class: Sixth Semester B. Pharm. **Subject Code:** 630
Subject: Pharmaceutical Analysis II (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To train students on calibration & validation of sophisticated instruments.
- To give hands on training on these sophisticated instruments.
- To train students on the application the aspects of these sophisticated instruments.
- To give practice on solving spectral problems

Sr.No.	Laboratory Experiments
1.	Exercises(3-4) based on acid base titration and oxidation-reduction titrations using potentiometric technique, Determination of acid-base disassociation constants and plotting of titration curves using pH meter
2.	Exercises (min 2) involving Conductometric titrations of strong acids and weak acids and bases
3.	Calibration & validation of colorimeter & UV-VIS spectrophotometer, spectrofluorimeter, IR spectrometer.
4.	Determination of Lambda Max and verification of Beer-Lambert law
5.	Experiments [8-10] involving UV-VIS spectrometry in, A] the assays of different dosage forms such as tablets, capsules, injections, suspensions, gels [official / unofficial] , etc. Calculation of drug content using A 1% 1cm , calibration curves, & reference standards, B] determination of linearity range, C] determination of limit of detection [LOD] & limit of quantitation [LOQ] .
6.	Experiments on flourimetry. Determination of Eex & Eem. Quantitative estimations of 2-3 drugs / vitamins.
7.	Estimation of Na+, K+, Ca++ ions using flame photometry.
8.	Use of paper [ascending & descending methods] & TLC [1-D & 2-D] techniques in qualitative analysis. Calculation of Rf value. Use of reference standard in identification of unknown compound. (Amino acids, sugars, volatile oils, metal ions etc) (4-6 experiments)
9.	Determination of ion-exchange capacity of resins.
10.	Demonstration of column chromatographic technique in qualitative analysis.
11.	Demonstration of separation of proteins by electrophoresis.
12.	Demonstration of known & unknown compounds identification of different functional groups. Use of finger print region in identification of a compound. Study of inter- & intramolecular H-bonding. Interpretation of functional groups in compounds of unknown spectra.

Class: Sixth Semester B. Pharm. **Subject Code:** 640
Subject: Pharmaceutical Jurisprudence (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- The subject exposes the student to important legislations related to Pharmacy profession in India
- It imparts knowledge about the Drug and Cosmetic Actand its Rules.
- It provides the basic idea regarding DPCO drug policies and patenting in India.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Historical background Drug legislation in India, Code of Ethics for Pharmacists	2
2	A detailed study (inclusive of recent amendments) of the Pharmacy Act 1948	4
3	Drugs and Cosmetics Act 1940, Rules 1945, including New Drug applications	17
4	Narcotic Drugs and Psychotropic Substances Act, and Rules there under	3
5	Drugs and Magic Remedies (Objectionable Advertisements) Act 1954	3
6	Medicinal and Toilet Preparations (Excise Duties) Act 1955, Rules 1976	2
	SECTION B	
7	Medical Termination of Pregnancy Act 1970 and Rules 1975	2
8	Prevention of Cruelty to Animals Act 1960	2
9	Drug (Price Control) Order	2
	Shop sand Establishment Act.	2
	Factory Act.	4
	Consumer Protection Act.	3
	Indian Pharmaceutical Industry-An Overview.	2
	Industrial Development and Regulationact 1951.	3
	Introduction to Intellectual Property Rights and Indian Patent Act1970.	3
	Minimum WagesAct1948.	3
	Prevention of Food Adulteration Act1954 and Rules1955.	2
	Bibligraphy	2
	TOTAL	60

Reference Books:

- Relevant Acts (Bare acts)and Rules Published, Govt. of India.
- SinghHarkishan, History of Pharmacy in India,vol-I,II,&III, VallabhPrakashan,Delhi
- S.W. Deshpande, Drug and Cosmetics Act., CBS Publications
- MittalB.M., Test Book of Forensic Pharmacy, VallabhPrakashan,NewDelhi
- NK Jain, Forensic Pharmacy, Vallabh Prakashan, NewDelhi

Syllabus for Seventh Semester B. Pharmacy

Class: Seventh Semester B. Pharm. **Subject Code:** 710
Subject: Pharmaceutics – III (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- The module aims to provides pecific principles involved in dosage form design
- To provide basic idea about the projection of stability in Pharmaceuticals.
- To get an overview on various novel drug delivery systems, cosmetics & pharmaceutical packaging.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Preformulations** Consideration of Importance, physical properties, physical forms, particle size, crystal forms, bulk control, solubility, wetting,flow cohesiveness,compressibility, organoleptic properties and its effect on final product consideration of Chemical properties,hydrolysis, oxidation, recemization, polymerization, somerization, decarboxylation, enzymatic decomposition, formulation additives, stabilizers, suspending and dispersing agents, dyes, solid excipients etc. and its effect on quality of finished product	7
2	**Radio Pharmaceuticals** Therapeutic uses, diagnostic uses, facilities and work area, preparation of radio pharmaceuticals, radio pharmaceuticals used in medicines	3
3	**Stability of formulated products** Requirements, drug regulatory aspects, pharmaceutical products stability, self life, overages, containers, closures	5
4	**Kinetic Principles and Stability Testing** Reaction rate and order, acid base catalysis, decomposition reactions, methods of stabilization and accelerated stability testing	7
5	**Prolonged Action Pharmaceuticals** Benefits, limitations, oral products, terminology, drug elimination rate, types and construction of implants products, products evaluation, parenteral products, absorption and evaluation	5
	SECTION B	
6	**Novel Drug delivery system** Critical fluid technology, transdermal drug delivery system, controlled drug delivery system, multiple emulsion, nano particles, targeted drug delivery system, aerosols, inhalation & new products reported etc	7
7	**Cosmetics** Formulation and preparation of dentifrices, hair creams, lipsticks, face powders, shaving preparations, skin creams, shampoos, hair dyes, depilatories, manicure preparations etc	11
8	**Packaging Materials** Role and features of Pharmaceutical packing materials. Glass, plastic, rubber, metal and paper as pharmaceutical packaging material. General quality control of pharmaceutical packages. Primary, secondary and tertiary packaging materials. Child resistant and pilfer proof packaging	4
9	**GMP and Validation** Concept and need of good manufacturing practice guidelines. Elements of GMP covering controls of area and processes and product. Regulations related to GMP. Introduction of validation process. Types of validation. Brief methodology of process, equipments and instrument validation	7
10	**Pilot plant scale up techniques** Need, organization and layout, scale up techniques for solid and liquid dosage forms. Technology transfer	4
	TOTAL	**60**

Reference Books:
• LeonLachmann, H.Liebermann, Principles And Practice Of Industrial Pharmacy, Churchill Livingston
• Aulton, Pharmaceutics, Churchill Livingston
• Govt. of India, Indian Pharmacopoeia, The Controller of Publications
• B.P.Commission, British Pharmacopoeia, H.M.S.O.London
• USGovt., United State Pharmacopoeia, USGovt
• Chein, Controlled Drug Delivery Systems, Marcel Dekker Publication

Class: Seventh Semester B. Pharm. **Subject Code:** 710
Subject: Pharmaceutics – III (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To train students in carrying out experiments involving different evaluation parameters in adosage form.
- To allow the students to study the effects of solubility, pH, oxidation etc. on stability of a preparation.
- To give actual training in preparation of modern drug delivery system /s.
- To train the students on determination of shelf life of a formulation.

Sr.No.	Laboratory Experiments
1.	To compare oxidative degradation of ascorbic acid at different pH.
2.	To compare degradation rate constant in presence of metallic ions.
3.	To study flow property, compressibility and compactness of the given powder material.
4.	To evaluate given suspending agent for F value.
5.	To study the effect of anti oxidant on given drug prone to oxidation.
6.	Determination of effect of solvent on aspirin solution stability.
7.	To determine pH solubility profile of a given drug.
8.	To study the component of TDDS system.
9.	To prepare o/w/o multiple emulsion.
10.	Preparation and quality control test for 1. Cold cream 2. Vanishing cream 3. Shaving cream 4. Tooth paste 5. Hair setting lotion 6. Moisturizing cream 7. Tooth powder
11.	To find out energy of activation at given pH.
12.	To evaluate chemically the given plastic material by I. P. method.
13.	To perform stability study of given formulation at 450C.
14.	To evaluate given glass container for hydrolytic resistance test I. P.
15.	To prepare liposomes.
16.	Determine the partition coefficient of the given drug.
17.	To study crystal habits and forms of given drugs.

Class: Seventh Semester B. Pharm. **Subject Code:** 720
Subject: Pharm. Medicinal Chemistry III (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To expose the students towards drugs related to the treatments of disorders of nervous system
- To develop the conceptual knowledge of drug design based upon structure activity relationship.
- To provide the basic ideas about important technologies used in drug discovery programs

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Different classes of therapeutic drugs** A detailed study of the following classes with respect to drug nomenclature, classification, physicochemical properties, mode of action [MOA], biosynthesis, structure activity relationships [SAR], wherever applicable, synthesis of simple & prototype molecules, drug metabolism, therapeutic uses & side effects. Drug resistance, wherever applicable, should be covered in respective classes of drugs 1. A.Narcotic [centrally acting] analgesics [analgetics]. Morphine & all its structural 2. modifications [peripheral & nuclear]. Narcotic agonists & antagonists [dual & pure]. Non-narcotic analgesics [NSAIDS]. Difference between narcotic & non-narcotic agents 3. Adrenergic drugs. Neurotransmitters & their role. General & specific adrenergic agonists & antagonists [up to ά-2 & β-2 only]. Cholinergic agents. Muscarinic & nicotinic cholinergic agonists & antagonists [up to M2 & N2]. Neuronal [transmission] blockers 4. D. Drugs used in neuromuscular disorders. Drugs used in the treatment of Parkinson's disease. Central & peripheral muscle relaxants **SECTION B** A. Antihypertensive, & antianginal agents. B. Eicosanoids.Prostaglandins prostacyclins, &t hromboxanes, Their biochemical role, biosynthesis, & inhibitors. C. Asymmetric synthesis. Chirality, chiral pool, sources of various naturally available chiral compounds. Eutomers, distomers, eudismicratio. Enantioselectivity & enantio specificity. Enantiomeric & diasteriomeric excess. Prochiral molecules. Asymmetric synthesis of captopril & propranolol.	9 8 8 6 6 5 6
2	Introduction to drug design and discovery, phases involved, different methods in brief, development of any one drug as case study. Introduction to QSAR, lead discovery & optimization, QSAR parameters, Hansch & Free Wilson analysis, Mechanism based drug design including Quantum mechanics, molecular mechanics,and molecular modeling.	6
3	Basic concept of combinatorial chemistry, compound libraries, combinatorial synthesis, general techniques used in combinatorial synthesis, screening and identification of lead compounds, Limitations of combinatorial synthesis. Introduction to throughput screening.	6
	Note: Synthesis of following drugs should be studied: carbachol, neostigmine, tacrine, cyclopentolate, dicyclomine, clonidine, terbutaline, norepinephrine, methyl dopa, isoxsuprine, naphazoline, ephedrine, pyridostigmine, salbutamol, propranolol, labetolol, guanethidine, bretylium tosylate, hydralazine, nifedipine, captopril, losartan, valsartan, carbidopa, benzotropine, meperidine, methadone, dextropropoxyphene, pethidine,fentanyl, ibuprofen, diclofenac, tolmetin, meclofenamate, flurbiprofen	
	TOTAL	60

Reference Books:

- FoyeW.O., PrinciplesOf Medicinal Chemistry, K. E.Varghese&Company,Mumbai,India
- Wilson,C.,Gisvold, O.,&Doerge.J.,B., Text Book Of Organic Medicinal & Pharmaceutical Chemistry, J.B. Lippincot Company,Toronto,Canada
- Abraham,D.J., Burger's"Medicinal Chemistry & Drug Discovery, John Wiley& SonsInc.,NewYork
- Lednicer Daniel, OrganicChemistryOfDrug Synthesis (Vol.I toVI), Wiley-Interscience,U.S.A.

Class: Seventh Semester B. Pharm. **Subject Code:** 720
Subject: Pharm. Medicinal Chemistry III (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To give an understanding regarding the use of different name reactions in preparation of some useful compounds for synthesis of simple drug molecules.
- To give training in use of different commercially available compounds for preparing drug /s.
- To train the students in safe handling of very reactive chemical reagents by giving suitable reactions or demonstration of the same.

Sr.No.	Laboratory Experiments
1.	Preparation of cinnamic acid from benzaldehyde.
2.	Preparation of 5,5-diphenyl hydantoin from benzoin.
3.	Preparationof o-benzoyl benzoic acid from phthalic anhydride.
4.	Preparation of anthranilic acidfromphthalicanhydride.
5.	Preparation of 5,5-diphenyl-2-thioimidazoline-4-one from benzil
6.	Preparation of benzilicacidfrombenzoin.
7.	Preparation of 2-phenyl indole
8.	Preparation of acetophenone/benzophenonefrombenzene.
9.	Preparation of benzhydrol from benzophenone
10.	Preparation of benzimidazole from o-phenylene diamine
11.	Preparation of benzocaine from paraamino benzoic acid.
12.	Preparation of benzotriazole from o-phenylene diamine
13.	Preparation of phenothiazine from diphenylamine.
14.	Preparation of fluorescein from phthalic anhydride.
15.	Demonstration of the use of NaH / $NaBH_4$/B_2H_6 /$LiAlH_4$.

Class: Seventh Semester B. Pharm. **Subject Code:** 730
Subject: Clinical Pharmacy and Therapeutics (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To understand dosage calculations appropriate for patient & be able to select the proper drug.
- To underst and the importance of rational prescribing of drugs and concept of essential drugs.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	General Principles, preparation, maintenance, analysis of observational records in clinical Pharmacy	3
2	Clinical trials, type and phases of clinical trials, placebo, ethical and regulatory issues including Good clinical practice in clinical trials	3
3	Therapeutic drug monitoring, adverse drug reaction (ADR), types of ADR, Mechanism of ADR. Drug interaction, Monitoring and reporting of ADR and its significance	5
4	Drug information services, Drug interactions	3
5	Drug interaction in pediatric and geriatric patients, drug treatment during pregnancy, lactation and menstruation	5
6	Pharmacovigilance, Therapeutic drug monitoring, Neutraceuticals, essential drugs and rational drug usage	4
7	Age related drug therapy: concept of posology, drug therapy for neonates, pediatrics and geriatrics. Drugs used in pregnancy and lactation	5
	SECTION B	
8	Drug therapy in gastrointestinal, hepatic, renal, cardiovascular and respiratory Disorders	6
9	Drug therapy for neurological and psychological disorders	6
10	Drug therapy in infections of respiratory system, urinary system, infective meningitis, TB, HIV, malaria and filarial	6
11	Drug therapy for thyroid and parathyroid disorders, diabetes mellitus, menstrual cycle disorders, menopause and male sexual dysfunction	5
12	Drug therapy for malignant disorders like leukemia, lymphoma and solid tumors	5
13	Drug therapy for rheumatic, eye and skin disorders	4
	TOTAL	**60**

Reference Books:

- AlainL.I., Non Prescription Drugs, BlackwellS cientific Publis, hers
- Carter S.J., Dispensing For Pharmaceutical Student, CBSPublishers
- ColletD.M.&AultonM. E., Pharmaceutical Practice, ChurchillLivingston
- MulhollandB.V., Drug Calculations, Mosby
- StoneP.&Curtis S.J., PharmacyPractice, SAGEPublisher
- Roger Walker, Clinical Pharmacy and therapeutics, Churchill Livingston

Class: Seventh Semester B. Pharm. **Subject Code:** 740
Subject: Pharmaceutical Analysis – III (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To provide the sound basis of advance analytical techniques like NMR, Mass and Thermal analysis .
- To develop the ability to solve simple spectroscopic problems involving UV, IR, NMR and Mass Spectrometry.
- To emphasize the concept of advanced techniques of chromatography and Pharmaceutical importance of it.
- To develop the basis for the Quality assurance and Good Laboratory practice.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Proton nuclear magnetic resonance spectrometry** Principle involved in the technique. Knowledge about fundamental terms involved such as quantized absorption, flipping of nucleus, spin number, magnetic moment, magnetogyric ratio, relaxation, etc. Equations relating these terms to frequency of radiation & magnetic field [without derivation of the equations]. Types of relaxation processes. Low & high resolution instruments. A brief discussion on the low resolution instrumentation [60 MHz]. Quantitative knowledge of relationship between MHz & magnetic field. An introduction to superconductivity magnets.Solvents & reference standards used. Setting up of a NMR scale. Samplepreparation. Shielding & deshielding of a proton & it's effect on chemical shift,Discussion on & importance of equivalent & non-equivalent protons [number of signals] , chemical shifts [position of signal] & their calculation from the spectrum, chemical shifts of different H's, splitting [multiplicity] of a signal, coupling constants [J values] , integration [area under the signal] . Importance of these terms in identification [or confirmation] of different functional groups should be covered. Significance & contribution of J value in stereochemistry should be emphasized. Prediction [expected theoretical values] of chemical shifts & multiplicities for all protons from simple structures containing up to 12-15 carbons. An introduction to FT-technique & its significance in 13C-NMRspectrometry.	10
2	**Mass spectrometry** Principle. Low & high resolution instruments. Components & importance of each in brief. Different types of mass spectrometric techniques. Brief knowledge of Chemical Ionization mass spectrometry. Calculations of hydrogen deficiency index [HDI] or unsaturation index [UI] . Base or parent peak, molecular ion, M + 1, M + 2 peaks. Calculations of molecular weight based on M +1 & M + 2 peaks. Formation of molecular ion & further fragmentation. Rearrangements in mass spectrometry. Major modes of fragmentations of hydrocarbons, hydroxyl compounds, halogen compounds, aldehydes, ketones, carboxylic acids, and amines. Introduction [only] to recent advances in MS.	07
3	**Advanced Chromatography.** Introduction, Chemical equilibrium and the properties of the equilibrium constant, Thermodynamics and kinetics in Chromatographic separations, Band Broadening and its mechanism, Multiple Path Processes, Broadening by diffusion, Resistance to mass transfer (RTMT), Development of Chromatogram, Capacity Factor, Column resolution, optimization of column performance, Qualitative and quantitative analysis by chromatography. Concept of Normal and Reverse Phase Chromatography. Principle, rate & plate theory, Van Deemter equation [no derivation] & the parameters affecting separation/band broadening. Classification of chromatography, retention factor.	05
4	**Gas Chromatography:** Introduction to Theory and Principle, Instrumentation, types of columns and detectors. Advantages and limitations. Pharmaceutical and other Applications.	04

5	**High Performance (Pressure) Liquid Chromatography (HPLC)** Introduction to Theory and Principle, importance of column purging. Instrumentation and types of columns and detectors. Concept of silinization and bonded-phases LC-MS. Introduction to UPLC and its applications.	04
	SECTION B	
6	**Ion Pair Chromatography**, Ion suppression and Ion Exchange Chromatography, Introduction to Theory and Principle, Instrumentation. Advantages and limitations. Pharmaceutical and other Applications. **Size exclusion chromatography:** Introduction, principle, instrument. Column packing, Applications.	04
7	**High Performance Thin Layer Chromatography (HPTLC)** Instrumentation, Importance of automation, Pharmaceutical and other Applications.Chiral Chromatography, Flash chromatography,Supercritical fluid chromatography	04
8	**Thermal Methods or analysis :** Introduction to thermal analysis. Thermogravimetry; Isothermal/Static Thermogravimetry, Quasistatic Thermogravimetry, Factors affecting Thermogravimetric curve, Instrumentation, Applications. Differential Thermal Analysis and Differential Scanning Calorimetry; Comparison of DTA and DSC, Types of DSC analysis, Instrumentation, DTA and DSC Curves and their interpretation and Applications.	06
9	**Quality Assurance** Concept of Quality control and Quality Assurance, Quality Assurance and Quality Management in the Pharma industry, ISO 9000, TQM Functions & advantages of QC & QA, Organizational structure Introduction- History of GLP, QA in GLP.	08
10	Introduction to Validation of analytical methods as per ICH guidelines.	04
12	Test of packaging materials, cartons, aluminum foils, strip packing, blister packing, ampoules, vials, etc.	04
	TOTAL	60

Reference Books:

- Willard, Merrit, Dean & Settle, Instrumental methods of analysis Van Nostrand.
- Silverstein, spectrometric identification of organic compounds, Willey.
- Beckett & Stenlake, Practical Pharmaceutical chemistry, CBS publisher, New Dehli.
- KempWilliam, Organic spectroscopy, Pal Grav, N. Y.
- Kalsi P. S., Spectroscopy of organic compounds, New age publishers, New Delhi.
- Sinder, Text book of HPLC.
- Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
- Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
- Identification of Drugs and Pharmaceutical Formulations by Thin Layer
- Chromatography – P. D. Sethi, Dilip Charegaonkar, 2nd Edition.
- HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.

Class: Seventh Semester B. Pharm. **Subject Code:** 750
Subject: Project Work **Allotted Hrs.:** 3

OBJECTIVE:

- To train student for literature search, collection of appropriate material on their selected topic.
- To impart training on proper sequencing of the collected material for presentation
- To develop the writing and oral communication skills.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	A student will give a seminar on the literature collected and present a report on the topic given to him / her	30
	TOTAL	30

Syllabus for Eighth Semester B. Pharmacy

Class: Eighth Semester B. Pharm. **Subject Code:** 810
Subject: Biopharmaceutics & Pharmacokinetics (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To have a basic understanding of scope and impact of biopharmaceutics and pharmacokinetics
- To have general knowledge of various factors affecting drug absorption, distribution, metabolism and excretion
- To expose the students towards applications of kinetic principles in understanding blood levels of the drug and their effect on therapeutic cperformance on dosage forms

Sr. No.	Unit and Contents	Hrs.
1	**Biopharmaceutics** Fate of drug after drug absorption, various mechanisms for drug absorption, drug concentration in blood, biological factors in drug absorption, physicochemical factors, dosage form consideration for gastrointestinal absorption. Drug Absorption: a) Gastrointestinal absorption – biological consideration. b) Gastrointestinal absorption –physicochemical consideration c) Gastrointestinal absorption – role of the dosage form. Pharmacokinetics. Compartmental and non-compartmental pharmacokinetics. Biotransformation, drug disposition – distribution, drug disposition – elimination. Pharmacokinetic variability – body weight, age, sex and genetic factors, disease, drug interaction. Individualization and optimization of drug dosing regimens.	18
2	**Bio-availability& Bio-equivalence** Quality parameters of dosage forms. Assay methods & its validation. Physico - chemical properties of drugs &added substances and its effect on preparations and biological availability of dosage forms. Pharmaceutical properties of dosage forms, disintegration, dissolution rate .Biological, pharmacological effects of dosage forms. Factors affecting Bioavailability, determination of bioavailability. Significance of bio-equivalence studies. Statistical analysis of bioequivalence studies. Development, scaleup & post approval changes [SUPAC] & *invitro* [dissolution] *invivo* [plasma concentration profile] correlation or IV/IV correlation (IVIVC). Multi stage Bioequivalence studies. Therapeutic equivalence. Titration design for clinical rational. New deug applications.	22
3	**Biopharmaceutical Statistics** Post marketing surveillance, Probability, chi-square test, t test, parametic and non-parametric analysis, ANOVA, correlation, regression analysis.	20
	TOTAL	60

Reference Books:

- Leon Shargel,, Comprehensive Review of Pharmacy, Lippincott
- MiloGibaldi, Bio Pharmaceutics and Clinical Pharmacokinetics, Marcel Dekker Inc.USA
- WellingandTSE, Pharmacokinetics Regulatory, Industrial andAcademic Prospectives(Vol.57), Marcel Dekker Inc.USA
- WillingandTSE, Pharmaceutical Bioequivalence (Vol.48), Marcel Dekker Inc.USA
- MadanP.I., Biopharmaceutics and Practical Pharmacokinetics, Whittier Publications

Class: Eighth Semester B. Pharm. **Subject Code:** 820
Subject: Biotechnology (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To impart the knowledge about tool sof biotechnology useful in pharmaceutical sciences.
- To develop theoretical and practical knowledge about tissue culture techniques.
- To expose the students toward biotechnical processs of industrial importance.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Plant Cell and Tissue Culture** Structure of plant cell, DNA, Genes and chromosomes. 1. Cell and tissue culture, a. Requirements. b. Callus culture, suspension culture, batch culture. c. Concept of somatic hybridization, somatic embryogenesis. 2. Processes and applications, a. Isolation and immobilization of enzymes and plant cells and application. b. Protoplast and cell fusion. c. Germ plasm conservation. d. Production of secondary metabolites by plant tissue culture. e. Gene transfer techniques.	6
2	**Animal Cell Culture** Introduction to animal cell culture, medium used in ATC. Use of FCS, primary culture, secondary culture, cell line. Cloning: concept and application with technical hurdles. Transgenic animals as source of food, organs and tissues, concept of xeno transplant	6
3	**Fermentation Technology and Industrial Microbiology** 1. Fermentation as biochemical process, types of fermentations. 2. Fermenter – working and construction, accessory components, modification. 3. Fermentation monitoring and in situ recovery of products	8
4	**Recombinant DNA Technology** BASIC CONCEPTS a. Introduction. b. Role of restriction endonuclease, DNA ligase, DNA polymerase, Reverse transcriptase	6
5	**Process and Applications** A. Constructing Recombinant DNA molecules. I. DNA Clones sources of DNA for cloning. II. DNA vectors, role of expression vectors. III. Host cell for recombinant work. IV. Method for screening and selecting transformants. V. Expression of foreign genes. VI. Uses of recombinant DNA. B. PCR and applications. Human gene therapy concept and applications. C. Drug delivery systems in gene therapy	9
	SECTION B	
6	**Biotechnology Derived Products** A. Sources and upstream processing. 1. Introduction. 2. Escherichia coli as a source of recombinant, therapeutic protein. 3. Additional production systems, i) Yeast. ii) Fungal production systems. iii) Transgenic animals. iv) Transgenic plants. v) Insects cell based systems. 4. Upstream processing.	10

	[Note: Time allotted for point ii and iii is 1 hr] B. Downstream processing. a. Product analysis, 1. Introduction. 2. Protein –based contaminant. 3. Removal of altered form of protein of interest from product stream. b. Determination of protein concentration. C. Immunological approaches to detection of contaminant, Endotoxin and other pyrogenic contaminants. i] Pyrogen detection. ii] DNA as contaminant. ii] Microbial and viral contaminant. iv] Viral assays. v] Miscellaneous contaminants. vi] . Validation studies. D. Production and purification of recombinant proteins like, Insulin, Growth hormones, somatostatin, Interferons. Only examples of recombinant blood products.	
7	**Proteomics** 1. Introduction 2. Genomic study, structural and functional genomes, human genome project. 3. Technologies for Proteomics. 4.Protein identification, 1-D-SDS-PAGE (1-dimensional sodium dodecyl sulfate–polyacrylamide gel electrophoresis). 2-Dimensional electrophoresis. 5. Applications of DNA and Protein Microarray Technology. 6.Pharmaceutical and Medical Application of Proteomic	8
8	**Formulation of Proteins and Peptides** 1. Introduction. 2. Making Small Protein Particles: Precipitation of proteins from Supercritical Fluids. 3. Aseptic Assembly. 4. Quality Control Issues. 5. Lyophilization (Freeze-Drying). 6. Protein Compaction	7
	TOTAL	**60**

Reference Books:

- KeshavTreha, Biotechnology, New Age International publishers
- DaanJA Crommelin and RobertD Sindelar, Pharmceutical Biotechnololgy, Taylor And Francis
- MichelG.Grooves, Pharmaceutical Biotechnology, Taylor and Francis groupSecond edition
- Gary Walsh, Pharmaceutical Biotechnology Concepts And Application, Wiley InterscienceLtd.
- AluizioBorem Fabrico R.S antos, DavidE., Understanding Biotechnology, Bowen,,Prentice& Hall

Class: Eighth Semester B. Pharm. **Subject Code:** 820
Subject: Biotechnology (Practical) **Allotted Hrs. :** 6

OBJECTIVE:

- To train students to carryout different sterilization experiments.
- To train students infermentative techniques of production of bioactivemolecules.
- To isolate the genetic material lfrom various living organisms.

Sr.No.	Laboratory Experiments
1.	Sterilization by autoclave (moist heat) and perform test for sterility by membrane filtration method
2.	Sterilization by autoclave (moist heat) and perform test for sterility by direct inoculation method.
3.	Sterilization by dry heat and perform test for sterility by membrane filtration method.
4.	Sterilization by dry heat and perform test for sterility by direct inoculation method.
5.	Sterilization by treatment with bactericide and perform test for sterility by membrane filtration method
6.	Fermentative method of preparation of penicillin.
7.	Fermentative method of preparation of L-glutamic acid.
8.	Estimation of DNA by DPA Method.
9.	Isolation of DNA from Fungi.
10.	Production of lactic acid from lacto bacillus sporogenes.
11.	Production of alcohol by fermentation techniques.
12.	Immobilization of microbial cells by entrapment in sodium alginate.
13.	Isolation of plasmid DNA from bacillus (using standard kit)
14.	Isolation of plasmid and genomic DNA from bacterial cell using kits.
15.	Isolation of RNA and proteins from E. coli, liver and plant cells.
16.	Restriction endonuclease assay (using standard kit).
17.	DNA Ligation assay (using standard kit).
18.	Plant tissue culture callus /organ.
19.	PCR demonstration.
20.	Gel electrophoresis (demonstration).

Class: Eighth Semester B. Pharm. **Subject Code:** 830
Subject: Industrial Natural Products (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To impart knowledge of plant tissue culture.
- To develop the concept of value addition to herbal drugs in terms of quality standards and standardization of herbal drugs.
- To impart the knowledge of isolating active principles from crude drugs.
- To make learners aware about the regulatory aspects of intellectual properties related to theherbs.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Plant biotechnology: Plant tissue culture technology importance, types of cultures, requirements, and maintenance. Applications of plant tissue culture in Pharmacognosy. Importance of Polyploidy, Mutation and Hybridization with reference to medicinal plants.	5
2	Herbal cosmetics: Importance of herbals as shampoos (soapnut), conditioners and hair darkeners, (amla, henna, hibiscus, tea), skin care (aloe, turmeric, lemon peel, vetiver)	3
3	Colouring and Flavouring agents from plants	2
4	Plants based industries and research institutes in India Knowledge about the herbal products being manufactured by premier herbal industries and thrust area of the institutes involved in plant research	5
5	Utilization and production of phytoconstituents such as quinine, calcium sennosides, Diosgenin, and Atropine in India	4
6	World-wide trade in medicinal plants and derived products with special reference to diosgenin (disocorea), taxol (Taxus sps) digitalis, tropane alkaloid containing plants, Papain, cinchona, Ipecac, Liquorice, Ginseng, Aloe, Valerian, Rauwolfia and plants containing laxatives	6
7	Herbal formulations: Principles involved in Sidha, Unani, Chinese and Homeopathic systems of medicines. Preparation and evaluation of Unani formulations like majooms, Safoofs.	4
	SECTION B	
8	Utilization of aromatic plants and derived products with special reference to sandalwood oil, mentha oil, lemon grass oil, vetiver oil, geranium oil and eucalyptus oil. List of commercial Indian essential oils	5
9	Phytopharmaceuticals: Isolation, identification and estimation of: caffeine, eugenol, digoxin, piperine, tannic acid, diosgenin, hesperidine, berberine, calcium sennosides, rutin, glycyrrhizin, menthol, ephedrine, quinine, andrographolides and guggul lipids	8
10	Nutraceuticals and Health Foods: Classification of Nutraceuticals, Health foods: Source, Chemical constituents, uses, actions and commercial preparations of, following health foods, Alfalfa, Bran, Angelica, Chamomile, Corn oil, Fenugreek, Ferverfew, Garlic, Ginseng, Ginkgo, Honey, Hops, Safflower oil, Soyabean Oil, Turmeric. Concept and examples of Adaptogens	6
11	Patents: Indian and International patent laws, proposed amendments as applicable to herbal/natural products and processes: Intellectual Property Rights with special reference to phytoconstituents, Global herbal drug regulation	3
12	Study of herbal monograph as per Pharmacopoeia	2
13	Recent review on Tumour inhibitors, Hepatoprotective, antidiabetic activities, and immmunomodulator plants	5
14	Plant products: Introduction to plant bitters, and sweeteners.	2
	TOTAL	60

Reference Books:
• Manual K. Lindsey, Plant Tissue Culture, . Springer U.K. Wagner
• Wagner and Bladt, Plant Drug analysis, Springer U.K.
• A.R.Kashi, Industrial Pharmacognosy, Universities press
• S.S.Agrawal, Herbal drug technology, Universities press
• Quality standards of herbal formulation., ICMR New delhi

Class: Eighth Semester B. Pharm. **Subject Code:** 830
Subject: Industrial Natural Products (Practical) **Allotted Hrs. :** 6

Sr.No.	**Laboratory Experiments**
1.	Extraction and TLC profile of Reserpine, Caeffine, Pectin, Hesperidin, Diosgenin, Ginger resin.
2.	Phytochemical testing of Phytoconstituents (Alkaloids, Glycosides, Tannin, Resin and Volatile mentioned in theory).
3.	Extraction of Volatile oil (Mentha and Clove) by using Clevenger Apparatus.
4.	Extraction and Chemical evaluation of Papain.
5.	Evaluation of any two crude drugs as per WHO guidelines.
6.	Separation of Leaf pigments by column chromatography.
7.	Development of Callus culture.
8.	Preparation and evaluation of Herbal cosmetics (Shampoo, Cold cream).
9.	Preparation and evaluation of Ayurvedic formulation (Ghutica, Vatika, Asava and Arishta).
10.	Standardization of marketed herbal formulation by using Spectroscopy and Chromatography

Class: Eighth Semester B. Pharm. **Subject Code:** 840
Subject: Pharmaceutical management (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To provide various aspects of management in pharmaceutical business
- To provide information on planning & forecasting
- To familiarize students with the significance of communication, marketing strategies, motivation, leadership aspects inbusiness

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Introduction to management** Types of management. Basic concepts of management, management process, function and principles. Levels of management, pharmaceutical management art, science or profession.	4
2	Social responsibilities of management, functions of management	3
3	**Planning and Forecasting** Planning: Nature, process and types of planning, steps in planningprocess, planning premises. Advantages and limitations of planning. Management by objective, meaning, objective features, advantages and limitations. Forecasting: meaning, nature, importance, limitations. Techniques of forecasting	8
4	**Organization** Definition, nature, theories, functions, line and staff organization concepts	4
5	**Research Management** R&D organizations and research categories. Elements needed for an R&D organization. Technology transfer.	3
6	**Inventory Management** Objective and functions of inventory control. Types of inventories. Requirements of effective inventory control	3
7	**Communication** Nature, types of communication, process, channels and barriers of communication. Limitations of communications. Importance in pharmaceutical industries	5
	SECTION B	
8	**Marketing Research** New product selection, product management, advertising	3
9	**Leadership and motivation** Leadership: meaning, nature, leadership styles. Theories of leadership. Motivation meaning, nature, importance. Theories of motivation	6
10	**Human resource and development (HRD)** Definition, HRD methods, HRD process, HRD in Indian industry	4
11	**GATT** General Agreement on Tariff and Trade and its impact on pharmaceutical industry. History of GATT, its impact on pharmaceutical industry. Pharmaceutical market in India.	6
12	**World trade organization (WTO) and trade related intellectual property rights (TRIPS)** Introduction to WTO. Types of intellectual property rights: industrial property and copy rights Indian Patent Acts, 1970 with latest amendment. Definition, types of patents	6
13	**Standard institutions and regulatory authorities** 1 Bureau of Indian standards (BIS). 2 International Organization for Standardization (ISO). 3 United States of Food and Drug Administration (USFDA). Central Drug Standard Control Organization (CDSCO). International Conference on Harmonization-ICH 4 World Health Organization (WHO).	5
	TOTAL	60

Reference Books:
• HeinzWeihrich and HaroldKoontz, Managementa Global Perspective, Mc Graw Hills,New Jersey
• B.Gupta, Management Theory and Practice, Sultan ChandandSons, Educational publishers, NewDelhi
• N.Subbaram, What every one should know about patents?, PharmaBook syndicate,Hyderabad
• PeterBamfield, Research and Development Management in the Chemical and Pharmaceutica lIndustry, Wiley-VCHVerlag GmbH&Co.KgaA, Germany
• Ian Beard well, len Holden, Human Resource management A contemporary Perspective, MacMillan IndianLtd NewDelhi

PART - B

M. Pharm. Syllabus
(Ordinance, Rules and structure)

Dr. BabasahebAmbedkarMarathwada University, Aurangabad

Masters of Pharmacy (M. Pharm.)

