

UNIVERSITY OF PUNE

FACULTY OF PHARMACEUTICAL SCIENCES



MASTER OF PHARMACY (M.PHARM.) in

- 1. Pharmaceutics**
- 2. Pharmaceutical chemistry**
- 3. Pharmacology**
- 4. Pharmacognosy**
- 5. Quality assurance techniques**

COURSE STRUCTURE & SYLLABI

(EFFECTIVE FROM ACADEMIC YEAR 2013-2014)

I. NOMENCLATURE:

University of Pune offers Master of Pharmacy (M. Pharm) course of two years (four semesters) duration in the following specialization.

1. Pharmaceutics
2. Pharmaceutical Chemistry
3. Pharmacology
4. Pharmacognosy
5. Quality Assurance Techniques

II. ELIGIBILITY:

The eligibility for admission to the M Pharm course is as under:

The candidate who has passed the examination for the degree of B. Pharm of University of Pune or any other statutory University, recognized as equivalent thereto by this university, with at least 50 % marks (at least 45% marks in case of SC/ST category & Physically Handicapped candidates belonging to Maharashtra State only) will be eligible for admission to any specializations of pharmacy mentioned above.

The post-graduate student in the faculty of Pharmaceutical Sciences will not be permitted to register his/her name simultaneously for any Diploma or Degree Course of University of Pune or any other College / Institution.

NOTE: In case of eligibility criterion decided by the Govt. of Maharashtra differs from above, university authorities shall decide the eligibility criterion from time to time.

III. FEES:

The Fees and deposits shall be as prescribed by the competent Authority appointed by Govt of Maharashtra.

IV. SCHEME OF TEACHING AND EXAMINATION:

The scheme of Teaching and Examination for M. Pharm. First, Second, Third and Fourth Semester shall be as follows:

V. DURATION:

The duration of M. Pharm: Course shall be of two years consisting of four semesters. Each semester shall be of six months duration.

VI. SEMINAR:

The candidate for M. Pharm. course shall have to give seminar in each semester. The topics for the seminar during First, Second, Third Semester & Fourth Semester shall be as under:

First Semester: Seminar topics to be selected from the papers of specialization.

Second Semester: Seminar topics to be selected from the papers of specialization.

Third Semester: 1. Seminar on Research work Envisaged for dissertation.
(Evaluation by External Examiner)

2. Seminar on Recent trends in Pharmaceutical Sciences

Fourth Semester: Seminar shall be on entire work of dissertation.

*Note:

- Seminar on Research work Envisaged for dissertation will be evaluated jointly by Guide (internal) and External Examiner appointed by Principal of the respective institute.
- Maximum number of students to be evaluated by single examiner should not exceed FIVE.

The candidate will have to give seminar with the help of audio visual aids.

Evaluation of Seminar: The seminar will be evaluated by two recognized Post-graduate teachers of the subject of specialization, ordinarily one of whom will be the guide of the student. The two examiners will jointly award the Marks for the seminar out of 50.

The candidate securing less than 50 % marks shall be treated as failed. If the candidate fails to secure minimum '50%' marks in the seminar, he/she will have to give the seminar in the next semester. The marks secured by the candidate in the seminar shall be communicated to the University for showing in the statement of marks of the

concerned semester.

VII. DISSERTATION:

The topics for the dissertation shall be assigned by the Guide, a recognized Post-graduate Teacher, within one month of the beginning of second semester. Every candidate presenting himself/herself for the M. Pharm. fourth semester examination is required to submit four typewritten copies of the dissertation duly certified by the Guide. Out of four copies of dissertation, one copy is to be submitted in the college Library. The dissertation also needs to be certified by the Principal of the college.

The candidate should submit the dissertation carried out during his 3rd and 4th Semester before 31st May of the calendar year. If candidate fails to submit his/her dissertation before 31st May of the calendar year, he/she will have to submit dissertation in subsequent semester i.e. before 31st December of the calendar year. The Principal of the concerned College/Institute will forward the dissertation to the University office.

There shall be not more than EIGHT submissions of dissertations in one academic year under each fulltime recognized PG guide of institute.

If the subject of dissertation entails collaboration with other departments or specialties, the collaborative portion of the work will be supervised by Co-Guide, appointed by the Principal of the College/Institute in consultation with the Guide. Where a Co-Guide is involved, the dissertation will be certified jointly by the Guide & Co-guide.

The Guide or any other Recognized Post-graduate teacher in the subject (Internal Examiner) and an External Examiner appointed by the University will examine the dissertation. The Examiners shall jointly assign the marks for dissertation out of 300 which includes Seminar of 50 marks, Research work of 150 marks and viva-voce of 100 marks. The allotment of marks of the dissertation shall be as under.

A. Seminar on Dissertation

Contents	Marks
1. Presentation and communication	25
2. Quality of Research work	25
Total	50

B. Research work

Contents	Marks
1. Literature Survey	10
2. Experimental Work	50
3. Scientific Contents	25
4. Result/ Conclusion	25
5. Organization of scientific material, thesis, dissertation and references	20
6. Patent or Publication on thesis work	20
Total	150

VIII. VIVA-VOCE:

The candidates will have to appear for Viva-Voce on dissertation. This test will be of 100 marks. The student will have to defend the dissertation. The examiners will jointly assign the marks for Viva voce. The allotment of marks for Viva-voce shall be as under:

C. Dissertation & Defense (viva/voce)

Contents	Marks
i. Depth of knowledge on research work done	50
ii. Result and Discussion	25
iii. Defence	25
Total	100

IX. EXAMINATION RULES:

Assessment shall consist of A) In – semester continuous assessment and B) end semester assessment. Both shall have an equal weightage of 50% each.

a. In- semester assessment –

An in-semester assessment of 50 marks should be continuous, procedures and marks for theory and practical examination are as follows –

i. For theory Examination –

An In-semester assessment for 50% marks should be continuous and at least five tests should be conducted for full course (1 written test for 30 marks and any four test of 5 marks i.e 4 X 5 = 20 marks should be conducted) and the teacher must select a variety of procedures for examination such as :

- i. Term Paper
- ii. Seminar Presentation
- iii. Short Quizzes
- iv. Assignments
- v. Extension work
- vi. An open book test (with the concern teacher deciding what books are to be allowed for this purpose)
- vii. Mini research project by individual student or group of students
- viii. Case Study

The concern teacher in consultation with the head of PG Department shall decide the nature of question for the written test.

ii. For practical Examination –

Day to Day Assessment of Journal (Individual Practical's will be evaluated) (Evaluation includes Journal, Day to day Performance, Viva etc.)	20 marks
Sessional Exam (Evaluation of sessional exam includes Experiment, Viva, Synopsis etc.)	30 marks
Total	50 marks

If a student misses an internal assessment examination he/she will have a second chance with the permission of the Principal in consultation with concern teacher. Such a second chance shall not be the right of the student.

In case he/she wants to repeat internal assessment he/she can do only by registering for the said courses during the 3rd and 4th Semester.

b. End- semester assessment –

End Semester examination will be conducted by University of Pune.

Student who have failed semester end exam may reappear for semester end exam only twice in subsequent period. The student will be finally declared as failed if he/ she do not pass in all credits within a total period of 2 years. After that such students will have to seek fresh admission as per the admission rules prevailing at that time, if wish to complete the course.

The student has to obtain 50 % marks in the combined examination of in-semester assessment and semester end assessment with minimum passing of 40% in both these separately.

To pass the degree course a student shall have to get minimum aggregate 50% marks (E and above on grade point scale) in each course. Their shall be separate head of passing for theory and practical for each subject.

A student cannot register for the third semester if he/she fails to complete 50% credits of the total credits expected to be ordinarily completed within two semesters.

There shall be revaluation of answer scripts of semester end examination but not of internal assessment papers as per ordinance number 134 A & B.

While marks will be given for all examinations, they will be converted into grades. The semester end grade sheets will have only grade and final grade sheets and transcripts shall have grade points average and total % of marks (up to two decimal points). The final grade sheet will also indicate the PG Center to which the candidate belongs.

X. ASSESSMENT AND GRADE POINT AVERAGE:

a. The system of evaluation will be as follows:

Each assignment / test shall be evaluated in terms of grades. The grades for separate assignments and the final (Semester end) examination will be added together and then converted into a grade and later a grade point average. Results shall be declared for each semester and the final examination will have total grades and grade point average.

Marks / Grade/ Grade point

Grade	Marks out of 100	Marks out of 50	Grade Points
O: Outstanding	100 to 75	50 to 38	6
A: Very Good	74 to 65	37 to 33	5
B: Good	64 to 55	32 to 28	4
C: Average	54 to 50	27 to 25	3
D: Satisfactory	49 to 45	24 to 22	2
E: Pass	44 to 40	21 to 20	1
F: Fail	39 to 0	19 to 0	0

Final Grade Points

Grade Points	Grade
05.00 – 6.00	O
04.50 – 04.99	A
03.50 – 04.49	B
02.50 – 03.49	C
01.50 – 02.49	D
00.50 – 01.49	E
0.00 – 00.49	F

The formula for GPA will be based on weighted average. The final GPA will not be printed unless a student passes courses equivalent to 100 credits.

(i) **Semester Grade Point Average (SGPA) =**

$$\text{SGPA} = \frac{\sum_{i=1}^P C_i G_i}{\sum_{i=1}^P C_i}$$

$$\text{SGPA} = \frac{\sum \text{Grade Points Earn} \times \text{Credits for each course}}{\text{Total Credits}}$$

(ii) Cumulative Grade Point Average (CGPA) =

$$\text{CGPA} = \frac{\sum_{i=1}^P C_i G_i}{\sum_{i=1}^P C_i}$$

$$\text{SGPA} = \frac{\sum \text{Total Points Earn} \times \text{Credits for each course}}{\text{Total Credits}}$$

If the GPA is higher than the indicated upper limit in the three decimal digit then the student be awarded higher final grade (e.g. a student getting GPA of 4.492 may be awarded 'A')

There will be only final compilation and moderation at GPA (Final) level done at the department. While declaring the result the existing relent ordinances are applicable. There is also a provision for verification and revaluation. In case of verification, the existing rules will be applicable. The revaluation result will be adopted if there is a change of at least 10 % marks and in the grade of course.

b. The description for each of the grades will be as follows –

Grade proposed norms

O : Outstanding : Excellent analysis of Topic, (75 % to 100%)

Accurate Knowledge of primary material, wide range of reading, logical development of ideas, originality in approaching the subject, neat and systematic organization of content, elegant and lucid style.

A : Very Good : Excellent analysis of Topic, (65% to 74%)

Accurate Knowledge of primary material, acquaintance with seminal publications, logical development of ideas, neat and systematic organization of content, effective and clear expression.

B : Good : Good analysis and treatment of topic (55% to 64%)

Basic Knowledge of primary material, logical development of ideas, neat and systematic organization of content, effective and clear expression

C : Average : Some important points covered (50% to 54%)

Basic Knowledge of primary material, logical development of ideas, neat and systematic organization of content, effective and clear expression

D : Satisfactory : Some Points Discussed (45% to 49%)

Basic Knowledge of primary material, Sum organization, acceptable language or expression

XI. FEATURES OF THE CREDIT SYSTEM

- 1) Master's degree would be of 100 credits each.
- 2) Four credit course of theory will be of four clock hour per week running for 15 weeks.
- 3) Four credit course of practicals will consist of 8 hours of laboratory exercise for 15 weeks.
- 4) Every student shall have to complete minimum 75% credits in all semesters.
- 5) First year may divide into two semesters (Semester-I & II) and shall have

6 Theory courses x 4 credits	= 24 credits
2 Theory courses x 3 credits	= 06 credits
3 Practical courses x 4 credits	= 12 credits
2 Seminar	= 04 credit
Research work	= 06 credits
Total	= 52 credits

XII. GRADE IMPROVEMENT PROGRAM:

For grade improvement a student must reappear for semester end examination for a minimum 30 credits. These courses will be from the parent department. Grade improvement program will be implemented at the end of the academic year. A student can opt for the grade improvement program only after the declaration of final semester examination.

If candidate wish to improve the class, he/she shall be allowed to do so in maximum three consecutive attempts in university theory examination within maximum five years from date of declaration of his final result.

XIII. ACADEMIC CALENDAR AND TERMS

The terms and academic activities of the college affiliated to University of Pune, Pune under SGPA shall be as per the dates given below, only the years shall be changed i.e. the dates shall remain same as given below irrespective of the year.

Beginning of First Term (Semester I, and III)	: As per University academic calendar
Vacation	: As per University academic calendar
Beginning of Second Term (Semester II, and IV)	: As per University academic calendar

**MASTER OF PHARMACY COURSE STRUCTURE
SPECIALIZATION : PHARMACEUTICS**

Sem. No	Paper	Scheme of Teaching Hrs/Weeks		Scheme of Credit		Scheme of Examination Theory			Practical			Total (Including 50 marks of Internal assessment)
		Theory	Practical	Theory	Practical	Hrs.	Marks		Hrs.	Marks		
						UE	UE	IE		UE	UE	
I	Advanced Analytical Techniques	4	8	4	4	3	50	50	8	50	50	200
	Research Methodology	4		4		3	50	50				100
	Advanced Pharmaceutics	4	8	4	4	3	50	50	8	50	50	200
	Elective-I	3		3		3	50	50				100
	Seminar				2			50				50
II	Formulations & Development	4	8	4	4	3	50	50	8	50	50	200
	Drug Regulatory Affairs	4		4		3	50	50				100
	Novel Drug Delivery Systems	4		4		3	50	50				100
	Elective-II	3		3		3	50	50				100
	Seminar		4		2			50				50
	Research work		12		6							
III	Seminar on Research Envisaged for Dissertation				4		50					50
	Seminar on recent trends in Pharmaceutical Sciences				4			50				50
	Research work		36		18							
IV	Seminar on Dissertation				4		50					50
	Research work		36		18		150					150
	Dissertation & Defense (viva/voce)						100					100
			Total	30	70					Grant Total		1600
			Total Credits = 100									

MASTER OF PHARMACY COURSE STRUCTURE
SPECIALIZATION : PHARMACEUTICAL CHEMISTRY

Sem. No	Paper	Scheme of Teaching Hrs/Weeks		Scheme of Credit		Scheme of Examination Theory			Practical			Total (Including 50 marks of Internal assessment)
		Theory	Practical	Theory	Practical	Hrs.	Marks		Hrs.	Marks		
						UE	UE	IE	UE	UE	IE	
I	Advanced Analytical Techniques	4	8	4	4	3	50	50	8	50	50	200
	Research Methodology	4		4		3	50	50				100
	Advanced Pharmaceutical Chemistry	4	8	4	4	3	50	50	8	50	50	200
	Elective-I	3		3		3	50	50				100
	Seminar				2			50				50
II	Advanced Medicinal Chemistry	4	8	4	4	3	50	50	8	50	50	200
	Drug Regulatory Affairs	4		4		3	50	50				100
	Drug Design	4		4		3	50	50				100
	Elective-II	3		3		3	50	50				100
	Seminar		4		2			50				50
	Research work		12		6							
III	Seminar on Research Envisaged for Dissertation				4		50					50
	Seminar on recent trends in Pharmaceutical Chemistry				4			50				50
	Research work		36		18							
IV	Seminar on Dissertation				4		50					50
	Research work		36		18		150					150
	Dissertation & Defense (viva/voce)						100					100
			Total	30	70					Grant Total		1600
			Total Credits = 100									

**MASTER OF PHARMACY COURSE STRUCTURE
SPECIALIZATION : PHARMACOLOGY**

Sem. No	Paper	Scheme of Teaching Hrs/Weeks		Scheme of Credit		Scheme of Examination Theory			Practical			Total (Including 50 marks of Internal assessment)
		Theory	Practical	Theory	Practical	Hrs.	Marks		Hrs.	Marks		
						UE	UE	IE	UE	UE	IE	
I	Advanced Analytical Techniques	4	8	4	4	3	50	50	8	50	50	200
	Research Methodology	4		4		3	50	50				100
	Advanced Pharmacology (Preclinical Evaluation of Drugs)	4	8	4	4	3	50	50	8	50	50	200
	Elective-I	3		3		3	50	50				100
	Seminar				2			50				50
II	Clinical Pharmacology	4	8	4	4	3	50	50	8	50	50	200
	Drug Regulatory Affairs	4		4		3	50	50				100
	Molecular Pharmacology	4		4		3	50	50				100
	Elective-II	3		3		3	50	50				100
	Seminar		4		2			50				50
	Research work		12		6							
III	Seminar on Research Envisaged for Dissertation				4		50					50
	Seminar on recent trends in Pharmacology				4			50				50
	Research work		36		18							
IV	Seminar on Dissertation				4		50					50
	Research work		36		18		150					150
	Dissertation & Defense (viva/voce)						100					100
			Total	30	70					Grant Total		1600

Total Credits = 100

**MASTER OF PHARMACY COURSE STRUCTURE
SPECIALIZATION : PHARMACOGNOSY**

Sem. No	Paper	Scheme of Teaching Hrs/Weeks		Scheme of Credit		Scheme of Examination Theory			Practical			Total (Including 50 marks of Internal assessment)
		Theory	Practical	Theory	Practical	Hrs.	Marks		Hrs.	Marks		
						UE	UE	IE		UE	UE	
I	Advanced Analytical Techniques	4	8	4	4	3	50	50	8	50	50	200
	Research Methodology	4		4		3	50	50				100
	Advanced Pharmacognosy	4	8	4	4	3	50	50	8	50	50	200
	Elective-I	3		3		3	50	50				100
	Seminar				2			50				50
II	Phytochemistry & Phytopharmaceuticals	4	8	4	4	3	50	50	8	50	50	200
	Drug Regulatory Affairs	4		4		3	50	50				100
	Industrial Pharmacognosy	4		4		3	50	50				100
	Elective-II	3		3		3	50	50				100
	Seminar		4		2			50				50
	Research work		12		6							
III	Seminar on Research Envisaged for Dissertation				4		50					50
	Seminar on recent trends in Pharmacognosy				4			50				50
	Research work		36		18							
IV	Seminar on Dissertation				4		50					50
	Research work		36		18		150					150
	Dissertation & Defense (viva/voce)						100					100
			Total	30	70					Grant Total		1600
		Total Credits = 100										

MASTER OF PHARMACY COURSE STRUCTURE
SPECIALIZATION : QUALITY ASSURANCE
TECHNIQUES

Sem. No	Paper	Scheme of Teaching Hrs/Weeks		Scheme of Credit		Scheme of Examination Theory			Practical			Total (Including 50 marks of Internal assessment)
		Theory	Practical	Theory	Practical	Hrs.	Marks		Hrs.	Marks		
						UE	UE	IE	UE	UE	IE	
I	Advanced Analytical Techniques	4	8	4	4	3	50	50	8	50	50	200
	Research Methodology	4		4		3	50	50				100
	Advanced Quality Assurance Techniques (CGMP & Documentation)	4	8	4	4	3	50	50	8	50	50	200
	Elective-I	3		3		3	50	50				100
	Seminar				2			50				50
II	Pharmaceutical Validation	4	8	4	4	3	50	50	8	50	50	200
	Drug Regulatory Affairs	4		4		3	50	50				100
	Quality Planning and Analysis	4		4		3	50	50				100
	Elective-II	3		3		3	50	50				100
	Seminar		4		2			50				50
	Research work		12		6							
III	Seminar on Research Envisaged for Dissertation				4		50					50
	Seminar on recent trends in Quality Assurance Techniques				4			50				50
	Research work		36		18							
IV	Seminar on Dissertation				4		50					50
	Research work		36		18		150					150
	Dissertation & Defense (viva/voce)						100					100
			Total	30	70					Grant Total		1600

Total Credits = 100

UNIVERSITY OF PUNE

FACULTY OF PHARMACEUTICAL SCIENCES



Syllabi of Master of Pharmacy in

- 1. Pharmaceutics**
- 2. Pharmaceutical Chemistry**
- 3. Pharmacology**
- 4. Pharmacognosy**
- 5. Quality Assurance Techniques**

(EFFECTIVE FROM ACADEMIC YEAR 2013-14)

SEMESTER-I

(M. 1. 1) ADVANCED ANALYTICAL TECHNIQUES

(Theory 4 hrs/week)

CREDITS 04

UNIT I

- 1. UV-Visible spectroscopy:** Principle of UV-Visible Spectroscopy, Chromophores and their interaction with UV-visible radiation and their utilization in structural, qualitative and quantitative analysis of drug molecules. Woodward-Fieser rule, use of schiff reagents for elucidation of structures.
- 2. Infrared spectroscopy:**

Introduction, types of vibrations, characteristic regions of the spectrum, influence of substituents, ring size, hydrogen bonding, vibrational coupling, field effects on frequency, methodology, spectral interpretation with example. The basic principle, instrumentation and different attachments to FTIR for sample handling. NIR: Principle and applications

UNIT II

- 3. Nuclear magnetic resonance spectroscopy:** Magnetic properties of nuclei, field and precession, chemical shift concept, isotopic nuclei, reference standards and solvents. ^1H NMR spectra, chemical shifts, first order spin-spin splitting rules & patterns and coupling constants, integration of signals, interpretation of spectra, spin-decoupling using double resonance techniques, use of shift reagents for simplification of NMR spectra. Principles of FT-NMR with reference to ^{13}C NMR, free induction decay, average time domain and frequency domain signals. Spin-spin and spin-lattice relaxation phenomenon. Proton noise decoupled ^{13}C NMR spectra, Off-resonance ^{13}C NMR and Nuclear Overhauser enhanced ^{13}C NMR spectra, their interpretation and application. DEPT techniques. Introduction of 2D NMR techniques, HOMO and HETERO COSY, NOESY with applications.
- 4. Mass spectrometry:** Basic principles and instrumentation (components and their significance). Ionization techniques (FAB, MALDI, SELDI, APCI, APPI, ESI and DART). Mass analyzers [Quadrupole, Ion Trap, FT-ICR, TOF and tandem mass (MS-MS)]. Mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure of organic compound classes. Relative abundances of isotopes and their contribution to characteristic peaks.

UNIT III

5. Structure elucidation using combined spectroscopic data.
6. **Chromatographic techniques:** Principle, instrumentation and applications of HPLC, LC-MS, HPTLC, GC, GC-MS, Supercritical Fluid Chromatography, and UPLC.

UNIT IV

7. **Thermal analysis:** Theory, Instrumentations and applications of Thermogravimetric Analysis (TGA), Differential Thermal Analysis (DTA) and Differential Scanning Calorimetry (DSC).
8. **Electron microscopy:** Introduction to Scanning Electron Microscopy and Travelling Electron Microscopy.

(M. 1.2) ADVANCED ANALYTICAL TECHNIQUES
(Practical 8 hrs/week)
CREDITS 04

1. Study effect of solvent on wavelength maxima of drugs.
2. Find Beer's law limit of drugs in suitable solvent.
3. Multicomponent analysis by UV-Spectrophotometry
 - a) Absorbance corrected for interference method
 - b) Simultaneous equation method
 - c) Absorbance ratio method
 - d) Area under curve method
 - e) First derivative spectrophotometric method
4. Assay of drugs official in various pharmacopoeias (Any five). This should cover UV-spectrophotometry, titrimetric, HPLC methods. The titrimetric method should include potentiometric end point determination.
5. Interpretation of UV, IR, NMR and Mass spectra of some unknown intermediates and drugs [**Note:** For interpretation NMR and Mass spectral data, the spectra can be obtained from available literature] (Any five)
6. Validation of assay methods for pharmaceutical formulations (Note: Students should be familiar with ICH and USP guidelines).

7. Demonstration: Separation of mixture of drugs (At least binary mixture) using HPLC and calculation of system suitability parameters.

Recommended Books:

1. M. Orchin and H.H. Jaffe – Theory and applications of Ultraviolet spectroscopy. (John Wiley and Sons. N.Y).
2. Silverstein, Basseler, Morrill- Spectrometric identification of organic compounds (John Wiley and Sons. N.Y).
3. Willard, Merritt, Dean – Instrumental methods of analysis (CBS Publishers and Distributors, Delhi).
4. J.R. Dyer – Application of absorption Spectroscopy of Organic Compounds (Prentice Hall, London).
5. C.N.R. Rao – Chemical Applications of Infrared spectroscopy. (Academic Press, N.Y.).
6. L.M. Jackmann and B.D. Sternhell – Application of NMR spectroscopy in organic chemistry (Pergamon Press, London.).
7. F.W. McLafferty and F. Turecek- Interpretation of Mass Spectra.
8. R.J. Hamilton and P. A. Sewell- Introduction to High Performance Liquid Chromatography.(Chapman and Hall, London).
9. J.W. Munson- Pharmaceutical Analysis: Modern methods –Part A and Part B (Marcel Dekker, Inc., New York).
10. Introduction to Spectroscopy, 3rd edition, Pavia, Lampman, Kriz, Thomson Publisher.
11. Analytical chemistry: A Modern Approach to Analytical Science, 2nd edition by Kellner, Mermet, Otto, Valcarcel Wiley ECH.
12. Ewing's Analytical Instrumentation Handbook, 3rd edition, edited by Jack, Cazes, Marcel Dekker.
13. P.D. Sethi – Quantitative Analysis of Drugs in Pharmaceutical Formulations (VBS Publishers, Delhi).
14. Pharmacopoeia of India (latest edition).
15. United State Pharmacopoeia (latest edition).

16. British Pharmacopoeia (latest edition).

17. A.H. Beckett, J.B. Stenlake – Practical Pharmaceutical Chemistry, Part I and Part II (CBS Publishers Delhi)

18. F. D. Snell and C. T. Snell- Colorimetric Methods of analysis (Van Nostrand Reinhold Company, N.Y.).

(M.1.3) RESEARCH METHODOLOGY

Theory: (4hrs/week)

CREDITS 04

UNIT I

1. **Research:**

Meaning and objective of research, types of research (basic, applied and patent oriented research), selecting a problem & preparing a research proposal for different types of research as mentioned above.

2. **Literature survey and documentation:**

Methods of Literature survey, Use of library, books, journals, e journals, thesis, chemical abstracts and patent data base, techniques of documentation, importance of documentation, uses of computer packages in documentation.

UNIT II

3. **Technical writing:**

Research report, paper, thesis writing [Title, abstract, key words, methodology, results, discussion, conclusion, acknowledgement, references, errata, foot notes], types of research paper [review article, research papers and short communications and meeting report], detailed study of 'Instruction to Authors' of IJPS journal, a thorough understanding of steps involved in submitting articles electronically to IJPS [registration, new article submission, tracking the process, submitting revised articles]. Impact factor, Rating, Indexing and citation etc.

4. **Presentation:** (Specially for oral)

Importance, types different skills, contained, format of model, introduction & ending, posture, gestures, eye contact, facial expressions, stage, fright, volume, pitch, speed, pause & language, visual aids & seating, questionnaire.

UNIT III

5. **Project [cost] management :**

Cost analysis of the project- cost incurred on raw materials, procedure, instrumentations & clinical trials.

6. Research organizations and procurement of research grants:

Introduction to various research organization (DST, DBT, AICTE, UGC, CSIR, DRDO, ICMR) along with their function in India, sources for procurement of research grants.

UNIT IV

7. Basic Definitions And Concepts:

Variables and variation [continuous variables and discrete variables], sample and population [population parameters and sample statistics, random sampling], precision, accuracy and bias; significant figures.

8. Experimental design:

Meaning, need, features, basic principle and important concepts of experimental design different types of research designs [before-and-after without control design, after-only with control design, before-and-after with control design, completely randomized design, randomized block design, latin square design, factorial design], crossover design and bioavailability / bioequivalence studies.

UNIT V

9. Descriptive Data Analysis:

What is statistics?, parametric and non-parametric data, descriptive and inferential analysis, the organization of data (grouped data distributions), statistical measures (measures of central tendency & measures of spread or dispersion) , normal distribution (normal & non normal distribution, interpreting the normal probability distribution, practical applications of the normal curve) , measures of relative position (standard scores : the Z score, the T Score, the percentile rank), measures of relationship [pearson's product-moment coefficient of correlation (r), rank order correlation (ρ), phi correlation coefficient (ϕ)], interpretation of a correlation coefficient [outliers, misinterpretation of the coefficient of correlation, prediction], standard error of estimate.

Application of linear regression and correlation to analysis of standard curves and drug analysis.

10. Inferential data analysis:

Statistical inference, the central limit theorem, parametric tests, testing statistical significance [the significance of the difference between the means of two independent groups, the null hypothesis (H_0), the level of significance], decision making [two tailed and one tailed tests of significance, degrees of freedom], a one sample Z test, student's distribution (t) [significance of

the difference between two small sample independent means], homogeneity of variance [significance of the difference between the means of two matched or correlated groups (nonindependent samples), statistical significance of coefficient of correlation], one way and two way analysis of variance

(ANOVA), multiple regression and correlation, nonparametric tests [the chi square test (X^2), the mann-whitney test], outliers and missing data, multiple comparisons [Bonferroni t-test, Student Newman-Keuls, Tukey test, Dunnett's test].