0.527 There shall be four semesters during M. Pharm. each of 6 months (90 working days) duration.

There shall be four examinations leading to the Degree of Masters of Pharmacy (M. Pharm.) namely:

1. The First Semester M. Pharm.
   : Examination at the end of the First semester of M. Pharm.
2. The Second semester M. Pharm.
   : Examination at the end of the Second semester M. Pharm.
3. The Third semester M, Pharm.
   : Examination at the end of the Third semester of M. Pharm.
4. The Fourth semester M. Pharm.
   : Examination at the end of the Fourth semester M.Pharm.

0.528 The examination specified above shall be twice a year at such places and on such dates as may be appointed by the University

There shall be three parts of examination (at first, second and third semester) and one part of dissertation at fourth semester.

0.529 An applicant for the admission to the examination specified in ordinance shall complete a regular course of the study in the course prescribed for examination concerned for not less than one semester year in the college of Pharmacy / Pharmaceutical Sciences recognized by the Dr. BabasahebAmbedkarMarathwada University, Aurangabad.

0.530 A candidate shall be admitted to the first year M. Pharm. if he / she has:

- A student holding B. Pharm. degree of Dr. BabasahebAmbedkarMarathwada University, Aurangabad or any other university recognized as equivalent to is eligible for admission to post graduate course in pharmacy in various subjects. The candidate should have minimum % marks (55% in case of SC and ST category candidates from Maharashtra State only) at the bachelor's degree e (B. Pharm.) as awarded by the respective university.
- Appear for GPAT Common entrance test conducted by competent authority of All India Council for Technical Education, New Delhi, and qualified with valid score. OR
- Appear for common entrance test conducted by Govt. of Maharashtra or Govt. of India, for that academic year and secured non-zero score in that

common entrance test.

The above and further eligibility criteria may be subjected to change from time to time depending upon the rules and regulations of Govt. of Maharashtra.

0.531

- A candidate shall be admitted to the Second semester of M. Pharm. if he / she has passed the First semester M. Pharm. examination.
- A candidate shall be admitted to the Third semester M. Pharm. if he / she has passed the Second semester M. Pharm. examination.
- A candidate shall be admitted to the Fourth (Final) semester M. Pharm. if he has passed the Third semester M. Pharm. examination.
- No candidate shall be allowed to admit for the examination,if he / she does not fulfill the attendance criteria as per the university norms. A candidate shall have attendance at theory hours as well as practical sessions minimum 75%. The Head / Principal / Director of the department / college / institute shall establish a suitable method for monitoring of the attendance of admitted candidates like daily attendance sheet for each subject, thumb impression attendance machine etc.

0.532 An applicant for admission to an examination shall satisfy the Head / Principal / Director of the Department / College / Institute in the terminal and other tests conducted during the academic year regarding his / her suitability to take the examination.

0.533 Omitted

0.534 No candidate shall be admitted to any of the examination if he has already passed the same examination or equivalent examination of any other statutory university / board.

R.646 The structure of M. Pharm. course, scheme of examination including maximum marks allotted to the sessional examination in each paper, the written part and practical part for each of four examination, shall be as indicated in **(Annexure C).**

R.647 The scope of the subject shall be as indicated in the syllabus**(Annexure C)**.

R.648 The head / Principal / Director of the Department / College / Institute shall maintain in his office a complete record of the marks obtained by the candidates in the sessional examinations.

R.649 The head / Principal / Director shall send sessional examination marks secured by the candidate to the registrar / Controller of examination of the university in the sealed cover not less than 15 days before the commencement of semester

examination.

R.650 In order to pass examination, candidate must have obtained

- At least 50% of marks in theory and practical examination (excluding sessional examination marks) separately in each subject theory and practical andMust obtain at least 50% of the total marks assigned to that examination.

R.651

- There shall not be classification of successful examiners at the First, Second and Third semester M. Pharm. examinations.
- The rank in order of merit of first five students shall be declared on the basis of aggregate marks obtained at the first, second, third and fourth semester M. Pharm. examination combined together.

R.652 The division of successful examinee at the M. Pharm. examination shall be declared on the basis of the aggregate marks obtained at the first, second Third and Final M. Pharm. examination taken together.

R.653 The name of candidate passing the examination as whole in the minimum prescribed period and obtained the prescribed number of places in the first class be arranged in the merit, separately for each subject specialization offered at M. Pharm. examination as provided in the examination.

Candidate passing examination by taking exemption in the subject shall be declared pass in pass class.

The following shall be the mode of Awards of the class at an examination

- Candidate obtaining 75% or more marks of grant total
  : First class with distinction
- Candidate obtaining 60% or more but less than 75% marks of grant total
  : First class
- Candidate obtaining 50% or more but less than 60% marks of grant total
  : Second class

R.654

- An examinee who is successful at an examination and obtained not less than 75% marks of the total marks prescribed in a subject shall be declared to have passed the examination with Distinction in that subject

  Explanation: Distinction in a subject will be awarded at the first, second, third and fourth semester of M. Pharm examination separately
- Only those candidates who have passed an examination in one attempt will be eligible for any price, scholarship, to be awarded for that examination.

R.655 Omitted

R.656 An examinee failing in any number of theory papers and / or practical examination may reappear at his / her at subsequent examination in the subject in which he / she has failed on, payment of fresh fee. Such candidate will be allowed to keep the term in next higher class.

A candidate can proceed from semester first to semester second, from semester second to semester third and from semester third to semester fourth, irrespective of number of subject in which candidate has failed in semester first, second and third the candidate is allowed to continue research work and submit the dissertation in accordance with the relevant regulation but the result of dissertation will not be declared until all the subject has cleared from Semester first, second and third examination.

R657

- Minimum one sessional examinations (Sessional examination) will be held by the teaching institute every semester for the purpose of theory and practical internal assessment.
- A candidate failing in any of the university examination may, at the discretion of the Head / Principal / Director of the department / institute / College be permitted, for such period as the head / Principal / Director consider necessary to attend the course instruction on the paper or practical in which he / she has failed as the case may be, in such case the Head / Principal/ Director shall award him / her fresh sessional examination marks on the basis of his / her fresh performance.
- A separate Improvement sessional shall be conducted for assessment of such performance on the complete syllabus of the particular subject. Oneimprovement examinations shall be conducted by the department / institute / college every semester. Separate time table shall be declared after application of candidate for such examination.
- This new curriculum (including regulation, structure and syllabus) will be for the academic year 2013-14 onward for First and second semester M. Pharm., for academic year 2014-15 onwards for third and fourth semester M. Pharm.

  The candidate failing in an examination with old course (All previous courses) will have to clear that examination as per old syllabus. Candidate will have to take the subsequent higher examinations as per the carry on rule decided by the University.

The examinee shall carry out his research dissertation work for the period of not

less than one semester, during the course under the guidance who shall be recognized post graduate teacher in the relevant subject of specialization.

The examinee shall submit two copies of dissertation to the university through the principal of the college duly certified by the guide that the work has been done satisfactorily under the guidance. No extension of time shall ordinarily be granted to a candidate for the submission of the dissertation.

The board of examiners shall carry out the defense examination based on the dissertation. The guide shall be internal examiner for the candidate concerned. The external examiner (for dissertation assessment) shall not be associated with examination of more than three examinee in the subject.

One copy of the dissertation shall be send to the external examiner by the university as early as possible but not less than four week before the defense examination.

An examinee after the third semester of M. Pharm. who fail to submit his dissertationwithin the prescribed date and who fails to present for defense, require to keep one fresh term and can be appear for the examination after submitting the revised dissertation, if necessary on submission of new application and payment of fresh fees for the examination.

An examinee that fails to secure minimum marks required for passing forth semester of M. Pharm. shall resubmit work with such an additional work as may be directed by at the next examination. However an examinee wishing to submit dissertation on fresh subject shall be required to joint college as a regular student for fourth semester of M. Pharm.

For the purpose of exemption, theory, practical, seminar and dissertation shall be considered as separate subject head.

Provision of ordinance related to condition of deficiency of marks for passing an examination shall apply to the examination under the concerned ordinance implemented time to time.

An examinee that does not pass or who fails to present for the examination shall be eligible for admission to the same examination subsequently on payment of the fresh fees and such other fee may be prescribe by the university time to time.

The external examiner for M. Pharm. examination shall be at least Ph.D. after master degree in Pharmacy and minimum five year of teaching experience out of which at least two years at the degree level after M. Pharm. level.

Annexure C
Structure of Syllabus

There shall be five subject specializations at the Masters of Pharmacy (M. Pharm.)

- Pharmaceutics
- Quality Assurance Techniques (Quality Assurance)
- Pharmaceutical Chemistry
- Pharmaceutical Analysis
- Pharmacology
- Pharmacognosy

Abbreviations: TH: Theory, **PR:** Practical, **SC:** Subject Code, **INT:** Internal, **EXT:** External

Semester 1: All subject specialization

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
I	S1-MPH1	1	Research Methodology	4	--	3	--	80	20	--	--	100	--	4	--
I	S1-MPH2	2	Modern Analytical Techniques	4	8	3	8	80	20	80	20	100	100	4	4
I	S1-MPH3	3	Computers & Statistics	4	4	3	4	80	20	40	10	100	50	4	2
I	S1-MPH4	4	Nanotechnology & Biotechnology	4	8	3	8	80	20	80	20	100	100	4	4

Pharmaceutics

Semester 2:

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
II	S2-MPH1	1	Research Project	--	8	3	--	--	--	40	10	--	50	--	2
II	S2-MPT2	2	Formulation Concepts and Industrial Pharmacy	4	8	3	8	80	20	80	20	100	100	4	4
II	S2-MPT3	3	Biopharmaceutics and Pharmacokinetics	4	8	3	4	80	20	80	20	100	100	4	4
II	S2-MPT4	4	Advanced Pharmaceutics - I	4	--	3	--	80	20	--	--	100	--	4	--

Semester 3:

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
III	S3-MPH1	1	Drug Regulatory aspects and IPR	4	--	3	--	80	20	--	--	100		4	--
III	S3-MPT2	2	Research work Seminar	--	8	--	1	--	--	100	--	--	100	--	4
III	S3-MPT3	3	Research Project	--	16	--	2	--	--	150	--	--	150	--	6
III	S3-MPT4	4	Novel Drug Delivery Systems	4	--	3	--	80	20	--	--	100		4	--
III	S3-MPT5	5	Advanced Pharmaceutics - II	4	--	3	--	80	20	--	--	100		4	--

Quality Assurance Techniques (Quality Assurance)

Semester 2:

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
II	S2-MPH1	1	Research Project	--	8	3	--	--	--	40	10	--	50	--	2
II	S2-MPQ2	2	Pharmaceutical and Biological Evaluation	4	8	3	8	80	20	80	20	100	100	4	4
II	S2-MPQ3	3	Validation	4	8	3	4	80	20	80	20	100	100	4	4
II	S2-MPQ4	4	Stability of drugs and dosage form	4	--	3	--	80	20	--	--	100	--	4	--

Semester 3:

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
III	S3-MPH1	1	Drug Regulatory aspects & IPR	4	--	3	--	80	20	--	--	100		4	--
III	S3-MPQ2	2	Research work Seminar	--	8	--	1	--	--	100	--	--	100	--	4
III	S3-MPQ3	3	Research Project	--	16	--	2	--	--	150	--	--	150	--	6
III	S3-MPQ4	4	Quality Management	4	--	3	--	80	20	--	--	100		4	--
III	S3-MPQ5	5	Advanced Quality Assurance	4	--	3	--	80	20	--	--	100		4	--

Pharmaceutical Chemistry

Semester 2:

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
II	S2-MPH1	1	Research Project	--	8	3	--	--	--	40	10	--	50	--	2
II	S2-MPC2	2	Advanced Pharmaceutical Chemistry - 1	4	8	3	8	80	20	80	20	100	100	4	4
II	S2-MPC3	3	Advanced Organic Chemistry	4	8	3	4	80	20	80	20	100	100	4	4
II	S2-MPC4	4	Advanced Pharmaceutical Chemistry - 2	4	--	3	--	80	20	--	--	100	--	4	--

Semester 3:

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
III	S3-MPH1	1	Drug Regulatory aspects & IPR	4	--	3	--	80	20	--	--	100		4	--
III	S3-MPC2	2	Research work Seminar	--	8	--	1	--	--	100	--	--	100	--	4
III	S3-MPC3	3	Research Project	--	16	--	2	--	--	150	--	--	150	--	6
III	S3-MPC4	4	Advanced Pharmaceutical Chemistry – 3	4	--	3	--	80	20	--	--	100		4	--
III	S3-MPC5	5	Advanced Pharmaceutical Chemistry – 4	4	--	3	--	80	20	--	--	100		4	--

Pharmaceutical Analysis

Semester 2:

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
II	S2-MPH1	1	Research Project	--	8	3	--	--	--	40	10	--	50	--	2
II	S2-MPA2	2	Chromatographic Methods of Analysis	4	8	3	8	80	20	80	20	100	100	4	4
II	S2-MPA3	3	Analytical Method Development and Validation	4	8	3	4	80	20	80	20	100	100	4	4
II	S2-MPA4	4	Advanced Analytical Techniques	4	--	3	--	80	20	--	--	100	--	4	--

Semester 3:

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
III	S3-MPH1	1	Drug Regulatory aspects & IPR	4	--	3	--	80	20	--	--	100		4	--
III	S3-MPA2	2	Research work Seminar	--	8	--	1	--	--	100	--	--	100	--	4
III	S3-MPA3	3	Research Project	--	16	--	2	--	--	150	--	--	150	--	6
III	S3-MPA4	4	Quality Control and Quality Assurance	4	--	3	--	80	20	--	--	100		4	--
III	S3-MPA5	5	Bio analytical Techniques	4	--	3	--	80	20	--	--	100		4	--

Pharmacology

Semester 2:

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
II	S2-MPH1	1	Research Project	--	8	3	--	--	--	40	10	--	50	--	2
II	S2-MPL2	2	Advanced Pharmacology-I	4	8	3	8	80	20	80	20	100	100	4	4
II	S2-MPL3	3	Methods in Pharmacology	4	8	3	4	80	20	80	20	100	100	4	4
II	S2-MPL4	4	Advanced Pharmacology - 2	4	--	3	--	80	20	--	--	100	--	4	--

Semester 3:

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
III	S3-MPH1	1	Drug Regulatory aspects and IPR	4	--	3	--	80	20	--	--	100		4	--
III	S3-MPL2	2	Research work Seminar	--	8	--	1	--	--	100	--	--	100	--	4
III	S3-MPL3	3	Research Project	--	16	--	2	--	--	150	--	--	150	--	6
III	S3-MPL4	4	Advanced Pharmacology-3	4	--	3	--	80	20	--	--	100		4	--
III	S3-MPL5	5	Advanced Pharmacology - 4I	4	--	3	--	80	20	--	--	100		4	--

Pharmacognosy

Semester 2:

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
II	S2-MPH1	1	Research Project	--	8	3	--	--	--	40	10	--	50	--	2
II	S2-MPG2	2	Advances In Pharma cognosy & Phytochemistry	4	8	3	8	80	20	80	20	100	100	4	4
II	S2-MPG3	3	Medicinal Plant cultivation and Biotechnology	4	8	3	4	80	20	80	20	100	100	4	4
II	S2-MPG4	4	Advanced Herble Technology - 1	4	--	3	--	80	20	--	--	100	--	4	--

Semester 3: Pharmacognosy

SEM	SC	S. N.	Subject	HRS. /WEEK		EXAM HRS		TH MARKS		PR MARKS		TOTAL MARKS		CREDITS	
				TH	PR	TH	PR	EXT	INT	EXT	INT	TH	PR	TH	PR
III	S3-MPH1	1	Drug Regulatory aspects & IPR	4	--	3	--	80	20	--	--	100		4	--
III	S3-MPG2	2	Research work Seminar	--	8	--	1	--	--	100	--	--	100	--	4
III	S3-MPG3	3	Research Project	--	16	--	2	--	--	150	--	--	150	--	6
III	S3-MPG4	4	Standardization and Evaluation ofNatural Product Drugs & Formulations	4	--	3	--	80	20	--	--	100		4	--
III	S3-MPG5	5	Advanced Herble Technology - 2	4	--	3	--	80	20	--	--	100		4	--

Semester 4: All subject specialization

SEM	SC	S.N.	Subject	HRS. PER WEEK	EXAM. HRS.	TOTAL MARKS	CREDITS
IV	S4-MPH1	1	Research Project and Colloquium	36	2	400	16

PART - C

M. Pharm. Syllabus

(Pharmaceutics)

Class: First Semester M. Pharm. **Subject Code:** S1-MPH1
Subject: Research Methodology **Allotted Hrs.:** 4

OBJECTIVE:

- To familiarize students regarding teaching methodology & research projects.
- To teach students preparation of are search projects & different aspects associated with it.
- To acquaint students with experimental data analysis.
- To impresss upon students the importance of ethical issues in the profession & plagiarism.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Learning and instruction** Principles of Instructional design and learning theory, Merrill's five principles and Gagne'scon dition of learning. Active learning, group learning, collaborative learning, problem-based learning, team-based learning, Experiential learningmodel of Kolb.	8
2	**Curriculum development** Asix step approach-Problem identification and general needs assessment, targeted needs assessment, goals and objectives, educational strategies, implementation, evaluation and feedback. Bloom's Taxonomy, three domains of educational objectives.	6
3	**Funding &Scholarship** Agencies funding research in pharmaceutical sciences, Scholarship ,types of scholarships in education.	3
4	**Assessment** Definition and methods, Georges Millers pyramid, assessment, measurement and tests, types of numbers, formative and summative assessment.	3
5	**Basicsof Research** Definition, objectives, motivation, types of research and approaches: Descriptive research, conceptual, theoretical, applied and experimental.	3
6	**Formation of Research Problem** A. Research Process: To determine what type of research to be done, plan of research work. B. Selection of research area, prioritization of research. C. Literaturere view: importance and methods, sources, D. Objectives and scope of work, developing research plan and schedule: Scheduling constraints ,steps, problems in scheduling, limitations.	4
7	**Mathematical Modeling and Simulation** Concept of modeling, classification of mathematical models, modeling with ordinary differential equations, difference equations, partial differential equations, graphs, simulation: concept, types (quantitative , experimental, computer, fuzzy theory, statistical) processes of formulation of model based on simulation. Variables and measurement.	5
	SECTION B	
8	**Experimental Modeling** A. Definition of experimental design, examples, single factor experiments B. Blocking and Nuisance factors, guidelines for designing experiments. C. General model of process: Input factors/ variables, Out put parameters/ variables controllable /uncontrollable variables, dependent/ independent variables experimental validity. D. Introduction to Risk assessment, reliability, sustainability, and uncertainty.	4

9	**Analysisof data** A. Types of data: parametric and nonparametric, descriptive and inferential data, B. Collection of data: normal distribution, calculation of co-relation coefficient C. Data processing: analysis, error analysis, meaning, and different methods: analysis of variance, significance of variance, analysis of covariance, multiple regressions, testing linearity / nonlinearity of model, testing adequacy of model. D. Test to be used in data exploration and their choice E. Introduction of software used in data analysis.	8
10	**Research Deliverables** A. Various Forms of Publication: Thesis, paper, research proposal. B. Thesis Writing: Introduction, literature reviewor state-of-the-art, research approach (methodology), results or findings, discussions, conclusions, scope for future work, references, appendices. C. Presentation: Poster, thesis, proposal, and paper.	4
11	**Ethical issues in research** Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/ vaccines /herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good clinical practices norms, Ethical principles related to animal experiments.	10
12	**Plagiarism** Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscriptwriting, documentation, organization of reference material, bibliography, end note.	2
	TOTAL	60

Reference Books:

- B.D.John,A.L.BrownandR.R.Cocking,1999."How People Learn: brain, mind, experience and school".Washington, D C: National Academy Press.
- J.R.Fraenkel,N.E. Wallen,2008."How to Designand Evaluate Researchin Education*",7th Ed*. Bostan McGraw-Hill
- K.E.David,2009. Curriculum Development for Medical Education:*A Six-Step Approach* 2nd Ed. The John Hopkins University Press. ISBN0-8018-9367-4.
- N.Peter,2009."Leadership: Theory and Practice*." 3rd Ed.* Thousand Oaks: Sage Publications.
- G.Bordage,B.Dawson,2003. Experimental study design and grant writing in eight steps and 28 questions *MedicalEducation, 37*(4):376-385.
- B.J.Avolio, F.O.Walumbwa, T.J.Weber, 2009. Leadership: Current theories, research, and future directions. *Annual Review of Psychology, 60*:421-449.
- C.R.Kothari, 2004."Research Methodology".2nd Ed.New Ag eInternational(p) Limited,Publishers.
- D.Montgomary, 2000."Designof Experiments". 5thEd. Wiley Interscience.
- K.P. Willkinsion, L. Bhandarkar, "Formulation of Hypothesis". 3rd ed. Himalaya publishing, Mumbai.
- SchankFr, 2008."Theories of Engineering Experiments".2nd Ed.Tata McGraw Hill.
- D.C.Montgomery, 2009."Introduction to SQC"6th Ed.JohnWilly& sons.
- Cochran& Cocks, 1957.2nd Ed."Experimental Design" New York,JohnWilly& sons.
- J.W.BestandJ.V.Kahn, 2006."Research in Education". 10th Ed.PHI publication.
- S.S.Rao,1983."Optimization Theory & Applications".2nd Ed.WileyEasternLtd.ND.
- P.D.Kulkarni,1986."Independent Study Techniques",TTTI Chandigarh

Class: First Semester M. Pharm. **Subject Code:** S1-MPH2
Subject: Modern Analytical Techniques (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To familiarize students in use of modern techniques of analysis used indifferent areas/ fields of pharmacy.
- To give training in use of the technique & its applications in day to day practice.
- To build on the basics learned at UG level & give latest advances in the area.
- To give more stress on application based knowledge than instrumentation based one.
- To give hands on training on use of as many different ophisticated instruments as possible.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Ultraviolet–Visible spectrometry: Woodward–Fisher rules for calculation of λmax. Derivative spectroscopy. Introduction to Optical rotator Dispersion and Circular Dichroism.	5
2	Fourier Transformed Infrared Spectrometry. Interpretation of Infrared spectrum.	3
3	High Resolution ^{1}H &^{13}C NMR Spectrometry. Theoretical calculation of chemical shifts of various carbon atoms. Technique used for finding types of carbon like attached protontest(APT), distortionless energy polarization transfer (DEPT). Homonuclear & heteronuclear correlation spectrometry. Different 1D & 2D NMR correlation spectrometric techniques such as COSY, NOESY, HETCOR INADE QUATE, SBC, HMQC etc. Use of this technique in determination of absolute configuration.	15
4	Mass spectrometry: use of isotopic abundance in molecular formula calculation. Different ionization techniques like EI,CI, FD, FI, MALDI, API,ESI. Fragmentation of molecule using these techniques. Tandem mass spectrometry and its applications in pharmacy.	8
	SECTION B	
5	HPTLC: Basic instrumentation and its calibration. Analytical methoddevelopment andits validation as per ICH guidelines. Quantification using HPTLC	5
6	HPLC: Instrumentation covering detailed discussion about pumps, injector system, columns and detectors. Calibration of instrument. Analytical method development, validation as per ICH guidelines and trouble shooting. Quantification methods usedin HPLC. Ultra pressure liquidchromatography.	8
7	Thermoanalytical techniques: Differential Scanning Calorimetry (DSC), Thermogravimetry (TG),Thermo mechanical analysis (TMA): Principles instrumentation and applications (including interpretation of data) in pharmacy.	5
8	Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmuneassay, ELISA etc.	6
9	Microscopy: SEM, TEM, cryomicroscopy, AFM, confocalmicroscopy.	5
	TOTAL	60

Reference Books:

- RobertM. Silverstein, FrancisX. Webster, DavidJ. Kiemle,2009."Spectrometric identification of organic compounds".7thEd. John Wiley & Sons
- Pavia D. L.,2009."Introduction to spectroscopy".4th, Belmont CA
- Munson&Munson,"Pharmaceutical analysis: modern methods".,New York: M. Dekker
- KennethA. Connors, 2007."A Text book Of Pharmaceutical Analysis"3rdEd. WileyIndia-wse
- JensThuroCarstensen, 2001."Advanced pharmaceutical solids"Marcel Dekker, NewYork
- JosephB. Lambert, ScottGronert, Herbert F.Shurvell, David Lightner,Robert Graham Cooks, 2010. "Organic structural spectroscopy",2ndEd. Pearson Education, Limited.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH2
Subject: Modern Analytical Techniques (Practical) **Allotted Hrs. :** 8

Sr.No.	Laboratory Experiments
1.	Estimation of two drugs by simultaneous equation method and absorbance ratio method.
2.	Calibration of UV spectrometer for wavelength and stray light.
3.	Analysis of drugs by second derivative UV spectrometry.
4.	Determination of pK value by UV visible spectrometry.
5.	Calculation of λmax values using Woodward Fisher rules.
6.	Study of hydrogen bonding using IR spectrometer.
7.	Interpretation of IR spectra.
8.	Calibration of IR spectrometer using standard polystyrenefilm.
9.	Interpretation of 1D proton NMR spectrum of simple compounds (10-12carbons).
10.	Interpretation of 1D 13C NMR spectrum of simple compounds(10-12carbons).
11.	Calculation of carbon chemical shifts for various carbons such as sp3,sp2,sp carbonetc.
12.	Assignmen tof m/z values to various fragments in the mass spectrum.
13.	Qualitative and quantitative analysis using HPTLC.
14.	Analytical method development for three component mixture using HPTLC.
15.	Calibrationof HPLC instrument for flow rate & wavelength.
16.	Determination of theoretical plate, HETP resolution, tailing factor for two component mixture
17.	Determination of caffeine contentin tea/coffee/other beverages.
18.	Quantitation using different methods such as area normalization, one point,two point method with the help of internal standard.
19.	Determination of melting point & heat of fusion usingDSC.
20.	Determination of glass transition temperature using DSC.
21.	Interpretation of ORD and CD spectrum.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH3
Subject: Computer and statistics (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To train students in basics of computer hardware.
- To train them on hands on experience in use of different software.
- To teach them applications of computers in different areas of Pharmacy.
- To train the students for applications of various statistical methods available for analysis of data.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	Hardware: Current hardware & their performance, New devices / technology useful in teaching & research like Cameras, Scanner, touch screens, tablets, projection devices etc. Basic idea of computer networking.	03
Unit -2	Operating systems: Common operating systems used in day to day task & instrumentation like Windows, Linux & Unix (only interface and basic commands).	15
Unit -3	Language: Evolution of computer languages. Common languages used in scientific fraternity (no specific language detailing is required).	06
Unit -4	Software: Idea of popular soft ware's like MS Office, structure drawing software's, chemical structure visualizing software's, statistical software's & mathematical software, reference managing software's (only introduction).	05
Unit -5	Web page design: Need, concept and use of HTML.	08
Unit -6	Databases: Meaning, Need and creating table, record creating and maintenance.	05
Unit -7	Internet concept: History, creating internet connection, common problems & solutions.	06
Unit -8	Important Databases of free domain: Patents, Pub med, Pubchem, Science direct, protein database.	05
	SECTION B	
Unit -1	Data & Graphs.	03
Unit -2	Basic statistics.	02
Unit -3	Sampling.	04
Unit -4	Hypothesis testing.	06
Unit -5	Optimization.	06
Unit -6	Designing experiment.	06
Unit -7	Clinical data management.	02
Unit -8	Meta analysis.	03
Unit -9	Statistical Quality control.	05
Unit-10	Introduction to common statistical software.	03
	Total	**60**

Reference books :

- W.E. Fassett, 1986. "Computer Applications in Pharmacy", Lea & Febiger Publisher.
- C.N. Madu, 2003. "Statistics as easy as one, two, three with Microsoft Excel for Windows", 1st Ed. Chi Publishers Inc.
- A.N. Armstrong, 2006. "Pharmaceutical experimental design and interpretation", CRC/Taylor & Francis.
- G.A. Lewis, D. Mathieu, R.T. Phan, 1999. "Pharmaceutical experimental design", CRC Press.
- W.G. Cochran, W.G. Cochran, G.M. Cox, 1992. "Experimental designs". Wiley.
- http://pages.stern.nyu.edu/~jsimonof/classes/1305/pdf/excelreg.pdf
- www.Pubmed.com
- www.Pubchem.com
- www.mdl.com
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- www.uspto.gov
- www.esp.gov
- Lambert M Surhone, Miriam T Timpledon, Susan F Marseken, 2010. "Rasmol", VDM Verlag Dr. Mueller AG & Co. Kg.
- http://www.vlifesciences.com

Class: First Semester M. Pharm. **Subject Code:** S1-MPH3

Subject: Computer and statistics (Practical) **Allotted Hrs. :** 4

1	To understand computer hardware & their integration (computer, printer, scanner, display device, Bluetooth & IR devices).
2	To understand operating system / s.
3	To know theevolution of computer languages.
4	To design simple web page using HTML editor (Word, FrontPage etc.).
5	To make simple database using MS Access (i.e. Plant database, reference database etc.).
6	To create, editing & formatting worksheet using excel.
7	To make use of formula in excel.
8	To write macros in spreadsheet.
9	To create graphs for representing data.
10	To perform statistical operations on the obtained data.
11	To make decisions using formula in spreadsheet.
12	To develop ability to create master document in MS word.
13	To make PowerPoint presentations with hyper linking & animation effects.
14	To learn & develop expertise in use of structure drawing software like ISIS, Chem sketch etc.
15	To learn use of structure visualization software like Rasmol.
16	To visualize protein molecules using Protein explorer.
17	To learn searching internet based databases like Pub med, US Patents.
18	To develop technique for calculating molecular properties on line.
19	To perform simple optimization exercises using MS Excel / any statistics software.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH4
Subject: Nanotechnology & Biotechnology (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give basics of nanotechnology.
- To impart advanced level training in bio & nanotechnology with emphasis on their use in Pharmacy.
- To make use of this advanced level knowledge in drug discovery.
- To impart training on carrying out the sophisticated experiments in these areas.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	**BIONANOTECHNOLOGY:** History, opportunities and challenges of bionanotechnology, growth potential of bionanotechnology, significance of nanosize in biotechnology and medicine.	04
Unit -2	**NANO-DRUG DELIVERY:** Conventional delivery of biotechnologicals and its limitations, biological barriers in delivery of therapeutics, importance of nano-size in site-selective delivery. Targeted delivery of biotechnological using nanoconstructures, application of nanocarriers in delivery of biotechnologicals, nano-drug delivery chip.	10
Unit -3	**BIONANOCARRIERS:** Design and fabrications of nanocapsules, nanoliposomes, nanoparticles, nanoemulsion, nanopore technology, nano-self assembling systems, bionanoarrays, dendrimers, carbon nanotubes, nanosomes and polymersomes, inorganic nanoparticles (gold-gold colloids, gold nanofilm, gold nanorods, titanium and zinc oxide), structured DNA nanotechnology.	11
Unit -4	**NANOMEDICINE, NANOBIOLOGY AND NANOBIOTECHNOLOGY:** Synthesis and assembling of nanoparticles/nanostructures using bio-derived templates, proteins and nanoparticles, covalent and non-covalent conjugates, cantilevers array sensors for bioanalysis and diagnostics, nanowire and nanotube biomolecular sensors for in-vitro diagnosis of cancer and other diseases. Biologically inspired hybrid nanodevices, nanotube membranes for biotechnology, shelf-assembling of short peptides for nanotechnologicals applications.	10
	SECTION B	
Unit -5	**BIONANOIMAGING:** Quantum dots-luminescent semiconductor QD in cell and tissue imaging, fluoroimmunoassay using QD. Ultrasound contrast agents, magnetic nanoparticles, nanoparticles in molecular imaging, nanoforce and imaging-AFM, molecules, cells, materials and systems design based on nanobiotechnology for use in bioanalytical technology.	08
Unit -6	**DRUG DISCOVERY:** Drug screening, technoglobalism and drug development, biodiagnostics.	02
Unit -7	chemogenomics, computational chemistry, new pharmaceuticals from marine sources, cell based therapies, encapsulated cells for disease treatment.	03
Unit -8	**INSTRUMENTATION AND PRINCIPLES:** Electrophoresis techniques, laser confocal microscopy, digital image analysis, biosensors in diagnostics, enzyme purification and assay techniques. Techniques in cytogenetics: DNA sequencing, DNA microarray.Spectral analysis techniques: Introduction, estimation of proteins, DNA and RNA.	08
Unit -9	**SAFETY CONCERN OF BIONANOTECHNOLICALS:** Inhalation, contact/dermal delivery, environmental impact, explosion hazards.	04
	Total	**60**

Reference books :

- E.S. Papazoglou and A. Parthasarathy, "Bionanotechnology". 1st Ed. Morgan and Claypool.
- N.H. Malsch. 2005. "Biomedical nanotechnology" CRC Press.
- D.S. Goodsell, 2004. "Bionanotechnology: lessons from nature" Wiley-Liss Publication.
- T. Vo-Dinh, "Nanotechnology in biology and medicine: methods, devices, and applications" CRC Press.
- V. Labhasetwar, D.L. Leslie-Pelecky, 2007. "Biomedical applications of nanotechnology".Wiley-Interscience: Hoboken.
- S.P. Vyas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and controlled drug delivery" CBS Publishers and Distributors.

- **It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.**

Class: First Semester M. Pharm. **Subject Code:** S1-MPH4

Subject: Nanotechnology & Biotechnology (Practical) **Allotted Hrs. :** 8

Suggested List of Laboratory Experiments :

- Development of nanoparticles by solvent-evaporation method.
- Design of nanospheres by emulsification method.
- Preparation of polymeric nanocapsules by solvent-diffusion method.
- Evaluation of nanoparticles for particle size, zeta potential, drug entrapment efficiency, stability and other parameters.
- Development of solid lipid nano particles using various lipids.
- Preparation of nano-liposomes by solvent dispersion/film hydration method.
- Development and evaluation of nano-niosomes.
- Development and evaluation of nano-suspensions.
- Preparation of nanoemulsions by using ternaray phase diagrams.
- Incorporation of nanoemulsions in topical gels.
- Evaluation of dermal retention, penetration, skin irritation and toxicity potential of nano topical formulations.
- Development of nanosponges based on cyclodextrin complexes.
- Assessment of solubility enhancement by nano formulations.
- Pegylation of nanoparticles.
- Synthesis of Al_2O_3 nanoparticles using soi.gel method.
- Synthesis of Fe_2O_3 nanoparticles by chemical method.
- Synthesis of nanoparticles using biological process (2-3 methods).
- Functionalization of nanoparticles for biological application- (4-5 methods).
- Detection of nanoparticles in colloidal solutions using UV-Visible Absorption technique size determination of nanoparticles using laser beam.
- Analysis of ANM, SEM AND TEM pictures.
- Polyacrylamide gel electrophoresis: native gel.
- Isolation and separation of secondary metabolites.
- 2-D Gel electrophoresis of proteins and isoelectrofocusing.
- Synthesis of nanometer scale particles of colloidal semiconductors such as TiO_2, CdS, ZnO, SnO_2, Cu_2S, CuCNS, Cu_2O, $BaTiO_3$, $SrTiO_3$ by wet chemical methods, hydrothermal methods, and pyrolytic or high temperature methods.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPH1
Subject: Research Project **Allotted Hrs.:** 8

OBJECTIVE:

- To give exposure on how to do literature survey for the project work
- To develop technical writing skill in the form of a research report
- To develop report presentation ability, orally
- To develop question answer capability confidently.