Comparison of dissolution various tablet formulations by two way ANOVA, comparison of three drug treatments at three sites by two way ANOVA.

Recommended Books: -

1. Research In Education- John V. Best, John V. Kahn 10th edition
2. Presentation skills - Michael Hallon- Indian Society for Institute education
3. Thesis projects in Science & Engineering – Richard M. Davis.
4. Thesis & Assignment – Jonathan Anderson
5. Writing a technical paper- Donald Menzel
6. Protection of industrial Property rights- P. Das & Gokul Das
7. Preparation for publication – King Edward Hospital Fund for London
8. Manual for evaluation of industrial projects-United Nations
9. Manual for the preparation of industrial feasibility studies
Pharmaceutical Statistics: Practical and Clinical
10. Applications by Sanford Bolton and Charles Bon, fourth edition.
Research methodology: Methods and Techniques by C. R.
11. Kothari, second edition
Research in Education by John W. Best and James V. Kahn, 11th
12. edition
13. Instruction to Authors of IJPS journal.

(M.1.4) ADVANCED PHARMACEUTICS
(Theory 4hrs/week)
CREDITS 04

UNIT I

1. PREFORMULATION: Introduction and concept, need, advantages, Principles of preformulation, Solid state characterization, Analytical techniques to characterize physical and chemical properties of NCE's , Solubility & pKa, Thermal Analysis, X-ray Diffraction, Techniques to generate & characterize amorphous & crystalline forms. Stability. Brief account of preformulation of i) Conventional tablet - ii) Oral liquids, Suspension, iii) Semisolid, iv) Aerosol products, Preformulation studies of Biotechnologically derived products.
2. POLYMER SCIENCES:- Introduction and Classification , Preparation , Molecular weight determination , Applications, Thermal characterization and Rheology of polymers. Introduction to Biodegradable polymers.

UNIT II

3. STABILITY:- Concept and objectives of stability of pharmaceuticals. Understanding of statistical aspects expiry period. Degradation pathways, Physical instabilities & evaluation methods.
4. EXCIPIENTS: Overview of excipients used in formulations. Factors affecting the selection. Introductory aspects of drug-excipient and excipient, package interactions. Study of newer excipients like cyclodextrin, ion exchange resins, film coating materials, superdisintegrants, directly compressible vehicles, surfactants- micelle formation, liquid crystal phase, thickeners. Standardization of excipients. Co processed excipients

UNIT III

5. QUALITY ASSURANCE:- Importance of QA, Concept of quality control, quality assurance & total quality controls. Sources of variation, Quality control of raw materials & pharmaceutical process & finished products. Documentation concepts of statistical quality control. Validation of pharmaceutical process (at least one case study of a unit operation in the manufacturing of dosage forms & analytical method).
6. DIFFUSION & DISSOLUTION: Concept and importance of dissolution. Steady state diffusion. Determination of diffusion coefficient & its importance. Concept & importance of dissolution. Dissolution test, Historical development & USP dissolution test. Dissolution model like Hixson-Crowell, Higuchi's Model. Model independent method similarity and dissimilarity factor. Drug release modelling through polymer matrix & laminates. Concept of membrane controlled delivery & its importance in dosage form design.

UNIT IV

7. MICRO ENCAPSULATION: Theory, methods, applications, kinetics of release of drugs from microcapsules, formulations and evaluation.
8. OPTIMIZATION:- Definition ,need ,advantages ,Meaning of general terms involved in optimization process .Classification of optimization methods. Brief description and importance of experimental design with special reference to designs adequate for large number of variables. Introduction of correlation & regression analysis & mathematical model, contour plots. Detail study with at least one example of following optimization techniques:-Simplex method, Langarengian method.

(M.1.5) ADVANCED PHARMACEUTICS

(Practical 8hrs/week)

CREDITS 04

1. An assignment on undertaking of the instruction to authors of any one of the high impact factor journal
2. Preformulation study of tablets, Compressibility index, Heckle treatment, Kawakita plots.
3. To determine intrinsic and saturation solubility of a given drug sample.
4. To study the effect of pH (2, 4, 6.2 and 8.0) on the apparent partition coefficient of a drug in n-octanol- water buffer system.
5. To determine the best compatible additive for a tablet dosage form of any drug.
6. Accelerated stability study of any one dosage form.
7. To characterize polymers Rheologically and Thermally.
8. To study the dissolution kinetics of IR and ER dosage form of given drug.
9. To interpret DSC, IR and PXRD from any reported data
10. Select any five drugs from different categories:

Find out theoretically Physicochemical and Biological properties of drug

Based on the information generated set the objectives regarding-

Which dosage form will be more suitable for the drug, Technique to formulate the dosage form, Choice of excipients that can be used with explanation of role of each excipient used in formulation, Formulate dosage form and evaluate in comparison with marketed dosage form.

Recommended books:

1. Theory and Practice of Industrial Pharmacy By Lachmann and Libermann. Third edition, Varghese Publishing House.
2. Pharmaceutical dosage forms: Tablets Vol. 1-3 by Leon Lachmann. Second Ed.

3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1,2,3; By Leon Lachmann. Second edition.
4. Modern Pharmaceutics; By Gillbert and S. Banker. Fourth Edition. Volume 121.
5. Remington's Pharmaceutical Sciences. Vol.I-II, 21st Edition.
6. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
7. Physical Pharmacy; By Alfred martin. Fourth Edition, Published by B. I. Waverly Pvt. Ltd.
8. Bentley's Textbook of Pharmaceutics – Rawbins.
9. Good manufacturing practices for Pharmaceuticals: A plan for total quality control, By Sidney H. Willig, Second Ed.
10. Quality Assurance Guide; By Organization of Pharmaceutical producers of India.
11. Drug formulation manual; By D.P.S. Kohli and D.H. Shah. Eastern publishers, New Delhi.
12. How to practice GMPs; By P. P. Sharma. Vandhana Publications, Agra.
13. Pharmaceutical Process Validation; By Fra. R. Berry and Robert A. Nash. Vol-57, Second Edition. Revised and Expanded.
14. Pharmaceutical Preformulations; By J.J. Wells.
15. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.

(M.1.6) ADVANCED PHARMACEUTICAL CHEMISTRY
(Theory 4 hrs/week)
CREDITS 04

UNIT I

1. Stereochemistry & Chiral Techniques:

- i. Principles of stereochemistry including geometric isomerism, optical isomerism and conformational isomerism. Conformational Isomerism with examples.
- ii. Racemic modification and their resolution, epimerization, mutarotation.
- iii Asymmetric Synthesis with examples

UNIT II

2. Mechanisms, stereochemistry and applications of following individual reactions:

- i. **Molecular Rearrangements:** Rearrangement of electron deficient systems, migration to oxygen, nitrogen, and carbon, Mechanism and stereochemistry of Baeyer-Villiger and Dakin oxidation, Wagner–Meerwein rearrangement, Wolff rearrangement, Pinacol-Pinacolone rearrangement, Beckmann, Curtius, Lossen, Hofmann and Schmidt rearrangements. Rearrangements of electron rich system inclusive of Stevens, Wittig, Sommelet, Favorskii, Neber and Benzilic acid rearrangement. Willgerodt reaction, Cope rearrangement.
- ii. **Reactions of importance :** Hydrogenation, Reduction with metallic hydrides, Clemmensen Reduction, Wolf Kishner reduction, Birch Reduction, Meerwein–Ponndorf–Verley reduction, Oppeneur oxidation, Free radical reaction, Allylic Bromination, Use of diazomethane and peracids in synthesis, Grignard Reaction, Ozonolysis, Heck reaction, Sharpless oxidation, Suzuki coupling .
- iii. **Multi-component synthesis:** Biginelli reaction, Hantzsch reaction, Ugi reaction, Passerini reaction and Strecker synthesis.

UNIT III

3. **Synthon approach:** Definition, terms and abbreviation, rules and guidelines of synthon approach including all types of disconnections with examples.
5. **Green Chemistry:** Water as solvent, ionic liquids, supercritical fluids, Supported reagents and catalysts, Solvent free reactions, Microwave and Ultrasound assisted reactions.
6. **Introduction to Environment protection and effluent treatment aspects** (pollution control board rules and regulations).

(M.1.7) ADVANCED PHARMACEUTICAL CHEMISTRY

(Practical 8 hrs/week)

CREDITS 04

1. Experimental techniques – Fractional distillation, Vacuum distillation, Preparative chromatography- Column and TLC.
2. Synthesis of any ten different compounds using reactions discussed under point 2 of theory syllabus.

3. Isolation and characterization of phytochemical principles (e.g. alkaloids, steroids) from natural origin.

Recommended Books:

1. "Stereochemistry of Carbon Compounds", Eliel, E. J., Tata McGraw-Hill Publishing Company Ltd., New Delhi, **1975**.
2. "Advanced Organic Chemistry, Reactions, Mechanisms and Structures", March, J. IV (ed.), published by Wiley-Interscience Publication, printed and bounded in India by Replika Publisher, **2000**.
3. "Stereochemistry of Organic Compounds", Nasipuri, D., Published by New Age International Pvt. Ltd. Publisher.
4. "Name Reactions: A Collective Detailed Reaction Mechanisms", Jie Jack Lee, III (ed.) First Indian reprint, **2007**, Published by Spriger International Edition, Printed in India by Rajkamal Electronic Press, Delhi.
5. "Advanced Organic Chemistry Part-B: Reaction and Synthesis", Carey, F. A. and Sundberg, R. J., IV (ed.), Published by Kluwer Academic/ Plenum Publisher.
6. "Organic Chemistry Volume I and II", Finar, I. L., V (ed.), Pearson Education Ltd., Printed in India by Saurabh Printers Pvt. Ltd.
7. Elementary Practical Organic Chemistry, Part 3: Quantitative Organic Analysis", Vogel, A. I., II (ed.), Published by CBS Publishers and Distributors.
8. "Vogel's Textbook of Practical Organic Chemistry", Furniss, B. S.; Hannaford, A. J.; Smith, P. W.G. and Tatchell, A. R. (Ed.), V (ed.), Published by Dorling Kindersly (India) Pvt. Ltd., Licensees of Pearson Education in South Asia, **2006**.
9. "Practical Organic Chemistry", Mann, F. G. and Saunders, B. C. (Ed.), IV (ed.), Pearson Education Ltd., U. K., **2009**
10. "Purification of Laboratory Chemicals", Armarego, W. L.F.; Chai, C. L. L., VI. (ed.), Published by Butterworth- Heinemann (Elsevier), Printed in United States of America.
11. "Modern Methods of Organic Synthesis", Caruthers, W. and Caldham, I., IV (ed.), Published by Cambridge University Press.
12. "Experimental Organic Chemistry Standard and Microscale", Harwood, L. M.; Moody, C.J. and Percy, J.M., II (ed.), Published by Wiley India Pvt. Ltd., New Delhi.
13. "Organic Synthesis, Collective Volumes" Volume I-XI, II (ed.), Published by John Wiley and Sons (Asia) Pvt. Ltd. Singapore, Printed and bound by Replika Press India.

(M.1.8) ADVANCE PHARMACOLOGY (PRECLINICAL EVALUATION OF DRUGS)
(Theory 4 hrs/week)
CREDITS 04

UNIT I

- 01 Regulation for Laboratory Animal care and Ethical Requirements: Introduction to commonly used experimental animals and their limitations in biological screening. Guidelines for care and handling of laboratory animals CPCSEA (including IAEC), OECD, ICH, GLP and ICMR Guidelines. Proforma (s) for performing experiments on animals as per various guidelines. Maintenance and Breeding techniques for laboratory animals. Recent advances in Transgenic and Knockout animals. Importance of animal screening procedures, its advantages and disadvantages.
- 02 Organization of screening: Pharmacological activity of new substances and safety assessment tests. Toxicity studies: acute, subacute (Repeated dose), subchronic and chronic toxicity.

UNIT II

- 03 In vivo and in vitro screening of following category of drugs:
Cardiac glycosides, anti-arrhythmic, antihypertensive, anti-atherosclerotic, Sedatives, hypnotics, anxiolytics, antidepressants, antipsychotics, nootropics, antiparkinsonian agents, analgesics, antipyretics, anti-inflammatory, anticonvulsants, local anesthetics, CNS stimulants, anti-ulcer agents, bronchodilators, laxatives, bronchodilators, diuretics, histamine antagonists, muscle relaxants, anticholinesterases, anticholinergics, adrenolytics, hypoglycemics, anti-fertility agents, anti- thyroid agents and anti-oxidants.

UNIT III

- 04 Principles of biological standardization:
Methods of biological assay, principles of biological assays, official bioassays of some important drugs (Digitalis, insulin, nor adrenaline and histamine).
- 05 Knowledge of Modern Techniques and New Approaches in drug evaluations:
Animal cell lines and their uses
Radioligand binding assay
Patch clamp and ELISA
Stem cell research
Introduction to Pharmacogenomics, Proteomics and Array technology

Recommended books:

1. Vogel HG and Vogel WH. Drug Discovery and Evaluation: Pharmacological Assays, Springer, New York.
2. Tuner RA. Screening Methods in Pharmacology. Academic Press London.
3. Lawrence DR and Bacharch AL. Evaluation of Drug Activities, Pharmcometrics, Academic Press.
4. Georg J Krinke. The Handbook of Experimental animals “The Laboratory Rat”.
5. Burn JH. Practical Pharmacology Blackwell Scientific, Oxford London.
6. Ghosh MN. Fundamental of Experimental Pharmacology, Hilton & Company, Calcutta.
7. Jaju BP. Pharmacology: A Practice Exercise Book, Jaypee Brothers, New Delhi.
8. Kulkarni SK. Handbook of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
9. Perry WLM. Pharmacological Experiments on Isolated Preparation, E&S Livingstone, London.
10. Thomson EB. Drug Bioscreening, VCH, New York.
11. Arnold Schwartz, Methods in Pharmacology.

(M.1.9) ADVANCE PHARMACOLOGY (PRECLINICAL EVALUATION OF DRUGS)
(Practical 8 hrs/week, Minimum 15 practical)
CREDITS 04

- 1 To study the care, handling, routes of drug administrations, standard techniques for collection of blood samples from experimental animals and study of normal biochemical reference values in various animal species.
- 2 To determine the time required for induction and recovery from anesthesia for various Volatile general anesthetics. Introduction of different methods used for anesthesia and euthethanesia.
- 3 To study various preclinical pharmacological experiments using suitable computer simulation.
- 4 To perform the blind screening of given drug.
- 5 To determine LD50 of given drug (as per OECD Guidelines).

- 6 To study the screening of following categories of drugs using suitable animal models: antihypertensive, analgesics, anti-depressant, anxiolytic, diuretics, tranquilizers and sedatives, muscle relaxants, anti-inflammatory, anticonvulsants, antidiabetics, neuropathy, antioxidants etc. (min six practical's should be conducted)
- 7 To carry out in situ isolation of various organs of laboratory animal and study the bioassays of following drugs using suitable type of bioassay: Acetylcholine, adrenaline, histamine etc. (min three practical's should be conducted)
- 8 Any other experiment based on the topics mentioned in theory.

Recommended books:

1. Vogel HG and Vogel WH. Drug Discovery and Evaluation: Pharmacological Assays, Springer, New York.
2. Tuner RA. Screening Methods in Pharmacology. Academic Press, London.
3. Lawrence DR and Bacharch AL. Evaluation of Drug Activities, Pharmcometrics, Academic Press.
4. Nodine Siegler. Animal and Clinical Pharmacological Techniques in Drug Evaluation.
5. Burn JH. Practical Pharmacology, Blackwell Scientific, Oxford, London.
6. Ghosh MN. Fundamental of Experimental Pharmacology, Hilton & Company, Calcutta.
7. Jaju BP. Pharmacology: A Practice Exercise Book. Jaypee Brothers, New Delhi.
8. Lawrence DR and Bacharch AL. Evaluation of Drug Activities, Pharmacometrics, Academic Press.
9. Kulkarni SK. Handbook of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
10. Perry WLM. Pharmacological Experiments on Isolated Preparations, E & S, Livingston, London.
11. Sheth UK, Dadkar NK and Kamat UG. selected topics in experimental pharmacology, (Kothari Book Depot, Mumbai)
12. Thomson, E.B., Drug Bioscreening, VCH, New York.
13. Goldsteine. Principles of Drug Action, John Wiley and Sons, New York.

(M.1.10) ADVANCED PHARMACOGNOSY
(Theory 4 Hrs/Week)
CREDITS 04

UNIT I

1. Biosynthesis of secondary metabolites:

A] Comparative account of primary and secondary metabolites; Building blocks for secondary metabolites derived from primary metabolites; the construction mechanisms of secondary metabolites

B] *The products of acetate pathway: Fatty acids and Polyketides*

- a. General biosynthetic pathways for saturated & unsaturated fatty acids;
- b. Aromatic Polyketides: Cyclization: Simple phenols, Structural modifications: anthraquinones, C-Alkylation reactions, Phenolic oxidative coupling, Oxidative cleavage of aromatic rings, Starter groups other than acetate, Extender groups other than Malonate, Cyclization through Diels–Alder reactions, Genetic manipulation of the acetate pathway.

C] *The products of the shikimate pathway: Aromatic amino acids and Phenylpropanoids:*

Aromatic amino acids and simple benzoic acids, Cinnamic acids, Lignans and lignin, Phenylpropenes, Benzoic acids from C₆C₃ compounds, Coumarins, Flavonoids and Stilbenes, Flavonolignans, Isoflavonoids, & Terpenoid quinones.

UNIT II

2. Natural product-based drug discovery

A] *Evolution of secondary metabolites from an ecological perspective:* Comparative account of primary and secondary metabolism; Need & types of defenses in autotrophs; meaning of phytoalexin, allelopathic & phytoanticipin compounds; Ecological functions of plant secondary metabolites (defense & competition, attraction & stimulation & role in abiotic stresses); Molecular interactions of secondary metabolites in animals and bacterial cells (rationale in use of secondary metabolites as medicinal compounds).

B] *Natural product-based drug discovery:* Empirical & rational approaches of drug discovery; Characteristics of natural products that make them appropriate material in discovering new drugs (Chemical diversity, drug likeness, molecular chirality and complexity, receptor binding properties etc);

C] *Contribution of natural products in modern drug discovery: Overview of drug molecules discovered from natural products; detailed study of following in drug discovery:* Withania alkaloids, Vinca alkaloids, Morphine, Atropine, D-Tubocurarine, Khelline, Ephedrine, Artemisinin, Camptothecin, Taxol, Curcumin, Forskolin, Vasicine.

D] *Ethnobotanical approach to drug discovery:* Overview of methods, merits & limitations.

UNIT III

3. Herbal formulations:

Types, difficulties in preparation & remedies thereof to rectify these problems, study of herbal formulations such as tablets, capsules, syrups, nutraceutical powders/granules, topical preparation such as creams & shampoo.

UNIT IV

4. Plant products and High Throughput Screening (HTS):

Biological assays and HTS; Sample availability & selection strategies for HTS; Process for identification of plants for targeted sets; Sample preparation; dereplication & isolation of active compounds; recent case studies.

(M.1.11) ADVANCED PHARMACOGNOSY

(Practical: 8 hrs/Week)

CREDITS 04

1. Preparative TLC and column chromatography
2. Estimation of Phytoconstituents by U.V. methods
3. Characterization of Phytoconstituents by I.R. Spectroscopy
4. Estimation of Phytoconstituents by HPLC methods
5. Preparation of monograph of herbal drugs by considering the following parameters.
 - Pharmacognostic study of crude drugs: morphology, microscopy, quantitative microscopy, chemical tests etc.
 - Extraction, fractionation, proximate chemical analysis.
 - Physical parameters of evaluation: Moisture content, ash values, extractive values etc.
6. Estimation of total Phenolics content
7. Estimation of total Flavonoid content
8. Preparation and evaluation of herbal formulations
9. Demo of molecular modeling software.

Recommended Books:

1. Benny K-H Tan et al., *Novel Compounds from Natural Products in the New Millennium*, World Scientific, 2004. ISBN 981-256-1 13-7.
2. *Camille G. Wermuth, The Practice of Medicinal Chemistry*, 2nd Ed., Academic Press, 2003. ISBN: 0-12-744481-5.
3. Cseke L. J., *Natural products from plants*. 2nd Ed., CRC Press, 2006. ISBN 0-8493-2976-0.
4. David J. Newman et al., *Natural Products as sources of new drugs over the period 1981-2002*. *J. Nat. Prod.* 2003, *66*, 1022-1037.
5. Devlin J. P., *High throughput Screening*, Marcel Dekker, INC. 2002.
6. Evans W. C., Trease G. E., *Trease and Evan's Pharmacognosy*. W.B. Saunders, 2002. 16th Ed. ISBN-10: 0702029335.
7. Francisco A. Macias et al., *Evolution and current status of ecological Phytochemistry*. *Phytochem* 68 (2007) 2917–2936.
8. Frank Petersen et al., *Progress in Drug Research: Natural Compounds as Drugs (Vol I)*, Birkhäuser Verlag AG, 2008. ISBN 978-3-7643-8098-4.
9. Geoffrey A. Cordell, *Natural products in drug discovery – Creating a new vision*. *Phytochem Rev* 1: 261–273, 2002.
10. Iqbal Ahmad et al., *Modern Phytomedicine*, WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim 2006. ISBN-10: 3-527-31530-6.
11. Iwu and Wootton, *Ethnomedicine and Drug Discovery*, Elsevier Science, 2002.
12. Manuchair Ebadi, *Pharmacodynamic basis of herbal medicine*, 2nd Ed., CRC Press, 2007. ISBN: 10: 0-8493-7050-7.
13. Paul M Dewick, *Medicinal Natural Products: A Biosynthetic Approach*, 2nd Ed., John Wiley & Sons Ltd., 2002. ISBN 0-471-49640-5.
14. Salim A.A. et al., *Drug Discovery from Plants In: Bioactive Molecules and Medicinal Plants*, 2008. Chapter DOI: 10.1007 / 978-3-540-74603-4_1, c Springer.
15. Shayne Cox Gad, *Drug Discovery Handbook*, John Wiley & Sons, Inc. 2005.

16. Thomas Hartmann, From waste products to ecochemicals: Fifty years research of plant secondary metabolism, *Phytochem* 68 (2007) 2831–2846.
17. Thomas Hartmann, The lost origin of chemical ecology in the late 19th century, *PNAS*, 105 (12) 2008, 4541–4546.
18. Tringali Corrado, *Bioactive compounds from natural sources*, Taylor & Francis, 2001. ISBN: 0-7484-0890-8.
19. Wink M., Evolution of secondary metabolites from an ecological and molecular phylogenetic perspective. *Phytochem* 64 (2003) 3–19.
20. Wink M., Evolution of Secondary Plant Metabolism. In: *Encyclopedia of Life Sciences (ELS)*, 2008, John Wiley & Sons, Ltd: Chichester. DOI: 10.1002/9780470015902.a0001922.pub2.

Recommended Journals

1. Biological and Pharmaceutical Bulletin
2. Indian Drugs
3. Indian Journal of Pharmacology
4. Journal of Agriculture and Food Chemistry
5. Journal of Chromatography
6. Journal of Ethnopharmacology
7. Journal of Natural Products
8. Natural Product Reporter
9. Phytochemistry
10. Phytomedicine
11. Phytotherapy Research
12. *Planta Medica*

**(M.1.12) ADVANCED QUALITY ASSURANCE TECHNIQUES
(CGMP & DOCUMENTATION)
(Theory 4 Hrs/Week)
CREDITS 04**

UNIT I

TOPIC 1: PERSONNEL

- | | |
|--|---|
| 1.0 Introduction | 1.1 Qualification Experience and Training |
| 1.2 Responsibilities and Key Personnel | 1.3 Personal hygiene and clothing |
| 1.4 Legal Aspects | 1.5 Consultants |

TOPIC 2: SURROUNDING, BUILDING AND FACILITIES

- | | |
|--|-----------------------------------|
| 2.0 Introduction | 2.1 Principal Area |
| 2.2 Plumbing and Drainage system | 2.3 Lighting |
| 2.4 Sewage, Refuse and Disposal of Water | 2.5 Washing and Toilet Facilities |
| 2.6 Sanitation | 2.7 Maintenance |

TOPIC 3: EQUIPMENT

- 3.0 Introduction
- 3.1 Design, size, location and Construction of Equipment
- 3.2 Equipment Identification
- 3.3 Equipment log
- 3.4 Cleaning and Maintenance of Equipment
- 3.5 Automatic, Mechanical and Electronic Equipment

UNIT II

TOPIC 4: MATERIALS MANAGEMENT

- | | |
|------------------------------------|--------------------------------------|
| 4.0 Introduction | 4.1 Purchasing |
| 4.2 Raw Materials | 4.3 Packaging Materials |
| 4.4 Intermediate and Bulk Products | |
| 4.5 Finished Products | 4.6 Rejected and Recovered Materials |
| 4.7 Recalled Products | 4.8 Returned goods |
| 4.9 Reagents and Culture Media | |
| 4.10 Waste Materials | 4.11 Reference standards |
| 4.12 Miscellaneous Materials | |

TOPIC 5: QUALITY MANAGEMENT

- 5.0 Introduction
- 5.1 Quality Assurance
- 5.2 Components of Q.A.
- 5.3 Good Manufacturing Practice
- 5.4 Quality Control

TOPIC 6: MANUFACTURING OPERATIONS AND CONTROL

- 6.0 Introduction
- 6.1 Sanitation of Manufacturing Premises
- 6.2 Mix-ups and Cross Contamination
- 6.3 Processing of Intermediates and Bulk product
- 6.4 Packaging Operations
- 6.5 I.P.Q.C.
- 6.6 Release of Finished Product
- 6.7 Process Deviations
- 6.8 Charge-in of Components
- 6.9 Time Limitations on Production
- 6.10 Drug product Inspection
- 6.11 Expiration Dating
- 6.12 Calculation of Yields
- 6.13 Production Record Review

UNIT III

TOPIC 7: DOCUMENTATION AND RECORDS

- 7.0 Introduction
- 7.1 specifications
- 7.2 Master Production and Control Record
- 7.3 Batch Production and Control Record
- 7.4 Important SOPs and Record
- 7.5 Change Control
- 7.6 Site Master File

TOPIC 8: OUTSOURCING

- 8.0 Introduction
- 8.1 Manufacturing and Packaging Outsourcing
- 8.2 Analytical Outsourcing
- 8.3 Other Services- Outsourcing

TOPIC 9: POST OPERATIONAL ACTIVITIES

- 9.0 Introduction
- 9.1 Distribution
- 9.2 Recall Products
- 9.3 Returned Products
- 9.4 Complaints and Adverse Effects
- 9.5 Drug Product Salvaging

UNIT IV

TOPIC 10: SITE AND PLANT SECURITY

- 10.0 Introduction
- 10.1 Security Personnel
- 10.2 Entry to Site
- 10.3 Entry to Plant Buildings
- 10.4 Internal Security
- 10.5 Current Issues

11: SAFETY AND ENVIROMENTAL PROTECTION

- 11.0 Introduction
- 11.1 Safety
- 11.2 Environmental Protection and Procedures

TOPIC 12: STERILE PHARMACEUTICAL PRODUCTS

- 12.0 Introduction
- 12.1 Personnel
- 12.2 Building and Premises
- 12.3 HVAC system
- 12.4 Water and Steam System
- 12.5 Equipment
- 12.6 Processes
- 12.7 Sterilization

- 12.8 Quality Control 12.9 Sanitation
 12.10 Finishing of Sterile Products 12.11 Documentation
 12.12 Documents and Formats

UNIT V

TOPIC 13: PHARMACEUTICAL QUALITY AUDITS

- 13.0 Plant Level documentation
 13.1 Plant Level Department wise Quaternaries
 13.3 Principle of Quality Audit
 13.4 *Preparing for FDA Inspection of manufacturing site*

TOPIC 14: Creating and Managing a Quality Management System

TOPIC 15: Emerging concepts in QA of drugs - PAT, CAPA, HACCP, GAMP and GEP

TOPIC 16: National and International Guide for primary, secondary and reference standard characterization and application

**(M.1.13) ADVANCED QUALITY ASSURANCE TECHNIQUES
 (CGMP & DOCUMENTATION)
 (Practicals 8 Hrs/Week)
 CREDITS 04**

1. Learning different programming languages, writing programmes for simple Calculation, statistical analysis, data acquisition, processing and retrievals.
2. Physical and Chemical Examination of plastic containers.
3. Examination of labels, cartons and other printed materials.
4. Designing of following key documents
 - a. Site master file
 - b. SOP on SOP
 - c. MPCR / BPCR (For sterile & non-sterile products)
 - d. Change contract format
 - e. Product complaint document
 - f. Internal audit document
 - g. Product recall document
 - h. IPQC document

- i. Material receipt, sampling, dispensing & storage document
5. Experiment & documentation of dissolution test
6. IPQC tests for Tablets / Capsules / Injections / Liquid / Ointment
7. Oro dispersible tablet formulation by application of experimental design and its evaluation
8. Formulation and evaluation of Gel/cream with emphasis on permeation studies and other Parameters

Recommended Books:

1. Pharmaceutical Quality Assurance, M.A. Potdar, Nirali Prakashan, Pune.
2. Current Good Manufacturing Practices, M.A. Potdar, Pharma-Med Press, Hyderabad.
3. GMP for Pharmaceuticals, 5th Edition, Sidney H. Willing, Marcel Decker Series
4. Regulatory guidelines related to GMP by
 - a. Australian code of GMP for medicinal products, 16th Aug. 2002.
 - b. 21 Code of Federal Regulation, parts 210, 211 & 58. (USFDA guidelines)
 - c. MHRA, UK Guidelines on GMP
 - d. GMP Guidelines by Medicines Control Council of South Africa
 - e. Schedule M of D & C Act
5. Assurance of Quality, Pharmaceutical Total Quality Approach, M. S. P. Khan, Chitgaon, Bangladesh, Signet Press-1990
6. Shayne Cox Gad, "Pharmaceutical Manufacturing Handbook; Regulations and Quality" John Wiley
7. New Drug Approval Process: Accelerating global registrations, RA Guarino, Ed. 4th Edn. Marcel Decker Inc.
8. Quality Assurance of Pharmaceuticals Vol I & II, PP Sharma, How to practice GMPs, 6th edition, 2010

SEMESTER-II

(M.2.1) DRUG REGULATORY AFFAIRS

(Theory 4 hrs/week)

CREDITS 04

UNIT I

1.1 Drug Regulatory Aspects (India) –

Indian drug regulatory authorities, Central and State regulatory bodies (State FDA, DCGI, CDSO); Drugs and Cosmetics Act and Rules with latest Amendments (Special emphasis – Schedule M and Y); New Drugs – (Importation, Registration, Development, Clinical Trials, B.E. studies); Various licenses – (Test license, Import license for testing of drugs and API's, Mfg., Contract and Loan license manufacturing.)