Sr. No.	Unit and Contents	Hrs.
1	NIL	

Class: Second Semester M. Pharm. **Subject Code:** S2-MPT2
Subject: Formulation Concepts and Industrial Pharmacy (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give training at advanced level in preformualtion studies of drugs and other requisites aspects.
- To impart knowledge regarding several other ingredients used in formulation of a dosage form.
- To train students in formulation of various dosage forms their evaluation and quality control packing material used for packing these dosage forms.
- To give practical training to students in these aspects.

Sr. No.	Unit and Contents	Hrs.
A	**Preformulation**	**07**
	The Scope of Preformulation Studies: Introduction, Preformulation Testing Criteria, Regulatory Requirements, Testing Systems, Solid-State Characterization, Transport Across Biological Membranes **Dissociation, Partitioning, and Solubility:** Introduction, The Ionization Principle, Quantitative Structure–Activity Relationships, Partitioning, Measurement Strategies **Release, Dissolution, and Permeation:** Introduction, Release, Assay Systems, The Biopharmaceutics Drug Classification Systems **Solid-State Properties**: Introduction, Crystal Morphology, Polymorphism, High-Throughput Crystal Screening, Solvates, Hydrates, Amorphous Forms, Hygroscopicity, Solubility, Study Methods **Dosage Form Considerations in Preformulation**: Introduction, Solid Dosage Form Considerations, Solution Formulations, Emulsion Formulations, Freeze-Dried Formulations, Suspensions, Topical, Pulmonary Delivery, General Compatibility **Chemical Drug Substance Characterization:** Introduction, Scheme of Characterization, Impurities, Good Manufacturing Practice **Characterization of Biopharmaceutical Drugs**: Introduction, Preformulation Studies, Packaging and Materials, Physio-Chemical Characterization Tests, Design of Preformulation Studies	
C	**Formulation Development**	24
	The Importance of Formulation Design and Development **Biopharmaceutical Support in Formulation Development:** In Vitro Dissolution, Bioavailability Studies, In Vitro/In Vivo Correlations, Animal Models, Imaging Studies **Formulation Optimization:** Product Optimization Purpose and Scope, Excipients and Pack Optimization Considerations, Pharmaceutical Preformulation and Formulation, Sources of Information, Expert Systems, Experimental Design, Stability Testing, Developing Specifications, Process Design, Process Optimization and Scale-Up, Validation and Launch **Oral Solid Dosage Formulation development:** Powder Technology, Powder Flow, Mixing, Compaction, Solid Dosage Forms, Tablets, Hard Gelatin Capsules, Soft Gelatin Capsules **Parenteral Dosage Formulation development:** Guiding Principles for Simple Parenteral Solutions, Choice of Excipients, Sterility Considerations, Strategies for Formulating Poorly Soluble Drugs, Strategies for Formulating Unstable Molecules, Strategies for the Formulation of Macromolecules, Liposomal Delivery Systems, Sustained-Release Parenteral Formulations, In Vitro and In Vivo Testing Methods, Packaging of Parenteral Products, Manufacturing of Parenteral Products, Administration of Parenteral Products, Parenteral Products and the Regulatory Environment **Inhalation Dosage Formulation development:** Lung Deposition, Particle zone, impurities in stability study, photo stability testing.	

D	**Package development**	**06**
	Introduction and importance of packaging **Design and development of packaging units:** Recent advances in packaging techniques for various types of sterile and non sterile dosage forms. Regulatory aspects of packaging, Stability aspects of packaging, Specifications and quality. **Different packaging materials:** Paper- and board-based packaging materials and their use in pack security systems, Glass containers, Plastic, Films, foils and laminations, Metal containers, Closures and closure systems, Sterile products and the role of rubber components, Blister, strip and sachet packaging, The packaging line, Warehousing, handling and distribution, Printing and decoration, Present and future trends.	
E	**Production area design**	**10**
	Pharmaceutical Industry Profile, Current Good Manufacturing Practices, Facility Planning, Mechanical Utilities, High Purity Water, Automation and Process Controls, Process Engineering, Oral Solid Dosage Facilities, Sterile Manufacturing Facilities, Biotechnology Facilities, API Facilities, Building Code Compliance, Containment/Isolation, Occupational Health and Safety, Technology Transfer Environmental Considerations, Support Laboratories, Packaging/Warehousing	
F	**Advances in Industrial Process:**	**10**
	Granulation: Roller Compaction Technology, High-Shear Granulation, Low-Shear Granulation, Batch Fluid Bed Granulation, Extrusion/Spheronization as a Granulation Technique, Effervescent Granulation, Melt Granulation and Pelletization, Rapid Release Granulation, Continuous Granulation Technologies **Compression** **Lyophilization: LYOGUARD (New Concept for Bulk Freeze-Drying)** **Coating:** Film-coating materials and their properties **Sterilization** **Air handling:** AHUs, Laminar Airflow Equipment, HEPA and VEPA filters, HVAC, Clean room classification	
H	**Quality control**	**05**
	Concept and evaluation of quality control **Concept of quality control:** quality assurance and total quality control. Statistical quality control. Validation of pharmaceutical process (at least one case study of a process & analytical method.) **Quality control for:** raw materials, pharmaceutical process, finished products.	
I	**Methods in material characterization**	**06**
	Particle dimensions: Particle size and powder surface area, Particle shape and surface morphology. **Characterization of solid state structure:** Spectroscopy in pharmaceutical analysis, X-ray diffraction, Solid-state nuclear magnetic resonance, Vibrational spectroscopy, Calorimetry in pharmaceutical analysis, Thermal analysis techniques, Isothermal microcalorimetry, Water vapor sorption, Microscopy, Density measurements. **Characterization of specific surface area and inter/intra particulate pores:** Permeametry, Gas adsorption, Mercury porosimetry, Solid-state NMR.	
	Total	**60**

Reference books :

1. M. Gibson, 2001. "Pharmaceutical preformulation and formulation"1st Ed. Informa Healthcare.
2. A. Hickey, 2009. "Pharmaceutical process engineering" 2nd Ed. Marcel Dekker, Inc
3. J. Swarbrick, 2006. Encyclopedia of Pharmaceutical Technology, Third Edition, Volume 1-3, Informa Healthcare.
4. R. Sheskey and Quinn, "Pharmaceutical excipients" Pharmaceutical Press.
5. M. Chaubal, "Excipients development for. Pharmaceutical, Biotechnology, and Drug Delivery System". Informa Healthcare.
6. A. A. Signore and T. Jacobs, "Good Design Practices for GMP Pharmaceutical Facilities" Taylor & Francis Group.
7. D. A.Dean, E.R.Evans, I.H.Hall, "Pharmaceutical Packaging Technology", Taylor & Francis Group
8. H. R. Brittain, "Physical Characterization Of Pharmaceutical Solids", Marcel Dekker.
9. L. Rey, J.C. May, "Freeze-Drying/ lyophilization of Pharmaceutical and Biological Products" Marcel Dekker, Inc.
10. D. M. Parikh, "Handbook of Pharmaceutical Granulation Technology". Taylor & Francis Group
11. G. Cole, "Pharmaceutical Coating Technology". Taylor & Francis Group
12. **It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.**

Class: Second Semester M. Pharm. **Subject Code:** S2-MPT2

Subject: Formulation Concepts and Industrial Pharmacy (Practical) **Allotted Hrs. :** 8

Suggested List of Laboratory Experiments :

1. To study the effect of solvent composition on solubility of given drug
2. To study the effect of pH on stability of aspirin
3. To determine total microbial count in given antacid tablet
4. To prepare and evaluate micromeritic properties of prepared microcapsules by phase separation conservation technique
5. To study release kinetics of given powder drug sample and construct Hixon Crowell cube root model for drug release.
6. To determine comparative release of a drug from different ointment bases using agar gel techniques
7. To compare the effect of IPA on release of drug from membranes
8. To determine molecular weight of polymer using Ostwalds viscometer
9. To perform single surface dissolution of a drug and develop a dissolution model.
10. To study water vapor transmission through various polymeric membranes
11. To determine solubility of a drug as a function of surfactant concentration
12. To determine stability constant of cyclodextrin drug complex using phase solubility analysis.
13. To study effect of spherunizing agents on spherunization process.
14. To develop effervescent tablet of a water insoluble drug.
15. To prepare granules by melt granulation techniques.
16. To study the effect of super disintegrates on release of drugs.
17. To determine the energy of activation of drug at different pH.
18. To evaluate air quality in clean room using air sampler
19. To formulate table, capsules, suspension, emulsions, parenteral preparations etc.
20. To perform various quality control tests for different packaging material.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPT3
Subject: Biopharmaceutics and Pharmacokinetics (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give advanced level knowledge in different areas of pharmaceuticals
- To impart advanced level training in Biopharmaceutics
- To give training in vivo – I vitro correlation
- To give practical exposure in performing some of these studies

Sr. No.	Unit and Contents	Hrs.
Unit-1	**Mathematical and fundamentals in Pharmacokinetics** Concept of differential and integral calculus, curve fitting, rates and order of reactions	04
Unit-2	**Compartmental modeling** One compartment open model: IV and oral route if administration, volume of distribution, elimination half-life, first order elimination, fraction of drug remaining, renal clearance, total clearance, calculation of elimination rate constant from urinary excretion data.	06
Unit-3	Multi compartment modeling: two compartment and three compartment open IV and oral administration model.	04
Unit-4	**Non-linear Pharmacokinetics** Saturable enzymatic elimination process, drug elimination by capacity limited pharmacokinetics, mixed drug elimination, time dependent pharmacokinetics, bioavailability of drug that follow non-linear pharmacokinetics due to protein binding (e.g. phenytoin)	04
Unit-5	**Non compartment analysis** Statistical moment analysis, mean residence time and bioavailability , clearance, half-life, absorption kinetics, Apparent volume of distribution etc, steady state concentration	04
Unit-6	**Therapeutic response and toxicity** Concentration and response, therapeutic concentration range, therapeutic index, therapeutic window, factors affecting plasma concentration and toxicity.	04
Unit-7	**Multiple dosage regimen** Drug level-time relationship, steady state plateau value, mean residence tie, time to reach plateau, bolus and infusion, practical issues, drug accumulation, average amount and concentration at plateau, accumulation index, maintenance dose, loading dose, maintenance of dose in therapeutic range.	04
Unit-8	**Biopharmaceutics and Kinetics of drug absorption** Zero order absorption model, first order, absorption model, significance of absorption rate constants.	04
Unit-9	**Drug distribution and protein binding** Physiological factors, calculations of apparent volume of distribution, protein binding of drugs, kinetics of protein binding, determination of binding constant and binding sites, graphic method, clinical significance of drug – protein binding	04
Unit-10	**Drug elimination and clearance concept** Drug elimination, drug clearance, physiological approach to clearance, renal clearance, renal drug excretion, drug clearance, determination of renal clearance, relationship of clearance elimination half-life and volume of distribution, hepatic elimination of drugs. Fraction of drug excretion unchanged (fe) and fraction of drug metabolized, (1-fe), clinical focus, Pharmacokinetics of drug and metabolites, enzyme involved in the biotransformation of drug, drugs biotransformation reactions, route of drug administration and extra hepatic drug metabolism, first-pass effect, hepatic clearance, significance of drug metabolism.	04

Unit-11	**Application of Pharmacokinetics in clinical situations** Individualization of dosing regimen, variability in clinical response and drug Pharmacokinetics with special reference to renal and hepatic diseases, genetic factors age and weight, altering / affecting the pharmacokinetic parameters, therapeutics drug monitoring, conversion from IV and dose to oral dosing, determination of dose, frequency of drug administration and route of administration, dosing of drugs in infants, elders and patients.	04
Unit-12	**Bioavilability and bioequivalence** Biopharmaceutical classification of drugs, absorption of permeability and solubility limited drugs. Biowavers for bioequivalence studies, strategies to enhance bioavailability	06
Unit-13	***In vivo, in vitro* correlation** Concept of correlation, types and establishment If correlation	04
	Total	**60**

Reference books :

1. M. Rowland, T. N. Tozer, 1989. "Clinical Pharmacokinetics: Concept and Applications", 3rd Ed. B. I. Lea & Febiger.
2. L. Shargel, S. Wu-Pong, B. C Andrew, 2005. "Applied Biopharmaceutics and pharmacokinetics", 3rd Ed. McGraw-Hill Medical Pub. Division.
3. M. Gibaldi and D. Perrier, 1982. "Pharmacokinetics", M. Dekker.
4. B. N. LaDu, H. G. Mandel & E. L. way, 1972. "Fundamental of drug metabolism and disposition". Williams & Wilkins, Baltimore.
5. T. Z. Csaky, 1975. "Intestinal absorption and mal absorption". Raven Press.
6. S. Niazi, "Handbook of Bioequivalence testing". Informa Health Care.
7. D. J. Cutler, 1978. "Pharmaceutical Product Development: In vitro-In vivo Correlation". Informa Health Care.
8. **It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.**

Class: Second Semester M. Pharm. **Subject Code:** S2-MPT3

Subject: Biopharmaceutics and Pharmacokinetics (Practical) **Allotted Hrs. :** 8

Suggested Laboratory Experiments.

1. To study hydrodynamic model of one compartment open model after intravenous bolus administration.
2. To study in vitro presystemic metabolism using intestinal microorganism.
3. To study plasma protein binding of drug using egg albumin
4. To study erythrocytic binding of drug using blood
5. To study urinary excretion of aspirin after oral administration
6. To study effect of pH on urinary excretion of aspirin
7. To study effect of tablet hardness on dissolution of aspirin
8. To calculate pharmacokinetic parameters using supplied data after oral administration in one compartment open model
9. To perform statistical analysis of given data for bioequivalence.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPT4
Subject: Advanced Pharmaceutics – I (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give additional Knowledge to students based on their choice of topic

Sr. No.	Unit and Contents	Hrs.
Unit-1	Design of experiment	
Unit-2	BCS & Dosage form design	
Unit-3	Formulation development of protieneous drugs	
Unit-4	Polymorphism	
Unit-5	Drug targeting	
Unit-6	IVIVC	
	Total	**60**

Class: Third Semester M. Pharm. **Subject Code:** S3-MPH1
Subject: Drug Regulatory Aspects and IPR (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To impart information on various drug regulatory aspects involved in the profession.
- To teach the import / export related regulations with respect to some countries
- To make the students understand the importance and implication of IPR and related matters.
- To train the students in GMP and the latest developments there.

Sr. No.	Unit and Contents	Hrs.
Unit-1	**DRUG REGULATORY ASPESTS**	**40**
a)	Drug Regulatory Aspects (India) – 1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA) 2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective) 3. Special emphasis – Schedule M and Y 4. New Drugs – Importation, Registration, Development, Clinical Trials, BE NOC & B.E. studies 5. Various licenses – Test lic., Import lic. for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	10
b)	Good Manufacturing Practices (GMP) – 1. Indian GMP certification, WHO GMP certification 2. ICH guidelines for stability testing and other relevant ones (Q1 – Q10) 3. Export permissions and manufacturing for semi-regulated countries 4. Understanding of the plant lay-outs with special emphasis on the environment & safety. (HVAC, Water systems, Stores management, Effluent etc.) 5. Quality Assurance and Quality Control – Basic understanding for in-built quality.	12
c)	Drug Regulatory Aspects (International & highly regulated markets) – 1. US Requirements – (for Generic Drugs especially formulations) 2. CDER, INDA, NDA, ANDA's (types), CTD Formats of dossiers, E-submission, US DMF (various types), IIG Limits, Orphan Drugs, Vanilla ANDA's, Exhibit/Pivotal batches, Validation batches, Various Guidance issued by CDER, OGD, Orange Book (and patents), RLD (Reference listed drug) for BE studies and the norms for US submission, Bioequivalence and dissolution recommendations, Packaging, Stability studies and the Product Information Leaflet, US FDA Inspection (audits), Pre-approval Inspections and approvals 3. European Union Requirements – 4. All the aspects for European Registration of formulations for generic drugs sale in the European markets under EU. EMEA guidelines on various aspects as above (C 1) 5. A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries. 6. GMP audits, role of Quality Assurance, product approvals and supplies.	18
Unit-2	**INTELLECTUAL PROPERTY RIGHTS (IPR)**	**20**
a)	**Introduction to IPR & Patents** – Development of IP law in India, IPR regime, Introduction to IP laws in India, Role of IP in pharma industry growth.	
b)	**Patenting in India** – Introduction, Patent legislation, Indian Patents Act 1970 and amendments, Procedure for patent application, Grant and opposition proceedings, Patent licensing, Patent infringement proceedings, IPAB – role and functions (IP Appellate Board), Indian IP Case laws	
c)	**American & European patent system** – Requirements for patenting, utility, novelty Non-obviousness, Patent specification & claims, Patent infringement and Doctrine of Equivalents, Federal circuit and Patent system in Europe	
d)	**International treaties and conventions on IPR** - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO	
e)	**Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003**	
f)	**Introduction to** Geographical indication / Trademark/ copyright: Filing procedures	
g)	**Patent search, Patent analysis & Patent drafting**.	
h)	**Allied Patents Related Issues**: Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage	
	Total	60

Reference books :
1. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).
2. CDER Publications and Guidance
3. EMEA Publications and Guidance
4. Orange Book, ICH guidelines, Indian Patents Act
5. Country specific Regulatory Guidelines (available from internet)
6. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
7. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.
8. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
9. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.
10. Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPT2
Subject: Research work Seminar **Allotted Hrs. :** 8

OBJECTIVE:

- To effectively present the research work carried out by the student.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPT3
Subject: Research Project **Allotted Hrs. :** 16

OBJECTIVE:

- To manage the research work in time bound manner.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPT4
Subject: Novel Drug Delivery System **Allotted Hrs. :** 4

OBJECTIVE:

- To train students in different novel drug delivery system
- To train students in formulation strategies involved in the system
- To update the knowledge in these areas

Sr. No.	Unit and Contents	Hrs.
1.	**Pulmonary** Pulmonary Delivery of Drugs by Inhalation, Aerogen Pulmonary Delivery Technology, The AERx Pulmonary Drug Delivery System, Formulation Challenges of Powders for the Delivery of Small Molecular Weight Molecules as Aerosols Nebulizer Technologies, The Pressurized Metered-Dose Inhaler, Passive Dry Powder Inhalation Technology, Formulation Challenges: Protein Powders for Inhalation, The Development of Large Porous Particles for Inhalation Drug Delivery, Dry Powder Inhalation Systems from Inhale Therapeutic Systems Spiros Inhaler Technology, The Respimat.	5
2.	**Intranasal** Intranasal Drug Delivery, Metered dose inhalers, Dry powder inhalers, Inhalation nasal sprays, Inhalation solutions & suspensions (for nebulizers), Poly(ethylene oxide) - b-Poly(propylene oxide) - b-Poly(ethylene oxide) –g –Poly (acrylic acid) Copolymers as In Situ Gelling Vehicle for Nasal Delivery.	5
3.	**Solid dispersion technology** Overview of Solid dispersion technology, MELTREX technology, Controlled Release with Meltrex Technology, Solid Dispersions with Meltrex Technology.	5
4.	**Brain delivery** Enhancing Drug Influx in the Blood–Brain Barrier: Drug Modification, Drug Solubilization in Nano- or Microcontainers, Disrupting of the Blood–Brain Barrier Restricting Drug Efflux in the Blood–Brain Barrier.	6
5.	**Oral delivery** Introduction of new technologies as TIMERx, MASSRx & COSRx, Procise technology, RingCap technology, Theriform Technology, Accudep Technology, THREEFORM Technology, DissoCube IDD Technology, Zydis Technology for poorly soluble drugs, Orasolv & Durasolv technolohy, Egalet Technology, Buccal Mucoadhesives, Periochips etc.	15
6.	**Carrier & vector mediated delivery** • Carrier-Mediated Delivery Systems: Barriers to oral delivery of macromolecular drugs, Design of macromolecular drugs through chemical modification, Design of colloidal drug carriers • Design of Vector-Mediated Delivery Systems for Genetic Materials: Barriers to vector-mediated gene delivery, Viral vector, Nonviral vector • Future	6
7.	**Physical & chemical targeting** • Physical: Introduction, Design of a Physically Targeted Delivery System: Modulation of Physicochemical Parameters (Molecular weight and size, Surface hydrophobicity, Charge, Membrane destabilization, Physicochemical functionalities for triggered release), Current Drug Delivery Systems (Polymers, Lipidic colloids, Nanospheres) • Chemical: Introduction, Design of Ligand-Based Targeting Drug Delivery Systems (Ligand-receptor-based interaction, Targeted enzyme prodrug therapy), Factors Affecting Design of Ligand-Based Targeting Drug Delivery Systems (Kinetics of active targeting systems, Internalization of ligand-based targeting drug delivery systems, Drug release from delivery systems, Immunogenicity), Current Status and Future of Actively Targeted Drug Delivery Systems	6

8.	**Transdermal delivery** • The Skin Barrier, Theoretical advantages of the transdermal route • Theory & Optimization of percutaneous absorption, Passive Methods for Enhancing (Trans)dermal Drug Delivery. • Development of the transdermal therapeutic system: Transdermal penetration of drugs, Formulation, Adhesion, Bioactivity, Polymers in transdermal delivery systems. • Passive Methods for Enhancing (Trans) dermal Drug Delivery • Active Methods for Enhancing (Trans) dermal Drug Deliver: Electroporation, Iontophoresis, Ultrasound (Sonophoresis and Phonophoresis), Laser Radiation and Photomechanical Waves, Radio-Frequency, Magnetophoresis, Temperature ("Thermophoresis"), Microneedle-Based Devices, Skin Puncture and Perforation, Needleless Injection, Suction Ablation, Application of Pressure, Skin Stretching, Skin Abrasion.	6
9.	**Rectal delivery** Advantages, Limitation, Drug delivery development, Solid suppositories, Solutions Gels/ foams/ ointments, Controlled-release formulations, Marketed drugs and therapeutic classes.	6
	Total	**60**

Reference books :

1. R. Williams, D. Taft and J. McConville, "Advanced formulation design to optimize therapeutic outcomes" Marcel Dekker, Inc.
2. L. Xiaoling, B.R. Jasti, "Design of Controlled Release Drug Delivery Systems" McGraw-Hill.
3. B. O. Mashkevich, "Drug delivery research advances" Nova Science Publishers, Inc.
4. W. M. Saltzman, 2001 "Drug Delivery_Engineering Principles for Drug Thera". Oxford University Press.
5. E. Touitou, W.B. Boca "Enhancement in Drug Delivery" CRC Press Britain.
6. M. J. Rathbone, J. Hadgraft, M.S. Roberts, "Modified-Release Drug Delivery Technology" Marcel Dekker Inc.
7. J. Swarbrick, "Encyclopedia of pharmaceutical Technology". Informa healthcare.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPT5
Subject: Advanced Pharmaceutics – II **Allotted Hrs.:** 4

OBJECTIVE:

- To entrich the knowledge of a student desirous of studing special topic of interest

Sr. No.	Unit and Contents	Hrs.
Uni-1	Advances in clean room technology	
Uni-2	Biopolymers in drug delivery system design	
Uni-3	Biopharmaceutical aspects in dosage form design	
Uni-4	Dissolution and diffusion controlled systems	
Uni-5	Pharmaceutical excipients	
	Total	**60**

Class: Fourth Semester M. Pharm. **Subject Code:** S4-MPH1
Subject: Research Project and Colloquium **Allotted Hrs.:** 36

OBJECTIVE:

- To complete the given research project
- The effectively defense the work before a group of qualified evaluators.

Sr. No.	Unit and Contents	Hrs.
1.	• Completion of research project and submission of dissertation to University. • Defence / viva voce	36

PART - D

M. Pharm. Syllabus

(Quality Assurance Techniques / Quality Assurance)

Class: First Semester M. Pharm. **Subject Code:** S1-MPH1
Subject: Research Methodology **Allotted Hrs.:** 4

OBJECTIVE:

- To familiarize students regarding teaching methodology & research projects.
- To teach students preparation of are search projects & different aspects associated with it.
- To acquaint students with experimental data analysis.
- To impresss upon students the importance of ethical issues in the profession & plagiarism.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Learning and instruction** Principles of Instructional design and learning theory, Merrill's five principles and Gagne'scon dition of learning. Active learning, group learning, collaborative learning, problem-based learning, team-based learning, Experiential learningmodel of Kolb.	8
2	**Curriculum development** Asix step approach-Problem identification and general needs assessment, targeted needs assessment, goals and objectives, educational strategies, implementation, evaluation and feedback. Bloom's Taxonomy, three domains of educational objectives.	6
3	**Funding &Scholarship** Agencies funding research in pharmaceutical sciences, Scholarship ,types of scholarships in education.	3
4	**Assessment** Definition and methods, Georges Millers pyramid, assessment, measurement and tests, types of numbers, formative and summative assessment.	3
5	**Basics of Research** Definition, objectives, motivation, types of research and approaches: Descriptive research, conceptual, theoretical, applied and experimental.	3
6	**Formation of Research Problem** A. Research Process: To determine what type of research to be done, plan of research work. B. Selection of research area, prioritization of research. C. Literaturere view: importance and methods, sources, D. Objectives and scope of work, developing research plan and schedule: Scheduling constraints ,steps, problems in scheduling, limitations.	4
7	**Mathematical Modeling and Simulation** Concept of modeling, classification of mathematical models, modeling with ordinary differential equations, difference equations, partial differential equations, graphs, simulation: concept, types (quantitative , experimental, computer, fuzzy theory, statistical) processes of formulation of model based on simulation. Variables and measurement.	5
	SECTION B	
8	**Experimental Modeling** A. Definition of experimental design, examples, single factor experiments B. Blocking and Nuisance factors, guidelines for designing experiments. C. General model of process: Input factors/ variables, Out put parameters/ variables controllable /uncontrollable variables, dependent/ independent variables experimental validity. D. Introduction to Risk assessment, reliability, sustainability, and uncertainty.	4

9	**Analysisof data** A. Types of data: parametric and nonparametric, descriptive and inferential data, B. Collection of data: normal distribution, calculation of co-relation coefficient C. Data processing: analysis, error analysis, meaning, and different methods: analysis of variance, significance of variance, analysis of covariance, multiple regressions, testing linearity / nonlinearity of model, testing adequacy of model. D. Test to be used in data exploration and their choice E. Introduction of software used in data analysis.	8
10	**Research Deliverables** A. Various Forms of Publication: Thesis, paper, research proposal. B. Thesis Writing: Introduction, literature reviewor state-of-the-art, research approach (methodology), results or findings, discussions, conclusions, scope for future work, references, appendices. C. Presentation: Poster, thesis, proposal, and paper.	4
11	**Ethical issues in research** Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/ vaccines /herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good clinical practices norms, Ethical principles related to animal experiments.	10
12	**Plagiarism** Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscriptwriting, documentation, organization of reference material, bibliography, end note.	2
	TOTAL	60

Reference Books:

- B.D.John,A.L.BrownandR.R.Cocking,1999."How People Learn: brain, mind, experience and school".Washington, D C: National Academy Press.
- J.R.Fraenkel,N.E. Wallen,2008."How to Designand Evaluate Researchin Education*",7th Ed*. Bostan McGraw-Hill
- K.E.David,2009. Curriculum Development for Medical Education:*A Six-Step Approach* 2nd Ed. The John Hopkins University Press. ISBN0-8018-9367-4.
- N.Peter,2009."Leadership: Theory and Practice*." 3rd Ed.* Thousand Oaks: Sage Publications.
- G.Bordage,B.Dawson,2003. Experimental study design and grant writing in eight steps and 28 questions *MedicalEducation, 37*(4):376-385.
- B.J.Avolio, F.O.Walumbwa, T.J.Weber, 2009. Leadership: Current theories, research, and future directions. *Annual Review of Psychology, 60*:421-449.
- C.R.Kothari, 2004."Research Methodology".2nd Ed.New Ag eInternational(p) Limited,Publishers.
- D.Montgomary, 2000."Designof Experiments". 5thEd. Wiley Interscience.
- K.P. Willkinsion, L. Bhandarkar, "Formulation of Hypothesis". 3rd ed. Himalaya publishing, Mumbai.
- SchankFr, 2008."Theories of Engineering Experiments".2nd Ed.Tata McGraw Hill.
- D.C.Montgomery, 2009."Introduction to SQC"6th Ed.JohnWilly& sons.
- Cochran& Cocks, 1957.2nd Ed."Experimental Design" New York,JohnWilly& sons.
- J.W.BestandJ.V.Kahn, 2006."Research in Education". 10th Ed.PHI publication.
- S.S.Rao,1983."Optimization Theory & Applications".2nd Ed.WileyEasternLtd.ND.
- P.D.Kulkarni,1986."Independent Study Techniques",TTTI Chandigarh

Class: First Semester M. Pharm. **Subject Code:** S1-MPH2
Subject: Modern Analytical Techniques (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To familiarize students in use of modern techniques of analysis used indifferent areas/ fields of pharmacy.
- To give training in use of the technique & its applications in day to day practice.
- To build on the basics learned at UG level & give latest advances in the area.
- To give more stress on application based knowledge than instrumentation based one.
- To give hands on training on use of as many different ophisticated instruments as possible.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Ultraviolet–Visible spectrometry: Woodward–Fisher rules for calculation of λmax. Derivative spectroscopy. Introduction to Optical rotator Dispersion and Circular Dichroism.	5
2	Fourier Transformed Infrared Spectrometry. Interpretation of Infrared spectrum.	3
3	High Resolution ^{1}H &^{13}C NMR Spectrometry. Theoretical calculation of chemical shifts of various carbon atoms. Technique used for finding types of carbon like attached protontest(APT), distortionless energy polarization transfer (DEPT). Homonuclear & heteronuclear correlation spectrometry. Different 1D & 2D NMR correlation spectrometric techniques such as COSY, NOESY, HETCOR INADE QUATE, SBC, HMQC etc. Use of this technique in determination of absolute configuration.	15
4	Mass spectrometry: use of isotopic abundance in molecular formula calculation. Different ionization techniques like EI,CI, FD, FI, MALDI, API,ESI. Fragmentation of molecule using these techniques. Tandem mass spectrometry and its applications in pharmacy.	8
	SECTION B	
5	HPTLC: Basic instrumentation and its calibration. Analytical methoddevelopment andits validation as per ICH guidelines. Quantification using HPTLC	5
6	HPLC: Instrumentation covering detailed discussion about pumps, injector system, columns and detectors. Calibration of instrument. Analytical method development, validation as per ICH guidelines and trouble shooting. Quantification methods usedin HPLC. Ultra pressure liquidchromatography.	8
7	Thermoanalytical techniques: Differential Scanning Calorimetry (DSC), Thermogravimetry (TG),Thermo mechanical analysis (TMA): Principles instrumentation and applications (including interpretation of data) in pharmacy.	5
8	Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmuneassay, ELISA etc.	6
9	Microscopy: SEM, TEM, cryomicroscopy, AFM, confocalmicroscopy.	5
	TOTAL	60

Reference Books:

- RobertM. Silverstein, FrancisX. Webster, DavidJ. Kiemle,2009."Spectrometric identification of organic compounds".7thEd. John Wiley & Sons
- Pavia D. L.,2009."Introduction to spectroscopy".4th, Belmont CA
- Munson&Munson,"Pharmaceutical analysis: modern methods".,New York: M. Dekker
- KennethA. Connors, 2007."A Text book Of Pharmaceutical Analysis"3rdEd. WileyIndia-wse
- JensThuroCarstensen, 2001."Advanced pharmaceutical solids"Marcel Dekker, NewYork
- JosephB. Lambert, ScottGronert, Herbert F.Shurvell, David Lightner,Robert Graham Cooks, 2010. "Organic structural spectroscopy",2ndEd. Pearson Education, Limited.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH2
Subject: Modern Analytical Techniques (Practical) **Allotted Hrs. :** 8

Sr.No.	Laboratory Experiments
1.	Estimation of two drugs by simultaneous equation method and absorbance ratio method.
2.	Calibration of UV spectrometer for wavelength and stray light.
3.	Analysis of drugs by second derivative UV spectrometry.
4.	Determination of pK value by UV visible spectrometry.
5.	Calculation of λmax values using Woodward Fisher rules.
6.	Study of hydrogen bonding using IR spectrometer.
7.	Interpretation of IR spectra.
8.	Calibration of IR spectrometer using standard polystyrenefilm.
9.	Interpretation of 1D proton NMR spectrum of simple compounds (10-12carbons).
10.	Interpretation of 1D 13C NMR spectrum of simple compounds(10-12carbons).
11.	Calculation of carbon chemical shifts for various carbons such as sp3,sp2,sp carbonetc.
12.	Assignmen tof m/z values to various fragments in the mass spectrum.
13.	Qualitative and quantitative analysis using HPTLC.
14.	Analytical method development for three component mixture using HPTLC.
15.	Calibrationof HPLC instrument for flow rate & wavelength.
16.	Determination of theoretical plate, HETP resolution, tailing factor for two component mixture
17.	Determination of caffeine contentin tea/coffee/other beverages.
18.	Quantitation using different methods such as area normalization, one point,two point method with the help of internal standard.
19.	Determination of melting point & heat of fusion usingDSC.
20.	Determination of glass transition temperature using DSC.
21.	Interpretation of ORD and CD spectrum.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH3
Subject: Computer and statistics (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To train students in basics of computer hardware.
- To train them on hands on experience in use of different software.
- To teach them applications of computers in different areas of Pharmacy.
- To train the students for applications of various statistical methods available for analysis of data.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	Hardware: Current hardware & their performance, New devices / technology useful in teaching & research like Cameras, Scanner, touch screens, tablets, projection devices etc. Basic idea of computer networking.	03
Unit -2	Operating systems: Common operating systems used in day to day task & instrumentation like Windows, Linux & Unix (only interface and basic commands).	15
Unit -3	Language: Evolution of computer languages. Common languages used in scientific fraternity (no specific language detailing is required).	06
Unit -4	Software: Idea of popular soft ware's like MS Office, structure drawing software's, chemical structure visualizing software's, statistical software's & mathematical software, reference managing software's (only introduction).	05
Unit -5	Web page design: Need, concept and use of HTML.	08
Unit -6	Databases: Meaning, Need and creating table, record creating and maintenance.	05
Unit -7	Internet concept: History, creating internet connection, common problems & solutions.	06
Unit -8	Important Databases of free domain: Patents, Pub med, Pubchem, Science direct, protein database.	05
	SECTION B	
Unit -1	Data & Graphs.	03
Unit -2	Basic statistics.	02
Unit -3	Sampling.	04
Unit -4	Hypothesis testing.	06
Unit -5	Optimization.	06
Unit -6	Designing experiment.	06
Unit -7	Clinical data management.	02
Unit -8	Meta analysis.	03
Unit -9	Statistical Quality control.	05
Unit-10	Introduction to common statistical software.	03
	Total	**60**

Reference books :

- W.E. Fassett, 1986. "Computer Applications in Pharmacy", Lea & Febiger Publisher.
- C.N. Madu, 2003. "Statistics as easy as one, two, three with Microsoft Excel for Windows", 1st Ed. Chi Publishers Inc.
- A.N. Armstrong, 2006. "Pharmaceutical experimental design and interpretation", CRC/Taylor & Francis.
- G.A. Lewis, D. Mathieu, R.T. Phan, 1999. "Pharmaceutical experimental design", CRC Press.
- W.G. Cochran, W.G. Cochran, G.M. Cox, 1992. "Experimental designs". Wiley.
- http://pages.stern.nyu.edu/~jsimonof/classes/1305/pdf/excelreg.pdf
- www.Pubmed.com
- www.Pubchem.com
- www.mdl.com
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- www.uspto.gov
- www.esp.gov
- Lambert M Surhone, Miriam T Timpledon, Susan F Marseken, 2010. "Rasmol", VDM Verlag Dr. Mueller AG & Co. Kg.
- http://www.vlifesciences.com

Class: First Semester M. Pharm. **Subject Code:** S1-MPH3
Subject: Computer and statistics (Practical) **Allotted Hrs. :** 4

1	To understand computer hardware & their integration (computer, printer, scanner, display device, Bluetooth & IR devices).
2	To understand operating system / s.
3	To know theevolution of computer languages.
4	To design simple web page using HTML editor (Word, FrontPage etc.).
5	To make simple database using MS Access (i.e. Plant database, reference database etc.).
6	To create, editing & formatting worksheet using excel.
7	To make use of formula in excel.
8	To write macros in spreadsheet.
9	To create graphs for representing data.
10	To perform statistical operations on the obtained data.
11	To make decisions using formula in spreadsheet.
12	To develop ability to create master document in MS word.
13	To make PowerPoint presentations with hyper linking & animation effects.
14	To learn & develop expertise in use of structure drawing software like ISIS, Chem sketch etc.
15	To learn use of structure visualization software like Rasmol.
16	To visualize protein molecules using Protein explorer.
17	To learn searching internet based databases like Pub med, US Patents.
18	To develop technique for calculating molecular properties on line.
19	To perform simple optimization exercises using MS Excel / any statistics software.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH4
Subject: Nanotechnology & Biotechnology (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give basics of nanotechnology.
- To impart advanced level training in bio & nanotechnology with emphasis on their use in Pharmacy.
- To make use of this advanced level knowledge in drug discovery.
- To impart training on carrying out the sophisticated experiments in these areas.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	**BIONANOTECHNOLOGY:** History, opportunities and challenges of bionanotechnology, growth potential of bionanotechnology, significance of nanosize in biotechnology and medicine.	04
Unit -2	**NANO-DRUG DELIVERY:** Conventional delivery of biotechnologicals and its limitations, biological barriers in delivery of therapeutics, importance of nano-size in site-selective delivery. Targeted delivery of biotechnological using nanoconstructures, application of nanocarriers in delivery of biotechnologicals, nano-drug delivery chip.	10
Unit -3	**BIONANOCARRIERS:** Design and fabrications of nanocapsules, nanoliposomes, nanoparticles, nanoemulsion, nanopore technology, nano-self assembling systems, bionanoarrays, dendrimers, carbon nanotubes, nanosomes and polymersomes, inorganic nanoparticles (gold-gold colloids, gold nanofilm, gold nanorods, titanium and zinc oxide), structured DNA nanotechnology.	11
Unit -4	**NANOMEDICINE, NANOBIOLOGY AND NANOBIOTECHNOLOGY:** Synthesis and assembling of nanoparticles/nanostructures using bio-derived templates, proteins and nanoparticles, covalent and non-covalent conjugates, cantilevers array sensors for bioanalysis and diagnostics, nanowire and nanotube biomolecular sensors for in-vitro diagnosis of cancer and other diseases. Biologically inspired hybrid nanodevices, nanotube membranes for biotechnology, shelf-assembling of short peptides for nanotechnologicals applications.	10
	SECTION B	
Unit -5	**BIONANOIMAGING:** Quantum dots-luminescent semiconductor QD in cell and tissue imaging, fluoroimmunoassay using QD. Ultrasound contrast agents, magnetic nanoparticles, nanoparticles in molecular imaging, nanoforce and imaging-AFM, molecules, cells, materials and systems design based on nanobiotechnology for use in bioanalytical technology.	08
Unit -6	**DRUG DISCOVERY:** Drug screening, technoglobalism and drug development, biodiagnostics.	02
Unit -7	chemogenomics, computational chemistry, new pharmaceuticals from marine sources, cell based therapies, encapsulated cells for disease treatment.	03
Unit -8	**INSTRUMENTATION AND PRINCIPLES:** Electrophoresis techniques, laser confocal microscopy, digital image analysis, biosensors in diagnostics, enzyme purification and assay techniques. Techniques in cytogenetics: DNA sequencing, DNA microarray.Spectral analysis techniques: Introduction, estimation of proteins, DNA and RNA.	08
Unit -9	**SAFETY CONCERN OF BIONANOTECHNOLICALS:** Inhalation, contact/dermal delivery, environmental impact, explosion hazards.	04
	Total	**60**

Reference books :

- E.S. Papazoglou and A. Parthasarathy, "Bionanotechnology". 1st Ed. Morgan and Claypool.
- N.H. Malsch. 2005. "Biomedical nanotechnology" CRC Press.
- D.S. Goodsell, 2004. "Bionanotechnology: lessons from nature" Wiley-Liss Publication.
- T. Vo-Dinh, "Nanotechnology in biology and medicine: methods, devices, and applications" CRC Press.
- V. Labhasetwar, D.L. Leslie-Pelecky, 2007. "Biomedical applications of nanotechnology".Wiley-Interscience: Hoboken.
- S.P. Vyas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and controlled drug delivery" CBS Publishers and Distributors.

- **It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.**

Class: First Semester M. Pharm. **Subject Code:** S1-MPH4

Subject: Nanotechnology & Biotechnology (Practical) **Allotted Hrs. :** 8

Suggested List of Laboratory Experiments :

- Development of nanoparticles by solvent-evaporation method.
- Design of nanospheres by emulsification method.
- Preparation of polymeric nanocapsules by solvent-diffusion method.
- Evaluation of nanoparticles for particle size, zeta potential, drug entrapment efficiency, stability and other parameters.
- Development of solid lipid nano particles using various lipids.
- Preparation of nano-liposomes by solvent dispersion/film hydration method.
- Development and evaluation of nano-niosomes.
- Development and evaluation of nano-suspensions.
- Preparation of nanoemulsions by using ternaray phase diagrams.
- Incorporation of nanoemulsions in topical gels.
- Evaluation of dermal retention, penetration, skin irritation and toxicity potential of nano topical formulations.
- Development of nanosponges based on cyclodextrin complexes.
- Assessment of solubility enhancement by nano formulations.
- Pegylation of nanoparticles.
- Synthesis of Al_2O_3 nanoparticles using soi.gel method.
- Synthesis of Fe_2O_3 nanoparticles by chemical method.
- Synthesis of nanoparticles using biological process (2-3 methods).
- Functionalization of nanoparticles for biological application- (4-5 methods).
- Detection of nanoparticles in colloidal solutions using UV-Visible Absorption technique size determination of nanoparticles using laser beam.
- Analysis of ANM, SEM AND TEM pictures.
- Polyacrylamide gel electrophoresis: native gel.
- Isolation and separation of secondary metabolites.
- 2-D Gel electrophoresis of proteins and isoelectrofocusing.
- Synthesis of nanometer scale particles of colloidal semiconductors such as TiO_2, CdS, ZnO, SnO_2, Cu_2S, CuCNS, Cu_2O, $BaTiO_3$, $SrTiO_3$ by wet chemical methods, hydrothermal methods, and pyrolytic or high temperature methods.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPH1
Subject: Research Project **Allotted Hrs.:** 8

OBJECTIVE:

- To give exposure on how to do literature survey for the project work
- To develop technical writing skill in the form of a research report
- To develop report presentation ability, orally
- To develop question answer capability confidently.

Sr. No.	Unit and Contents	Hrs.
1	NIL	

Class: Second Semester M. Pharm. **Subject Code:** S2-MPQ2
Subject: Pharmaceutical Biological Evaluation (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give training the students various biological evaluation methods & the significance of such tests.
- To impart knowledge about official / non-official methods of evaluation for a wide range of pharmaceutical dosage forms.
- To give wide exposure to students in the area of New Chemical Entity pre-clinical evaluations & related areas.
- To give them training in carrying out some of these techniques in the laboratory

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Pharmacopeia Testing for Tablets and Capsules:** Pharmaceutical Methods-Friability test, Disintegration test, Uniformity of Weight, Uniformity of Content, Particle Size by Microscopy, Loss on drying, Sampling procedures-Quality Acceptance Levels. Various USP Dissolution Apparatus and Dissolution/Drug release Tests in IP, USP and BP and their Acceptance criteria	06
2	Pharmacopoeial Testing for Aerosols**,** Nasal Sprays, Metered-Dose Inhalers, and Dry Powder Inhalers: Pharmaceutical Methods-General Sampling Procedure, Approximate Boiling Temperature, High-Boiling Residues, Water Content, Delivery Rate and Delivered Amount, Minimum Fill, Leakage Test, Number of Discharges per Container , Delivered-Dose Uniformity, Aerodynamic assessment of Fine particle fraction. Sampling and Sampling apparatus for Metered-Dose Inhalers and Dry Powder inhalers	06
3	General Pharmacopoeial requirements for parenterals.	05
4	Microbial contamination test procedures, Tests for effectiveness of antimicrobial preservatives.	04
5	Sterility tests: Methodology & Interpretation Suitability of Media, Test procedures, Validation of Tests, Growth Promotion Test, sterility testing of pharmaceutical products.	04
6	Pyrogens- Production, chemistry and properties of pyrogens, Mechanism of action of pyrogens. Pharmaceuticals aspects, pyrogen test of IP compared to that of BP & USP, Interpretation of data, and comparison of LAL and official pyrogen tests.	03
	SECTION B	
7	Microbiological assay of antibiotics Media selection and preparation, Test organisms, Inoculums preparation, Test methods, Assay designs, Interpretation of results.	05
8	Biological Assay Methods: General principles, scope and limitations of bioassay, Bacterial endotoxin Test Procedures.	04

9	Radioimmunoassay: General principles, scope and limitations. Radioimmunoassay of some drugs like insulin, digitalis etc. Fluoroimmunoassay, Fluorescent Labeling.	04
10	Pre-clinical drug evaluation of NCE and Biological as per Schedule Y and ICH guidelines: single dose, repeat dose toxicity studies, safety pharmacology, genetic toxicology, reproduction toxicity studies (including segment I, II, and III), and carcinogenicity studies.	05
11	Extraction, fractionation, proximate chemical analysis of herbal drugs. Herbal Evaluation of Extracts, Extractive values & standardization. WHO Guidelines for assessment of crude drugs- Evaluation of identity, purity, & quality of crude drugs, Determination of pesticide residue, Determination of Arsenic and heavy metals, Determination of Micro-organisms.	04
12	Assessment of containers used for packaging of pharmaceutical products, Tests for Parenteral and Non-parenteral product packaging materials-Glass containers, Metal containers, Plastic containers and Closures, Unit dose packages- Blisters and Strips. Use worthiness.	05
13	Bioavailability and bioequivalence- regulatory prospective	05
	TOTAL	**60**

Reference books :

1. M.N.Ghosh, "Fundamental of Experimental Pharmacology". Latest Edition. Scientific book Agency, Kolkata.
2. J.H. Burn, D.J. Finney & L.G. Goodwin, "Biological standardization". Latest Oxford University Press, Oxford.
3. I.P., B.P., USP., Extra Pharmacopeia- Current Editions
4. J.G. Hardman, L.E. Limbird, 2001. "Goodman and Gilman's The Pharmacological Basis of Therapeutics" 1oth Ed. McGraw-Hill Professional.
5. B. Ljunggvist and B. Davis, "Microbiological Risk Assessment in Pharm. Clean rooms". Latest Edition. Harwood International Publishing,
6. R. Prince, D. Harwoo, "Microbiology in Pharmaceutical Manufacturing". Latest Edition. International Publishing.
7. Akers, "Parenteral Quality Control: Sterility, Pyrogen, and Package Integrity Testing". 2nd Ed. Marcel Dekker.

Class:	Second Semester M. Pharm.	**Subject Code:**	S2-MPQ2
Subject:	Pharmaceutical Biological Evaluation (Practical)	**Allotted Hrs. :**	8

1. Effectiveness of antimicrobial agents by cup plate and Ditch plate method.
2. To perform Sterility test of given samples.
3. To determine Minimum Inhibitory Concentration of given antibiotic
4. To perform the Microbial limit test of the given sample
5. To perform quality control tests on glass ampoules, glass vials & glass bottles & closures as per IP & USP.
6. To perform quality control tests on paper, paper board, corrugated fiber board and polyethylene content of polyethylene coated paper
7. Identification of HDPE, LDPE, PVC, Polystyrene Plastics.
8. To perform quality control tests on plastic containers including water vapor transmission test.
9. Dissolution Rate Test by pH change method of Modified Release dosage forms and acceptance criteria for the same.
10. To determine drug content, uniformity of weight/content of unit dose preparations and data interpretation as per pharmacopoeia
11. Determination of degree of powder fineness, particle size distribution and pulmonary deposition pattern from Dry Powder Inhalers (DPI)
12. Particulate Contamination and pyrogen testing for Injectables
13. Standardization of herbal products as per IP
14. Preparation of in-process quality control sheet and using the same for in-process testing of tablets and capsules.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPQ3
Subject: Validation (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give introduction to the concept of validation.
- To train them in different aspects of validation. & significance of each activity.
- To acquaint the students about calibration of instruments & special dosage forms.
- To train students in carrying out some selected experiments in these areas.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Validation:** a. Introduction, history, definition, b. Types of validation, prospective validation, retrospective validation, concurrent validation, revalidation, c. Validation Master Plan	06
2	**Process Validation of Solid Dosage forms:** a. Process validation of low dose tablet manufacturing process b. Uniformity of blend (US FDA guideline) for tablets subjected to content uniformity test as per USP c. Process validation of compression machine giving details of control charts	06
3	**Sterilization Validation** a. Process validation of terminally sterilized product. Validation of sterilization process including heat distribution, heat penetration studies, and sterility assurance level b. Process validation of aseptically filled product with special emphasis on media fill test.	06
4	**Equipment Validation:** a. Definition of DQ, IQ, OQ, PQ. b. Comparison of different types of liquid filling machines(vacuum / volumetric), c. process capability of filling machines, d. Performance qualification of bottle washing/ ampoules washing machines - challenge test.	06
5	**Utilities Validation:** a) Validation of water system- for production of DM water, distilled water b. Validation of Air handling Units- classification of environment (class 100, 10,000, 1,00,000) b) Performance qualification & parameter of cleanliness such as no. of airborne particles, microbes filter integrity test of HEPA filter, air velocity, air flow pattern, no. of air changes, pressure differentials etc.	06
	SECTION B	
6	**Analytical Method Validation:** a. Recommendation of ICH guideline- Definition of accuracy, precision, linearity, LOD, LOQ, range, robustness, ruggedness, specificity, system suitability test. b. USP requirement of analytical validation- different category of assays. c. Stability indicating methods.	06

7	**Instruments calibration:** a. Analyticalbalance calibration. b. Calibration of weight box. c. Calibration of UV-spectrophotometer. d. Calibration of IR spectrophotometer. e. Calibration of HPLC system. f. Calibration of Gas Chromatography instrument. g. Performance check of HPLC/GC column. h. Out of Calibration.	05
8	**Cleaning Validation:** a. Validation of cleaning process. b. Elements of validation protocol. c. Determination of acceptable limits for cleaning process. d. Factors to consider in setting the limits. e. Numerical calculation of limits.	03
9	**Bioanalytical method validation** A. Introduction and background a. Full validation. b. Partial validation. c. Cross-validation. B. Method development: chemical assay a. Selectivity. b. Accuracy, precision, and recovery. c. Calibration/standard curve. d. Stability. e. Principles of bioanalytical method validation and establishment. f. Specific recommendations for method validation. C. Method development: microbiological and ligand-binding assays a. Selectivity issues. b. Quantification issues. D. Documentation a. Summary information. b. Documentation for method establishment. c. Application to routine drug analysis. d. Other information.	06
10	**Transdermal Process Validation** a. Essential transdermal validation elements. b. Matrix transdermal system equipment Qualification & Process validation. c. Validation and Documentation for the matrix of transdermal system.	04
11	**Validation of Lyophilization Process.**	03
12	**Computer System Validation:** Introduction, Regulatory background, validation life cycle, Planning, Requirements Definition, Supplier selection, Design and development, system qualification, ongoing evaluation.	03
	Total	**60**

Reference books :

1. R. Nash and Wachter, "Pharmaceutical Process Validation". Volume 129, Latest Edition. Marcel Dekker Inc., New York.
2. K.L. Williams, "Microbial Contamination Control in Parenteral Manufacturing". Latest Edition. Marcel Dekker Inc., New York.
3. Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing — Current Good Manufacturing Practice-USFDA.
4. J.T. Carstensen, C.T. Rhodes, "Drug stability: principles & Practices". Latest Edition. Marcel Dekker Inc., New York
5. www.ich.org – Q7 a guideline
6. www.fda.org
7. United State Pharmacopoeia
8. US-FDA guideline for bio analytical studies. Dekker Inc., New York

Class: Second Semester M. Pharm. **Subject Code:** S2-MPQ3
Subject: Validation (Practical) **Allotted Hrs. :** 8

Suggested Laboratory Experiments.

1. Calibration of Weighing balance, DT apparatus, Melting Point Apparatus
2. Calibration of pH meter by USP and I.P. procedure and Calibration of IR Spectrometer
3. Calibration of HPLC instrument- determination of flow rate
4. Calibration of Dissolution Apparatus
5. Standard Calibration Curve by UV at λmax and wavelengths 10nm below and above λmax.
6. Calibration of UV spectrophotometer
7. Assay determination by Simultaneous equation method
8. Assay determination by Absorbance ratio method
9. Validation of Dissolution Rate Test Apparatus
10. To check HPLC Column performance- resolution
11. To determine Linearity of HPLC instrument
12. To determine repeatability of HPLC instrument
13. To determine LOD & LOQ of HPLC instrument
14. To Determine Robustness
15. To study effect of wavelength selection in HPLC analysis
16. Determination of response factor
17. To check GC Column performance- resolution
18. To determine Linearity of GC instrument
19. To determine repeatability of GC instrument
20. To determine LOD & LOQ of GC instrument
21. To Determine Robustness
22. To study effect of wavelength selection in GC analysis
23. Determination of response factor

Class: Second Semester M. Pharm. **Subject Code:** S2-MPQ4
Subject: Stability of drugs and Dosage form (Theory) **Allotted Hrs.:** 4

Sr. No.	Unit and Contents	Hrs.
	Section A	
1	**Introductory Overview**	02
2	**Chemical Stability of Drug Substances:** Pathways of Chemical Degradation, Factors affecting Chemical Stability, Stabilization of Drug Substances against Chemical degradation.	06
3	**Physical Stability of Drug Substances:** Physical Degradation, Factors affecting physical stability, Kinetics of solid phase transitions.	06
4	**Stability of Dosage Forms:** Preformulation and formulation stability studies, Functional changes of dosage form with time, effect of packaging on stability of drug products, Estimation of shelf life of drug products.	08
5	**Stability of Peptide and Protein Pharmaceuticals:** Degradation of Peptides and Protein Pharmaceuticals, Factors affecting the degradation of Peptide and Protein Drugs, Degradation Kinetics of Peptide and Protein Pharmaceuticals.	08
	Section B	
6	**Physical Testing:** Physical stability of solutions, Physical testing of; Parenteral Solutions, Disperse systems, Emulsions, Aerosols, Powders, Tablets, Sustained release Products, Coated Tablets, Hard and soft shell capsules, Microcapsules, Light sensitivity testing, Diagnostic papers, Accelerated testing and Predictions, expiration periods.	12
7	**Development and validation of HPLC Stability indicating Assay Method (SIAM):** Introduction to SIAM, Method development , Method validation as per ICH	04
8	**A Rational approach to stability testing and analytical development of NCE. Drug Substance and Drug Products: Marketed Product stability Testing:** Introduction, Stress and accelerated testing with the Drug Substance, Preformulation and Formulation finding for the toxicological and clinical samples, Final Dosage Form, Stress and accelerated testing with selected formulation, selection of Packaging materials, upscaling pilot plant, registration batches, Accelerated and longterm testing with registration batches upto registration application for drug substance and drug product, ongoing stability testing, Follow up stability testing.	10
9	**Regulations:** ICH harmonized tripartite guideline for stability testing of new Drug substance and Products, ICH harmonized tripartite guideline for Photo stability testing of new Drug substance and Product.,	04
	TOTAL	**60**

Reference books :

1. Sumie Yoshioka and Valentino J.Stella, , "Stability Drugs and Dosage Forms". Springer Int. Edition
2. A.R. Gennaro, 2000."Remington: The Science & Practice of Pharmacy". Lippincott Williams & Wilkins, Philadelphia.
3. L.V. Allen, Jr., N.G. Popovich, H.C. Ansel, W. Kluer, "Ansel's Pharmaceutical Dosage Forms and Drug Delivery Systems". Latest Edition. Lippincott Williams & Wilkins.
4. Jens T. Cartensen, C.T.Rhodes, Drug Stability Principles & Practices, Third Edition, Marcel Dekker.
5. A.N. Martin, "Physical Pharmacy" 4th Ed. B. I. Waverley Pvt. Ltd., New Delhi,.
6. G.S. Banker and C.T. Rhodes, "Modern Pharmaceutics". Marcel Dekker Inc., New York.
7. ICH Guidelines on Stability
8. J.T. Carstensen, 1987. "Pharmaceutical Preformulation". Informa Healthcare.
9. S.K. Niazi., 2006. "Handbook of Preformulation: Chemical, Biological, & Botanical Drugs". Informa Healthcare.
10. M.C. Adeyeye., 2008. "Preformulation in solid dosage form development". Informa Healthcare.
11. H.G. Brittain, 1999. "Polymorphism in pharmaceutical solids". Informa Health Care.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPH1
Subject: Drug Regulatory aspects and IPR (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To impart information on various drug regulatory aspects involved in the profession.
- To teach the import / export related regulations with respect to some countries
- To make the students understand the importance and implication of IPR and related matters.
- To train the students in GMP and the latest developments there.

Sr. No.	Unit and Contents	Hrs.
Unit-1	**DRUG REGULATORY ASPESTS**	**40**
a)	Drug Regulatory Aspects (India) – 1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA) 2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective) 3. Special emphasis – Schedule M and Y 4. New Drugs – Importation, Registration, Development, Clinical Trials, BE NOC & B.E. studies 5. Various licenses – Test lic., Import lic. for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	10
b)	Good Manufacturing Practices (GMP) – 1. Indian GMP certification, WHO GMP certification 2. ICH guidelines for stability testing and other relevant ones (Q1 – Q10) 3. Export permissions and manufacturing for semi-regulated countries 4. Understanding of the plant lay-outs with special emphasis on the environment & safety. (HVAC, Water systems, Stores management, Effluent etc.) 5. Quality Assurance and Quality Control – Basic understanding for in-built quality.	12
c)	Drug Regulatory Aspects (International & highly regulated markets) – 1. US Requirements – (for Generic Drugs especially formulations) 2. CDER, INDA, NDA, ANDA's (types), CTD Formats of dossiers, E-submission, US DMF (various types), IIG Limits, Orphan Drugs, Vanilla ANDA's, Exhibit/Pivotal batches, Validation batches, Various Guidance issued by CDER, OGD, Orange Book (and patents), RLD (Reference listed drug) for BE studies and the norms for US submission, Bioequivalence and dissolution recommendations, Packaging, Stability studies and the Product Information Leaflet, US FDA Inspection (audits), Pre-approval Inspections and approvals 3. European Union Requirements – 4. All the aspects for European Registration of formulations for generic drugs sale in the European markets under EU. EMEA guidelines on various aspects as above (C 1) 5. A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries. 6. GMP audits, role of Quality Assurance, product approvals and supplies.	18
Unit-2	**INTELLECTUAL PROPERTY RIGHTS (IPR)**	**20**
a)	**Introduction to IPR & Patents** – Development of IP law in India, IPR regime, Introduction to IP laws in India, Role of IP in pharma industry growth.	
b)	**Patenting in India** – Introduction, Patent legislation, Indian Patents Act 1970 and amendments, Procedure for patent application, Grant and opposition proceedings, Patent licensing, Patent infringement proceedings, IPAB – role and functions (IP Appellate Board), Indian IP Case laws	
c)	**American & European patent system** – Requirements for patenting, utility, novelty Non-obviousness, Patent specification & claims, Patent infringement and Doctrine of Equivalents, Federal circuit and Patent system in Europe	
d)	**International treaties and conventions on IPR** - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO	
e)	**Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003**	
f)	**Introduction to** Geographical indication / Trademark/ copyright: Filing procedures	
g)	**Patent search, Patent analysis & Patent drafting**.	
h)	**Allied Patents Related Issues**: Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage	
	Total	60

Reference books :
1. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).
2. CDER Publications and Guidance
3. EMEA Publications and Guidance
4. Orange Book, ICH guidelines, Indian Patents Act
5. Country specific Regulatory Guidelines (available from internet)
6. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
7. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.
8. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
9. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.
10. Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPQ2
Subject: Research work Seminar **Allotted Hrs. :** 8

OBJECTIVE:

- To effectively present the research work carried out by the student.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPQ3
Subject: Research Project **Allotted Hrs. :** 16

OBJECTIVE:

- To manage the research work in time bound manner.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPQ4
Subject: Quality Management (Theory) **Allotted Hrs. :** 4

OBJECTIVE:

- To introduce & build on the concept of quality in Pharmacy profession.
- To expand the concept of quality at industrial level, including plant design / layout, environmental controls, etc.
- To teach this concept with respect to manufacturing activities & related areas, management of all store requirement & related matters.
- To give updated knowledge in these & related areas.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Concept of Total Quality Management, Quality control and quality assurance, Four M's responsible for quality variation.	06
2	GMP, Organization of pharmaceutical manufacturing unit, production management, Revised schedule M.	07
3	Personnel: Introduction, Human resource development, Qualification Experience and Training, Responsibilities, Personal Hygiene and Gowning, Legal aspects.	05
4	Premises: Introduction, Surrounding, Plant layout, Principal Area, Plumbing and drainage system, Lighting, Sewage, Water handling-Sewage, Refuge and Disposal, Washing and toilet facility, Sanitation, Controls of contamination and Environmental controls.	07
5	Equipments: Selection of Design, Size, Location and design of equipments, Purchase specifications, Equipment identification systems, Equipment log-Usage, Cleaning and Maintenance, Preventive maintenance and Calibration.	05

	SECTION B	
6	Materials Management: API's, raw materials & packaging materials, Purchase specifications, Selection of vendors, Intermediates & Finished products, Rejected and Recovered materials, Recalled products, Reagents & culture media, Reference standards, Waste materials, Warehousing, Good Warehousing Practices.	05
7	Manufacturing Operations and Control: Sanitation of Manufacturing Premises, Line clearance, Mix-ups and Cross contamination, Processing and holding of Intermediates and Bulk Products, Packaging, I.P.Q.C., Release and storage of Finished Product, Process Deviations and Incidents, Drug product inspection, Yield calculations, Expiry dating, Manufacturing record review and approval.	05
8	Post Operational Activities: Distribution, Complaints and recalls, evaluation of complaints, Recall procedures, related records and documents. Outsourcing: Facility audit, Manufacturing, Packaging, Analytical, Clinical and other services outsourcing.	06
9	Site and Plant security: Security personnel, Entry procedures to site & plant, Internal security, Vehicle parking, Fuel storage, Canteen & cooking, Garden & horticulture.	03
10	Sterile Products: Building and premises, Personnel, Gowning, Entry, HVAC system, Water and steam system, Equipments, Processes, Sterilization, Quality control, Sanitation, Documentation and formats.	05
11	Concept of GLP and GCP, Quality control laboratory responsibilities, good laboratory practices, routine controls, instruments and standard test procedures, non-clinical testing, controls on animal house, site, Data generation and storage.	06
	TOTAL	**60**

Reference books :

1. Quality Assurance of Pharmaceuticals, Vol. 2, Updated Edition, World Health Organization, Geneva.
2. M.A. Potdar, Pharmaceutical Quality Assurance, Nirali Prakashan, Pune.
3. S.H. Willing, GMP for Pharmaceuticals, Latest Edition, Marcel Dekker.
4. Regulatory guidelines related to GMP by
    - Australian code of GMP for medicinal products, 16th Aug 2002
    - 21 Code of Federal Regulation, Parts 210, 211&58 (USFDA guidelines)
    - EU, MHRA, UK Guidelines on GMP
    - GMP Guidelines by Medicines Control Council of South Africa.
    - Schedule M of Drug & Cosmetics Act

Class: Third Semester M. Pharm. **Subject Code:** S3-MPQ5
Subject: Advanced Quality Assurance **Allotted Hrs.:** 4

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Standard Operating Procedures:** Introduction and purpose of SOP, Benefits of SOP, Types of SOP, Contents of Typical SOP, Level of detail, Writing style, SOP development, SOP format, Transition to electronic SOPs, Advantages of electronic SOPs, system requirements, Structure of eSOP.	07
2	**Change control and SUPAC:** Introduction, change control- current regulations, Proposed regulations, contents of change control procedures, SUPAC- History and philosophy of SUPAC, SUPAC-IR, Post approval changes-analytical testing laboratory site, SUPAC MR, proposed SUPAC documents.	08
3	**Quality Standard -ISO:** A general introduction to Quality standards, advantages and disadvantages, Introduction of the ISO 9000 Standards, key features of ISO 9000, The requirements, Changes in the ISO 9000 standards, Implementation strategy for ISO, ISO guidelines for documentation, structure of documents.	06
4	**Pharmaceutical Quality System:** Introduction , Scope, Relationship of ICH Q10 to Regional GMP Requirements, ISO Standards and ICH Q7, Relationship of ICH Q10 to Regulatory Approaches , ICH Q10 Objectives , Enablers, Design and Content Considerations, Quality Manual, Management Commitment, Quality Policy, Quality Planning, Resource Management Internal Communication, Management Review ,Oversight of Outsourced Activities, Lifecycle Stage, Goals, Pharmaceutical Quality System Elements , Management Review of the Pharmaceutical Quality System, Monitoring of Internal and External Factors Impacting the Pharmaceutical Quality System Outcomes of Management Review and Monitoring.	08
	SECTION B	
5	**Quality by design:** Introduction, Defining Product Design Requirements and Critical Quality Attributes, The Role of Quality Risk Management in QbD, QbD for ANDAs- Analysis of the Reference Listed Drug Product, Quality Target Product Profile for the ANDA Product, Components of Drug Product, Drug Product, Manufacturing Process Development, Container Closure System, Microbiological Attributes,Compatibility, Control Strategy.	10
6	**Process Analytical Technology:** background , PAT framework, process understanding principles and tools, PAT tools , risk-based approach, integrated systems approach , strategy for implementation , PAT regulatory approach .	06
7	**Impurities in Drug Substances and Drug Products:** Description of Impurities**,** Ich documents on impurities, specifications, Qualification of impurities, Analytical procedures for degradation products or drug excipients reaction products, impurities in ANDAs, validation, Impurity issues related to manufacturing, processing, or holding drug substances.	07
8	**Quality Audit:** Introduction , Types of audit, Principles of quality audit program, subject matter of audits, structuring the audit program, Planning audits of activities, audit performance, audit reporting, corrective action follow up, quality assessment, product audit, sampling for product audit, reporting the result of product audit.	08
	TOTAL	**60**

Reference books :

1. J. Kreuter, "Colloidal drug delivery systems", Marcel Dekker Inc., New York.
2. A. N. Martin, "Physical Pharmacy", B. I. Waverley Pvt. Ltd., New Delhi.
3. Published Research and Review articles on Colloidal and disperse systems.
4. H. A. Liebermann, M.R. Martin, G.S. Banker, 1996. "Pharmaceutical dosage forms: Dispersed systems", Vol. I, II, III, Marcel Dekker Inc., New York.
5. J. T. Carstensen and C.T. Rhodes, Latest edition. "Drug stability: Principles and Practices", Informa Healthcare.
6. K. Huynh-Ba, 2008. "Handbook of Stability Testing in Pharmaceutical development: Regulations, Methodologies and Best Practices", Springer Science, USA.
7. ICH Guidelines:
8. Gennaro, 2000."Remington: The Science & Practice of Pharmacy". Lippincott Williams & Wilkins, Philadelphia
9. J. P. Agalloco, F. J. Carleton, 2007. "Validation of pharmaceutical processes", Informa Healthcare.
10. Avis, Lachman, and Liebermann, "Pharmaceutical dosage forms: Tablets", Marcel Dekker Inc, New York.
11. I. R. Berry, R.A. Nash, 1993. "Pharmaceutical process validation", Marcel Dekker, New York.
12. S. H. Willig and J.R. Stoker, 1997. "Good manufacturing practices for pharmaceuticals: A plan for total quality control", Marcel Dekker.

Class: Fourth Semester M. Pharm. **Subject Code:** S4-MPH1
Subject: Research Project and Colloquium **Allotted Hrs.:** 36

OBJECTIVE:

- To complete the given research project
- The effectively defense the work before a group of qualified evaluators.