1.2 Good Manufacturing Practices (GMP) –

Indian GMP certification, WHO GMP certification; ICH guidelines for stability testing and other relevant ones (Q1 – Q10); Export permissions and manufacturing for semi-regulated countries; Understanding of the plant lay-outs with special emphasis on the environment & safety (HVAC, Water systems, Stores management, Effluent etc.); Quality Assurance and Quality Control – Basic understanding for in-built quality.

UNIT II

1.3 Drug Regulatory Aspects (International & highly regulated markets) –

US Requirements – (for Generic Drugs especially formulations); CDER, INDA, NDA, ANDA's (types), CTD Formats of dossiers, E-submission, US DMF (various types), IIG Limits, Orphan Drugs, 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; A brief introduction to the guidelines for Europe, Japan, Australia, South Africa, Rest of the World (ROW) and South & Latin American countries; GMP audits, role of Quality Assurance, product approvals and supplies.

1.4 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.

UNIT III

1.5 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).

1.6 Patent search, Patent analysis & Patent drafting.

1.7 Allied Patents Related Issues:

1.8 Indian IP case studies-

The Novartis case, Lipitor case, Natco versus Bayer case of compulsory license, Patenting and traditional knowledge [Neem, Basmati, Haldi patent], Patenting of life forms [Diamond versus Chakravarty case].

UNIT IV

1.9 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

2.0 International treaties and conventions on IPR –

Paris convention, PCT – an introduction, PCT application & general rules, WTO / GATT system & Uruguay TRIPS, WIPO, Doha declaration.

UNIT V

2.1 Hatch Waxman Act and amendments, FDA Medicare Modernization Act, 2003

2.2 Introduction to Geographical indication / Trademark/ copyright: Filing Procedures

Exploitation of patent, Abuse of patents, Compulsory licensing, Infringement analysis, Drug-Patent Linkage

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.
11. Pharmaceutical Product Dev. IVIVC by Murthy, Sunkara and David

12. USPTO and WIPO Guidelines.

13. S. W. Deshpande, Drugs and Cosmetics Act, 1940 and Rules, 1945 and Drugs [Price Control] Order, 1995.

(M.2.2) FORMULATIONS & DEVELOPMENT
(Theory 4 hrs/week)
CREDITS 04

Recent advances in the following topics should be emphasized

UNIT I

1. Details study of ICH Q8 (R2) Guidelines for pharmaceutical development
2. SOLIDS: Basics of process automation of solid dosage form production with suitable example, different approaches of mouth dissolving formulation, taste masked formulation.
3. LIQUIDS: Phase behaviour of surfactants in binary and ternary systems. Factors affecting phase behaviour. Micellization, micelle structure, shape, size. Factors affecting CMC and micellar size thermodynamics and kinetics of micelle formation. Pharmaceutical aspects of solubilisation in nonaqueous systems, interaction with polymers and oppositely charged species.

Study of advances in liquid formulation including multiple emulsion, micro emulsion including Self Emulsified Drug Delivery Systems and Self Micro Emulsified Drug Delivery Systems.

UNIT II

4. SEMISOLIDS: Semisolid formulation with special reference to penetration enhancers. Emulgels, semisolids based on Liposomes, Niosomes.
5. INHALATION AEROSOLS: Inhalation products- Types and clinical role. Basic components of aerosol formulations. Therapeutic aerosols, Metered Dose Inhalers, Dry powder inhalers etc. Detailed discussion on propellants, package and filling technology. Quality assurance of components and formulations

UNIT III

6. PACKAGING OF PHARMACEUTICALS: Regulatory perspective of selection and evaluation of Pharmaceutical packaging materials for conventional dosage forms, sterile formulations and Novel drug delivery Systems.

7. NUTRACEUTICALS: Food as medicine, classification of nutraceuticals, effectiveness & safety, formulation design.

UNIT IV

8. VETERINARY DOSAGE FORMS: Need & problems of designing veterinary dosage forms. Specialized dose dispensers. Formulation strategy with special reference to dosage forms administered via feed or drinking water. Brief idea about quality control & regulatory aspects.
9. Introduction to QBD (Quality by Design)

(M.2.3) FORMULATIONS & DEVELOPMENT
(Practical 8 hrs/week)
CREDITS 04

- 1 To determine stability constant of β cyclodextrin complex of drug using phase solubility analysis
- 2 Optimization of designing of dosage forms by 3^2 factorial designs.
- 3 To compare the dissolution efficiency of a drug in plain and its solid dosage form.
- 4 To compare the dissolution profile of two marketed solid oral preparation by f_1 and f_2 factor.
- 5 To prepare and evaluate transdermal drug delivery system and compare the release of drug through treated egg membrane Or treated cellophane membrane.
- 6 To prepare liposome and determine particle distribution and drug entrapment efficiency.
- 7 To plot the ternary phase diagram in the formulation development of emulsion.
- 8 To interpret IVIVC for any dosage form.
- 9 Select any Three poorly water soluble drugs. Plan method for solubility enhancement of those drugs. Based on the method determine any three parameters like the effect of dielectric constant, stability constant, solubility parameter and effect of excipients on solubility and thermodynamic parameters of the drug.

Recommended books:

1. Applied production and operations management; By Evans, Anderson, Sweeney and Williams.
2. Advances in Pharmaceutical Sciences Vol. 1-5; By H.S. Bean & A.H. Beckett.
3. Pharmaceutical Dosage forms: Disperse systems, Vol, 1-2; By Leon Lachmann.
4. Modern Pharmaceutics; By Gilbert and S. Banker and Christofer T. Rhodes, Fourth Edition, Marcel Decker Series.
5. Remington's Pharmaceutical Sciences. 21-st editions, Vol. I-II Lippincott Williams and Wilkins.
6. H.G.Brittain, Physical Characterization of Pharmaceutical solids, Marcel Dekker
7. Advanced Pharmaceutics: Physicochemical principles by Cherng-Ju uim, 2004. CRC Press.
8. J. C. Salomon's Polymeric materials encyclopedia.
9. Physical characterization of Pharmaceutical Solids edited by H. T. Brittain. Volume 70. Marcel-Decker Series.

(M.2.4) NOVEL DRUG DELIVERY SYSTEMS
(Theory: 4Hrs/ week)
CREDITS 04

UNIT I

1.1 Fundamentals of Controlled Release Drug Delivery:

Influence of drug properties and routes of drug administration on the design of sustained and controlled release systems.

1.2 Oral controlled drug delivery systems:

Formulation, fabrication and evaluation of various oral controlled drug delivery systems including gastro retentive, colon targeted and pulsatile drug delivery.

1.3 Parenteral controlled release system:

Scope, terminology & techniques used, injectable controlled release, formulation of long acting contraceptive formulations; implantable drug delivery; micro spheres, liposomes & quality control.

UNIT II

1.4 Mucosal drug delivery models:

Buccal, sublingual, rectal, nasal, mucosal & vaginal drug delivery: Mechanisms of transports of drugs through mucosal routes, penetration enhancers, formulation development, in-vitro, ex-vivo and in-vivo methods of evaluation (for each route).

1.5 Transdermal drug delivery system:

Permeation through skin including mechanism, permeation enhancers, in-vitro skin permeation, technologies for developing transdermal drug delivery system & evaluation parameters.

1.6 Bioavailability and bioequivalence:

Biopharmaceutical classification of drugs, absorption of permeability and solubility limited drugs. Biowavers for bioequivalence studies, strategies to enhance bioavailability.

UNIT III

1.7 Vesicular Drug Delivery System:

Liposomes [composition, preparation, characterisation, stability, pharmacokinetics, clinical applications, production and scale up]; Niosomes [structure & classification, methods of preparation, properties, release behaviour, characterisation, pharmacokinetics & in-vivo evaluation, applications and toxicity]; Micro emulsion [structures, theories of formation, formulation consideration, factors affecting formation of micro emulsion, phase diagrams, characterisation, stability and application].

1.8 Particulate Drug Delivery System:

Microparticles [Polymers used & their selection, general methods of preparation, characterisation, kinetics of release, evaluation of efficacy, applications]; Nanoparticles [Polymeric Nanoparticles, solid lipid particles, hydrogel, peptide nanoparticles, nanocrystals & nanosuspensions and targeting strategies employing nanoparticles]; Dendrimers [structure & properties, general methods of dendrimer synthesis, characterisation of dendrimer, application & commercial products].

UNIT IV

1.9 Site specific drug delivery system:

Active & passive targeting, resealed erythrocyte, monoclonal antibodies drug targeting particulate carrier system, specific drug delivery to targeted organs like brain & colon, freeze drying of parenteral, environmental controlled parenteral manufacturing.

2.0 Ocular Drug Delivery:

Ocular Topical Drug Delivery, Issues and Challenges, Drug Candidate Selection, Product Design Considerations, Product Optimization Considerations, Processing Considerations.

2.1 Protein & peptide drug delivery system:

Physical aspects, biochemistry of protein drug (structure, properties & stability- Mechanisms of destabilization. Techniques of stabilization of Proteins and Peptides.); general methods of analysis of protein & peptide drugs, barrier to transport & pharmacokinetics, different route of delivery, practical considerations; importance of pre-formulation & formulation considerations, toxicity immunogenicity, stability & regulatory perspective.

2.2 Regulatory consideration in controlled release:

Modification requirements to demonstrate safety, efficacy & controlled release nature.

Recommended Books:

1. Remington's pharmaceutical sciences. 21 st Edition, Lippincott Williams and Wilkins- Vol. I & II
2. Novel drug delivery system – Marcel Dekker N.Y. Second Edition, Revised and Expanded by Yie W. Chien. Vol- 50.
3. Controlled drug delivery system – Vicent H.L., Marcel Dekker Second Edition, Revised and Expanded by J. R. Robinson and Vincent H. L. Lee. Vol- 29.
4. Bentley's textbooks of pharmaceuticals – E.A. Rawlin
5. Vesicular and Particulate Drug Delivery Systems, Edited by R.S.R Murty, Career Publications.
6. Novel and controlled drug delivery systems – N.K. Jain
7. Advances in Novel and Controlled Drug Delivery- N.K. Jain
8. Chien, Y.W.: Novel Drug Delivery Systems, Marcel Dekker, New York and Basel

(M.2.5) ADVANCED MEDICINAL CHEMISTRY
(Theory 4 hrs/week)
CREDITS 04

UNIT I

1. **Microorganism in drug development:** Microbial conversions of drugs like steroids, microbial production of antibiotics, enzymes, enzymes as catalyst and drug targets, enzyme immobilization techniques.

2. Molecular concept of drug-target interactions.

Receptor Theory, types of receptor-drug interactions

Advances in receptors of following classes, SAR studies of drugs and ligands belonging to following classes including mechanism of actions:

- a) Opioids, Adrenergics, Cholinergics, Histamine, 5-HT_{1A}, GABA, Drugs used in Neurodegenerative disorders, CNS depressants, neuroleptics, analeptics, CNS stimulants.
- b) Antihyperlipidemic, Cardiotonic drugs, Antianginal agents, Antiarrhythmic agents, Antihypertensive agents, Oral hypoglycemic agents.
- c) **Chemotherapeutic Agents:** Antimalarials, Anti-mycobacterials, Anti-HIV, Anti-cancer, Antibacterials, Antiamoebics, Anthelmintic and Antifungal agents.
- d) Anti-inflammatory Steroids and receptors for steroidal drugs including SAR.

UNIT II

3. Synthesis of following drugs describing reaction conditions mechanism and strategies involved in the synthesis: Gefitinib, Cetrizine, Fexofenadine, Linezolid, Risperidone, Ziprasidone, Alprazolam, Ethinyl estradiol, Quetiapine.

4. Solid phase synthesis: Different types of polymer supports, Linkers, Strategies of library synthesis and characterization. Solid phase synthesis of peptide and polypeptide.

UNIT III

5. Gene therapy: A brief introduction, concept with suitable examples, scope, techniques and application.

6. Introduction to Biomolecules (human insulin, tissue plasminogen activator (TPA), interleukins, interferons, growth hormones, monoclonal antibodies, and factor VIII etc).