Sr. No.	Unit and Contents	Hrs.
1.	• Completion of research project and submission of dissertation to University. • Defence / viva voce	36

PART - E

M. Pharm. Syllabus

(Pharmaceutical Chemistry)

Class: First Semester M. Pharm. **Subject Code:** S1-MPH1
Subject: Research Methodology **Allotted Hrs.:** 4

OBJECTIVE:

- To familiarize students regarding teaching methodology & research projects.
- To teach students preparation of are search projects & different aspects associated with it.
- To acquaint students with experimental data analysis.
- To impresss upon students the importance of ethical issues in the profession & plagiarism.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Learning and instruction** Principles of Instructional design and learning theory, Merrill's five principles and Gagne'scon dition of learning. Active learning, group learning, collaborative learning, problem-based learning, team-based learning, Experiential learningmodel of Kolb.	8
2	**Curriculum development** Asix step approach-Problem identification and general needs assessment, targeted needs assessment, goals and objectives, educational strategies, implementation, evaluation and feedback. Bloom's Taxonomy, three domains of educational objectives.	6
3	**Funding &Scholarship** Agencies funding research in pharmaceutical sciences, Scholarship ,types of scholarships in education.	3
4	**Assessment** Definition and methods, Georges Millers pyramid, assessment, measurement and tests, types of numbers, formative and summative assessment.	3
5	**Basicsof Research** Definition, objectives, motivation, types of research and approaches: Descriptive research, conceptual, theoretical, applied and experimental.	3
6	**Formation of Research Problem** A. Research Process: To determine what type of research to be done, plan of research work. B. Selection of research area, prioritization of research. C. Literaturere view: importance and methods, sources, D. Objectives and scope of work, developing research plan and schedule: Scheduling constraints ,steps, problems in scheduling, limitations.	4
7	**Mathematical Modeling and Simulation** Concept of modeling, classification of mathematical models, modeling with ordinary differential equations, difference equations, partial differential equations, graphs, simulation: concept, types (quantitative , experimental, computer, fuzzy theory, statistical) processes of formulation of model based on simulation. Variables and measurement.	5
	SECTION B	
8	**Experimental Modeling** A. Definition of experimental design, examples, single factor experiments B. Blocking and Nuisance factors, guidelines for designing experiments. C. General model of process: Input factors/ variables, Out put parameters/ variables controllable /uncontrollable variables, dependent/ independent variables experimental validity. D. Introduction to Risk assessment, reliability, sustainability, and uncertainty.	4

9	**Analysisof data** A. Types of data: parametric and nonparametric, descriptive and inferential data, B. Collection of data: normal distribution, calculation of co-relation coefficient C. Data processing: analysis, error analysis, meaning, and different methods: analysis of variance, significance of variance, analysis of covariance, multiple regressions, testing linearity / nonlinearity of model, testing adequacy of model. D. Test to be used in data exploration and their choice E. Introduction of software used in data analysis.	8
10	**Research Deliverables** A. Various Forms of Publication: Thesis, paper, research proposal. B. Thesis Writing: Introduction, literature reviewor state-of-the-art, research approach (methodology), results or findings, discussions, conclusions, scope for future work, references, appendices. C. Presentation: Poster, thesis, proposal, and paper.	4
11	**Ethical issues in research** Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/ vaccines /herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good clinical practices norms, Ethical principles related to animal experiments.	10
12	**Plagiarism** Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscriptwriting, documentation, organization of reference material, bibliography, end note.	2
	TOTAL	60

Reference Books:

- B.D.John,A.L.BrownandR.R.Cocking,1999."How People Learn: brain, mind, experience and school".Washington, D C: National Academy Press.
- J.R.Fraenkel,N.E. Wallen,2008."How to Designand Evaluate Researchin Education*",7th Ed*. Bostan McGraw-Hill
- K.E.David,2009. Curriculum Development for Medical Education:*A Six-Step Approach* 2nd Ed. The John Hopkins University Press. ISBN0-8018-9367-4.
- N.Peter,2009."Leadership: Theory and Practice*." 3rd Ed.* Thousand Oaks: Sage Publications.
- G.Bordage,B.Dawson,2003. Experimental study design and grant writing in eight steps and 28 questions *MedicalEducation, 37*(4):376-385.
- B.J.Avolio, F.O.Walumbwa, T.J.Weber, 2009. Leadership: Current theories, research, and future directions. *Annual Review of Psychology, 60*:421-449.
- C.R.Kothari, 2004."Research Methodology".2nd Ed.New Ag eInternational(p) Limited,Publishers.
- D.Montgomary, 2000."Designof Experiments". 5thEd. Wiley Interscience.
- K.P. Willkinsion, L. Bhandarkar, "Formulation of Hypothesis". 3rd ed. Himalaya publishing, Mumbai.
- SchankFr, 2008."Theories of Engineering Experiments".2nd Ed.Tata McGraw Hill.
- D.C.Montgomery, 2009."Introduction to SQC"6th Ed.JohnWilly& sons.
- Cochran& Cocks, 1957.2nd Ed."Experimental Design" New York,JohnWilly& sons.
- J.W.BestandJ.V.Kahn, 2006."Research in Education". 10th Ed.PHI publication.
- S.S.Rao,1983."Optimization Theory & Applications".2nd Ed.WileyEasternLtd.ND.
- P.D.Kulkarni,1986."Independent Study Techniques",TTTI Chandigarh

Class: First Semester M. Pharm. **Subject Code:** S1-MPH2
Subject: Modern Analytical Techniques (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To familiarize students in use of modern techniques of analysis used indifferent areas/ fields of pharmacy.
- To give training in use of the technique & its applications in day to day practice.
- To build on the basics learned at UG level & give latest advances in the area.
- To give more stress on application based knowledge than instrumentation based one.
- To give hands on training on use of as many different ophisticated instruments as possible.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Ultraviolet–Visible spectrometry: Woodward–Fisher rules for calculation of λmax. Derivative spectroscopy. Introduction to Optical rotator Dispersion and Circular Dichroism.	5
2	Fourier Transformed Infrared Spectrometry. Interpretation of Infrared spectrum.	3
3	High Resolution ^{1}H &^{13}C NMR Spectrometry. Theoretical calculation of chemical shifts of various carbon atoms. Technique used for finding types of carbon like attached protontest (APT), distortionless energy polarization transfer (DEPT). Homonuclear & heteronuclear correlation spectrometry. Different 1D & 2D NMR correlation spectrometric techniques such as COSY, NOESY, HETCOR INADE QUATE, SBC, HMQC etc. Use of this technique in determination of absolute configuration.	15
4	Mass spectrometry: use of isotopic abundance in molecular formula calculation. Different ionization techniques like EI, CI, FD, FI, MALDI, API,ESI. Fragmentation of molecule using these techniques. Tandem mass spectrometry and its applications in pharmacy.	8
	SECTION B	
5	HPTLC: Basic instrumentation and its calibration. Analytical methoddevelopment andits validation as per ICH guidelines. Quantification using HPTLC	5
6	HPLC: Instrumentation covering detailed discussion about pumps, injector system, columns and detectors. Calibration of instrument. Analytical method development, validation as per ICH guidelines and trouble shooting. Quantification methods usedin HPLC. Ultra pressure liquidchromatography.	8
7	Thermoanalytical techniques: Differential Scanning Calorimetry (DSC), Thermogravimetry (TG), Thermo mechanical analysis (TMA): Principles instrumentation and applications (including interpretation of data) in pharmacy.	5
8	Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmuneassay, ELISA etc.	6
9	Microscopy: SEM, TEM, cryomicroscopy, AFM, confocalmicroscopy.	5
	TOTAL	60

Reference Books:

- RobertM. Silverstein, FrancisX. Webster, DavidJ. Kiemle,2009."Spectrometric identification of organic compounds".7thEd. John Wiley & Sons
- Pavia D. L.,2009."Introduction to spectroscopy".4th, Belmont CA
- Munson&Munson,"Pharmaceutical analysis: modern methods".,New York: M. Dekker
- KennethA. Connors, 2007."A Text book Of Pharmaceutical Analysis"3rdEd. WileyIndia-wse
- JensThuroCarstensen, 2001."Advanced pharmaceutical solids"Marcel Dekker, NewYork
- JosephB. Lambert, ScottGronert, Herbert F.Shurvell, David Lightner,Robert Graham Cooks, 2010. "Organic structural spectroscopy",2ndEd. Pearson Education, Limited.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH2
Subject: Modern Analytical Techniques (Practical) **Allotted Hrs. :** 8

Sr.No.	Laboratory Experiments
1.	Estimation of two drugs by simultaneous equation method and absorbance ratio method.
2.	Calibration of UV spectrometer for wavelength and stray light.
3.	Analysis of drugs by second derivative UV spectrometry.
4.	Determination of pK value by UV visible spectrometry.
5.	Calculation of λmax values using Woodward Fisher rules.
6.	Study of hydrogen bonding using IR spectrometer.
7.	Interpretation of IR spectra.
8.	Calibration of IR spectrometer using standard polystyrenefilm.
9.	Interpretation of 1D proton NMR spectrum of simple compounds (10-12carbons).
10.	Interpretation of 1D 13C NMR spectrum of simple compounds(10-12carbons).
11.	Calculation of carbon chemical shifts for various carbons such as sp3,sp2,sp carbonetc.
12.	Assignmen tof m/z values to various fragments in the mass spectrum.
13.	Qualitative and quantitative analysis using HPTLC.
14.	Analytical method development for three component mixture using HPTLC.
15.	Calibrationof HPLC instrument for flow rate & wavelength.
16.	Determination of theoretical plate, HETP resolution, tailing factor for two component mixture
17.	Determination of caffeine contentin tea/coffee/other beverages.
18.	Quantitation using different methods such as area normalization, one point,two point method with the help of internal standard.
19.	Determination of melting point & heat of fusion usingDSC.
20.	Determination of glass transition temperature using DSC.
21.	Interpretation of ORD and CD spectrum.

Class:	First Semester M. Pharm.	**Subject Code:**	S1-MPH3
Subject:	Computer and statistics (Theory)	**Allotted Hrs.:**	4

OBJECTIVE:

- To train students in basics of computer hardware.
- To train them on hands on experience in use of different software.
- To teach them applications of computers in different areas of Pharmacy.
- To train the students for applications of various statistical methods available for analysis of data.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	Hardware: Current hardware & their performance, New devices / technology useful in teaching & research like Cameras, Scanner, touch screens, tablets, projection devices etc. Basic idea of computer networking.	03
Unit -2	Operating systems: Common operating systems used in day to day task & instrumentation like Windows, Linux & Unix (only interface and basic commands).	15
Unit -3	Language: Evolution of computer languages. Common languages used in scientific fraternity (no specific language detailing is required).	06
Unit -4	Software: Idea of popular soft ware's like MS Office, structure drawing software's, chemical structure visualizing software's, statistical software's & mathematical software, reference managing software's (only introduction).	05
Unit -5	Web page design: Need, concept and use of HTML.	08
Unit -6	Databases: Meaning, Need and creating table, record creating and maintenance.	05
Unit -7	Internet concept: History, creating internet connection, common problems & solutions.	06
Unit -8	Important Databases of free domain: Patents, Pub med, Pubchem, Science direct, protein database.	05
	SECTION B	
Unit -1	Data & Graphs.	03
Unit -2	Basic statistics.	02
Unit -3	Sampling.	04
Unit -4	Hypothesis testing.	06
Unit -5	Optimization.	06
Unit -6	Designing experiment.	06
Unit -7	Clinical data management.	02
Unit -8	Meta analysis.	03
Unit -9	Statistical Quality control.	05
Unit-10	Introduction to common statistical software.	03
	Total	**60**

Reference books :

- W.E. Fassett, 1986. "Computer Applications in Pharmacy", Lea & Febiger Publisher.
- C.N. Madu, 2003. "Statistics as easy as one, two, three with Microsoft Excel for Windows", 1st Ed. Chi Publishers Inc.
- A.N. Armstrong, 2006. "Pharmaceutical experimental design and interpretation", CRC/Taylor & Francis.
- G.A. Lewis, D. Mathieu, R.T. Phan, 1999. "Pharmaceutical experimental design", CRC Press.
- W.G. Cochran, W.G. Cochran, G.M. Cox, 1992. "Experimental designs". Wiley.
- http://pages.stern.nyu.edu/~jsimonof/classes/1305/pdf/excelreg.pdf
- www.Pubmed.com
- www.Pubchem.com
- www.mdl.com
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- www.uspto.gov
- www.esp.gov
- Lambert M Surhone, Miriam T Timpledon, Susan F Marseken, 2010. "Rasmol", VDM Verlag Dr. Mueller AG & Co. Kg.
- http://www.vlifesciences.com

Class: First Semester M. Pharm. **Subject Code:** S1-MPH3

Subject: Computer and statistics (Practical) **Allotted Hrs. :** 4

1	To understand computer hardware & their integration (computer, printer, scanner, display device, Bluetooth & IR devices).
2	To understand operating system / s.
3	To know theevolution of computer languages.
4	To design simple web page using HTML editor (Word, FrontPage etc.).
5	To make simple database using MS Access (i.e. Plant database, reference database etc.).
6	To create, editing & formatting worksheet using excel.
7	To make use of formula in excel.
8	To write macros in spreadsheet.
9	To create graphs for representing data.
10	To perform statistical operations on the obtained data.
11	To make decisions using formula in spreadsheet.
12	To develop ability to create master document in MS word.
13	To make PowerPoint presentations with hyper linking & animation effects.
14	To learn & develop expertise in use of structure drawing software like ISIS, Chem sketch etc.
15	To learn use of structure visualization software like Rasmol.
16	To visualize protein molecules using Protein explorer.
17	To learn searching internet based databases like Pub med, US Patents.
18	To develop technique for calculating molecular properties on line.
19	To perform simple optimization exercises using MS Excel / any statistics software.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH4
Subject: Nanotechnology & Biotechnology (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give basics of nanotechnology.
- To impart advanced level training in bio & nanotechnology with emphasis on their use in Pharmacy.
- To make use of this advanced level knowledge in drug discovery.
- To impart training on carrying out the sophisticated experiments in these areas.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	**BIONANOTECHNOLOGY:** History, opportunities and challenges of bionanotechnology, growth potential of bionanotechnology, significance of nanosize in biotechnology and medicine.	04
Unit -2	**NANO-DRUG DELIVERY:** Conventional delivery of biotechnologicals and its limitations, biological barriers in delivery of therapeutics, importance of nano-size in site-selective delivery. Targeted delivery of biotechnological using nanoconstructures, application of nanocarriers in delivery of biotechnologicals, nano-drug delivery chip.	10
Unit -3	**BIONANOCARRIERS:** Design and fabrications of nanocapsules, nanoliposomes, nanoparticles, nanoemulsion, nanopore technology, nano-self assembling systems, bionanoarrays, dendrimers, carbon nanotubes, nanosomes and polymersomes, inorganic nanoparticles (gold-gold colloids, gold nanofilm, gold nanorods, titanium and zinc oxide), structured DNA nanotechnology.	11
Unit -4	**NANOMEDICINE, NANOBIOLOGY AND NANOBIOTECHNOLOGY:** Synthesis and assembling of nanoparticles/nanostructures using bio-derived templates, proteins and nanoparticles, covalent and non-covalent conjugates, cantilevers array sensors for bioanalysis and diagnostics, nanowire and nanotube biomolecular sensors for in-vitro diagnosis of cancer and other diseases. Biologically inspired hybrid nanodevices, nanotube membranes for biotechnology, shelf-assembling of short peptides for nanotechnologicals applications.	10
	SECTION B	
Unit -5	**BIONANOIMAGING:** Quantum dots-luminescent semiconductor QD in cell and tissue imaging, fluoroimmunoassay using QD. Ultrasound contrast agents, magnetic nanoparticles, nanoparticles in molecular imaging, nanoforce and imaging-AFM, molecules, cells, materials and systems design based on nanobiotechnology for use in bioanalytical technology.	08
Unit -6	**DRUG DISCOVERY:** Drug screening, technoglobalism and drug development, biodiagnostics.	02
Unit -7	chemogenomics, computational chemistry, new pharmaceuticals from marine sources, cell based therapies, encapsulated cells for disease treatment.	03
Unit -8	**INSTRUMENTATION AND PRINCIPLES:** Electrophoresis techniques, laser confocal microscopy, digital image analysis, biosensors in diagnostics, enzyme purification and assay techniques. Techniques in cytogenetics: DNA sequencing, DNA microarray.Spectral analysis techniques: Introduction, estimation of proteins, DNA and RNA.	08
Unit -9	**SAFETY CONCERN OF BIONANOTECHNOLICALS:** Inhalation, contact/dermal delivery, environmental impact, explosion hazards.	04
	Total	**60**

Reference books :

- E.S. Papazoglou and A. Parthasarathy, "Bionanotechnology". 1st Ed. Morgan and Claypool.
- N.H. Malsch. 2005. "Biomedical nanotechnology" CRC Press.
- D.S. Goodsell, 2004. "Bionanotechnology: lessons from nature" Wiley-Liss Publication.
- T. Vo-Dinh, "Nanotechnology in biology and medicine: methods, devices, and applications" CRC Press.
- V. Labhasetwar, D.L. Leslie-Pelecky, 2007. "Biomedical applications of nanotechnology".Wiley-Interscience: Hoboken.
- S.P. Vyas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and controlled drug delivery" CBS Publishers and Distributors.

- **It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.**

Class: First Semester M. Pharm. **Subject Code:** S1-MPH4

Subject: Nanotechnology & Biotechnology (Practical) **Allotted Hrs. :** 8

Suggested List of Laboratory Experiments :

- Development of nanoparticles by solvent-evaporation method.
- Design of nanospheres by emulsification method.
- Preparation of polymeric nanocapsules by solvent-diffusion method.
- Evaluation of nanoparticles for particle size, zeta potential, drug entrapment efficiency, stability and other parameters.
- Development of solid lipid nano particles using various lipids.
- Preparation of nano-liposomes by solvent dispersion/film hydration method.
- Development and evaluation of nano-niosomes.
- Development and evaluation of nano-suspensions.
- Preparation of nanoemulsions by using ternaray phase diagrams.
- Incorporation of nanoemulsions in topical gels.
- Evaluation of dermal retention, penetration, skin irritation and toxicity potential of nano topical formulations.
- Development of nanosponges based on cyclodextrin complexes.
- Assessment of solubility enhancement by nano formulations.
- Pegylation of nanoparticles.
- Synthesis of Al_2O_3 nanoparticles using soi.gel method.
- Synthesis of Fe_2O_3 nanoparticles by chemical method.
- Synthesis of nanoparticles using biological process (2-3 methods).
- Functionalization of nanoparticles for biological application- (4-5 methods).
- Detection of nanoparticles in colloidal solutions using UV-Visible Absorption technique size determination of nanoparticles using laser beam.
- Analysis of ANM, SEM AND TEM pictures.
- Polyacrylamide gel electrophoresis: native gel.
- Isolation and separation of secondary metabolites.
- 2-D Gel electrophoresis of proteins and isoelectrofocusing.
- Synthesis of nanometer scale particles of colloidal semiconductors such as TiO_2, CdS, ZnO, SnO_2, Cu_2S, CuCNS, Cu_2O, $BaTiO_3$, $SrTiO_3$ by wet chemical methods, hydrothermal methods, and pyrolytic or high temperature methods.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPH1
Subject: Research Project **Allotted Hrs.:** 8

OBJECTIVE:

- To give exposure on how to do literature survey for the project work
- To develop technical writing skill in the form of a research report
- To develop report presentation ability, orally
- To develop question answer capability confidently.

Sr. No.	Unit and Contents	Hrs.
1	NIL	

Class: Second Semester M. Pharm. **Subject Code:** S2-MPC2
Subject: Advanced Pharmaceutical Chemistry – 1 (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To teach students the basics & applications of drug design using computer software.
- To impart training in handling these drug design software by means of laboratory experiments.
- To give latest developments in some of the therapeutically useful classes of drugs.
- To develop the laboratory skills by giving advanced level reactions.

Sr. No.	Unit and Contents	Hrs.
1	Drug design & various rational approaches to the same, concept of bioisosterism & its applications, Introduction to biopharmaceutical consideration in drug design.	10
2	QSAR, CADD, molecular modeling, & docking. Use of these methods in the development of fluoroquinolones, dihydropyridines& other drugs. Study of software like ISIS, Chemsketch, RASMOL, Protein Explorer etc for structure drawing & visualization.	10
3	Prodrug concept, choice and function of pro-moiety, bioreversible derivatives for various functional groups, applications of the pro-drug approach and their design.	08
4	A detailed study of the following types of enzyme inhibitors, related drugs and their pharmaceutical significance (P.G. Synthetase (Cyclooxygenase and Lipoxygenase) inhibitors, Phosphodiesterase inhibitors, HMG CoA reductase inhibitors, Xanthine oxidase inhibitors, Angiotensin convertin enzyme (ACE) inhibitors. and recent advances in enzyme inhibitors.	10
5	Recent advances in drugs used in the treatment of: a] cancer, b] AIDS, c] ardiovascular disorders, d] diabetes, e] hepatitis, and f] immunosuppression.	14
6	Recent advances in the area of lipid / cholesterol lowering agents.	04
7	Antisense drugs & gene therapy.	04
	TOTAL	**60**

Reference books :

- J. H. Block & J. M. Beale, "Wilson &Giswold's Text Book of Organic Medicinal & Pharmaceutical Chemistry", Lippincott Williams & Wilkins, Baltimore, U. S. A
- T. L. Lemke & D. A. Williams, "Foye's Principles of Medicinal Chemistry", Lippincott Williams & Wilkins, Baltimore, U. S. A.
- R. B. Silverman, "The Organic Chemistry of Drug design & Drug Action". Academic Press, Massachusetts, U.S. A.
- Corwin Hansch, Peter George Sammes, John Bodenhan Taylor, 1990. "Comprehensive Medicinal Chemistry". Pergamon Press,
- Corwin Hansch, Albert Leo, D. H. Hoekman, 1995."Exploring QSAR: Fundamentals and applications in chemistry and biology". American Chemical Society.
- Alfred Burger, Manfred E. Wolff, "Burger's Medicinal Chemistry and Drug Discovery: Therapeutic agents". Wiley.
- http://pages.stern.nyu.edu/~jsimonof/classes/1305/pdf/excelreg.pdf
- www.Pubmed.com
- www. Pubchem.com
- www.mdl.com
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- http://www.organic-chemistry.org/prog/peo/cLogP.html
- http://intro.bio.umb.edu/111-112/OLLM/111F98/newclogp.html
- http://pdbbeta.rcsb.org/pdb/home/home.do

Class:	Second Semester M. Pharm.	**Subject Code:**	S2-MPC2
Subject:	Advanced Pharmaceutical Chemistry – 1 (Practical)	**Allotted Hrs. :**	8

Suggested List of Laboratory Experiments :

- Drawing, editing and cleaning structure
- Structure optimization using molecular mechanical & semiempirical method
- Creating function library
- Visualization
- Changing display style
- 2D & 3D rotation of structure
- Quarrying geometry
- Calculating structural parameters
- Calculating descriptors
- Creating worksheet
- Calculating correlation
- Building regression model
- Predicting activity
- Protein file downloading
- Protein molecule visualization & querying
- Performing simple Docking
- Multi-step synthesis of biologically active heterocycles.
- Synthesis of appropriate prodrug of aspirin/ salicylic acid / any other

Class: Second Semester M. Pharm. **Subject Code:** S2-MPC3
Subject: Advanced Organic Chemistry (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To teach different protecting groups used in synthesis & their applications.
- To provide advanced level knowledge in the area of stereochemistry, novel reagents, novel reactions, etc.
- To impart advanced level training in carbonyl chemistry such as asymmetric enolate anions formation & their applications in asymmetric synthesis.
- To give hands on training on the use of various reactive reagents & the necessary safety precautions.

Sr. No.	Unit and Contents	Hrs.
1	Protective groups for –OH, -NH_2, -COOH. Special protective groups for aldehydes / ketones such as oxazolines[A. I. Meyer's reagent] & 1,3- dithianes. Methods for deprotection of above groups. Concept of "Umplong". Reactions of 1,3-dithiane.	06
2	Nomenclature & stereochemistry of spiro- compounds. Stereochemistry of allenes & biphenyls.	03
3	Oxidations using Cr, Mn, Os, Ru, periodate, & Se reagents.	05
4	Homogeneous & heterogeneous reductions / hydrogenations. Metal - ammonia / amines reductions.	04
5	Preparation & reactions of P, S, & N ylides.	02
6	Fluorinating agents & their use in drug synthesis.	02
7	Preparation & use of boron reagents in asymmetric drug synthesis.	04
8	Regio- & stereoselective & stereospecific formation of enolate anions, their nucleoplillic& addition reactions. Role of Li, Na, K, Mg, & B metal ions in the regio- & stereoselective & reospecific formation of enolate anions.	06
9	Chemistry of active methylene compounds.	05
10	Different methods for the preparation of α-methylene lactones & similar functionalities.	02
11	Connection & disconnection approaches in drug synthesis.	04
12	Stereochemistry &its importance in medicinal chemistry. Methods for resolution of racemic mixtures.	03
13	Dynamic stereochemistry, conformations & reactivity in open chain & cyclic systems. Weinstein, Curtin – Hammett principle. Cram's rule & Prelog modification. Topicity & its significance in dynamic stereochemistry.	08
14	Pericyclic reactions. HOMO & LUMO. Conservation of orbital symmetry. Woodward rules for allowed & disallowed motions. Stereo specificity of these reactions.	06
	Total	**60**

Reference books :

- R. T. Morrison & R. N. Boyd, "Organic Chemistry". Allyn& Bacon, Inc., Boston, U. S. A.
- H. O. House, W. A. Benjamin, "Modern synthetic Reactions". , Inc., Menlo Park, California, U. S. A.
- E. L. Eliel, "Stereochemistry of Carbon Compounds", McGraw-Hill Book Company, Inc., New York,
- D. Nassipuri, "Stereochemistry of Organic Compounds". Wiley Eastern Limited, New Delhi, India.
- M. B. Smith, "Organic Synthesis", McGraw-Hill, Inc., New York, U. S. A.
- I. L. Finar, "Organic Chemistry", ELBS Series. Longman Publishers, London.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPC3
Subject: Advanced Organic Chemistry (Practical) **Allotted Hrs. :** 8

Suggested Laboratory Experiments.

Practicals based on some topics covered in the theory part including synthesis of drugs involving multistep. Monitoring of reaction by TLC and characterization of product by modern analytical techniques.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPC4

Subject: Advanced Pharmaceutical Chemistry 2 (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give additional Knowledge to students based on their choice of topic

Sr. No.	Unit and Contents	Hrs.
1	Technology involved in pharmaceutical manufacturing: Chemical process kinetics definition, factors affecting chemical processes, chemical reactors, reaction system, back mixing. Biochemical processes in synthesis-definition, examples with process, bio-ethanol, sugarcane and its byproducts, penicillin. Flow sheet for the generalized fermentation process.	14
2	Unit Processes(Each process with flow sheet diagram and at least two examples): Alkylation, Oxidation, Halogenations- with special emphasis on Freon, Nitration, Amination by reduction , Amination by ammonolysis, Esterification, Hydrolysis, Acylation, Hydrogenation.	16
3	Production: Detailed manufacturing aspects with flow sheet diagram, inclusive of process & operation involved in: Aspirin, Saccharin, diazepam, nitrazepam, penicillin, benzocaine, sulphathiazole, chloramphenicol.	10
4	Microwave assisted synthesis and its applications.	06
5	Green chemistry and its applications.	07
6	Supramolecular chemistry & its importance in pharmacy.	07
	Total	**60**

Reference books: The choice of literature is left to the concerned teacher depending on the selected topic.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPH1
Subject: Drug Regulatory aspects and IPR (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To impart information on various drug regulatory aspects involved in the profession.
- To teach the import / export related regulations with respect to some countries
- To make the students understand the importance and implication of IPR and related matters.
- To train the students in GMP and the latest developments there.

Sr. No.	Unit and Contents	Hrs.
Unit-1	**DRUG REGULATORY ASPESTS**	**40**
a)	Drug Regulatory Aspects (India) – 1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA) 2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective) 3. Special emphasis – Schedule M and Y 4. New Drugs – Importation, Registration, Development, Clinical Trials, BE NOC & B.E. studies 5. Various licenses – Test lic., Import lic. for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	10
b)	Good Manufacturing Practices (GMP) – 1. Indian GMP certification, WHO GMP certification 2. ICH guidelines for stability testing and other relevant ones (Q1 – Q10) 3. Export permissions and manufacturing for semi-regulated countries 4. Understanding of the plant lay-outs with special emphasis on the environment & safety. (HVAC, Water systems, Stores management, Effluent etc.) 5. Quality Assurance and Quality Control – Basic understanding for in-built quality.	12
c)	Drug Regulatory Aspects (International & highly regulated markets) – 1. US Requirements – (for Generic Drugs especially formulations) 2. CDER, INDA, NDA, ANDA's (types), CTD Formats of dossiers, E-submission, US DMF (various types), IIG Limits, Orphan Drugs, Vanilla ANDA's, Exhibit/Pivotal batches, Validation batches, Various Guidance issued by CDER, OGD, Orange Book (and patents), RLD (Reference listed drug) for BE studies and the norms for US submission, Bioequivalence and dissolution recommendations, Packaging, Stability studies and the Product Information Leaflet, US FDA Inspection (audits), Pre-approval Inspections and approvals 3. European Union Requirements – 4. All the aspects for European Registration of formulations for generic drugs sale in the European markets under EU. EMEA guidelines on various aspects as above (C 1) 5. A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries. 6. GMP audits, role of Quality Assurance, product approvals and supplies.	18
Unit-2	**INTELLECTUAL PROPERTY RIGHTS (IPR)**	**20**
a)	**Introduction to IPR & Patents** – Development of IP law in India, IPR regime, Introduction to IP laws in India, Role of IP in pharma industry growth.	
b)	**Patenting in India** – Introduction, Patent legislation, Indian Patents Act 1970 and amendments, Procedure for patent application, Grant and opposition proceedings, Patent licensing, Patent infringement proceedings, IPAB – role and functions (IP Appellate Board), Indian IP Case laws	
c)	**American & European patent system** – Requirements for patenting, utility, novelty Non-obviousness, Patent specification & claims, Patent infringement and Doctrine of Equivalents, Federal circuit and Patent system in Europe	
d)	**International treaties and conventions on IPR** - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO	
e)	**Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003**	
f)	**Introduction to** Geographical indication / Trademark/ copyright: Filing procedures	
g)	**Patent search, Patent analysis & Patent drafting**.	
h)	**Allied Patents Related Issues**: Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage	
	Total	60

Reference books :
1. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India). 2. CDER Publications and Guidance 3. EMEA Publications and Guidance 4. Orange Book, ICH guidelines, Indian Patents Act 5. Country specific Regulatory Guidelines (available from internet) 6. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc. 7. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare. 8. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare. 9. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare. 10. Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.

Class:	Third Semester M. Pharm.	**Subject Code:**	S3-MPC2
Subject:	Research work Seminar	**Allotted Hrs. :**	8

OBJECTIVE:

- To effectively present the research work carried out by the student.

Class:	Third Semester M. Pharm.	**Subject Code:**	S3-MPC3
Subject:	Research Project	**Allotted Hrs. :**	16

OBJECTIVE:

- To manage the research work in time bound manner.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPC4

Subject: Advanced Pharmaceutical Chemistry – III (Theory) **Allotted Hrs. :** 4

OBJECTIVE:

- To give detailed coverage of the following topics, including chemistry, biochemistry & pharmacology involved should be given.
- To provide latest knowledge on the topics mentioned in the units.
- To train the students in basic & newer approaches in synthesis of drug molecules /chemical entities.
- To expose the students on methodologies in synthesizing complex biologically active molecules.

Sr. No.	Unit and Contents	Hrs.
1	Antibiotics & drug resistance. Monobactam antibiotics. General approaches for their preparation. Asymmetric synthesis of thienamycin & aztreonam.	06
2	Endogenous opioids.	05
3	Methods used in the synthesis of glycosides, nucleosides, & nucleotides.	06
4	Synthetic methodology / approaches to the synthesis of bicyclo [4.3.2], [3.2.1], [2.2.2], & [2.2.1] systems. This should be illustrated by the synthesis of appropriate drug molecules like mecamylamine, atropine, scopolamine etc.	05
5	Preparation of recombinant insulin, γ- interferon, & streptokinase.	06
6	Biosynthesis of cholesterol, estrogen & progesterone from acetate. Biomimetic synthesis of steroids, illustration of Prof. W. S. Johnson's synthesis	05
7	Chiral technology in drug synthesis. Asymmetric synthesis of drugs like propranolol, metoprolol, naproxen, vit. C, using asymmetric epoxidations, asymmetric reductions / hydrogenations, asymmetric enzymatic / bacterial biotransformations. Illustration of 1^{st}, 2^{nd}, 3^{rd}, & 4^{th} generation methods of asymmetric synthesis giving one example each.	11
8	Total synthesis of the following drug molecules: A] Reserpine [Prof. Woodword's synthesis]. B] Progesterone from diosgenin. C] Stanazolol. D] Emetine. E] Quinine. F] Prostaglandins F and E [Profs. Corey, Stork & Sih's methods].	16
	Total	**60**

Reference Books:

- J. H. Block & J. M. Beale, "Wilson & Giswold's Text Book of Organic Medicinal & Pharmaceutical Chemistry", Lippincott Williams & Wilkins, Baltimore, U. S. A
- T. L. Lemke & D. A. Williams, "Foye's Principles of Medicinal Chemistry", Lippincott Williams & Wilkins, Baltimore, U. S. A.
- R. B. Silverman, "The Organic Chemistry of Drug design & Drug Action" Academic Press, Massachusetts, U.S. A.
- Triger and Taylor, "Comprehensive Medicinal Chemistry". All Volumes. Ist Ed. Elsevier Science.
- C. Hansch, Burger. "Medicinal Chemistry". All volumes. Interscience Publishers, Inc., New York-London.
- H. O. House, W. A. Benjamin, "Modern synthetic Reactions". Menlo Park, California, U. S. A.
- J. D. Morrison, "Asymmetric Synthesis" vols. 1 – 5. Academic Press, Orlando,U. S. A.
- R. A. Aitken & S. N. Kilenyi, "Asymmetric Synthesis" Edited by, Blackie Academic & Professional, An imprint of Chapman & Hall, London, U. K.
- R. A. Sheldon, "Chirotechnology, Industrial Synthesis of Optically Active Compounds". Marcel Dekker, Inc., New York, U. S. A.
- R. Porter, & S. Clark, "Enzymes in Organic Synthesis" Pitman, London, U. K.
- G. W. Moody, P. B. Baker, "Bioreactors & Biotransformations". Elsevier, Amsterdam

Class: Third Semester M. Pharm. **Subject Code:** S3-MPC5
Subject: Advanced Pharmaceutical Chemistry – IV (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To enrich the knowledge of a student desirous of studying special topic / s of interest.

Sr. No.	Unit and Contents	Hrs.
1	Structure elucidation studies of cholesterol, beta lactam antibiotics, tetracyclines	10
2	Structure elucidation studies of morphine, reserpine, insulin, anthocyanins, flavonoids.	10
3	Drug receptor interaction, G-protein coupled receptors, ion channel linked receptors. ligand gated ion channels (LGICs). Ligand-receptors theories and receptor isolation.	10
4	General Screening Techniques: High throughput screening and various models for chemotherapeutic drugs.	10
5	Chiral synthons	10
6	Special reagents in organic chemistry.	10
	Total	**60**

Class: Fourth Semester M. Pharm. **Subject Code:** S4-MPH1
Subject: Research Project and Colloquium **Allotted Hrs.:** 36

OBJECTIVE:

- To complete the given research project
- The effectively defense the work before a group of qualified evaluators.