(M.2.6) ADVANCED MEDICINAL CHEMISTRY

(Practical 8 hrs/week)

CREDITS 04

1. Demonstration of computer aided drug design techniques using suitable software.
2. ADMET prediction using suitable software.
3. Microwave assisted synthesis (minimum 5 experiments)

4. Synthesis based on ultrasonic technique (minimum 3 experiments)
5. Multistep synthesis (synthesis involving not less than 4 steps)

Recommended books:

1. "Foye's Principles of Medicinal Chemistry", Lemke, T. L.; Williams, D. A.; Roche, V. F. and Zito, S. W., VI (ed.), Lippincott Williams & Wilkins, Printed in Philadelphia PA 19106, U. S. A. , **2008**
2. Richard B. Silverman, "The Organic Chemistry Of Drug Design And Drug Action", second edition, reprint 2010, published by Elsevier, a division of Reed Elsevier India private limited, printed and bound at Rajkamal Electronic press Kundli(Haryana).
3. Graham Patrick," An Introduction to Medicinal Chemistry", 2nd edition, published in United States by Oxford University Press.
4. Donald J. Abraham," Burger's Medicinal Chemistry and Drug Discovery", Volume I-VI, 6th edition, 2007, published by John Wiley and Sons, Inc., Hoboken, New Jersey, printed in India by Replika press Pvt. Ltd.
5. John M. Beale Jr., John H. Block, "Wilson And Grisvold's Textbook of Organic Medicinal And Pharmaceutical Chemistry", 12th edition, published by Walters Kluwer Lippincott Williams And Wilkins.
6. Corwin Hansch, Peter G. Sammes and John B. Taylor, Comprehensive Medicinal Chemistry, The Rational Design, Mechanistic Study and Therapeutic Application of Chemicals Compounds, Volume I-VI: first printed in India 2005, published by Elsevier, a division of Reed Elsevier India Private limited New Delhi-110024.
7. E. J. Ariens, "Drug Design", Volume I-VIII, 2009, published by Elsevier, a division Of Reed Elsevier India Pvt. Ltd., Noida,New Delhi, printed and bound at Brijbasi Art press Ltd. Noida India.
8. Elementary Practical Organic Chemistry, Part 3: Quantitative Organic Analysis", Vogel, A. I., II (ed.), Published by CBS Publishers and Distributors.
9. "Vogel's Textbook of Practical Organic Chemistry", Furniss, B. S.; Hannaford, A. J.; Smith, P. W.G. and Tatchell, A. R. (Ed.), V (ed.), Published by Dorling Kindersly (India) Pvt. Ltd., Licensees of Pearson Education in South Asia, **2006**.
10. "Practical Organic Chemistry", Mann, F. G. and Saunders, B. C. (Ed.), IV (ed.), Pearson Education Ltd., U. K., **2009**
11. "Experimental Organic Chemistry Standard and Microscale", Harwood, L. M.; Moody, C.J. and Percy, J.M., II (ed.), Published by Wiley India Pvt. Ltd., New Delhi.

12. "Organic Synthesis, Collective Volumes", Volume I-XI", Published by John Wiley and Sons (Asia) Pvt. Ltd. Singapore, Printed and bound by Replika Press India.

(M.2.7) DRUG DESIGN

(Theory 4 hrs/week)

CREDITS 04

UNIT I

1. Introduction to role of drug design in drug discovery.
2. An overall treatment of various approaches to drug design including the method of variation, e.g.- Fibonacci search, Topliss Tree, Craigs plot, Simplex methods and Cluster analysis.

UNIT II

3. Quantitative Structure-Activity Relationships (QSAR) with detail coverage of Hansch's Linear method, Free and Wilson methods, mixed approach principal component analysis and application of above.
4. Drug design based on antagonism and enzyme inhibition.

UNIT III

5. Computational Chemistry: Basic concept of computational chemistry like Quantum Mechanics (*ab initio* method, Density Function Theory and Semi-empirical methods), Molecular Mechanics, Force Fields, Energy Minimization, Conformational Search, Molecular Dynamics, Monte Carlo Simulations, Artificial Intelligence methods.
6. Computer-Aided Drug Design: Ligand based Drug Design or Analog-based approach: 2D-QSAR, 3D-QSAR, Pharmacophore modelling.

UNIT IV

7. Structure-based drug design or Receptor-based approach: Target identification, Target selection, Molecular Docking, Genetic Algorithm, fragment based drug design, Homology modelling/Protein modelling. Virtual Screening Techniques and Applications.
8. Drug metabolism based drug design: Aims of prodrug design, Types of prodrugs, fundamental groups involved in prodrug designing, Bioprecursor products.

9. Recent Advances in drug discovery: Role of genomics, proteomics, metabolomics in drug discovery, Prediction/Identification of Drug side effects/off-target interactions, Fragment based drug design: fragment based drug design, receptor-based *de novo* design.

Books Recommended:

1. Wolff ME, ed "The Basis of Medicinal Chemistry, Burger's Medicinal Chemistry" John Wiley & Sons, New York.
2. Foye WO "Principles of Medicinal chemistry" Lea & Febiger.
3. Comprehensive Medicinal Chemistry by Hansch & Leo, Vol. 4.
4. Smith HJ, Williams H, eds, "Introduction to the principles of Drug Design" Wright Boston.
5. Silverman R.B. "The organic Chemistry of Drug Design and Drug Action" Academic Press New York.
6. Robert GCK, ed., "Drug Action at the Molecular Level" University Park Press, Baltimore.
7. Martin YC. "Quantitative Drug Design" Dekker, New York.
8. Lien EJ. SAR "Side effects and Drug Design" Dekker, New York.
9. William H, Malick JB "Drug Discovery and Development" Humana Press Clifton.
10. Delgado JN, Remers WA eds "Wilson & Gisvold's Text Book of Organic Medicinal & Pharmaceutical Chemistry" Lippincott, New York.
11. Koro lkovas A, Burckhalter JH. "Essentials of Medicinal Chemistry" Wiley Interscience.
12. Ariens EJ "Drug Design" Academic Press New York.
13. Olson EC "Computer Assisted Drug Design" American Chemical Society ACS Symposium Series 112.
14. Roberts SM, Price B.J.Eds. "Medicinal Chemistry. The Role of Organic Chemistry in Drug Research, Academic Press New York.
15. Roth HJ, Kleemann A. Pharmaceutical Chemistry. Vol-I. Drug synthesis. New York: Ellis Horwood Limited; 1988.
16. Woodridge, Progress in Pharmaceutical Research.

(M.2.8) CLINICAL PHARMACOLOGY
(Theory 4 hrs/week)
CREDITS 04

UNIT I

01. Clinical research:

Introduction to clinical Pharmacology, basic components and scope.

Clinical evaluation of new drugs: organization, types of clinical research, phases of clinical research.

Therapeutic drug monitoring (TDM): criterion for TDM, Clinical significance and its need on Patients associated with narrow therapeutic range of drugs.

UNIT II

02. Pharmacotherapeutics, Management & Current Good Clinical Practice of following diseases:

Cardiovascular disorders: Hypertension, congestive heart failure, angina pectoris, myocardial infarction and ischemia, cardiac arrhythmia, atherosclerosis, hyperlipidemia, peripheral vascular disorders and coagulation disorders.

Autoimmune and metabolic disorders: Rheumatoid arthritis, Osteoarthritis, gout and hyperuricemia, Diabetes mellitus (DM).

Gastrointestinal disorders: Peptic Ulcers, emesis, diarrhoea and constipation

Renal diseases: Acute and chronic renal failure, renal dialysis and transplantation, Drug doses in renal impairment.

Respiratory diseases: Asthma, chronic obstructive pulmonary edema. Pulmonary embolism.

Hepatic disorders: cirrhosis, hepatitis. Alcohol and drug induced complication associated with hepatic impairment.

Neoplastic disorders: General principles of cancer chemotherapy, monoclonal antibodies.

Immunotherapy: Immunostimulant, Immunomodulators and Immunosuppressant.

Chemotherapy of Infectious Diseases: mechanism of antibiotic resistance, antifungal and antiprotozoal, helminthiasis, tuberculosis, Malaria, leprosy, AIDS.

UNIT III

03. Drug interaction and rational for drug combinations: Various mechanisms of drug interaction, drug-food interaction and drug - drug interaction

04. Drug Toxicity and its prevention: Principles of toxicology, abnormal action of drugs such as tolerance, addiction, habituation, idiosyncrasy, allergy, hypersensitivity, antagonism, synergism, potentiation, tachyphylaxis. Adverse drug reactions and its monitoring.

UNIT IV

05. Novel Target Sites for drug action: (Physiological functions, pharmacological implications and therapeutic potential of the following target sites) Poly (ADP-ribose) polymerase (PARP) Caspases Peroxisome proliferator activator receptors (PPAR)- α and γ AMP activated protein kinases Protein kinases Phosphodiesterases

Recommended books:

1. Goodman and Gilman's. The Pharmacological Basic of Therapeutics, Mc Graw-Hill companies.
2. Harrison's Principle and Practice of Medicine, 18th Edition, Churchill, Livingston, London.
3. Roger and Walker. Clinical Pharmacy and Therapeutics, Churchill, Livingston, London.
4. Tussle TG. Pathology and Thereapeutics for Pharmacists: A Basic for Clinical Pharmacy Practice, Chapman and Hall, New York.
5. Dipiro Joseph L. A pathphysiological Approach, Elsevier.
6. Davidson's Principle of Internal Medicine, Mc Graw-Hill companies.
7. Herfindal ET and Gourley DR. Text Book of Therapeutics: Drug and Disease management. Lippincott Williams & Wilkins, USA.
8. Speight TM and Holford NHG (ed). Avey's Drug Treatment: Principals and Practice of Clinical Pharmacology and Therapeutics. ADIS Press, Sydney, Australia.
9. Katzung BG. Basic and Clinical Pharmacology, Lange Medical Publisher, USA.

(M.2.9) CLINICAL PHARMACOLOGY
(Practical, 8hr/Week, Minimum 15 Practical)
CREDITS 04

- 01 Monitoring of some marketed drugs in biological fluids.
- 02 To study the oestrus cycle in rats.
- 03 Determination of blood sugar and hemoglobin level in blood sample.
- 04 To study the effect of various agonist and antagonist on Dog/Rat Blood pressure using Computer simulated Software. (Number of two practical's should be conducted)
- 05 Isolation of DNA using standard DNA extraction kit. (Number of two practical's should be conducted)
- 06 To find out the concentration of given drug sample by three point and four point bioassay method using suitable isolated animal tissue. (Number of two practical's should be conducted)

- 07 To determine the PA₂ value of given drugs using suitable isolated animal tissue: adrenaline, atropine, Acetylcholine, histamine etc. (Number of five practical's should be conducted)
- 08 Determination of BMI & Clinical Pharmacology Case Study by Visiting Hospital

Recommended Books:

1. Burn JH. Practical Pharmacology, Blackwell Scientific, Oxford London.
2. Ghosh MN. Fundamental of Experimental Pharmacology. Hilton and Co., Calcutta.
3. Jaju BP. Pharmacology: A practice exercise book. Jaypee Brothers, New Delhi.
4. Lawrence DR and Bacharch AL. Evaluation of Drug Activities Pharmacometrics, Academic Press.
5. Kulkarni SK. Handbook Of Experimental Pharmacology, Vallabh Prakashan, New Delhi.
6. Perry WLM. Pharmacological Experiments on Isolated Preparation, E & S, Livingston, London.
7. Sheth UK, Dadkar N K and Kamat UG. Selected Topics in Experimental Pharmacology, (Kothari Book Depot, Mumbai).
8. Turner RA. Screening Methods in pharmacology, Academic Press, London.
9. Thomson EB. Drug Bioscreening, VCH, New York.
10. Vogel HG and Vogel WH. Drug Discovery and Evaluation: pharmacology Assays, Springer, New York.
11. Vyas SP and Kohli DV. Methods in Biotechnology and Bioengineering. CBS Publishers and distributors, New Delhi.

(M.2.10) MOLECULAR PHARMACOLOGY

(Theory 4 Hrs/Week)

CREDITS 04

UNIT I

- 01 Molecular mechanism of drug action: Receptor occupancy and cellular signaling systems such as G-proteins, cyclic nucleotides, calcium and calcium binding proteins, phosphatidyl inositol. Ion channels and their modulators
- 02 Endogenous bioactive molecules: Cytokines, neuropeptides and their modulators, neurosteroids, nitric oxide, phosphodiesterase enzyme and protein kinase C, arachidonic acid metabolites, COX-2 regulators and their role in inflammation, endothelium derived vascular substances (NO, endothelins) and their modulators.

Pharmacology of atrial peptides, reactive oxygen intermediates, antioxidants and their therapeutic implications.

UNIT II

- 03 Recent trends on different classes of receptors and drugs acting on them:
- a. Angiotensin receptors
 - b. Excitatory amino acid receptors
 - c. Kinin receptors
 - d. Adrenoceptors
 - e. Low molecular weight heparins, hirudins and GP II/IIIa receptor antagonists
 - f. Imidazole receptors
 - g. Cholinergic receptors
 - h. Dopamine receptors
 - i. Serotonin receptors
 - j. Hormone receptors
 - k. GABA and Benzodiazepine receptors
 - l. Opioid receptors
 - m. Purinergic receptors
 - n. Glutamate receptors

UNIT III

- 04 04 Ion channel and their modulators: calcium, potassium, sodium and chloride channels.
- 05 Apoptosis: basic functions, mechanisms and role of caspases. pharmacological and clinical implications
- 06 Adhesion therapy and cardiac and vascular remodeling

UNIT IV

- 07 Basic Concepts of Chronopharmacology and their implications to Drug Therapy.
- 08 Immunopharmacology: antibody dependent and cellular cytotoxicity. Monoclonal antibodies and its importance.

UNIT V

- 09 Gene therapy: Concept of gene therapy and recent development in the treatment of various hereditary diseases. Human genome mapping and its potential in drug research
- 10 Techniques for the study of Molecular Pharmacology: Western Blotting, Immunostaining, RT-PCR, Cloning, RIA, Cell Cultures etc.

Books Recommended:

1. Katzung BG. Basic and Clinical Pharmacology, Lange Medical Publisher, USA.
2. Goodman and Gilman; Pharmacological Basis of Therapeutics, Mc Graw Hill.
3. Rang HP and Dale MN. Pharmacology, Churchill Livingstone, UK.
4. Bacq ZM. Fundamentals of Biochemical Pharmacology.
5. Bowman WC and Rand MJ. Textbook of Pharmacology, Blackwell, Oxford.
6. Melmon KL and Morelli. Clinical Pharmacology: Basic Principle of Therapeutics, Mc Millan, New York.
7. Craig CR and Stitzel BE. Modern Pharmacology, Little Brown and Co, Boston.
8. Drill VA. Pharmacology in Medicine, McGraw Hill, New York.