Sr. No.	Unit and Contents	Hrs.
1.	• Completion of research project and submission of dissertation to University. • Defence / viva voce	36

PART - F

M. Pharm. Syllabus

(Pharmaceutical Analysis)

Class: First Semester M. Pharm. **Subject Code:** S1-MPH1
Subject: Research Methodology **Allotted Hrs.:** 4

OBJECTIVE:

- To familiarize students regarding teaching methodology & research projects.
- To teach students preparation of are search projects & different aspects associated with it.
- To acquaint students with experimental data analysis.
- To impresss upon students the importance of ethical issues in the profession & plagiarism.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Learning and instruction** Principles of Instructional design and learning theory, Merrill's five principles and Gagne'scon dition of learning. Active learning, group learning, collaborative learning, problem-based learning, team-based learning, Experiential learningmodel of Kolb.	8
2	**Curriculum development** Asix step approach-Problem identification and general needs assessment, targeted needs assessment, goals and objectives, educational strategies, implementation, evaluation and feedback. Bloom's Taxonomy, three domains of educational objectives.	6
3	**Funding &Scholarship** Agencies funding research in pharmaceutical sciences, Scholarship ,types of scholarships in education.	3
4	**Assessment** Definition and methods, Georges Millers pyramid, assessment, measurement and tests, types of numbers, formative and summative assessment.	3
5	**Basics of Research** Definition, objectives, motivation, types of research and approaches: Descriptive research, conceptual, theoretical, applied and experimental.	3
6	**Formation of Research Problem** A. Research Process: To determine what type of research to be done, plan of research work. B. Selection of research area, prioritization of research. C. Literaturere view: importance and methods, sources, D. Objectives and scope of work, developing research plan and schedule: Scheduling constraints ,steps, problems in scheduling, limitations.	4
7	**Mathematical Modeling and Simulation** Concept of modeling, classification of mathematical models, modeling with ordinary differential equations, difference equations, partial differential equations, graphs, simulation: concept, types (quantitative , experimental, computer, fuzzy theory, statistical) processes of formulation of model based on simulation. Variables and measurement.	5
	SECTION B	
8	**Experimental Modeling** A. Definition of experimental design, examples, single factor experiments B. Blocking and Nuisance factors, guidelines for designing experiments. C. General model of process: Input factors/ variables, Out put parameters/ variables controllable /uncontrollable variables, dependent/ independent variables experimental validity. D. Introduction to Risk assessment, reliability, sustainability, and uncertainty.	4

9	**Analysisof data** A. Types of data: parametric and nonparametric, descriptive and inferential data, B. Collection of data: normal distribution, calculation of co-relation coefficient C. Data processing: analysis, error analysis, meaning, and different methods: analysis of variance, significance of variance, analysis of covariance, multiple regressions, testing linearity / nonlinearity of model, testing adequacy of model. D. Test to be used in data exploration and their choice E. Introduction of software used in data analysis.	8
10	**Research Deliverables** A. Various Forms of Publication: Thesis, paper, research proposal. B. Thesis Writing: Introduction, literature reviewor state-of-the-art, research approach (methodology), results or findings, discussions, conclusions, scope for future work, references, appendices. C. Presentation: Poster, thesis, proposal, and paper.	4
11	**Ethical issues in research** Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/ vaccines /herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good clinical practices norms, Ethical principles related to animal experiments.	10
12	**Plagiarism** Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscriptwriting, documentation, organization of reference material, bibliography, end note.	2
	TOTAL	60

Reference Books:

- B.D.John,A.L.BrownandR.R.Cocking,1999."How People Learn: brain, mind, experience and school".Washington, D C: National Academy Press.
- J.R.Fraenkel,N.E. Wallen,2008."How to Designand Evaluate Researchin Education*",7th Ed*. Bostan McGraw-Hill
- K.E.David,2009. Curriculum Development for Medical Education:*A Six-Step Approach* 2nd Ed. The John Hopkins University Press. ISBN0-8018-9367-4.
- N.Peter,2009."Leadership: Theory and Practice*." 3rd Ed.* Thousand Oaks: Sage Publications.
- G.Bordage,B.Dawson,2003. Experimental study design and grant writing in eight steps and 28 questions *MedicalEducation, 37*(4):376-385.
- B.J.Avolio, F.O.Walumbwa, T.J.Weber, 2009. Leadership: Current theories, research, and future directions. *Annual Review of Psychology, 60*:421-449.
- C.R.Kothari, 2004."Research Methodology".2nd Ed.New Ag eInternational(p) Limited,Publishers.
- D.Montgomary, 2000."Designof Experiments". 5thEd. Wiley Interscience.
- K.P. Willkinsion, L. Bhandarkar, "Formulation of Hypothesis". 3rd ed. Himalaya publishing, Mumbai.
- SchankFr, 2008."Theories of Engineering Experiments".2nd Ed.Tata McGraw Hill.
- D.C.Montgomery, 2009."Introduction to SQC"6th Ed.JohnWilly& sons.
- Cochran& Cocks, 1957.2nd Ed."Experimental Design" New York,JohnWilly& sons.
- J.W.BestandJ.V.Kahn, 2006."Research in Education". 10th Ed.PHI publication.
- S.S.Rao,1983."Optimization Theory & Applications".2nd Ed.WileyEasternLtd.ND.
- P.D.Kulkarni,1986."Independent Study Techniques",TTTI Chandigarh

Class: First Semester M. Pharm. **Subject Code:** S1-MPH2
Subject: Modern Analytical Techniques (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To familiarize students in use of modern techniques of analysis used indifferent areas/ fields of pharmacy.
- To give training in use of the technique & its applications in day to day practice.
- To build on the basics learned at UG level & give latest advances in the area.
- To give more stress on application based knowledge than instrumentation based one.
- To give hands on training on use of as many different ophisticated instruments as possible.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Ultraviolet–Visible spectrometry: Woodward–Fisher rules for calculation of λmax. Derivative spectroscopy. Introduction to Optical rotator Dispersion and Circular Dichroism.	5
2	Fourier Transformed Infrared Spectrometry. Interpretation of Infrared spectrum.	3
3	High Resolution ^{1}H &^{13}C NMR Spectrometry. Theoretical calculation of chemical shifts of various carbon atoms. Technique used for finding types of carbon like attached protontest(APT), distortionless energy polarization transfer (DEPT). Homonuclear & heteronuclear correlation spectrometry. Different 1D & 2D NMR correlation spectrometric techniques such as COSY, NOESY, HETCOR INADE QUATE, SBC, HMQC etc. Use of this technique in determination of absolute configuration.	15
4	Mass spectrometry: use of isotopic abundance in molecular formula calculation. Different ionization techniques like EI,CI, FD, FI, MALDI, API,ESI. Fragmentation of molecule using these techniques. Tandem mass spectrometry and its applications in pharmacy.	8
	SECTION B	
5	HPTLC: Basic instrumentation and its calibration. Analytical methoddevelopment andits validation as per ICH guidelines. Quantification using HPTLC	5
6	HPLC: Instrumentation covering detailed discussion about pumps, injector system, columns and detectors. Calibration of instrument. Analytical method development, validation as per ICH guidelines and trouble shooting. Quantification methods usedin HPLC. Ultra pressure liquidchromatography.	8
7	Thermoanalytical techniques: Differential Scanning Calorimetry (DSC), Thermogravimetry (TG),Thermo mechanical analysis (TMA): Principles instrumentation and applications (including interpretation of data) in pharmacy.	5
8	Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmuneassay, ELISA etc.	6
9	Microscopy: SEM, TEM, cryomicroscopy, AFM, confocalmicroscopy.	5
	TOTAL	60

Reference Books:

- RobertM. Silverstein, FrancisX. Webster, DavidJ. Kiemle,2009."Spectrometric identification of organic compounds".7thEd. John Wiley & Sons
- Pavia D. L.,2009."Introduction to spectroscopy".4th, Belmont CA
- Munson&Munson,"Pharmaceutical analysis: modern methods".,New York: M. Dekker
- KennethA. Connors, 2007."A Text book Of Pharmaceutical Analysis"3rdEd. WileyIndia-wse
- JensThuroCarstensen, 2001."Advanced pharmaceutical solids"Marcel Dekker, NewYork
- JosephB. Lambert, ScottGronert, Herbert F.Shurvell, David Lightner,Robert Graham Cooks, 2010. "Organic structural spectroscopy",2ndEd. Pearson Education, Limited.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH2
Subject: Modern Analytical Techniques (Practical) **Allotted Hrs. :** 8

Sr.No.	Laboratory Experiments
1.	Estimation of two drugs by simultaneous equation method and absorbance ratio method.
2.	Calibration of UV spectrometer for wavelength and stray light.
3.	Analysis of drugs by second derivative UV spectrometry.
4.	Determination of pK value by UV visible spectrometry.
5.	Calculation of λmax values using Woodward Fisher rules.
6.	Study of hydrogen bonding using IR spectrometer.
7.	Interpretation of IR spectra.
8.	Calibration of IR spectrometer using standard polystyrenefilm.
9.	Interpretation of 1D proton NMR spectrum of simple compounds (10-12carbons).
10.	Interpretation of 1D 13C NMR spectrum of simple compounds(10-12carbons).
11.	Calculation of carbon chemical shifts for various carbons such as sp3,sp2,sp carbonetc.
12.	Assignmen tof m/z values to various fragments in the mass spectrum.
13.	Qualitative and quantitative analysis using HPTLC.
14.	Analytical method development for three component mixture using HPTLC.
15.	Calibrationof HPLC instrument for flow rate & wavelength.
16.	Determination of theoretical plate, HETP resolution, tailing factor for two component mixture
17.	Determination of caffeine contentin tea/coffee/other beverages.
18.	Quantitation using different methods such as area normalization, one point,two point method with the help of internal standard.
19.	Determination of melting point & heat of fusion usingDSC.
20.	Determination of glass transition temperature using DSC.
21.	Interpretation of ORD and CD spectrum.

Class:	First Semester M. Pharm.	**Subject Code:**	S1-MPH3
Subject:	Computer and statistics (Theory)	**Allotted Hrs.:**	4

OBJECTIVE:

- To train students in basics of computer hardware.
- To train them on hands on experience in use of different software.
- To teach them applications of computers in different areas of Pharmacy.
- To train the students for applications of various statistical methods available for analysis of data.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	Hardware: Current hardware & their performance, New devices / technology useful in teaching & research like Cameras, Scanner, touch screens, tablets, projection devices etc. Basic idea of computer networking.	03
Unit -2	Operating systems: Common operating systems used in day to day task & instrumentation like Windows, Linux & Unix (only interface and basic commands).	15
Unit -3	Language: Evolution of computer languages. Common languages used in scientific fraternity (no specific language detailing is required).	06
Unit -4	Software: Idea of popular soft ware's like MS Office, structure drawing software's, chemical structure visualizing software's, statistical software's & mathematical software, reference managing software's (only introduction).	05
Unit -5	Web page design: Need, concept and use of HTML.	08
Unit -6	Databases: Meaning, Need and creating table, record creating and maintenance.	05
Unit -7	Internet concept: History, creating internet connection, common problems & solutions.	06
Unit -8	Important Databases of free domain: Patents, Pub med, Pubchem, Science direct, protein database.	05
	SECTION B	
Unit -1	Data & Graphs.	03
Unit -2	Basic statistics.	02
Unit -3	Sampling.	04
Unit -4	Hypothesis testing.	06
Unit -5	Optimization.	06
Unit -6	Designing experiment.	06
Unit -7	Clinical data management.	02
Unit -8	Meta analysis.	03
Unit -9	Statistical Quality control.	05
Unit-10	Introduction to common statistical software.	03
	Total	**60**

Reference books :

- W.E. Fassett, 1986. "Computer Applications in Pharmacy", Lea & Febiger Publisher.
- C.N. Madu, 2003. "Statistics as easy as one, two, three with Microsoft Excel for Windows", 1st Ed. Chi Publishers Inc.
- A.N. Armstrong, 2006. "Pharmaceutical experimental design and interpretation", CRC/Taylor & Francis.
- G.A. Lewis, D. Mathieu, R.T. Phan, 1999. "Pharmaceutical experimental design", CRC Press.
- W.G. Cochran, W.G. Cochran, G.M. Cox, 1992. "Experimental designs". Wiley.
- http://pages.stern.nyu.edu/~jsimonof/classes/1305/pdf/excelreg.pdf
- www.Pubmed.com
- www.Pubchem.com
- www.mdl.com
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- www.uspto.gov
- www.esp.gov
- Lambert M Surhone, Miriam T Timpledon, Susan F Marseken, 2010. "Rasmol", VDM Verlag Dr. Mueller AG & Co. Kg.
- http://www.vlifesciences.com

Class: First Semester M. Pharm. **Subject Code:** S1-MPH3
Subject: Computer and statistics (Practical) **Allotted Hrs. :** 4

1	To understand computer hardware & their integration (computer, printer, scanner, display device, Bluetooth & IR devices).
2	To understand operating system / s.
3	To know theevolution of computer languages.
4	To design simple web page using HTML editor (Word, FrontPage etc.).
5	To make simple database using MS Access (i.e. Plant database, reference database etc.).
6	To create, editing & formatting worksheet using excel.
7	To make use of formula in excel.
8	To write macros in spreadsheet.
9	To create graphs for representing data.
10	To perform statistical operations on the obtained data.
11	To make decisions using formula in spreadsheet.
12	To develop ability to create master document in MS word.
13	To make PowerPoint presentations with hyper linking & animation effects.
14	To learn & develop expertise in use of structure drawing software like ISIS, Chem sketch etc.
15	To learn use of structure visualization software like Rasmol.
16	To visualize protein molecules using Protein explorer.
17	To learn searching internet based databases like Pub med, US Patents.
18	To develop technique for calculating molecular properties on line.
19	To perform simple optimization exercises using MS Excel / any statistics software.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH4
Subject: Nanotechnology & Biotechnology (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give basics of nanotechnology.
- To impart advanced level training in bio & nanotechnology with emphasis on their use in Pharmacy.
- To make use of this advanced level knowledge in drug discovery.
- To impart training on carrying out the sophisticated experiments in these areas.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	**BIONANOTECHNOLOGY:** History, opportunities and challenges of bionanotechnology, growth potential of bionanotechnology, significance of nanosize in biotechnology and medicine.	04
Unit -2	**NANO-DRUG DELIVERY:** Conventional delivery of biotechnologicals and its limitations, biological barriers in delivery of therapeutics, importance of nano-size in site-selective delivery. Targeted delivery of biotechnological using nanoconstructures, application of nanocarriers in delivery of biotechnologicals, nano-drug delivery chip.	10
Unit -3	**BIONANOCARRIERS:** Design and fabrications of nanocapsules, nanoliposomes, nanoparticles, nanoemulsion, nanopore technology, nano-self assembling systems, bionanoarrays, dendrimers, carbon nanotubes, nanosomes and polymersomes, inorganic nanoparticles (gold-gold colloids, gold nanofilm, gold nanorods, titanium and zinc oxide), structured DNA nanotechnology.	11
Unit -4	**NANOMEDICINE, NANOBIOLOGY AND NANOBIOTECHNOLOGY:** Synthesis and assembling of nanoparticles/nanostructures using bio-derived templates, proteins and nanoparticles, covalent and non-covalent conjugates, cantilevers array sensors for bioanalysis and diagnostics, nanowire and nanotube biomolecular sensors for in-vitro diagnosis of cancer and other diseases. Biologically inspired hybrid nanodevices, nanotube membranes for biotechnology, shelf-assembling of short peptides for nanotechnologicals applications.	10
	SECTION B	
Unit -5	**BIONANOIMAGING:** Quantum dots-luminescent semiconductor QD in cell and tissue imaging, fluoroimmunoassay using QD. Ultrasound contrast agents, magnetic nanoparticles, nanoparticles in molecular imaging, nanoforce and imaging-AFM, molecules, cells, materials and systems design based on nanobiotechnology for use in bioanalytical technology.	08
Unit -6	**DRUG DISCOVERY:** Drug screening, technoglobalism and drug development, biodiagnostics.	02
Unit -7	chemogenomics, computational chemistry, new pharmaceuticals from marine sources, cell based therapies, encapsulated cells for disease treatment.	03
Unit -8	**INSTRUMENTATION AND PRINCIPLES:** Electrophoresis techniques, laser confocal microscopy, digital image analysis, biosensors in diagnostics, enzyme purification and assay techniques. Techniques in cytogenetics: DNA sequencing, DNA microarray.Spectral analysis techniques: Introduction, estimation of proteins, DNA and RNA.	08
Unit -9	**SAFETY CONCERN OF BIONANOTECHNOLICALS:** Inhalation, contact/dermal delivery, environmental impact, explosion hazards.	04
	Total	**60**

Reference books :

- E.S. Papazoglou and A. Parthasarathy, "Bionanotechnology". 1st Ed. Morgan and Claypool.
- N.H. Malsch. 2005. "Biomedical nanotechnology" CRC Press.
- D.S. Goodsell, 2004. "Bionanotechnology: lessons from nature" Wiley-Liss Publication.
- T. Vo-Dinh, "Nanotechnology in biology and medicine: methods, devices, and applications" CRC Press.
- V. Labhasetwar, D.L. Leslie-Pelecky, 2007. "Biomedical applications of nanotechnology".Wiley-Interscience: Hoboken.
- S.P. Vyas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and controlled drug delivery" CBS Publishers and Distributors.

- **It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.**

Class: First Semester M. Pharm. **Subject Code:** S1-MPH4

Subject: Nanotechnology & Biotechnology (Practical) **Allotted Hrs. :** 8

Suggested List of Laboratory Experiments :

- Development of nanoparticles by solvent-evaporation method.
- Design of nanospheres by emulsification method.
- Preparation of polymeric nanocapsules by solvent-diffusion method.
- Evaluation of nanoparticles for particle size, zeta potential, drug entrapment efficiency, stability and other parameters.
- Development of solid lipid nano particles using various lipids.
- Preparation of nano-liposomes by solvent dispersion/film hydration method.
- Development and evaluation of nano-niosomes.
- Development and evaluation of nano-suspensions.
- Preparation of nanoemulsions by using ternaray phase diagrams.
- Incorporation of nanoemulsions in topical gels.
- Evaluation of dermal retention, penetration, skin irritation and toxicity potential of nano topical formulations.
- Development of nanosponges based on cyclodextrin complexes.
- Assessment of solubility enhancement by nano formulations.
- Pegylation of nanoparticles.
- Synthesis of Al_2O_3 nanoparticles using soi.gel method.
- Synthesis of Fe_2O_3 nanoparticles by chemical method.
- Synthesis of nanoparticles using biological process (2-3 methods).
- Functionalization of nanoparticles for biological application- (4-5 methods).
- Detection of nanoparticles in colloidal solutions using UV-Visible Absorption technique size determination of nanoparticles using laser beam.
- Analysis of ANM, SEM AND TEM pictures.
- Polyacrylamide gel electrophoresis: native gel.
- Isolation and separation of secondary metabolites.
- 2-D Gel electrophoresis of proteins and isoelectrofocusing.
- Synthesis of nanometer scale particles of colloidal semiconductors such as TiO_2, CdS, ZnO, SnO_2, Cu_2S, CuCNS, Cu_2O, $BaTiO_3$, $SrTiO_3$ by wet chemical methods, hydrothermal methods, and pyrolytic or high temperature methods.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPH1
Subject: Research Project **Allotted Hrs.:** 8

OBJECTIVE:

- To give exposure on how to do literature survey for the project work
- To develop technical writing skill in the form of a research report
- To develop report presentation ability, orally
- To develop question answer capability confidently.

Sr. No.	Unit and Contents	Hrs.
1	NIL	

Class: Second Semester M. Pharm. **Subject Code:** S2-MPA2
Subject: Chromatographic Methods of Analysis (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To train students about various Chromatographic methods & the significance of such methods.
- To impart knowledge about official / non-official methods of evaluation for a wide range of pharmaceutical dosage forms.
- To give wide exposure to students in the area of New Chromatographic techniques
- To give additional knowledge to students based on their choice of topics.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Theory of Chromatography** General Separation Process, Theory: Basic Chromatographic Descriptors: Retention factor, Column dead time, Selectivity, Efficiency, tailing factor, Van Deemeter equation, resolution, Fundamental resolution equation (N,α, k etc.), Signal to noise ratio. Retention, Retention Mechanism, General Column Mass Balance, Partitioning Model, Adsorption Model, Total and Excess Adsorption, Mass Balance in Adsorption Model, Adsorption of the Eluent Components, Void Volume Considerations, Thermodynamic Relationships, Effect of the Eluent Composition, Adsorption-Partitioning Retention Mechanism, Secondary Equilibria, Inclusion of Secondary Equilibria in the Mass Balance, Salt Effect, Gradient Elution Principles, Types of Analyte Interactions with the Stationary Phase	10
2	**HPLC and UPLC:** Principle, instrumentation, structural types of column packings, optimization of column performance, separation columns, methods of chiral separations, derivatization, RP HPLC, its advantages in bio pharmaceutical analysis, detectors used in HPLC and applications. Principles of UPLC, modifications in UPLC compared to HPLC, advantages and applications.	10
3	**HPTLC:** Basic principle, instrumentation, advantages when compared to TLC, method of development and applications in pharmaceutical and phytochemical analysis. **Electrophoresis:** Moving boundary electrophoresis, zone electrophoresis, continuous electrophoresis (preparative) and applications.	10
	SECTION B	
4	**Supercritical fluid chromatography:** Introduction, History of SFC, Basic Principles, Instrumentation, Applications with emphasis on chiral separations, Polymer separations, high throughput screening of pharmaceuticals and herbal formulations.	06

5	**Flash column chromatography:** Theory, instrumentation and applications in natural products	07
6	**Hyphenated methods :** GC-MS: Principle, instrumentation, separators used, selected ion monitoring / mass fragmentography and applications. LCMS: Basic principle, instrumentation, ion formation and types, fragmentation processes and patterns, MS/MS detection, ionization sources, detectors employed and applications	07
7	**Chromatographic Method Validation:** General principles of analytical method validation, Validation of HPLC Instrument	10
	TOTAL	**60**

Recommended books:

1. HPLC for pharmaceutical scientists by Yuri Kazakevich and Rosario Lobrutto. Willey 2007.
2. Practical HPLC method development 2nd edition , Llyod R.synder (google.com)
3. Analytical Method Development and Validation, Michael Swartz, Swartz Swartz, Michael Swartz, CRC press.1997
4. Modern HPLC for practicing scientists, Michael W.Dong (google.com)
5. Pharmaceutical process validation, NashRA and Watcher AH, CBS publishers and Distributors, Newdelhi
6. Modern Pharmaceutical analysis, Volume1-4, Satish Ahuja, CBS publishers and Distributors, Newdelhi
7. US FDA, Guidance for industry: bioanalytical method validation 2001.
8. Remington's Pharmaceutical Sciences, L.Wiliams & Wilkins, 21st Ed. (Vol. I & II)
9. Theory & Practice of Industrial Pharmacy by Lachman.
10. Pharmaceutics of Solids and Solid dosage forms by J. Cartensen.
11. Advances in Pharm. Sciences by Beckett.
12. Pharmaceutical Technology by Parrot.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPA2

Subject: Chromatographic Methods of Analysis (Practical) **Allotted Hrs. :** 8

- Assay of Ibuprofen Tablet I.P., Tolbutamide Tablet I.P., Calcium Lactate and
- Ferrous Fumerate I.P.
- Determination of Water in Sorbitol, Sodium Citrate & Ampicillin.
- Determination of Total Chloride in Thiamine Chloride Hydrochloride.
- Quality control Tests for Tablets, Capsules, Injections, Ointments and Suppositories.
- Detection and Determination of Preservatives, Antioxidants and Colouring materials in Pharmaceuticals.
- Determination of related substances in Albendazole, Amiloride, Metronidazole,
- Betamethazone, Carbamazepine, Diclofenac, Ephedrine, Ibuprofen, Paracetamol,
- Eucalyptus oil, Phenylbarbitone and Sulphafurazone as per I.P.
- Quality Control tests for some cosmetics. (e.g.,) Determination of SLS in
- Shampoo.
- Estimation of drugs by UV spectroscopy (minimum 4 experiments)
- Interpretation of spectras by IR, NMR and MASS
- Calibration of HPLC instrument - determination of flow rate & Dissolution Apparatus

Class: Second Semester M. Pharm. **Subject Code:** S2-MPA3
Subject: Analytical Method Development and validation (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give introduction to the concept of Method development and validation.
- To train them in different aspects of Method development and validation. Significance of each activity.
- To acquaint the students about calibration of instruments & special dosage forms.
- To train students in carrying out some selected experiments in these areas.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Analytical method development**: a. Introduction, b. Parameters to optimize a new method for spectroscopy and chromatography c. Quantification and calibration of various analytical instruments for drug analysis and maintenance of instruments.	05
2	**Validation:** a. Introduction, history, definition, b. Types of validation, prospective validation, retrospective validation, concurrent validation, revalidation, c. Validation Master Plan d. Protocol for process e. Vendor validation and audit, f. f. Sample testing and trade analysis.	05
3	**Calibration of instruments:** a. Analytical balance calibration. b. Calibration of weight box. c. Calibration of UV-spectrophotometer. d. Calibration of IR spectrophotometer. e. Calibration of HPLC system. f. Calibration of Gas Chromatography instrument. g. Performance check of HPLC/GC column. h. Out of Calibration.	08
4	**Analytical Method Validation:** a. Recommendation of ICH guideline- Definition of accuracy, precision, linearity, LOD, LOQ, range, robustness, ruggedness, specificity, system suitability test. b. b. USP requirement of analytical validation- different category of assays using paper and thin layer chromatography, HPLC, LC-MS, GLC, GC-MS, HPTLC, Capillary electrophoresis for pharmaceutical dosage forms and bulk drugs.	07
5	**Validations activities:** Protocol preparations, protocol executions, deviations and change controls, summary and certification, Revalidations.	05
	SECTION B	
6	**Development of stability indicating methods and validation:** Introduction, force degradation studies-experimental approach to force degradation studies, stability indicating HPLC and UV-Vis method development-method for, preliminary requirements, method development approach, method optimization and validation.	08
7	**Dissolution method development and validation:** An industry perspective-Physical and chemical properties of API, dissolution apparatus selection, dissolution medium selection, key operating parameters, method optimization and validation	05

8	**Bioanalytical method validation:** Introduction and background , Method development: chemical assay , microbiological and ligand-binding assays, Documentation	08
9	**Validation methods of** a. Equipment b. Processing Techniques including mixing, granulation, drying, compression, filtration and filling c. Methods and equipment for dry heat sterilization, autoclaving and membrane filtration d. Air handling equipment and facilities in zones e. Water supply systems, deionised and distilled water and water for f. injection	09
	TOTAL	60

Reference books :

1. Skoog D. A., Holler F. J., Timothy A. N Principles of Instrumental Analysis - 5th edition, Eastern press, Bangalore, 1998.
2. Vogel's, Jeffery, Basset, et. al Text book of quantitative chemical analysis - 5th edition, ELDS Publications, 1991.
3. Willards and dean Instrumental methods of analysis –, 7th edition, CBS publishers New Delhi.
4. Beckett and Stenlake, Practical Pharmaceutical Chemistry – Vol. II, 4th edition, CBS Publishers, New Delhi, 1997.
5. Higuchi, Brochmman and Hassen Pharmacutical Analysis - 2nd Edition, Wiley – Interscience Publications, 1961.
6. Sethi P. D. Quantitative Analysis of Drugs in Pharmaceutical formulation - 3rd Edition, CBS Publishers, New Delhi, 1997.
7. Munson J. W. Pharmaceutical Analysis - Modern methods – Part B – Vol. 11, Marcel Dekker Series
8. Snyder and Kirkland Practical HPLC method development – 2nd edition, John Wiley & Sons.
9. Indian Pharmacopoeia,Vol I, II & III 2007 Controller of Publications, Govt. of India, New Delhi.
10. Pavia D. L., Lampman G. M. and Kriz G. S. Introduction to spectroscopy - A guide for students of Organic chemistry, Harcourt college publishers. (Latest edition).
11. Connors K. A. Text book of Pharmaceutical Analysis, 3rd Edition John wiley & sons, New York. 1975.
12. The chemical analysis of foods – David Pearson, Seventh edition, Churchill Livingstone, Edinburgh London, 1976
13. Nielsen S. Introduction to the Chemical analysis of foods – Jones & Bartlett publishers, Boston London, 1994.
14. Analysis of Food constituents – Multon, Wiley VCH.
15. Wilkinson, Moore Harry's Cosmeticology – 7th edition, George Godwin, 1982.

Class:	Second Semester M. Pharm.	**Subject Code:**	S2-MPA3
Subject:	Analytical Method Development and validation (Practical)	**Allotted Hrs. :**	8

Suggested Laboratory Experiments.

- Estimation of drugs official in IP by HPLC(Minimum 4 experiments)
- Assay of drugs in the sample using HPLC (minimum 4 experiments).
- Assay of Paracetamol in the sample using HPTLC
- Development of analytical method, optimization and validation using, HPLC, LC-MS, GLC, GC-MS, HPTLC, Capillary electrophoresis for pharmaceutical dosage forms and bulk drugs.
- Validation and calibration of various instruments used for drug analysis such as HPLC, HPTLC and GC.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPA4
Subject: Advanced Analytical Techniques (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To train students about various instrumental evaluation methods & the significance of such tests.
- To impart knowledge about official / non-official methods of evaluation for a wide range of drugs.
- To give wide exposure to students in the department of Quality Control.
- To give them training in carrying out some of these techniques in the laboratory.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	An advanced study of the principles and procedures involved in the assay of following methods with special emphasize of the official drugs in IP: a) Non aqueous titration b) Complexometric titration c) Redox titration d) Diazotization e) Potentiometric and Conductometric titrations.	05
2	An advanced study of the principles and procedures involved in the instrumental methods and applications of Flame photometry, Fluorimetry, Nephelo-turbidimetry, Polarimetry and Refractometry.	05
3	Theory, instrumentation and application of X – Ray diffraction methods, generation of x – rays, x-ray diffraction, Bragg's law, x- ray powder diffraction, interpretation of diffraction patterns and applications. Instrumentation, X-Ray absorption, X-Ray florescence and X-Ray powder diffractometry and its applications to pharmaceutical formulation development.	07
4	A detailed study of the principles, instrumentation and applications of Raman Spectroscopy	05
5	Impurity profiling: Forced degradation studies (Methodology), and Impurity profiling -Definition and sources of impurities: (Impurities associated in with APIs-Organic impurities (Process and Drug-related), Inorganic impurities, Residual solvents; Impurities related to formulation; Formation of impurities on aging). Guidance for Industry - Impurities in New Drug Substances Q3A; Guidance for Industry Impurities in New Drug Products.Q3B (R2).	10
	SECTION B	
6	WHO guide lines of the standardization of Herbal raw materials and finished products. Morphological, microscopical, cytomorphological and chemical examinations of raw materials and finished products.	06
7	Standardization of food and cosmetic products. Different types of additives used. Physicochemical characterization in whole form, separation and identification of active principles, excipients and their estimation by different techniques. Analysis of fermentation products like wine, spirits, beer and Vinegar.	07
8	Test of packaging materials, cartons, aluminum foils, strip packing, blister packing, ampoules, vials, etc.	6
9	General methods of analysis for oils and fats such as Iodine value, Saponification value, Acid value, Rancidity and special tests for individual oils like Arachis oil, sesame oil, Sunflower oil, cotton seed oil, fish oil and fat soluble vitamins	9
	TOTAL	**60**

Reference books :

1. Satinder Ahuja and Stehen Scypinski, Handbook of Modern Pharmaceutical Analysis, Elsevier publication, 2005.
2. Wilson and Wilsons, Comprehensive analytical chemistry, Elsevier publications, Volume 47, 2006.
3. Indian Pharmacopoeia, 2007 Controller of publications, Govt. of India, New Delhi.
4. Beckett & Stanlake, practical Pharmaceutical Chemistry Part-I & II, 4th Ed.
5. Bochmman & Hassan, Pharmaceutical Analysis, edited by: Higuchi.
6. D C Garrott, Quantitative Analysis of drugs, CBS Publisher, New Delhi.
7. R V Smith, J T Stewart, Textbook of Bio Pharmaceutical Analysis.
8. P D Sethi Quantitative analysis of drugs in pharmaceutical formulations
9. Howard C. Ansel, Michelle J. Stoklosa, Lippincott Williams & Willkins: Pharmaceutical Calculations.
10. Antimicrobial in food- Alfred larry branen. P Michael division publishing corporation
11. Method of protein analysis by istran kerese.
12. Cosmetic analysis- selective methods and techniques by P. Borc
13. Henry,s cosmeticology- Martin M. Rieger.
14. Cosmaceuticals Drug vs Cosmetics
15. Herbal cosmetics. Beuty through Herbs- Dr. Urjita jain.
16. Morris B. Jacobs. The chemical analysis of foods and food products.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPH1
Subject: Drug Regulatory aspects and IPR (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To impart information on various drug regulatory aspects involved in the profession.
- To teach the import / export related regulations with respect to some countries
- To make the students understand the importance and implication of IPR and related matters.
- To train the students in GMP and the latest developments there.

Sr. No.	Unit and Contents	Hrs.
Unit-1	**DRUG REGULATORY ASPESTS**	**40**
a)	Drug Regulatory Aspects (India) – 1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA) 2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective) 3. Special emphasis – Schedule M and Y 4. New Drugs – Importation, Registration, Development, Clinical Trials, BE NOC & B.E. studies 5. Various licenses – Test lic., Import lic. for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	10
b)	Good Manufacturing Practices (GMP) – 1. Indian GMP certification, WHO GMP certification 2. ICH guidelines for stability testing and other relevant ones (Q1 – Q10) 3. Export permissions and manufacturing for semi-regulated countries 4. Understanding of the plant lay-outs with special emphasis on the environment & safety. (HVAC, Water systems, Stores management, Effluent etc.) 5. Quality Assurance and Quality Control – Basic understanding for in-built quality.	12
c)	Drug Regulatory Aspects (International & highly regulated markets) – 1. US Requirements – (for Generic Drugs especially formulations) 2. CDER, INDA, NDA, ANDA's (types), CTD Formats of dossiers, E-submission, US DMF (various types), IIG Limits, Orphan Drugs, Vanilla ANDA's, Exhibit/Pivotal batches, Validation batches, Various Guidance issued by CDER, OGD, Orange Book (and patents), RLD (Reference listed drug) for BE studies and the norms for US submission, Bioequivalence and dissolution recommendations, Packaging, Stability studies and the Product Information Leaflet, US FDA Inspection (audits), Pre-approval Inspections and approvals 3. European Union Requirements – 4. All the aspects for European Registration of formulations for generic drugs sale in the European markets under EU. EMEA guidelines on various aspects as above (C 1) 5. A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries. 6. GMP audits, role of Quality Assurance, product approvals and supplies.	18
Unit-2	**INTELLECTUAL PROPERTY RIGHTS (IPR)**	**20**
a)	**Introduction to IPR & Patents** – Development of IP law in India, IPR regime, Introduction to IP laws in India, Role of IP in pharma industry growth.	
b)	**Patenting in India** – Introduction, Patent legislation, Indian Patents Act 1970 and amendments, Procedure for patent application, Grant and opposition proceedings, Patent licensing, Patent infringement proceedings, IPAB – role and functions (IP Appellate Board), Indian IP Case laws	
c)	**American & European patent system** – Requirements for patenting, utility, novelty Non-obviousness, Patent specification & claims, Patent infringement and Doctrine of Equivalents, Federal circuit and Patent system in Europe	
d)	**International treaties and conventions on IPR** - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO	
e)	**Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003**	
f)	**Introduction to** Geographical indication / Trademark/ copyright: Filing procedures	
g)	**Patent search, Patent analysis & Patent drafting**.	
h)	**Allied Patents Related Issues**: Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage	
	Total	60

Reference books :

1. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).
2. CDER Publications and Guidance
3. EMEA Publications and Guidance
4. Orange Book, ICH guidelines, Indian Patents Act
5. Country specific Regulatory Guidelines (available from internet)
6. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
7. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.
8. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
9. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.
10. Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPA2
Subject: Research work Seminar **Allotted Hrs. :** 8

OBJECTIVE:

- To effectively present the research work carried out by the student.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPA3
Subject: Research Project **Allotted Hrs. :** 16

OBJECTIVE:

- To manage the research work in time bound manner.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPA4

Subject: Quality Control and Quality Assurance (Theory) **Allotted Hrs. :** 4

OBJECTIVE:

- To introduce & build on the concept of quality in Pharmacy profession.
- To expand the concept of quality at industrial level, including plant design / layout, environmental controls, etc.
- To teach this concept with respect to manufacturing activities & related areas, management of all store requirement & related matters.
- To give updated knowledge in these & related areas.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Concept of Total Quality Management, Quality control and quality assurance, Four M's responsible for quality variation.	08
2	Quality control laboratory: sampling plan, distribution and distribution records – handling of returned goods, recovered materials and reprocessing.	05
3	US FDA guidelines for GLP in non clinical testing laboratories	05
4	Standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfection, sterilization, membrane filtration etc.	08
	SECTION B	
5	Packaging and labelling controls, line clearance, reconciliation of labels; cartons and other packaging material; types and tests assuring quality of glass. Types of plastics used, permeation, leaching, sorption, chemical reactions, biological tests, modification of plastics by drugs; Different types of closures and closure liners; film wrapper; Blister packs, Bubble packs, shrink handling; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; Quality control of packaging material and filling equipment	10
6	Concept of GLP and GCP, Quality control laboratory responsibilities, good laboratory practices, routine controls, instruments and standard test procedures, non-clinical testing, controls on animal house, site, Data generation and storage	08
7	Organization and personnel, responsibilities, training hygiene - Premises: Location, design, plan layout, construction, maintenance and sanitations, environmental control, sterile areas, control of contamination.	05
8	Audits: Principle of Quality audit, Plant level, Department wise documentation.	05
9	Stability testing of formulation and shelf life prediction. ICH guidelines for stability studies of drugs.	06
	Total	**60**

Reference books :

1. Quality Assurance of Pharmaceuticals, Vol. 2, Updated Edition, World Health Organization, Geneva.
2. M.A. Potdar, Pharmaceutical Quality Assurance, Nirali Prakashan, Pune.
3. S.H. Willing, GMP for Pharmaceuticals, Latest Edition, Marcel Dekker.
4. A guide to total quality management- Kaushik Maitra and sedhan K. Ghosh.
5. How to practice GMPs – P.P. Sharma.
6. Regulatory guidelines related to GMP by
7. Quality Assurance Guide by Organisation of Pharmaceutical products of India.
8. Good Laboratory Practice Regulations, 2nd Edition, Sandy Weinberg, Vo. 69,Decker Series.
9. Quality Assurance of Pharmaceuticals – A compendium of guidelines and related materials – Vol. I – WHO Publications.