(M.2.11) PHYTOCHEMISTRY & PHYTOPHARMACEUTICALS

(Theory 4 Hrs/Week)

CREDITS 04

UNIT I

1. Overview of natural product isolation:

- A. **Extraction techniques:** Counter current extraction, Supercritical fluid extraction, Solid phase extraction, Microwave-assisted extraction, Ultrasound extraction (Sonication), Phytonics process, parameters for selecting appropriate extraction method, steps in extraction process (size reduction, extraction, filtration, concentration, drying)
- B. **Essential oil extraction:** Distillation (mechanism & types), Expression methods, Enfleurage & defleurage, modern methods of essential oil extraction, SCF.
- C. **Non-chromatographic separation techniques:** Fractional distillation, fractional liberation, sublimation, chemical derivatization, fractional crystallization, centrifugation, Froth-floatation technique.
- D. **Chromatographic separation techniques:** Principle and applications of TLC, HPLC, HPTLC & Column chromatography, Flash column chromatography, RP-column chromatography.

UNIT II

2. Phytochemical screening of crude drugs:

A] Solvent extraction: Extraction, isolation, purification of Alkaloids: Piperine, Solasodine, Ergometrine, Emetine; Glycosides: Rhein, Sennosides; Flavonoids: Green tea flavonoids, Quercetin; Terpenoids: Taxol, Pyrethrin; Saponins: Glycyrrhizinic acid, Diosgenin.

B] Supercritical fluid extraction: Capsaicinoids, Flavonoids, resveratrol (*Vitis vinifera*), astaxanthin (red yeast) & mycotoxins.

3. Structural elucidation of following phytoconstituents: by physical, chromatographic & spectroscopic methods of characterization:

Glycyrrhizinic acid, Citral, Quercetin, Morphine, Pilocarpine, Nicotine, Ergometrine & Piperine

UNIT III

4. Standardization of herbal drugs:

A] Sources of variation in chemical make-up of plant derived drugs: genotypic, ecotypic and biotypic variations and variations resulting during processing and storage. Conventional methods used in herbal drug standardization and their limitations. WHO parameters used in herbal drug standardization; Overview of new approaches (System biology approach; Phytometabolomics, DNA Micro-array).

B] Identification of following phytochemical markers in crude drugs using HPTLC & HPLC: Vasicine, Andrographolides, Phylanthin, Solasodine, Gingerol, Bacoside, Curcumin & Lupeol.

5. Brief introduction to Pharmacological Screening Methods with examples of following category of medicinal Herbs:

Hepatoprotectives, Anti-diabetics, Anti-asthmatic, Hypolipidemics, Antioxidants, Anti-inflammatory, Analgesics & Anti-cancer.

(M.2.12) PHYTOCHEMISTRY & PHYTOPHARMACEUTICALS
(Practical 8 Hrs/Week)
CREDITS 04

1. Extraction, isolation, purification of important phytoconstituents belonging to different classes.
 - a. Nicotine from tobacco
 - b. Sennosides from Senna
 - c. Piperine from *Piper spp.*
 - d. Glycerrhizin from Liquorice
 - e. Tannic acid from myrobalan
 - f. Lawsone from henna
 - g. Carvone in various volatile oil
 - h. Cineole from Eucalyptus
 - i. Vasicine from vasaka
2. Generation of UV, Visible, IR Spectral data and chromatographic characterization of above extracted & purified compounds.
3. Determination/Estimation of following
 - a. Total Saponins by gravimetric method.
 - b. Rutin by UV-Visible Spectrophotometer
 - c. Alcohol content in Asava/Arishta Preparations
 - d. Aldehyde in Lemon oil
4. HPLC and HPTLC (if possible) profile of any phytochemical markers in crude drugs.
5. Antimicrobial screening of plant extracts
6. Determination of free radical scavenging activity by *in vitro* Spectrophotometric analysis.

Recommended books:

1. Chatwal G.R., **Organic Chemistry of Natural Products** by vol. I and II. Himalaya Publishing House, 2010. ISBN-14: 09789350246441.

2. Evans W. C., Trease G. E., **Trease and Evan's Pharmacognosy**. W.B. Saunders, 2002. 16th Ed. ISBN-10: 0702029335.
3. Finar I.L., **Organic Chemistry: Stereochemistry & the Chemistry of Natural Products**, Vol.II., Pearson Education India, 5th Ed. ISBN: 81-7758-541-X.
4. Handa S. S., Suman Preet Singh Khanuja, Gennaro Longo, Dev Dutt Rakesh, **Extraction technologies for medicinal & aromatic plants**, International centre for science and high technology, Trieste, Italy, 2008.
5. Hans-Jörg Bart & Stephan Pilz, **Industrial Scale Natural Products Extraction**, Wiley-VCH Verlag & Co., Germany, 2011. ISBN: 978-3-527-32504-7.
6. Mukherjee Pulok K., **Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals**. Business Horizons, 2002. ISBN 8190078844.
7. Otto Sticher, **Natural product isolation**. Natural Product Reporter, 25, 517– 554, 2008.
8. Kokate C. K., Practical Pharmacognosy, Vallabh Prakashan., Delhi, 1994.
9. **Quality control methods for medicinal plant materials**, World Health Organization, Geneva, 1998. ISBN 9241545100.
10. Rangari V.D., **Pharmacognosy & Phytochemistry** (Vol I), Career Pub., Nashik, 2009, ISBN: 978-81-88739-45-5.
11. Rangari V.D., **Pharmacognosy & Phytochemistry** (Vol II), Career Pub., Nashik, 2009, ISBN: 978-81-88739-65-3.
12. Satyajit D. Sarker, Zahid Latif, Alexander I. Gray, **Natural Products Isolation**, 2nd Ed., Humana Press Inc. Totowa, New Jersey; 2006. ISBN 1-59259-955-9.
13. Kadbadi S.S., Deore S.L. & Baviskar B.A., **Experimental Phytopharmacognosy**, Nirali Publication, Pune, 2011. ISBN 9381237131).

Recommended Journals

1. Biological and Pharmaceutical Bulletin
2. Indian Drugs
3. Indian Journal of Pharmacology
4. Journal of Agriculture and Food Chemistry
5. Journal of Chromatography
6. Journal of Ethnopharmacology

7. Journal of Natural Products
8. Natural Product Reporter
9. Phytochemistry
10. Phytomedicine
11. Phytotherapy Research
12. Planta Medica

(M.2.13) INDUSTRIAL PHARMACOGNOSY
(Theory 4 Hrs/Week)
CREDITS 04

UNIT I

1. Natural products in India:

Strengths & weakness in the study & commercialization of NPs in India. Comprehensive account of different segments of NPs in market along with their global & domestic market size/volume.

2. Indian herbal drug industry:

Size, turnover, domestic & international share, export potential, domestic & global market for prescription, OTC & TSM products, important plants used in indigenous systems of medicine & in modern medicine; major herbs/extracts exported from India, government agencies involved in development & promotion, promotional policy for entrepreneurship development: technical & funding assistance schemes, Industry oriented R & D institutes, leading manufacturer of herbal drugs, bottlenecks of plant based drug industry. Comprehensive study of top Indian herbs/ value-addition herbal products exported from India.

UNIT II

3. Herbal drug regulation:

Herbal drug regulation in India, licensing requirements for production & sale of herbal drugs in India; documentation; global regulatory status; ethical issues, WHO guidelines for regulation, The International Conference on Harmonization (ICH) guidelines, concepts of Quality by Design (QBD), GMP for Indian systems of medicine, GMP for production of phytomedicines; Other issues related to export of natural products (such as CITES Certificate, DGFT Notification, Negative list of herbs, TRAFFIC); Indian and international patent laws, patenting natural products, Indian traditional drugs & patents, Recent amendments as applicable to herbal/ natural products and processes Plant breeders right, traditional knowledge digital Library, Patent & Indian herbal drug industry; Preparation of sample application form for grant/renewal of a license to manufacture of Ayurvedic/Sidhha/Unnani drugs (Form No. 24-D rule 153).

UNIT III

4. Herbal Drug Formulation and Development:

Determination of Shelf life of raw drugs, powdered drugs, extracts, fractions and finished products. Factor affecting stability of herbal formulations, ICH and Other guidelines, method of stabilization and stability testing.

5. Toxicity & Pharmacovigilance of herbal medicines:

Different ways by which herbal preparations cause toxicity, pharmacokinetic & pharmacodynamic interactions, herbal-drug interaction of commonly used herbs; Special precautions in geriatric patients; Meaning, need, & significance of pharmacovigilance systems; WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems.

Reference Books

1. Textbook of Industrial Pharmacognosy, by A. N. Kalia, CBS Publishers and Distributors. New Delhi.
2. Chaudhari R D, Herbal Drug Industry, Eastern publication.
3. PDR for Herbal Medicines, Second Ed., Medicinal Economic Company, New Jersey.
4. Amitava Dasgupta, Catherine A. Hammtt-Stabler, **Herbal supplements: Efficacy, toxicity, interactions with Western drugs, and effects on clinical laboratory tests.** Wiley International, 2011. ISBN: 978-0-470-43350-8.
5. Ashok D.B. Vaidya and Thomas P.A. Devasagayam, **Current Status of Herbal Drugs in India: An Overview.** J. Clin. Biochem. Nutr., 41, 1–11, 2007.
6. Brendler, Thomas; Phillips, L Denzil; Spiess, Stefan, **A Practical Guide to Licensing Herbal Medicinal Products,** Pharmaceutical Press. ISBN: 978 0 85369 784 8.
7. Drugs and Cosmetics Act 1940.
8. Duke James A. *et al.*, **Medicinal Herbs.** 2nd Ed., CRC Press, 2002. ISBN 0-8493-1284-1.
9. **Entrepreneurship in Agriculture & Allied Sectors,** Government of India. http://business.gov.in/agriculture/aromatic_herbal_plantation.php
10. Evans W. C., Trease G. E., **Trease and Evan's Pharmacognosy.** W.B. Saunders, 2002. 16th Ed. ISBN-10: 0702029335.
11. Gupta, SK. *Textbook of Pharmacovigilance,* Jaypee Brothers Medical Publishers (P) Ltd. 2011. ISBN: 9789350252062
12. Iqbal Ahmad, Farrukh Aqil, and Mohammad Owais, **Modern Phytomedicine: Turning Medicinal Plants into Drugs.** WILEY-VCH Verlag GmbH & Co. KGaA, Weinheim, 2006. ISBN-10: 3-527-31530-6.
13. Jon C Tilburt & Ted J Kaptchuk, **Herbal medicine research and global health: an ethical analysis.** Bulletin of the World Health Organization, 86 (8), 2008.
14. Kashi Anusuya R., S. Ramachandran & Bindu Sukumaran **Textbook of Industrial Pharmacognosy,** University Press, 2012. ISBN: 978-81-7371-754-3.
15. Kokate C. K., Gokhale S.B. and Purohit A.P., **Textbook of Pharmacognosy,** Nirali Prakashan, Pune, 2008, ISBN: 8185790094.
16. Lakshman Karalleidie & Indika Gawarammana **Traditional Herbal Medicines: a Guide to Their Safer Use.** Hammersmith Press, London, 2008. ISBN 978-1-905140-04-6.
17. **Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review,** World Health Organization, Geneva, 2001.

18. Leland J. Cseke et al., **Natural Products from Plants**, 2nd Ed., CRC Press, 2006. ISBN: 10: 0-8493-2976-0.
19. Michael McGuffin, Art Tucker, Albert Y. Leung, John T. Kartesz, **Herbs of Commerce**, American Herbal Products Association, 2000. ISBN-10: 0967871905.
20. Mukherjee Pulok K., **Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals**. Business Horizons, 2002. ISBN 8190078844.
21. Rajpal V. & Kohli D. P. S., **Herbal Drug Industry**, Riddhi International, 2nd Ed., 2009. ISBN: 9788190646727.
22. Rangari V.D., **Pharmacognosy & Phytochemistry (Vol I)**, Career Pub., Nashik, 2009, ISBN: 978-81-88739-45-5.
23. Rangari V.D., **Pharmacognosy & Phytochemistry (Vol II)**, Career Pub., Nashik, 2009, ISBN: 978-81-88739-65-3.
24. **Regulatory situation of herbal medicines: A worldwide review**, WHO <http://apps.who.int/medicinedocs/pdf/whozip57e/whozip57e.pdf>
25. Roy Atul, **Herbal Drug Industry**, Oxford Book Company, 2012. ISBN 10: 9350300893.
26. Timothy S. Tracy & Richard L. Kingston, **Herbal products: Toxicology and Clinical Pharmacology**. Humana Press Inc. 2007. eISBN 10-digit: 1-59745-383-8.
27. Ved D.K. & Goraya, G.S. **Demand & supply of medicinal plants in India**, NMPB, New Delhi & FRLHT, Bangalore, India, 2008.
28. **WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems**, World Health Organization, Geneva, 2004.
29. Pharmacopoeial Standards for Ayurvedic formulations – CCRAS, Delhi.
30. Good manufacturing practices for pharmaceuticals, SH Willing, Vol. 78, Marcel Dekker, NY. New drug approval process, RA Guarino, Vol 100, Marcel Dekker, NY.
31. Ayurvedic formulary of India, Government of India, Ministry of Health and Family Welfare.
32. The Aurvedic Pharmacopoeia of India, 1999. Government of India, Ministry of Health and Family Welfare, Department of Indian Systems of Medicine and Homeopathy, New Delhi.
33. Indian Pharmacopoeia, 2010. Government of India, Ministry of Health and Family Welfare, Vol. I III, The Indian Pharmacopoeia Commission, Ghaziabad.
34. United States Pharmacopoeia, 2009. The Official Compendia of Standards, Vol. 1-3, the United States Pharmacopoeial Convention, Rockville.
35. Indian Herbal Pharmacopoeia, 1999. Vol I- II, Council of Scientific and Industrial Research, Jammu-Tawi, New Delhi.

Recommended Journals

1. Biological and Pharmaceutical Bulletin
2. Indian Drugs
3. Indian Journal of Pharmacology
4. Journal of Agriculture and Food Chemistry

5. Journal of Chromatography
6. Journal of Ethnopharmacology
7. Journal of Natural Products
8. Natural Product Reporter
9. Phytochemistry
10. Phytomedicine
11. Phytotherapy Research
12. Planta Medica

(M.2.14) PHARMACEUTICAL VALIDATION

(Theory 4 hrs /week)

CREDITS 04

UNIT I

- 1. Introduction to Pharmaceutical Validation:** Definition, Manufacturing Process Model, Government regulation, Scope of Validation, Advantage of Validation, Organization for Validation, Validation master Plan, Calibration Master plan, Validation Life cycle
- 2. Facility Qualification and Consideration of Validation aspects during facility design**
- 3. Validation of Equipment :** Concept of URS, DQ, IQ, OQ & PQ and

Validation of equipments: Dry Powder Mixers, Fluid Bed and Tray dryers, Tablet Compression M/c.