- Australian code of GMP for medicinal products, 16th Aug 2002
- 21 Code of Federal Regulation, Parts 210, 211&58 (USFDA guidelines)
- EU, MHRA, UK Guidelines on GMP
- GMP Guidelines by Medicines Control Council of South Africa.
- Schedule M of Drug & Cosmetics Act

Class: Third Semester M. Pharm. **Subject Code:** S3-MPA5
Subject: Bioanalytical Techniques (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To entrich the knowledge of a student desirous of studing special topic of interest

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Estimation of Drugs in Biological Fluids: Collection, handling of Whole blood, urine, CSF samples and their preparation for clinical studies and Therapeutic drug monitoring, such as immunological and microbiological procedures, and to other biological matrices, such as tissue and skin samples	06
2	Development of analytical methods for drugs in biological samples: Compartment kinetics and its effects on selection of in vitro methods for analysis, One compartment, two compartment models, Model independent statistics, Elimination characteristics of drugs clearance, half life, Volume of distribution, plasma drug concentration, zero and first order kinetics, Monoexponentional, biexponential, and triexponential dispositions. Calculating in vitro dissolution specifications based on pharmacokinetic and preliminary clinical data. Guideline on bioanalytical method validation.	08
3	Estimation of Pharmacokinetic data: Assessment of AUC , estimation of elimination half-life from serum and urinary data, estimation of absorption kinetics from plasma concentration data , mean residual Time, amount of drug in body on accumulation to plateau, distribution bound to plasma protein ,blood to plasma concentration ratio	10
4	Introduction Clinical researc1h: Definition of clinical research, Guidelines for undertaking clinical trails, Data to be submitted for clinical trails. Structure, content & format for clinical study report Approval for clinical trials. Responsibility of sponsor, investigator & ethical committee	06
	SECTION B	
5	Analytical solutions for clinical trials and Bioequivalence: Methods for establishment of bioavailability /bioequivalence, Dissolution testing, apparatus and method selection, Establishing IVIVC, Pharmacovigilance. Bioavailability, Bioequivalence and Drug Product Selection: Relative and Absolute Bioavailability. Factors Influencing Bioavailability, Methods of Assessing Bioavailability, Study Design, In-vitro Dissolution and Bioavailability, In-vitro / in-vivo correlation studies. Bioequivalence-Bioequivalence Regulations, Study Design , Assessment of bioequivalence, Controversies and Concerns in Bioequivalence. Generic Drugs and Product Selection, The Orange Book, Therapeutic equivalence.	10
6	Therapeutic Drug Monitoring: Introduction, Necessity, Organization criteria, Validatation of TDM , Information requirement of TDM, Effectiveness of TDM	10
7	Analytical Aspects of TDM: Analytical aspects of TDM. Chromatographic techniques, Immunoassys in TDM, Enzyme linked, Enzyme multiplied assays, Enzyme channelling immunochromatographic assays, Polarization immunoassay. TDM of drugs with narrow therapeutic margin of safety, TDM Of some selected Drugs like Amino glycosides, carbamazapine, cyclosporine, and methotrexate	10
	TOTAL	**60**

Reference books :

- Fundamentals Of Bioanalytical Techniques And Instrumentation, Author Ghosal & Srivastava, Publisher:PHI Learning Pvt. Ltd., 2009
- Modern analytical techniques in the pharmaceutical- and bioanalysis Dr. Istvan Bak
- RV Smith, JT Stewart, Textbook of Biopharmaceutical Analysis.
- Pulok K Mukherjee: Quality Control of Herbal Drugs, Business Horizons Pharmaceutical Publishers, New Delhi.
- Burn, Finiey and Godwin : Biological Standardisation, 2nd Edition, Oxford University Press, London.

Class: Fourth Semester M. Pharm. **Subject Code:** S4-MPH1
Subject: Research Project and Colloquium **Allotted Hrs.:** 36

OBJECTIVE:

- To complete the given research project
- The effectively defense the work before a group of qualified evaluators.

Sr. No.	Unit and Contents	Hrs.
1.	• Completion of research project and submission of dissertation to University. • Defence / viva voce	36

PART - G

M. Pharm. Syllabus

(Pharmacology)

Class: First Semester M. Pharm. **Subject Code:** S1-MPH1
Subject: Research Methodology **Allotted Hrs.:** 4

OBJECTIVE:

- To familiarize students regarding teaching methodology & research projects.
- To teach students preparation of are search projects & different aspects associated with it.
- To acquaint students with experimental data analysis.
- To impresss upon students the importance of ethical issues in the profession & plagiarism.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Learning and instruction** Principles of Instructional design and learning theory, Merrill's five principles and Gagne'scon dition of learning. Active learning, group learning, collaborative learning, problem-based learning, team-based learning, Experiential learningmodel of Kolb.	8
2	**Curriculum development** Asix step approach-Problem identification and general needs assessment, targeted needs assessment, goals and objectives, educational strategies, implementation, evaluation and feedback. Bloom's Taxonomy, three domains of educational objectives.	6
3	**Funding &Scholarship** Agencies funding research in pharmaceutical sciences, Scholarship ,types of scholarships in education.	3
4	**Assessment** Definition and methods, Georges Millers pyramid, assessment, measurement and tests, types of numbers, formative and summative assessment.	3
5	**Basicsof Research** Definition, objectives, motivation, types of research and approaches: Descriptive research, conceptual, theoretical, applied and experimental.	3
6	**Formation of Research Problem** A. Research Process: To determine what type of research to be done, plan of research work. B. Selection of research area, prioritization of research. C. Literaturere view: importance and methods, sources, D. Objectives and scope of work, developing research plan and schedule: Scheduling constraints ,steps, problems in scheduling, limitations.	4
7	**Mathematical Modeling and Simulation** Concept of modeling, classification of mathematical models, modeling with ordinary differential equations, difference equations, partial differential equations, graphs, simulation: concept, types (quantitative , experimental, computer, fuzzy theory, statistical) processes of formulation of model based on simulation. Variables and measurement.	5
	SECTION B	
8	**Experimental Modeling** A. Definition of experimental design, examples, single factor experiments B. Blocking and Nuisance factors, guidelines for designing experiments. C. General model of process: Input factors/ variables, Out put parameters/ variables controllable /uncontrollable variables, dependent/ independent variables experimental validity. D. Introduction to Risk assessment, reliability, sustainability, and uncertainty.	4

9	**Analysisof data** A. Types of data: parametric and nonparametric, descriptive and inferential data, B. Collection of data: normal distribution, calculation of co-relation coefficient C. Data processing: analysis, error analysis, meaning, and different methods: analysis of variance, significance of variance, analysis of covariance, multiple regressions, testing linearity / nonlinearity of model, testing adequacy of model. D. Test to be used in data exploration and their choice E. Introduction of software used in data analysis.	8
10	**Research Deliverables** A. Various Forms of Publication: Thesis, paper, research proposal. B. Thesis Writing: Introduction, literature reviewor state-of-the-art, research approach (methodology), results or findings, discussions, conclusions, scope for future work, references, appendices. C. Presentation: Poster, thesis, proposal, and paper.	4
11	**Ethical issues in research** Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/ vaccines /herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good clinical practices norms, Ethical principles related to animal experiments.	10
12	**Plagiarism** Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscriptwriting, documentation, organization of reference material, bibliography, end note.	2
	TOTAL	60

Reference Books:

- B.D.John,A.L.BrownandR.R.Cocking,1999."How People Learn: brain, mind, experience and school".Washington, D C: National Academy Press.
- J.R.Fraenkel,N.E. Wallen,2008."How to Designand Evaluate Researchin Education*",7th Ed*. Bostan McGraw-Hill
- K.E.David,2009. Curriculum Development for Medical Education:*A Six-Step Approach* 2nd Ed. The John Hopkins University Press. ISBN0-8018-9367-4.
- N.Peter,2009."Leadership: Theory and Practice*." 3rd Ed.* Thousand Oaks: Sage Publications.
- G.Bordage,B.Dawson,2003. Experimental study design and grant writing in eight steps and 28 questions *MedicalEducation, 37*(4):376-385.
- B.J.Avolio, F.O.Walumbwa, T.J.Weber, 2009. Leadership: Current theories, research, and future directions. *Annual Review of Psychology, 60*:421-449.
- C.R.Kothari, 2004."Research Methodology".2nd Ed.New Ag eInternational(p) Limited,Publishers.
- D.Montgomary, 2000."Designof Experiments". 5thEd. Wiley Interscience.
- K.P. Willkinsion, L. Bhandarkar, "Formulation of Hypothesis". 3rd ed. Himalaya publishing, Mumbai.
- SchankFr, 2008."Theories of Engineering Experiments".2nd Ed.Tata McGraw Hill.
- D.C.Montgomery, 2009."Introduction to SQC"6th Ed.JohnWilly& sons.
- Cochran& Cocks, 1957.2nd Ed."Experimental Design" New York,JohnWilly& sons.
- J.W.BestandJ.V.Kahn, 2006."Research in Education". 10th Ed.PHI publication.
- S.S.Rao,1983."Optimization Theory & Applications".2nd Ed.WileyEasternLtd.ND.
- P.D.Kulkarni,1986."Independent Study Techniques",TTTI Chandigarh

Class: First Semester M. Pharm. **Subject Code:** S1-MPH2
Subject: Modern Analytical Techniques (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To familiarize students in use of modern techniques of analysis used indifferent areas/ fields of pharmacy.
- To give training in use of the technique & its applications in day to day practice.
- To build on the basics learned at UG level & give latest advances in the area.
- To give more stress on application based knowledge than instrumentation based one.
- To give hands on training on use of as many different ophisticated instruments as possible.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Ultraviolet–Visible spectrometry: Woodward–Fisher rules for calculation of λmax. Derivative spectroscopy. Introduction to Optical rotator Dispersion and Circular Dichroism.	5
2	Fourier Transformed Infrared Spectrometry. Interpretation of Infrared spectrum.	3
3	High Resolution ^{1}H &^{13}C NMR Spectrometry. Theoretical calculation of chemical shifts of various carbon atoms. Technique used for finding types of carbon like attached protontest(APT), distortionless energy polarization transfer (DEPT). Homonuclear & heteronuclear correlation spectrometry. Different 1D & 2D NMR correlation spectrometric techniques such as COSY, NOESY, HETCOR INADE QUATE, SBC, HMQC etc. Use of this technique in determination of absolute configuration.	15
4	Mass spectrometry: use of isotopic abundance in molecular formula calculation. Different ionization techniques like EI,CI, FD, FI, MALDI, API,ESI. Fragmentation of molecule using these techniques. Tandem mass spectrometry and its applications in pharmacy.	8
	SECTION B	
5	HPTLC: Basic instrumentation and its calibration. Analytical methoddevelopment andits validation as per ICH guidelines. Quantification using HPTLC	5
6	HPLC: Instrumentation covering detailed discussion about pumps, injector system, columns and detectors. Calibration of instrument. Analytical method development, validation as per ICH guidelines and trouble shooting. Quantification methods usedin HPLC. Ultra pressure liquidchromatography.	8
7	Thermoanalytical techniques: Differential Scanning Calorimetry (DSC), Thermogravimetry (TG),Thermo mechanical analysis (TMA): Principles instrumentation and applications (including interpretation of data) in pharmacy.	5
8	Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmuneassay, ELISA etc.	6
9	Microscopy: SEM, TEM, cryomicroscopy, AFM, confocalmicroscopy.	5
	TOTAL	60

Reference Books:

- RobertM. Silverstein, FrancisX. Webster, DavidJ. Kiemle,2009."Spectrometric identification of organic compounds".7thEd. John Wiley & Sons
- Pavia D. L.,2009."Introduction to spectroscopy".4th, Belmont CA
- Munson&Munson,"Pharmaceutical analysis: modern methods".,New York: M. Dekker
- KennethA. Connors, 2007."A Text book Of Pharmaceutical Analysis"3rdEd. WileyIndia-wse
- JensThuroCarstensen, 2001."Advanced pharmaceutical solids"Marcel Dekker, NewYork
- JosephB. Lambert, ScottGronert, Herbert F.Shurvell, David Lightner,Robert Graham Cooks, 2010. "Organic structural spectroscopy",2ndEd. Pearson Education, Limited.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH2
Subject: Modern Analytical Techniques (Practical) **Allotted Hrs. :** 8

Sr.No.	Laboratory Experiments
1.	Estimation of two drugs by simultaneous equation method and absorbance ratio method.
2.	Calibration of UV spectrometer for wavelength and stray light.
3.	Analysis of drugs by second derivative UV spectrometry.
4.	Determination of pK value by UV visible spectrometry.
5.	Calculation of λmax values using Woodward Fisher rules.
6.	Study of hydrogen bonding using IR spectrometer.
7.	Interpretation of IR spectra.
8.	Calibration of IR spectrometer using standard polystyrenefilm.
9.	Interpretation of 1D proton NMR spectrum of simple compounds (10-12carbons).
10.	Interpretation of 1D 13C NMR spectrum of simple compounds(10-12carbons).
11.	Calculation of carbon chemical shifts for various carbons such as sp3,sp2,sp carbonetc.
12.	Assignmen tof m/z values to various fragments in the mass spectrum.
13.	Qualitative and quantitative analysis using HPTLC.
14.	Analytical method development for three component mixture using HPTLC.
15.	Calibrationof HPLC instrument for flow rate & wavelength.
16.	Determination of theoretical plate, HETP resolution, tailing factor for two component mixture
17.	Determination of caffeine contentin tea/coffee/other beverages.
18.	Quantitation using different methods such as area normalization, one point,two point method with the help of internal standard.
19.	Determination of melting point & heat of fusion usingDSC.
20.	Determination of glass transition temperature using DSC.
21.	Interpretation of ORD and CD spectrum.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH3
Subject: Computer and statistics (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To train students in basics of computer hardware.
- To train them on hands on experience in use of different software.
- To teach them applications of computers in different areas of Pharmacy.
- To train the students for applications of various statistical methods available for analysis of data.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	Hardware: Current hardware & their performance, New devices / technology useful in teaching & research like Cameras, Scanner, touch screens, tablets, projection devices etc. Basic idea of computer networking.	03
Unit -2	Operating systems: Common operating systems used in day to day task & instrumentation like Windows, Linux & Unix (only interface and basic commands).	15
Unit -3	Language: Evolution of computer languages. Common languages used in scientific fraternity (no specific language detailing is required).	06
Unit -4	Software: Idea of popular soft ware's like MS Office, structure drawing software's, chemical structure visualizing software's, statistical software's & mathematical software, reference managing software's (only introduction).	05
Unit -5	Web page design: Need, concept and use of HTML.	08
Unit -6	Databases: Meaning, Need and creating table, record creating and maintenance.	05
Unit -7	Internet concept: History, creating internet connection, common problems & solutions.	06
Unit -8	Important Databases of free domain: Patents, Pub med, Pubchem, Science direct, protein database.	05
	SECTION B	
Unit -1	Data & Graphs.	03
Unit -2	Basic statistics.	02
Unit -3	Sampling.	04
Unit -4	Hypothesis testing.	06
Unit -5	Optimization.	06
Unit -6	Designing experiment.	06
Unit -7	Clinical data management.	02
Unit -8	Meta analysis.	03
Unit -9	Statistical Quality control.	05
Unit-10	Introduction to common statistical software.	03
	Total	**60**

Reference books :

- W.E. Fassett, 1986. "Computer Applications in Pharmacy", Lea & Febiger Publisher.
- C.N. Madu, 2003. "Statistics as easy as one, two, three with Microsoft Excel for Windows", 1st Ed. Chi Publishers Inc.
- A.N. Armstrong, 2006. "Pharmaceutical experimental design and interpretation", CRC/Taylor & Francis.
- G.A. Lewis, D. Mathieu, R.T. Phan, 1999. "Pharmaceutical experimental design", CRC Press.
- W.G. Cochran, W.G. Cochran, G.M. Cox, 1992. "Experimental designs". Wiley.
- http://pages.stern.nyu.edu/~jsimonof/classes/1305/pdf/excelreg.pdf
- www.Pubmed.com
- www.Pubchem.com
- www.mdl.com
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- www.uspto.gov
- www.esp.gov
- Lambert M Surhone, Miriam T Timpledon, Susan F Marseken, 2010. "Rasmol", VDM Verlag Dr. Mueller AG & Co. Kg.
- http://www.vlifesciences.com

Class: First Semester M. Pharm. **Subject Code:** S1-MPH3

Subject: Computer and statistics (Practical) **Allotted Hrs. :** 4

1	To understand computer hardware & their integration (computer, printer, scanner, display device, Bluetooth & IR devices).
2	To understand operating system / s.
3	To know theevolution of computer languages.
4	To design simple web page using HTML editor (Word, FrontPage etc.).
5	To make simple database using MS Access (i.e. Plant database, reference database etc.).
6	To create, editing & formatting worksheet using excel.
7	To make use of formula in excel.
8	To write macros in spreadsheet.
9	To create graphs for representing data.
10	To perform statistical operations on the obtained data.
11	To make decisions using formula in spreadsheet.
12	To develop ability to create master document in MS word.
13	To make PowerPoint presentations with hyper linking & animation effects.
14	To learn & develop expertise in use of structure drawing software like ISIS, Chem sketch etc.
15	To learn use of structure visualization software like Rasmol.
16	To visualize protein molecules using Protein explorer.
17	To learn searching internet based databases like Pub med, US Patents.
18	To develop technique for calculating molecular properties on line.
19	To perform simple optimization exercises using MS Excel / any statistics software.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH4
Subject: Nanotechnology & Biotechnology (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give basics of nanotechnology.
- To impart advanced level training in bio & nanotechnology with emphasis on their use in Pharmacy.
- To make use of this advanced level knowledge in drug discovery.
- To impart training on carrying out the sophisticated experiments in these areas.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	**BIONANOTECHNOLOGY:** History, opportunities and challenges of bionanotechnology, growth potential of bionanotechnology, significance of nanosize in biotechnology and medicine.	04
Unit -2	**NANO-DRUG DELIVERY:** Conventional delivery of biotechnologicals and its limitations, biological barriers in delivery of therapeutics, importance of nano-size in site-selective delivery. Targeted delivery of biotechnological using nanoconstructures, application of nanocarriers in delivery of biotechnologicals, nano-drug delivery chip.	10
Unit -3	**BIONANOCARRIERS:** Design and fabrications of nanocapsules, nanoliposomes, nanoparticles, nanoemulsion, nanopore technology, nano-self assembling systems, bionanoarrays, dendrimers, carbon nanotubes, nanosomes and polymersomes, inorganic nanoparticles (gold-gold colloids, gold nanofilm, gold nanorods, titanium and zinc oxide), structured DNA nanotechnology.	11
Unit -4	**NANOMEDICINE, NANOBIOLOGY AND NANOBIOTECHNOLOGY:** Synthesis and assembling of nanoparticles/nanostructures using bio-derived templates, proteins and nanoparticles, covalent and non-covalent conjugates, cantilevers array sensors for bioanalysis and diagnostics, nanowire and nanotube biomolecular sensors for in-vitro diagnosis of cancer and other diseases. Biologically inspired hybrid nanodevices, nanotube membranes for biotechnology, shelf-assembling of short peptides for nanotechnologicals applications.	10
	SECTION B	
Unit -5	**BIONANOIMAGING:** Quantum dots-luminescent semiconductor QD in cell and tissue imaging, fluoroimmunoassay using QD. Ultrasound contrast agents, magnetic nanoparticles, nanoparticles in molecular imaging, nanoforce and imaging-AFM, molecules, cells, materials and systems design based on nanobiotechnology for use in bioanalytical technology.	08
Unit -6	**DRUG DISCOVERY:** Drug screening, technoglobalism and drug development, biodiagnostics.	02
Unit -7	chemogenomics, computational chemistry, new pharmaceuticals from marine sources, cell based therapies, encapsulated cells for disease treatment.	03
Unit -8	**INSTRUMENTATION AND PRINCIPLES:** Electrophoresis techniques, laser confocal microscopy, digital image analysis, biosensors in diagnostics, enzyme purification and assay techniques. Techniques in cytogenetics: DNA sequencing, DNA microarray.Spectral analysis techniques: Introduction, estimation of proteins, DNA and RNA.	08
Unit -9	**SAFETY CONCERN OF BIONANOTECHNOLICALS:** Inhalation, contact/dermal delivery, environmental impact, explosion hazards.	04
	Total	**60**

Reference books :

- E.S. Papazoglou and A. Parthasarathy, "Bionanotechnology". 1st Ed. Morgan and Claypool.
- N.H. Malsch. 2005. "Biomedical nanotechnology" CRC Press.
- D.S. Goodsell, 2004. "Bionanotechnology: lessons from nature" Wiley-Liss Publication.
- T. Vo-Dinh, "Nanotechnology in biology and medicine: methods, devices, and applications" CRC Press.
- V. Labhasetwar, D.L. Leslie-Pelecky, 2007. "Biomedical applications of nanotechnology".Wiley-Interscience: Hoboken.
- S.P. Vyas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and controlled drug delivery" CBS Publishers and Distributors.

- **It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.**

Class: First Semester M. Pharm. **Subject Code:** S1-MPH4

Subject: Nanotechnology & Biotechnology (Practical) **Allotted Hrs. :** 8

Suggested List of Laboratory Experiments :

- Development of nanoparticles by solvent-evaporation method.
- Design of nanospheres by emulsification method.
- Preparation of polymeric nanocapsules by solvent-diffusion method.
- Evaluation of nanoparticles for particle size, zeta potential, drug entrapment efficiency, stability and other parameters.
- Development of solid lipid nano particles using various lipids.
- Preparation of nano-liposomes by solvent dispersion/film hydration method.
- Development and evaluation of nano-niosomes.
- Development and evaluation of nano-suspensions.
- Preparation of nanoemulsions by using ternaray phase diagrams.
- Incorporation of nanoemulsions in topical gels.
- Evaluation of dermal retention, penetration, skin irritation and toxicity potential of nano topical formulations.
- Development of nanosponges based on cyclodextrin complexes.
- Assessment of solubility enhancement by nano formulations.
- Pegylation of nanoparticles.
- Synthesis of Al_2O_3 nanoparticles using soi.gel method.
- Synthesis of Fe_2O_3 nanoparticles by chemical method.
- Synthesis of nanoparticles using biological process (2-3 methods).
- Functionalization of nanoparticles for biological application- (4-5 methods).
- Detection of nanoparticles in colloidal solutions using UV-Visible Absorption technique size determination of nanoparticles using laser beam.
- Analysis of ANM, SEM AND TEM pictures.
- Polyacrylamide gel electrophoresis: native gel.
- Isolation and separation of secondary metabolites.
- 2-D Gel electrophoresis of proteins and isoelectrofocusing.
- Synthesis of nanometer scale particles of colloidal semiconductors such as TiO_2, CdS, ZnO, SnO_2, Cu_2S, CuCNS, Cu_2O, $BaTiO_3$, $SrTiO_3$ by wet chemical methods, hydrothermal methods, and pyrolytic or high temperature methods.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPH1
Subject: Research Project **Allotted Hrs.:** 8

OBJECTIVE:

- To give exposure on how to do literature survey for the project work
- To develop technical writing skill in the form of a research report
- To develop report presentation ability, orally
- To develop question answer capability confidently.

Sr. No.	Unit and Contents	Hrs.
1	NIL	

Class: Second Semester M. Pharm. **Subject Code:** S2-MPL2
Subject: Advanced Pharmacology - I **Allotted Hrs.:** 4

OBJECTIVE:

- To impart advance knowledge about receptor mechanism of drug action.
- To train the student in receptor mechanism, gene therapy, pharmacological actions of bioactive molecules.
- To give advanced knowledge in these areas

Sr. No.	Unit and Contents	Hrs.
Unit -1	**Molecular mechanism of drug action** • Drug receptor interactions and second messenger systems. • Signal transduction and termination of receptor activity. • G - proteins and receptor structures, cAMP pathway, Phospholipase C, IP3, DAQ pathway.	8
Unit -2	**Pharmacology of receptors** Classification, cellular signaling systems, associated diseases and advances in pharmacology of the following receptor types • Excitatory Amino Acid receptors • GABA and Benzodiazepine receptors • Cannabinoid receptors • Dopamine receptors • Serotonin receptors • Purinergic receptors • Opioid receptors • Sigma receptors • Imidazoline receptors	18
Unit -3	**Neuro peptides** Biological functions, pharmacological implications, their receptors systems and therapeutic potentials of the following neuropeptides:	12
	• Neuropeptide Y • Cholecystokinin • Tachykinins (Substance P/ Neurokinin) • Melanocortins (Alpha MSH) • Cortcotrophin releasing factor • Arginine vasopressin • Cocaine –Amphetamine Regulatory Transcript (CART) • Calcitonin gene-related peptide (CGRP)	
Unit -4	**Cytokines & Chemokines** Classification, physiology, pharmacology, pathological, and therapeutic implications of various cytokines and chemokines.	4
Unit -5	**Programmed Cell Death (Apoptosis)** Molecular biology, physiological and pharmacological implications and therapeutic potentials of apoptosis.	4

Unit -6	**Endogenous bioactive molecules** Physiology, pharmacology, and therapeutic potential of • Neurosteroids and its modulators • Endothelium derived vascular substances (Nitric oxide) and their modulators • Phosphodiestrase enzyme and protein kinase C, • Arachidonic acid metabolites, COX-2 regulators and their role in inflammation. • Endorphins • Neurotrophins	8
Unit -7	**Stem Cell Therapeutics** Biology of stem cells and their potentials in various disorders.	3
Unit -8	**Gene therapy** Concept of gene therapy and recent development in the treatment of various hereditary diseases.	3
	Total	**60**

Text Books:

Reference books :

1. Hardman J. G., Limbird L. E. 2001. "Goodman and Gilman's The Pharmacological Basis of Therapeutics" 1oth Ed.McGraw-Hill Professional.
2. H. P. Rang and M. M. Dale, "Pharmacology" 5th Ed. Churchill Livingstone.
3. B. G. Katzung, "Basic and Clinical Pharmacology" 9th Ed. McGraw-Hill Medical.
4. Annual Reviews of Pharmacology series.
5. Harvey R. A, Champe P. C., "Pharmacology-Lippincott's illustrated Reviews" 4th Ed. Lippincott Williams & Wilkins.
6. Journal Trends in Pharmacological sciences.
7. H.G. Vogel, 2003. "Drug Discovery and Evaluation-Pharmacological Assays" 3rd Ed. Springer Verlag, Berlin, Germany.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPL2

Subject: Advanced Pharmacology - I **Allotted Hrs. :** 8

Suggested List of Laboratory Experiments :

To demonstrate mechanism of action of a drug

1. Demonstration of muscarinic, nicotinic and 5HT activity of a drug using suitable isolated tissue
2. Demonstrate the effect of various drugs on rat /rabbit thoracic aorta
3. Demonstrate the effect of autonomic drugs on rat phrenic nerve diaphragm preparation
4. Study of effect of drugs on various cardiovascular parameters in animals: ECG, EKG, Langendorff's heart perfusion and blood pressure.
5. Note: Virtual /simulated experiments can be used.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPL3
Subject: Methods in Pharmacology (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To train in all the aspects of drug evaluation to conduct pharmacological experiment independently.

Sr. No.	Unit and Contents	Hrs.
Unit -1	Regulations for Laboratory animal use and care. Limitations and alternatives to animal use. Principles involved inpreclinical evaluation of new drugs. Blind screening programme, Preclinical Safety Assessment tests including carcinogenicity and reproductive studies.	10
Unit -2	Critical assessment, limitations, and validation criteria of animal models, employed to evaluate the drugs belonging to following categories: Hypertension Angina, Arrhythmia, Cardiac failure, Atherosclerosis. Epilepsy,Parkinsonism, Anxiety, Depression, Psychosis.	12
Unit -3	Stress Cognitive disorders andAlzheimer's disease.	6
Unit -4	CNS stimulants and Depressants, Analgesics and drugs used in Neuropathic pain, Inflammation and Arthritis.	10
Unit -5	Antihistaminics,Antidiabetics,Antifertility, Hepatoprotective andAntiobesity andAnticancer drugs.	10
Unit -6	Principles of molecular biology like Antisense Oligonucleotide, RNA interference and the generation of animals with specific gene mutations.	12
	Total	**60**

Text Books:
It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.

Reference books :

1. H.G. Vogel, 2002. "Drug Discovery and Evaluation-Pharmacological Assays", 2nd Ed. Springer Verlag, Berlin, Germany.
2. D.R. Laurence and A.L. Bacharach, 1964. "Evaluation of Drug Activities: Pharmacometerics" Vol. 1 and 2, Academic Press, London, U.K.
3. R.A. Turner, 1965. "Screening methods in pharmacology", Academic press, New York.
4. A. Schwartz, "Methods in Pharmacology".Plenum Publishing Corporation.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPL3
Subject: Methods in Pharmacology (Practical) **Allotted Hrs. :** 8

Suggested Laboratory Experiments.

1. Problem solving exercises on acute toxicity tests to find out LD50 of a drug
2. Drug mutagenicity study using mice bone marrow chromosomal aberration test and micronucleus test
3. Experiments to study anti-inflammatory , analgesic, antipyretic and anticonvulsant activity of a drug
4. Experiments to study the apomorphine induced compulsive behavior in mice
5. Experiments to study anti anxiety effect of diazepam in mice
6. Experiments to study antidiabetic and diuretic activity of a drug.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPL4
Subject: Elective Pharmacology - I (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give additional Knowledge to students based on their choice of topic

Sr. No.	Unit and Contents	Hrs.
Unit -1	Pharmacotherapeutics	
Unit -2	Clinical Research	
Unit -3	Hospital Pharmacy	
Unit -4	Molecular biology	
Unit -5	Drug design and development	
Unit -6	Tissue culture	
Unit -7	Biopharmaceutics	
	Total	**60**

Class: Third Semester M. Pharm. **Subject Code:** S3-MPH1
Subject: Drug Regulatory aspects and IPR (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To impart information on various drug regulatory aspects involved in the profession.
- To teach the import / export related regulations with respect to some countries
- To make the students understand the importance and implication of IPR and related matters.
- To train the students in GMP and the latest developments there.

Sr. No.	Unit and Contents	Hrs.
Unit-1	**DRUG REGULATORY ASPESTS**	**40**
a)	Drug Regulatory Aspects (India) – 1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA) 2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective) 3. Special emphasis – Schedule M and Y 4. New Drugs – Importation, Registration, Development, Clinical Trials, BE NOC & B.E. studies 5. Various licenses – Test lic., Import lic. for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	10
b)	Good Manufacturing Practices (GMP) – 1. Indian GMP certification, WHO GMP certification 2. ICH guidelines for stability testing and other relevant ones (Q1 – Q10) 3. Export permissions and manufacturing for semi-regulated countries 4. Understanding of the plant lay-outs with special emphasis on the environment & safety. (HVAC, Water systems, Stores management, Effluent etc.) 5. Quality Assurance and Quality Control – Basic understanding for in-built quality.	12
c)	Drug Regulatory Aspects (International & highly regulated markets) – 1. US Requirements – (for Generic Drugs especially formulations) 2. CDER, INDA, NDA, ANDA's (types), CTD Formats of dossiers, E-submission, US DMF (various types), IIG Limits, Orphan Drugs, Vanilla ANDA's, Exhibit/Pivotal batches, Validation batches, Various Guidance issued by CDER, OGD, Orange Book (and patents), RLD (Reference listed drug) for BE studies and the norms for US submission, Bioequivalence and dissolution recommendations, Packaging, Stability studies and the Product Information Leaflet, US FDA Inspection (audits), Pre-approval Inspections and approvals 3. European Union Requirements – 4. All the aspects for European Registration of formulations for generic drugs sale in the European markets under EU. EMEA guidelines on various aspects as above (C 1) 5. A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries. 6. GMP audits, role of Quality Assurance, product approvals and supplies.	18
Unit-2	**INTELLECTUAL PROPERTY RIGHTS (IPR)**	**20**
a)	**Introduction to IPR & Patents** – Development of IP law in India, IPR regime, Introduction to IP laws in India, Role of IP in pharma industry growth.	
b)	**Patenting in India** – Introduction, Patent legislation, Indian Patents Act 1970 and amendments, Procedure for patent application, Grant and opposition proceedings, Patent licensing, Patent infringement proceedings, IPAB – role and functions (IP Appellate Board), Indian IP Case laws	
c)	**American & European patent system** – Requirements for patenting, utility, novelty Non-obviousness, Patent specification & claims, Patent infringement and Doctrine of Equivalents, Federal circuit and Patent system in Europe	
d)	**International treaties and conventions on IPR** - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO	
e)	**Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003**	
f)	**Introduction to** Geographical indication / Trademark/ copyright: Filing procedures	
g)	**Patent search, Patent analysis & Patent drafting**.	
h)	**Allied Patents Related Issues**: Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage	
	Total	60

Reference books :

1. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).
2. CDER Publications and Guidance
3. EMEA Publications and Guidance
4. Orange Book, ICH guidelines, Indian Patents Act
5. Country specific Regulatory Guidelines (available from internet)
6. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
7. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.
8. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
9. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.
10. Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPL2
Subject: Research work Seminar **Allotted Hrs. :** 8

OBJECTIVE:

- To effectively present the research work carried out by the student.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPL3
Subject: Research Project **Allotted Hrs. :** 16

OBJECTIVE:

- To manage the research work in time bound manner.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPL4
Subject: Adanced Pharmacology - II **Allotted Hrs. :** 4

OBJECTIVE:

- To impact knowledge about latest drugs available for therapeutics
- To barin the student in new drug therpy various disease disease with respect to MOA dosage adverse effect.

Sr. No.	Unit and Contents	Hrs.
Unit -1	**Topics in Pharmacology** The subject should give emphasis on recent trends and advances in the following classes of drugs. CNS Drugs: Sedatives, hypnotics, and psychopharmacological agent.	10
Unit-2	Cardiotonics, antiarrhythemics, antihypertensive, antianginals, hypolipidemics, anticoagulants, antiplatlets, thrombolytics	16
Unit -3	**Renal drugs** Diuretics& antidiuretics	6
Unit -4	**Gastrointestinal agents** Antiulcer,antidiahorreal,antiemetic agents	6
Unit -5	**Endocrine drugs** Thyroid,antithyroid,antidiabetic,oral contraceptives,corticosteroids	8
Unit -6	**Chemotherapy** Cellular and molecular mechanism of action and resistance of antimicrobial and anticancer drugs	10
Unit -7	Molecular and cellular mechanism of immunomodulators	6
	Total	**60**

Reference books :

1. Goodman and Gilman's, 2001. "The Pharmacological Basis of Therapeutics" 10th ed., McGraw-Hill.
2. H.P. Rang, J.M. Ritter and M.M. Dale, 2007. "Pharmacology", Churchill Livingston.
3. B.G. Katzung, 2001. "Basic and Clinical Pharmacology" by 9th ed.Lange Medical Books/McGraw-Hill.
4. Annual Reviews of Pharmacology series

Class: Third Semester M. Pharm. **Subject Code:** S3-MPL5
Subject: Elective Pharmacology – II (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To train in conduct of animal toxicity studies
- To train in conduct of clinical toxicity studies
- To impact knowledge about animal anc clinical toxicity

Sr. No.	Unit and Contents	Hrs.
Unit -1	Safety pharmacology	
Unit -2	Community Pharmacy	
Unit -3	Pharmacoeconomics	
Unit -4	Basics of Pharmacological Evaluation	
	Total	**60**

Text Books: N A

Reference books :

1. S.C. Gad, 2000. "Safety assessment for pharmaceuticals", John Wiley & Sons, New York.
2. J.R. Turner, 2007. "New drug development: design, methodology, and analysis", Wiley-Interscience.
3. A. Dmitrienko, C. Chuang-Stein, and R. D'Agostino, 2007. "Pharmaceutical statistics using SAS: a practical guide", SAS Institute.
4. C.G. Smith, and J. O'Donnell, 2006. "The process of new drug discovery and development", 2nd ed., Informa Healthcare, New York.
5. R.D. Mann, and E.B. Andrews, 2007. "Pharmacovigilance" 2nd ed., John Wiley & Sons. Chichester, England.
6. World Health Organization, 2004. "WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems", World Health Organization.
7. B.L. Cobert, 2007. "Manual of drug safety and pharmacovigilance", Jones and Bartlett Publishers.
8. S.C. Gad, 2009. "Drug safety evaluation", Wiley Interscience, New York.
9. Relevant OECD guidelines (Internet resources).

Class: Fourth Semester M. Pharm. **Subject Code:** S4-MPH1
Subject: Research Project and Colloquium **Allotted Hrs.:** 36

OBJECTIVE:

- To complete the given research project
- The effectively defense the work before a group of qualified evaluators.

Sr. No.	Unit and Contents	Hrs.
1.	• Completion of research project and submission of dissertation to University. • Defence / viva voce	36

PART - H

M. Pharm. Syllabus

(Pharmacognosy)

Class: First Semester M. Pharm. **Subject Code:** S1-MPH1
Subject: Research Methodology **Allotted Hrs.:** 4

OBJECTIVE:

- To familiarize students regarding teaching methodology & research projects.
- To teach students preparation of are search projects & different aspects associated with it.
- To acquaint students with experimental data analysis.
- To impresss upon students the importance of ethical issues in the profession & plagiarism.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	**Learning and instruction** Principles of Instructional design and learning theory, Merrill's five principles and Gagne'scon dition of learning. Active learning, group learning, collaborative learning, problem-based learning, team-based learning, Experiential learningmodel of Kolb.	8
2	**Curriculum development** Asix step approach-Problem identification and general needs assessment, targeted needs assessment, goals and objectives, educational strategies, implementation, evaluation and feedback. Bloom's Taxonomy, three domains of educational objectives.	6
3	**Funding &Scholarship** Agencies funding research in pharmaceutical sciences, Scholarship ,types of scholarships in education.	3
4	**Assessment** Definition and methods, Georges Millers pyramid, assessment, measurement and tests, types of numbers, formative and summative assessment.	3
5	**Basicsof Research** Definition, objectives, motivation, types of research and approaches: Descriptive research, conceptual, theoretical, applied and experimental.	3
6	**Formation of Research Problem** A. Research Process: To determine what type of research to be done, plan of research work. B. Selection of research area, prioritization of research. C. Literaturere view: importance and methods, sources, D. Objectives and scope of work, developing research plan and schedule: Scheduling constraints ,steps, problems in scheduling, limitations.	4
7	**Mathematical Modeling and Simulation** Concept of modeling, classification of mathematical models, modeling with ordinary differential equations, difference equations, partial differential equations, graphs, simulation: concept, types (quantitative , experimental, computer, fuzzy theory, statistical) processes of formulation of model based on simulation. Variables and measurement.	5
	SECTION B	
8	**Experimental Modeling** A. Definition of experimental design, examples, single factor experiments B. Blocking and Nuisance factors, guidelines for designing experiments. C. General model of process: Input factors/ variables, Out put parameters/ variables controllable /uncontrollable variables, dependent/ independent variables experimental validity. D. Introduction to Risk assessment, reliability, sustainability, and uncertainty.	4

9	**Analysisof data** A. Types of data: parametric and nonparametric, descriptive and inferential data, B. Collection of data: normal distribution, calculation of co-relation coefficient C. Data processing: analysis, error analysis, meaning, and different methods: analysis of variance, significance of variance, analysis of covariance, multiple regressions, testing linearity / nonlinearity of model, testing adequacy of model. D. Test to be used in data exploration and their choice E. Introduction of software used in data analysis.	8
10	**Research Deliverables** A. Various Forms of Publication: Thesis, paper, research proposal. B. Thesis Writing: Introduction, literature reviewor state-of-the-art, research approach (methodology), results or findings, discussions, conclusions, scope for future work, references, appendices. C. Presentation: Poster, thesis, proposal, and paper.	4
11	**Ethical issues in research** Historical perspectives, General principles on ethical consideration involving human participation, General ethical evaluation of drugs/ device/ diagnostics/ vaccines /herbal remedies. Statement of specific principles for human genetics and genomic research. International Conference on Harmonization. Good clinical practices norms, Ethical principles related to animal experiments.	10
12	**Plagiarism** Issues related to plagiarism, copyright laws, acknowledging the sources, format for manuscriptwriting, documentation, organization of reference material, bibliography, end note.	2
	TOTAL	60

Reference Books:

- B.D.John,A.L.BrownandR.R.Cocking,1999."How People Learn: brain, mind, experience and school".Washington, D C: National Academy Press.
- J.R.Fraenkel,N.E. Wallen,2008."How to Designand Evaluate Researchin Education*",7th Ed*. Bostan McGraw-Hill
- K.E.David,2009. Curriculum Development for Medical Education:*A Six-Step Approach* 2nd Ed. The John Hopkins University Press. ISBN0-8018-9367-4.
- N.Peter,2009."Leadership: Theory and Practice*." 3rd Ed.* Thousand Oaks: Sage Publications.
- G.Bordage,B.Dawson,2003. Experimental study design and grant writing in eight steps and 28 questions *MedicalEducation, 37*(4):376-385.
- B.J.Avolio, F.O.Walumbwa, T.J.Weber, 2009. Leadership: Current theories, research, and future directions. *Annual Review of Psychology, 60*:421-449.
- C.R.Kothari, 2004."Research Methodology".2nd Ed.New Ag eInternational(p) Limited,Publishers.
- D.Montgomary, 2000."Designof Experiments". 5thEd. Wiley Interscience.
- K.P. Willkinsion, L. Bhandarkar, "Formulation of Hypothesis". 3rd ed. Himalaya publishing, Mumbai.
- SchankFr, 2008."Theories of Engineering Experiments".2nd Ed.Tata McGraw Hill.
- D.C.Montgomery, 2009."Introduction to SQC"6th Ed.JohnWilly& sons.
- Cochran& Cocks, 1957.2nd Ed."Experimental Design" New York,JohnWilly& sons.
- J.W.BestandJ.V.Kahn, 2006."Research in Education". 10th Ed.PHI publication.
- S.S.Rao,1983."Optimization Theory & Applications".2nd Ed.WileyEasternLtd.ND.
- P.D.Kulkarni,1986."Independent Study Techniques",TTTI Chandigarh

Class: First Semester M. Pharm. **Subject Code:** S1-MPH2
Subject: Modern Analytical Techniques (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To familiarize students in use of modern techniques of analysis used indifferent areas/ fields of pharmacy.
- To give training in use of the technique & its applications in day to day practice.
- To build on the basics learned at UG level & give latest advances in the area.
- To give more stress on application based knowledge than instrumentation based one.
- To give hands on training on use of as many different ophisticated instruments as possible.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
1	Ultraviolet–Visible spectrometry: Woodward–Fisher rules for calculation of λmax. Derivative spectroscopy. Introduction to Optical rotator Dispersion and Circular Dichroism.	5
2	Fourier Transformed Infrared Spectrometry. Interpretation of Infrared spectrum.	3
3	High Resolution ^{1}H &^{13}C NMR Spectrometry. Theoretical calculation of chemical shifts of various carbon atoms. Technique used for finding types of carbon like attached protontest(APT), distortionless energy polarization transfer (DEPT). Homonuclear & heteronuclear correlation spectrometry. Different 1D & 2D NMR correlation spectrometric techniques such as COSY, NOESY, HETCOR INADE QUATE, SBC, HMQC etc. Use of this technique in determination of absolute configuration.	15
4	Mass spectrometry: use of isotopic abundance in molecular formula calculation. Different ionization techniques like EI,CI, FD, FI, MALDI, API,ESI. Fragmentation of molecule using these techniques. Tandem mass spectrometry and its applications in pharmacy.	8
	SECTION B	
5	HPTLC: Basic instrumentation and its calibration. Analytical methoddevelopment andits validation as per ICH guidelines. Quantification using HPTLC	5
6	HPLC: Instrumentation covering detailed discussion about pumps, injector system, columns and detectors. Calibration of instrument. Analytical method development, validation as per ICH guidelines and trouble shooting. Quantification methods usedin HPLC. Ultra pressure liquidchromatography.	8
7	Thermoanalytical techniques: Differential Scanning Calorimetry (DSC), Thermogravimetry (TG),Thermo mechanical analysis (TMA): Principles instrumentation and applications (including interpretation of data) in pharmacy.	5
8	Radio analytical techniques used in pharmaceuticals: Isotopic dilution methods, Radioimmuneassay, ELISA etc.	6
9	Microscopy: SEM, TEM, cryomicroscopy, AFM, confocalmicroscopy.	5
	TOTAL	60

Reference Books:

- RobertM. Silverstein, FrancisX. Webster, DavidJ. Kiemle,2009."Spectrometric identification of organic compounds".7thEd. John Wiley & Sons
- Pavia D. L.,2009."Introduction to spectroscopy".4th, Belmont CA
- Munson&Munson,"Pharmaceutical analysis: modern methods".,New York: M. Dekker
- KennethA. Connors, 2007."A Text book Of Pharmaceutical Analysis"3rdEd. WileyIndia-wse
- JensThuroCarstensen, 2001."Advanced pharmaceutical solids"Marcel Dekker, NewYork
- JosephB. Lambert, ScottGronert, Herbert F.Shurvell, David Lightner,Robert Graham Cooks, 2010. "Organic structural spectroscopy",2ndEd. Pearson Education, Limited.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH2
Subject: Modern Analytical Techniques (Practical) **Allotted Hrs. :** 8

Sr.No.	Laboratory Experiments
1.	Estimation of two drugs by simultaneous equation method and absorbance ratio method.
2.	Calibration of UV spectrometer for wavelength and stray light.
3.	Analysis of drugs by second derivative UV spectrometry.
4.	Determination of pK value by UV visible spectrometry.
5.	Calculation of λmax values using Woodward Fisher rules.
6.	Study of hydrogen bonding using IR spectrometer.
7.	Interpretation of IR spectra.
8.	Calibration of IR spectrometer using standard polystyrenefilm.
9.	Interpretation of 1D proton NMR spectrum of simple compounds (10-12carbons).
10.	Interpretation of 1D 13C NMR spectrum of simple compounds(10-12carbons).
11.	Calculation of carbon chemical shifts for various carbons such as sp3,sp2,sp carbonetc.
12.	Assignmen tof m/z values to various fragments in the mass spectrum.
13.	Qualitative and quantitative analysis using HPTLC.
14.	Analytical method development for three component mixture using HPTLC.
15.	Calibrationof HPLC instrument for flow rate & wavelength.
16.	Determination of theoretical plate, HETP resolution, tailing factor for two component mixture
17.	Determination of caffeine contentin tea/coffee/other beverages.
18.	Quantitation using different methods such as area normalization, one point,two point method with the help of internal standard.
19.	Determination of melting point & heat of fusion usingDSC.
20.	Determination of glass transition temperature using DSC.
21.	Interpretation of ORD and CD spectrum.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH3
Subject: Computer and statistics (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To train students in basics of computer hardware.
- To train them on hands on experience in use of different software.
- To teach them applications of computers in different areas of Pharmacy.
- To train the students for applications of various statistical methods available for analysis of data.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	Hardware: Current hardware & their performance, New devices / technology useful in teaching & research like Cameras, Scanner, touch screens, tablets, projection devices etc. Basic idea of computer networking.	03
Unit -2	Operating systems: Common operating systems used in day to day task & instrumentation like Windows, Linux & Unix (only interface and basic commands).	15
Unit -3	Language: Evolution of computer languages. Common languages used in scientific fraternity (no specific language detailing is required).	06
Unit -4	Software: Idea of popular soft ware's like MS Office, structure drawing software's, chemical structure visualizing software's, statistical software's & mathematical software, reference managing software's (only introduction).	05
Unit -5	Web page design: Need, concept and use of HTML.	08
Unit -6	Databases: Meaning, Need and creating table, record creating and maintenance.	05
Unit -7	Internet concept: History, creating internet connection, common problems & solutions.	06
Unit -8	Important Databases of free domain: Patents, Pub med, Pubchem, Science direct, protein database.	05
	SECTION B	
Unit -1	Data & Graphs.	03
Unit -2	Basic statistics.	02
Unit -3	Sampling.	04
Unit -4	Hypothesis testing.	06
Unit -5	Optimization.	06
Unit -6	Designing experiment.	06
Unit -7	Clinical data management.	02
Unit -8	Meta analysis.	03
Unit -9	Statistical Quality control.	05
Unit-10	Introduction to common statistical software.	03
	Total	**60**

Reference books :

- W.E. Fassett, 1986. "Computer Applications in Pharmacy", Lea & Febiger Publisher.
- C.N. Madu, 2003. "Statistics as easy as one, two, three with Microsoft Excel for Windows", 1st Ed. Chi Publishers Inc.
- A.N. Armstrong, 2006. "Pharmaceutical experimental design and interpretation", CRC/Taylor & Francis.
- G.A. Lewis, D. Mathieu, R.T. Phan, 1999. "Pharmaceutical experimental design", CRC Press.
- W.G. Cochran, W.G. Cochran, G.M. Cox, 1992. "Experimental designs". Wiley.
- http://pages.stern.nyu.edu/~jsimonof/classes/1305/pdf/excelreg.pdf
- www.Pubmed.com
- www.Pubchem.com
- www.mdl.com
- http://www.vlifesciences.com
- http://spdbv.vital-it.ch
- http://www.winstat.com
- www.uspto.gov
- www.esp.gov
- Lambert M Surhone, Miriam T Timpledon, Susan F Marseken, 2010. "Rasmol", VDM Verlag Dr. Mueller AG & Co. Kg.
- http://www.vlifesciences.com

Class: First Semester M. Pharm. **Subject Code:** S1-MPH3
Subject: Computer and statistics (Practical) **Allotted Hrs. :** 4

1	To understand computer hardware & their integration (computer, printer, scanner, display device, Bluetooth & IR devices).
2	To understand operating system / s.
3	To know theevolution of computer languages.
4	To design simple web page using HTML editor (Word, FrontPage etc.).
5	To make simple database using MS Access (i.e. Plant database, reference database etc.).
6	To create, editing & formatting worksheet using excel.
7	To make use of formula in excel.
8	To write macros in spreadsheet.
9	To create graphs for representing data.
10	To perform statistical operations on the obtained data.
11	To make decisions using formula in spreadsheet.
12	To develop ability to create master document in MS word.
13	To make PowerPoint presentations with hyper linking & animation effects.
14	To learn & develop expertise in use of structure drawing software like ISIS, Chem sketch etc.
15	To learn use of structure visualization software like Rasmol.
16	To visualize protein molecules using Protein explorer.
17	To learn searching internet based databases like Pub med, US Patents.
18	To develop technique for calculating molecular properties on line.
19	To perform simple optimization exercises using MS Excel / any statistics software.

Class: First Semester M. Pharm. **Subject Code:** S1-MPH4
Subject: Nanotechnology & Biotechnology (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To give basics of nanotechnology.
- To impart advanced level training in bio & nanotechnology with emphasis on their use in Pharmacy.
- To make use of this advanced level knowledge in drug discovery.
- To impart training on carrying out the sophisticated experiments in these areas.

Sr. No.	Unit and Contents	Hrs.
	SECTION A	
Unit -1	**BIONANOTECHNOLOGY:** History, opportunities and challenges of bionanotechnology, growth potential of bionanotechnology, significance of nanosize in biotechnology and medicine.	04
Unit -2	**NANO-DRUG DELIVERY:** Conventional delivery of biotechnologicals and its limitations, biological barriers in delivery of therapeutics, importance of nano-size in site-selective delivery. Targeted delivery of biotechnological using nanoconstructures, application of nanocarriers in delivery of biotechnologicals, nano-drug delivery chip.	10
Unit -3	**BIONANOCARRIERS:** Design and fabrications of nanocapsules, nanoliposomes, nanoparticles, nanoemulsion, nanopore technology, nano-self assembling systems, bionanoarrays, dendrimers, carbon nanotubes, nanosomes and polymersomes, inorganic nanoparticles (gold-gold colloids, gold nanofilm, gold nanorods, titanium and zinc oxide), structured DNA nanotechnology.	11
Unit -4	**NANOMEDICINE, NANOBIOLOGY AND NANOBIOTECHNOLOGY:** Synthesis and assembling of nanoparticles/nanostructures using bio-derived templates, proteins and nanoparticles, covalent and non-covalent conjugates, cantilevers array sensors for bioanalysis and diagnostics, nanowire and nanotube biomolecular sensors for in-vitro diagnosis of cancer and other diseases. Biologically inspired hybrid nanodevices, nanotube membranes for biotechnology, shelf-assembling of short peptides for nanotechnologicals applications.	10
	SECTION B	
Unit -5	**BIONANOIMAGING:** Quantum dots-luminescent semiconductor QD in cell and tissue imaging, fluoroimmunoassay using QD. Ultrasound contrast agents, magnetic nanoparticles, nanoparticles in molecular imaging, nanoforce and imaging-AFM, molecules, cells, materials and systems design based on nanobiotechnology for use in bioanalytical technology.	08
Unit -6	**DRUG DISCOVERY:** Drug screening, technoglobalism and drug development, biodiagnostics.	02
Unit -7	chemogenomics, computational chemistry, new pharmaceuticals from marine sources, cell based therapies, encapsulated cells for disease treatment.	03
Unit -8	**INSTRUMENTATION AND PRINCIPLES:** Electrophoresis techniques, laser confocal microscopy, digital image analysis, biosensors in diagnostics, enzyme purification and assay techniques. Techniques in cytogenetics: DNA sequencing, DNA microarray.Spectral analysis techniques: Introduction, estimation of proteins, DNA and RNA.	08
Unit -9	**SAFETY CONCERN OF BIONANOTECHNOLICALS:** Inhalation, contact/dermal delivery, environmental impact, explosion hazards.	04
	Total	**60**

Reference books :

- E.S. Papazoglou and A. Parthasarathy, "Bionanotechnology". 1st Ed. Morgan and Claypool.
- N.H. Malsch. 2005. "Biomedical nanotechnology" CRC Press.
- D.S. Goodsell, 2004. "Bionanotechnology: lessons from nature" Wiley-Liss Publication.
- T. Vo-Dinh, "Nanotechnology in biology and medicine: methods, devices, and applications" CRC Press.
- V. Labhasetwar, D.L. Leslie-Pelecky, 2007. "Biomedical applications of nanotechnology".Wiley-Interscience: Hoboken.
- S.P. Vyas, S.R. Murthy and R.K. Narang, 2010. "Nanocolloidal carriers: site-specific and controlled drug delivery" CBS Publishers and Distributors.

- **It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.**

Class: First Semester M. Pharm. **Subject Code:** S1-MPH4
Subject: Nanotechnology & Biotechnology (Practical) **Allotted Hrs. :** 8

Suggested List of Laboratory Experiments :

- Development of nanoparticles by solvent-evaporation method.
- Design of nanospheres by emulsification method.
- Preparation of polymeric nanocapsules by solvent-diffusion method.
- Evaluation of nanoparticles for particle size, zeta potential, drug entrapment efficiency, stability and other parameters.
- Development of solid lipid nano particles using various lipids.
- Preparation of nano-liposomes by solvent dispersion/film hydration method.
- Development and evaluation of nano-niosomes.
- Development and evaluation of nano-suspensions.
- Preparation of nanoemulsions by using ternaray phase diagrams.
- Incorporation of nanoemulsions in topical gels.
- Evaluation of dermal retention, penetration, skin irritation and toxicity potential of nano topical formulations.
- Development of nanosponges based on cyclodextrin complexes.
- Assessment of solubility enhancement by nano formulations.
- Pegylation of nanoparticles.
- Synthesis of Al_2O_3 nanoparticles using soi.gel method.
- Synthesis of Fe_2O_3 nanoparticles by chemical method.
- Synthesis of nanoparticles using biological process (2-3 methods).
- Functionalization of nanoparticles for biological application- (4-5 methods).
- Detection of nanoparticles in colloidal solutions using UV-Visible Absorption technique size determination of nanoparticles using laser beam.
- Analysis of ANM, SEM AND TEM pictures.
- Polyacrylamide gel electrophoresis: native gel.
- Isolation and separation of secondary metabolites.
- 2-D Gel electrophoresis of proteins and isoelectrofocusing.
- Synthesis of nanometer scale particles of colloidal semiconductors such as TiO_2, CdS, ZnO, SnO_2, Cu_2S, CuCNS, Cu_2O, $BaTiO_3$, $SrTiO_3$ by wet chemical methods, hydrothermal methods, and pyrolytic or high temperature methods.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPH1
Subject: Research Project **Allotted Hrs.:** 8

OBJECTIVE:

- To give exposure on how to do literature survey for the project work
- To develop technical writing skill in the form of a research report
- To develop report presentation ability, orally
- To develop question answer capability confidently.

Sr. No.	Unit and Contents	Hrs.
1	NIL	

Class: Second Semester M. Pharm. **Subject Code:** S2-MPG2
Subject: Advances in Pharmacognosy and Phytochemistry (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To trai students in chemotaxonomy, biosynthesis of some important and useful phytochemicals and medicinally important compounds.
- To acquent students about the benifacial and harmful / poisoneous / toxic plants
- To give latest updates in this area

Sr. No.	Unit and Contents	Hrs.
Unit -1	Chemotaxonomy: Significance in classification of medicinal plants, distribution of chemotaxonomic groups of constituents in plant kingdom like alkaloids, glycosides and terpenoids.	10
Unit -2	Biogenetic pathways for the production of phytopharmaceuticals, such as cardiac glycosides,coumarins, flavones, menthol, nicotinic acid, quinidine, papaverine and ergocryptine.	10
Unit -3	Industrially important volatile oils: Natural occurrence, their chemistry, ontogenic variation and trade.	08
Unit -4	Application of UV, IR, NMR, ^{1}HNMR, ^{13}CNMR and Mass spectroscopy for structural elucidation of phytosterols, flavonoids and terpenoids.	08
Unit -5	Recent advances in the field of Pharmacognosy and Phytochemistry with special reference to anticancer, antidiabetic, anti-inflammatory, hepatoprotective, adaptogenic and immunomodulators, memory enhancers, antiviral agents and antihyperlipidemics.	10
Unit -6	Marine Pharmacognosy: Definition, present status, classification of important bioactive agents, general methods of isolation and purification, study of important bioactive agents, chemistry and uses.	06
Unit -7	Nutraceuticals: Global market prospects and study of five important plants and their products in the international market.	06
Unit-8	Poisonous and toxic plants with special reference to mushrooms.	02
	Total	60

Text Books:
It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.

Reference books :

1. W.C. Evans, 2002. "Trease& Evan's Pharmacognosy". WB.Saunders& co., London.
2. T. Swain, 1963. "Chemical plant Taxonomy". Academic Press, London.
3. C.A Stace, 1985. "Plant Taxonomy and Biosystematics". Edward Arnold, London.
4. C.K. Atal, "Cultivation and Utilization of Medicinal plants". R.R.L. Jammu
5. H.E. Street, 1997. "Plant Cell and Tissue Culture". Blackwell Scientific, London.
6. N. Takashashi, 1986. "Chemistry of Plant Hormones" CRC Press Inc., Florida.
7. A.R. Gennaro, 2000."Remington: The Science & Practice of Pharmacy". Lippincott Williams & Wilkins, Philadelphia.
8. Kaufmann, "Natural products for plants". CRC press New York.
9. K. Nakanishi, 1977. "Chemistry of Natural Products". Kodansha Book Publishing Company, Osaka (Japan).

Class:	Second Semester M. Pharm.	**Subject Code:**	S2-MPG2
Subject:	Advances in Pharmacognosy and Phytochemistry (Practical)	**Allotted Hrs. :**	8

Suggested List of Laboratory Experiments :

1. Isolation of Rutin from Rutagraveolens
2. Hesperidin from Orange peel
3. Aloin from Aloes
4. Rhein from rhizome of Rheum species
5. piperine from piper nigrum
6. Quinine from Cinchona bark
7. berberine from Berberisaristata
8. Caffeine from Tea leaves
9. Menthol from Mentha species
10. Diosgenin from Dioscorea and Trigonella species. Determination of Antharacene derivatives in Senna by spectrophotometric method (Fair Buarian 1975)
11. Reserpine in Rauwolfia by photometric method
12. Carvone content of Umbelliferous fruits
13. Citral content in Lemon grass oil
14. Bitter principles of Chirata
15. Solanaceous drugs
16. Tropane alkaloids using Vitali Morin reaction
17. quantitative estimation of Saponin as per W.H.O. protocol in suitable plant material
18. Resin content in sample of podophyllum by B.P.C. method
19. Optical rotation of oil of Lemon
20. Acid value of Colophony resin by B.P. method. Antimicrobial activity of some volatile oils.
21. Examination of Rhubarb for the presence of Rhapontic Rhubarb by the use of paper chromatography and ultraviolet light.

Class: Second Semester M. Pharm. **Subject Code:** S2-MPG3
Subject: Medicinal Pant Cultivation and Biotechnology (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To train students in the area of plant genetics and biotechnology with reference to plant.
- To impart training in tissue culture and economic significance of biomaterial
- To give latest update in the filed of pharmacognosy

Sr. No.	Unit and Contents	Hrs.
Unit -1	**Introduction:** Medicinal plant based industry, Export and import of plants, threatened / endangered plants, ecology, biodiversity, geographical variation of plant variety, genotypes.	05
Unit -2	**General aspects involved in cultivation of medicinal plants: GAP,** Conservation of medicinal plants: ex-situ and in-situ cultivation: biodiversity law: WTO and TRIPS agreement: CITES	05
Unit -3	**Factors involved in production of crude drugs:** Exogenous and edaphic factors: mineral supplements: nutrients: growth regulators and inhibitors.	04
Unit -4	**Insect and disease management of medicinal and aromatic plants:** Integrated pest plant-based insecticides, and microbial phytotoxins as herbicides. management,	05
Unit -5	**Cultivation technology, post harvest care and processing of medicinal and aromatic plants:** Profile of some high trade value plants: Chirata, Giloe, Gudmar, Isapgol, Jatamansi, Kalmegh, Kesar, Mulethi, Sarpagandha and Tulsi.	05
Unit -6	**Introduction to genetics and molecular biology:** Plant genome and genomic organization, gene families, genetic regulations in transcription and translation in plants: mutation and mutagenesis, transposable elements, genetic manipulations and plant genetic engineering.	07
Unit -7	**Gene mapping and molecular maps of plant genomes:** plant chromosome analysis, use of PCR in gene mapping, molecular maps-RFLP, RAPD. Physical maps in-situ hybridization.	05
Unit-8	**Tissue culture:** Principal and techniques: organogenesis, embryogenesis, micropropagation, haploids through anther, pollen culture, endosperm culture, induction of triploids, nucellus culture, ovary and embryo culture, floral bud culture, shoot primordial, stem and root culture, protoplast isolation, fusion and somatic hybridization.	07
Unit-9	**Application of tissue culture in improvement of medicinal plants:** Yield improvement, stress tolerant plants, disease resistant plants, pesticide tolerant plants, synthetic seed production, germplasm storage and cryopreservation for conservation of plants.	05
Unit-10	**Application of tissue culture in production and enhancement of secondary metabolites:** Strategies involving culture conditions, elicitors, precursors, biotransformation, immobilization and hairy root cultures.	05
Unit-11	**Transgenic plants:** Approaches for production of transgenic plants and applications.	03
Unit-12	**Enzymes of plant origin:** Types, properties, isolation, purification, immobilization, applications and enzyme formulations.	04
	Total	60

Text Books:

It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.

Reference books :

1. D.R. Murray, 1991. "Advanced Methods in plant Breeding and Biotechnology" CAB International Panima Book Distributors.
2. Dixon, 1985. "Plant Tissue Culture". IRL Press Oxford Washington DC.
3. Arun and Archana Sharma, 1999. "Plant Chromosome Analysis, Manipulation and Engineering" 1st Ed. Harwood academic publishers.
4. Murray Moo-Young, 1985. "Comprehensive Biotechnology". Volume I-IV, Pergamon Press Ltd.
5. R. Ranjan, 1999. "Transgenic Plants". Agrobotanica.
6. C.K. Atal and B.M. Kapur, "Cultivation and Utilization of Medicinal and Aromatic Plants". RRL, Jammu.

Class:	Second Semester M. Pharm.	**Subject Code:**	S2-MPG3
Subject:	Medicinal Pant Cultivation and Biotechnology (Practical)	**Allotted Hrs. :**	8

Suggested Laboratory Experiments.

1. Separation of Solanaceous alkaloids from Belladonna leaf by TLC using hyoscine and hyoscyamine as reference compound. To initiate and develop callus culture and root culture of TrigonellaFoenum-graecum on Murashige and Skoog's and Street &McGroger medium respectively.
2. Determination of Ascorbic acid (Vitamin C) by UV. Spectroscopic method in crude drugs
3. Determination of Hyoscymine/Hyoscine in datura species by UV. Spectroscopic method
4. Quantitative estimation of Reserpine in Rauwolfia serpentine by HPLC method
5. Quantitative estimation of Quinine in Cinchona bark by HPLC method
6. Quantitative estimation of Ephedrine in Ephedra extracts by HPTLC
7. Quantitative estimation of glycyrrhizine in Glycyrrhizaglabra by HPTLC
8. Exercises on Identification of simple Naturally occurring molecules by UV. & IR spectroscopy
9. Exercises on interpretation of at least 5-different known compounds of Natural origin by using spectroscopic data (NMR & MASS).
10. Determination of Microbial load in Crude drugs
11. Separation and identification of aflotoxins in Crude drugs.
12. Preparation of detailed monograph of at least one medicinal plant covering taxonomy physiochemical and pharmacological investigation and its use in traditional system of medicine. Preclinical studies of some herbal extracts like analgesic anti-inflammatory and anti anxiety etc

Class: Second Semester M. Pharm. **Subject Code:** S2-MPG4
Subject: Advanced Herbal Drug Technology - 1 **Allotted Hrs.:** 4

OBJECTIVE:

- To give additional Knowledge to students based on their choice of topic

Sr. No.	Unit and Contents	Hrs.
Unit-1	Herbal cosmetics	
Unit-2	Herbal drug Technology	
Unit-3	Marine derived natural products	
Unit-4	Plant biotechnology	
Unit-5	Quality assurance of Herbal formulations	
Unit-6	Biological evaluation of Herbal drugs	
	Total	**60**

Class: Third Semester M. Pharm. **Subject Code:** S3-MPH1
Subject: Drug Regulatory aspects and IPR (Theory) **Allotted Hrs.:** 4

OBJECTIVE:

- To impart information on various drug regulatory aspects involved in the profession.
- To teach the import / export related regulations with respect to some countries
- To make the students understand the importance and implication of IPR and related matters.
- To train the students in GMP and the latest developments there.

Sr. No.	Unit and Contents	Hrs.
Unit-1	**DRUG REGULATORY ASPESTS**	**40**
a)	Drug Regulatory Aspects (India) – 1. Indian drug regulatory authorities, Central and State regulatory bodies (FDA) 2. Drugs and Cosmetics Act and Rules with latest Amendments (Selective) 3. Special emphasis – Schedule M and Y 4. New Drugs – Importation, Registration, Development, Clinical Trials, BE NOC & B.E. studies 5. Various licenses – Test lic., Import lic. for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.	10
b)	Good Manufacturing Practices (GMP) – 1. Indian GMP certification, WHO GMP certification 2. ICH guidelines for stability testing and other relevant ones (Q1 – Q10) 3. Export permissions and manufacturing for semi-regulated countries 4. Understanding of the plant lay-outs with special emphasis on the environment & safety. (HVAC, Water systems, Stores management, Effluent etc.) 5. Quality Assurance and Quality Control – Basic understanding for in-built quality.	12
c)	Drug Regulatory Aspects (International & highly regulated markets) – 1. US Requirements – (for Generic Drugs especially formulations) 2. CDER, INDA, NDA, ANDA's (types), CTD Formats of dossiers, E-submission, US DMF (various types), IIG Limits, Orphan Drugs, Vanilla ANDA's, Exhibit/Pivotal batches, Validation batches, Various Guidance issued by CDER, OGD, Orange Book (and patents), RLD (Reference listed drug) for BE studies and the norms for US submission, Bioequivalence and dissolution recommendations, Packaging, Stability studies and the Product Information Leaflet, US FDA Inspection (audits), Pre-approval Inspections and approvals 3. European Union Requirements – 4. All the aspects for European Registration of formulations for generic drugs sale in the European markets under EU. EMEA guidelines on various aspects as above (C 1) 5. A brief introduction to the guidelines for Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries. 6. GMP audits, role of Quality Assurance, product approvals and supplies.	18
Unit-2	**INTELLECTUAL PROPERTY RIGHTS (IPR)**	**20**
a)	**Introduction to IPR & Patents** – Development of IP law in India, IPR regime, Introduction to IP laws in India, Role of IP in pharma industry growth.	
b)	**Patenting in India** – Introduction, Patent legislation, Indian Patents Act 1970 and amendments, Procedure for patent application, Grant and opposition proceedings, Patent licensing, Patent infringement proceedings, IPAB – role and functions (IP Appellate Board), Indian IP Case laws	
c)	**American & European patent system** – Requirements for patenting, utility, novelty Non-obviousness, Patent specification & claims, Patent infringement and Doctrine of Equivalents, Federal circuit and Patent system in Europe	
d)	**International treaties and conventions on IPR** - Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO	
e)	**Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003**	
f)	**Introduction to** Geographical indication / Trademark/ copyright: Filing procedures	
g)	**Patent search, Patent analysis & Patent drafting**.	
h)	**Allied Patents Related Issues**: Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage	
	Total	60

Reference books :

1. CDSO publications and updates of drug and Cosmetics act and rules (Govt. of India).
2. CDER Publications and Guidance
3. EMEA Publications and Guidance
4. Orange Book, ICH guidelines, Indian Patents Act
5. Country specific Regulatory Guidelines (available from internet)
6. Govt. Publications on issues affecting sales, distribution, manufacturing, excise, etc.
7. J. D. Nally, "Good manufacturing Practice for Pharmaceuticals" Informa Healthcare.
8. I. Kanfer & L. Shargel, "Generic Product Development BE issued" Informa Healthcare.
9. R. A. Guarino, "New Drug Approval Process. The Global challenges". Informa Healthcare.
10. Watcher and Nash, "Pharmaceutical Process Validation". Marcel Dekker.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPG2
Subject: Research work Seminar **Allotted Hrs. :** 8

OBJECTIVE:

- To effectively present the research work carried out by the student.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPG3
Subject: Research Project **Allotted Hrs. :** 16

OBJECTIVE:

- To manage the research work in time bound manner.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPG4

Subject: Standardization and Evaluation of Natural Products and Formulation (Theory) **Allotted Hrs. :** 4

OBJECTIVE:

- To introduce the concept of quality control of phytochemicals and their standardization
- To train students regarding various official monographs and their study
- To give latest knowledge in developing / thurst area in the subject

Sr. No.	Unit and Contents	Hrs.
Unit-1	Introduction: Factors affecting quality of crude drugs, methods for documentation and preservation of crude drugs and their products, detection of common adulterants, microbial contamination, toxic metals, pesticides, insecticides and insect infestation in whole and powdered drugs.	08
Unit-2	Standardization requirements of herbal medicines, traditional and folklore remedies and preparations: their quality, safety and efficacy assessment.	07
Unit-3	Importance of monographs of medicinal plants, their comparative study as per IP, API, Unani, Pharmacopoeia, Homoeopathic Pharmacopoeia, Siddha Pharmacopoeia, BHP, Japanese Pharmacopoeia, Chinese Pharmacopoeia, European Pharmacopoeia, USP (dietary supplements), WHO and EMEA guidelines and ESCOP monographs for medicinal products.	09
Unit-4	Quantitative assays to determine extraction efficiency: general methods of analysis: estimation of alkaloids, steroids, terpenoids and flavonoids: active component analysis and purity determination using UV, GLC, HPTLC and electrophoretic methods.	08
Unit-5	Quality control of single and multicomponent plant drugs and plant-derived classical Ayurvedic and Unani formulations by study of HPTLC and HPLC fingerprints.	06
Unit-6	Natural products-derived combinatorial libraries and their significance in drug discovery programs.	04
	Shelf life study, protocols to study stabilization of herbal based products. Assessment of physical, physic-chemical and chemical parameters at different stages.	06
Unit-7	Bioavailability and pharmacokinetic significance for herbal drugs with examples of clinically used herbal drugs.	05
Unit-8	Preparation of DMF for herbal medicines.	04
Unit-9	Patents: IPR and Regulatory Affairs related to plants and plant products.	04
	Total	**60**

Text Books:

It is strongly recommended that some standard book/s be used for practicals. The choice of book/s is left to the concerned teachers.

Reference books :

1. Indian Herbal Pharmacopoeia, Vol. 1&2, RRL, IDMA, 1998, 2000.
2. Indian Pharmacopoeia, 2010.
3. V. Rajpal, 2002. "Standardization of Botanicals", Eastern Publishers, New Delhi.
4. J.B. Harborne, 1998. "Phytochemical methods", Chapman and Hall.
5. K. Paech, 1956. "Modern methods of plant analysis"., Springer-Verlag.

Class: Third Semester M. Pharm. **Subject Code:** S3-MPG5
Subject: Advanced Herbal Drug Technology - 2 **Allotted Hrs.:** 4

OBJECTIVE:

- To entrich the knowledge of a student desirous of studing special topic of interest

Sr. No.	Unit and Contents	Hrs.

Class: Fourth Semester M. Pharm. **Subject Code:** S4-MPH1
Subject: Research Project and Colloquium **Allotted Hrs.:** 36

OBJECTIVE:

- To complete the given research project
- The effectively defense the work before a group of qualified evaluators.

Sr. No.	Unit and Contents	Hrs.
1.	• Completion of research project and submission of dissertation to University. • Defence / viva voce	36