Dry Heat Sterilization/Tunnels, Autoclaves, Capsule filling machines, Validation of Integrated lines by

Media fill test and Validation of existing equipment

UNIT II

- 4. Vendor Validation**
- 5. Support and Utilities Validation:** Validation of Pharmaceutical Water System, Pure steam system, Validation of HAVC system, Validation of Compressed air
- 6. Cleaning Validation:** Cleaning of Equipment, Cleaning of Facilities

UNIT III

7. Analytical Validation:

Analytical Method Validation - General Principles of analytical method validation, Bioanalytical and stability indicating method Validation.

Validation of analytical Instruments - HPLC, Dissolution test apparatus, UV Visible Spectrophotometers

8. Process Validation: Process Validation types of process - Prospective, concurrent, and retrospective & revalidation.

Processes Validation Following formulations -Tablet, Capsules, Ampoules & Vials, Ointment/Creams and Liquid Orals

9. Computer System Validation

UNIT IV

10. Validation of packaging operations: Integrated packaging validation, Validation of blister/strip packing machine.

11. Quality Assurance and Validation

12. Harmonization GMP and Validation

(M.2.15) PHARMACEUTICAL VALIDATION

(Practical 8 Hrs/week)

CREDITS 04

1. Validation of analytical method (minimum four exercises)
2. Validation / Qualification of following equipment
 - a. Dissolution test apparatus
 - b. Powder Mixer (Dry)
 - d. Tablet Compression Machine
 - e. Coating pan
3. Validation of a processing area
4. Validation of at least two analytical instruments.
5. Cleaning validation of one equipment.

Recommended books for theory and Practical:

1. Pharmaceutical Process Validation, Third Edition, Ira R. Berry & Robert Nash, Marcel Dekker Inc.

2. Validation of Pharmaceutical Process (Sterile Products), Third Edition Revised & Expanded, F.J. Carleton and J.P. Agalloco, Marcel Decker Inc.
3. Current Good Manufacturing Practices, M.A. Potdar, Pharma-Med Press, Hyderabad.
5. Chang Chow Chang

(M.2.16) QUALITY PLANNING AND ANALYSIS
(Theory) (4 Hrs /week)
CREDITS 04

UNIT I

1. Basic concepts of Quality

- Definition of Quality
- The quality function
- Managing for quality
- Perspective on Quality – Internal versus External

2. Quality Improvement and Cost Reduction

- Sporadic and chronic quality problems
- Need for quality improvement & cost reduction
- Causes of poor quality and high cost.
- Provide a remedy and prove its effectiveness for improving quality.
- Resistance to change
- Institute Controls to hold the Gains.

3. Control of Quality

- Definition of control
- Self control
- The control subject for quality
- Units of measure
- Setting a Goal for the Control subject
- The Sensor
- Measuring Actual performance
- Interpreting the difference between Actual performance and the goal.
- Taking action on the difference
- Continuous process regulation.

UNIT II

4. Developing: Quality Culture

- Technology and culture

- Theories of Motivation
- Create and Maintain Awareness of Quality
- Provide Evidence of management and empowerment
- Time to change the culture

5. Manufacturing

- Importance of manufacturing planning for quality
- Initial planning for quality
- Concept of controllability, self-control
- Defining quality responsibilities on the Factory floor
- Self Inspection
- Automated manufacturing
- Overall review of manufacturing planning
- Process quality audits
- Quality and production floor culture

6. Statistical Process control

- Definition and Importance of SPC
- Quality measurement in manufacturing
- Statistical control charts-general
- Advantages of statistical control
- Process capability
- Estimating Inherent or potential capability from a control chart analysis
- Measuring process control and quality improvement
- Pursuit of decreased process variability

UNIT III

7. Inspection, test and Measurement

- The terminology of Inspection
- Conformance to specification and fitness for use
- Disposition of Nonconforming product
- Inspection planning
- Seriousness classification
- Automated Inspection
- How much inspection is necessary?
- Inspection Accuracy
- Errors of Measurement

8. Inspection and test sampling plans

- The concept of acceptance sampling
- Economics of Inspections
- Sampling Risks: The operation characteristic curve
- Analysis of some rule of thumb sampling plans
- Evaluation of parameters affecting acceptance sampling plans

- Quality indices for acceptance sampling plans
- Types of sampling and Multiple sampling
- Characteristics of a good acceptance plan

9. Quality Assurance General Concepts

- Definition of quality assurance
- Concept of quality assurance
- Quality audit- The concept
- Subject matter of audits
- Structuring the audit programme
- Planning and performing audits of activities
- Human relations in auditing.
- Audit reporting
- Essential ingredients of a quality audit programme
- Quality surveys
- Product audit
- Sampling for product audit
- Reporting the results of product audit.

Recommended Books:

1. Quality planning and Analysis, 5th Edition, J. M. Juran and F. M. Gryna, Publisher, Tata McGraw Hill, India.
2. Improving Quality through planned experimentation By Moen: Tata McGraw Hill, India.
3. Statistical Quality Control by Grant – Publisher Tata McGraw Hill – India.
4. Juran's Quality Handbook, Fifth Edition, J. M. Juran , Publisher Tata McGraw Hill – India.

ELECTIVE SUBJECTS OF ALL SEMESTERS

(E.1.1) QUALITY CONTROL & ASSURANCE OF PHARMACEUTICALS

(Theory 3 Hrs/Week)

CREDITS 03

Note: Students of M. Pharm. in Quality Assurance Techniques cannot take this subject as elective.

UNIT I

1. Quality control and Assurance technique: Basis concepts of Quality:- Developing quality culture.
2. Quality Assurance General Concepts: Definition of quality assurance concept and components of Q. A., Good Manufacturing Practices, Quality control – The concept
3. Personnel, Premises and Equipments: Qualification, experience, training responsibilities and hygiene of personnel. Drainage system, Sewage, Sanitation, Lighting, maintenance of building and premises; Design, size, location, construction, cleaning and maintenance of equipments. Documents and formats related to personnel, premises and equipment.

UNIT II

4. Material Management: Purchasing, Raw material, packaging materials, Intermediate and Bulks products, Finished products, Rejected and recovered materials, recalled products, returned goods, Reagents and culture media, Waste materials, reference standards, Miscellaneous material. Documents and formats.
5. Manufacturing operations and control: Revised schedule M, sanitation of manufacturing premises, Mix –ups and cross contamination, processing of intermediates and Bulk product, Packaging operations, I.P.Q.C., Release of finished products process deviations, Drug product inspection, expiration dating, Document and formats.

UNIT III

6. Documents and Records: Specification, Master production and control record, Batch production and control record, Significance of SOPs and record, change control, Drug Master file, Documents and formats.
7. Pharmaceutical Validation: Definition & concept of validation, validation of building, equipments, instruments and facilities, process validation, cleaning –validation, validation master plan, Documents and formats.
8. Quality control of Biological products: International Biological standards, safety testing of pharmaceutical Quality control of antibiotics.
9. Pharmaceutical Plant Audit: Department wise documents and audit questionnaire.

10. Sterile Pharmaceutical Products: GMP aspects related to sterile products- General guidelines, personnel, building and premises, equipment, sanitation, processing, sterilization, Quality control and validation, Documentation

Recommended Books:

1. Pharmaceutical Quality Assurance, MA Potdar, Nirali Prakashan, Pune
2. Validation of Pharmaceutical process, F. J. Carleton and J. Agalloco, Marcel Dekker Inc.
3. Pharmaceutical Process Validation, Second Ed., Ira R. Ferry & Robert Nash., Marcel Dekker Inc.
4. Quality Planning & Analysis by J. M. Juran and F. M. Gryna, Tata Mcgraw Hill, India.
5. Improving Quality through Planned experimentation by Moen, Tata Mcgraw Hill.
6. Good Manufacturing Practices for Pharmaceutical; A Plan for total Quality Control, 4 th Ed, Sidney willing.
7. Quality Assurance Guide by Organization of Pharmaceutical producers of India.
8. Pharmaceutical Process Validation; By F. R., Berory and Robert A. Nash
9. Impurities Evaluation of Pharmaceutical; Satinder Ahiya Marcel Decker.42
10. Quality Control of Packaging material in the Pharmaceutical Industry: Kenneth Harburn, Marcel Dekker.
11. Juran's Quality Control Handbook J.M. Jupron.4th Ed. Good design practices for GMP Pharmaceutical facilities. Andrew A Signature, Marcel Dekker.
12. cGMP for Pharmaceuticals. Pharma. Med. Press, I st edition by Manohar H. Potdar

(E.1.2) PHARMACEUTICAL PLANT DESIGN AND OPERATIONS

(Theory 3 Hrs/Week)

CREDITS 03

UNIT I

1. Regulatory requirements of Pharma facilities with reference to cGMP, revised schedule M and Factory Act
2. Design, layout and operational facilities with services and utilities for Tablets, Capsules, Liquid orals, Ointments and Dry syrups.

UNIT II

3. Design, layout and operational facilities with services and utilities for sterile products powders ready for reconstitution

4. Design and operation of Q.C. Laboratory

UNIT III

5. Design of utility services - Water - steam- Compressed air and other gases
6. Design of effluent treatment plant

UNIT IV

7. Designing of plant support services like security office, vehicle parking, fuel storage, canteen and cooking, garden and horticulture, scrap yards, Administrative block and training centre, sports and entertainment block, resident managers bungalow, residences for essential service staff, toilet facilities, medical services, crush

Recommended Books:

1. Project Management by Clifford F. Gray and Erik W. Larson Publisher: McGraw Hill company.
2. Pharmaceutical Production facilities: Design and applications by Graham Cole. Publisher: Taylor & Francis
3. Production/Operations Management by: El wood Bufa Publisher: Wiley Eastern Limited (New Delhi)
4. S. J. Turco; Sterile Dosage Forms: their Preparation and Clinical Applications; Lee and Febiger.
5. N. K. Jain; Controlled and novel drug delivery: CBS Publication.
6. J. R. Robinson and H. L. Lee; Controlled Drug Delivery: Fundamentals and Applications; Marcel Dekker.
7. F.J. Carleton and J.P. Agalloco; Validation of aseptic pharmaceutical processes: Marcel Dekker.
8. L. A. Trissel; Handbook on injectable drugs; American Society for Hospital Pharmacist Publication.43
9. N.A. Halls; Achieving sterility in medical and pharmaceutical products; Marcel and Dekker.
10. Planning and control by: Samuel Eilon Publisher: Universal book corporation, Mumbai.

(E.1.3) BIOPHARMACEUTICS AND PHARMACOKINETICS

(Theory 3 Hrs/Week)

CREDITS 03

UNIT I

1. Dissolution:- Noyes- Whitney's dissolutions rate law, Study of various approaches to improve dissolution of poorly soluble drug, In –vitro dissolution testing models, In-vitro- In –vivo correlation.
2. Bioavailability:- Objectives and consideration in bio-availability studies, Concept of equivalents, Measurements of bio-availability, Determination of the rate of absorption, Bioequivalence and its importance, Regulatory aspects of bio-availability and bioequivalence studies for conventional dosage forms and controlled drug delivery systems.

UNIT II

3. Study of different in-vitro and in-vivo / biological models for determination of absorption, distribution, metabolism and excretion and permeability of drug
4. Study of physiological transporter systems like A B C. Dosage form design and physiological barriers like BBB, blood testis barrier and blood placental barrier

UNIT III

5. Pharmacokinetics:- Basic consideration, Pharmacokinetic models, Compartment modeling: One compartment model – IV bolus, IV infusion, Extra-vascular; Multi Compartment models; Two compartment model – Iv bolus, IV infusion, Extra-vascular, Three Compartment model in brie, Application of Pharmacokinetics in new drug development and designing of dosage forms and Novel drug delivery systems.
6. Non-Linear Pharmacokinetics:- Causes of non-linearity, Detection of non – linearity, Michaelis-Menten equation, Estimation of K_m and V_{max} .with respect to individualization of a drug

UNIT IV

7. Drug Distribution: - significance and kinetics of protein binding and drug displacement interactions
8. Case studies based on pharmacokinetic principles
9. Determination of various pharmacokinetic parameters.

Recommended Books:

1. Biopharmaceutics and Pharmacokinetic, A Treatise, D. M. Brahmkar and Sunil B. Jaiswal, Vallabh Prakashan, Pitampura, Delhi

2. Current Concepts in Pharmaceutical Sciences: Biopharmaceutics, Swarbrick. J, Lea and Febiger, Philadelphia.1970.
3. Clinical Pharmacokinetics Concepts and Applications 3rd edition by Malcolm Rowland and Thomas N. Tozer, Lea and Febiger, Philadelphia, 1987.
1. 44
4. Dissolution, Bioavailability and Bioequivalence, Abdou. H. M. Mack Publishing Company, Pennsylvania, 1989.
5. Biopharmaceutics and Clinical Pharmacokinetics, an Introduction, 4th edition, revised and expanded by Robert, E. Notari, Marcel Dekker Inc, New York and Basel, 1987.
6. Biopharmaceutics and relevant Pharmacokinetics, by John. G. Wagner and M. Pernarowski, 1st edition, Drug Intelligence Publications, Hamilton, Illinois, 1971.
7. Encyclopedia of Pharmaceutical Technology, Vol 13, James Swarbrick, James. C. Boylan, Marcel Dekker Inc, New York, 1996.
8. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi, 4th edition, Philadelphia, Lea and Febiger, 1991
9. Biopharmaceutics and Pharmacokinetics, A Treatise, D. M. Brahmankar and Sunil B. Jaiswal, Vallabh Prakashan, Pitampura, Delhi
10. Applied Biopharmaceutics and Pharmacokinetics by Shargel. L and Yu ABC, 2nd edition, Connecticut, Appleton Century Crofts, 1985.
11. Textbook of Biopharmaceutics and Pharmacokinetics, Dr. Shobha Rani R. Hiremath, Prism Books Pvt Ltd, Bangalore, 2000.

(E.1.4) STERILE PRODUCTS FORMULATION & TECHNOLOGY
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

A) FORMULATIONS

1. Preformulation: Physico-chemical properties of materials used in parenteral formulations. Selection of polymeric components. Selection of packaging components of packaging components.
2. Formulation of SVP and LVP: Requirement, components, materials, Pharmacopoeial requirements, special types of parenterals such as suspensions, emulsions, dried forms, Variables in formulation development.

3. Ophthalmic Products: Ocular anatomy and physiology relevant to ocular drug delivery, ocular Pharmacokinetics, conventional products, ocular inserts, particulate and liposome drug delivery, protein and peptide delivery.
4. Sustained Release Parenterals: Liposome's, and niosomes, nanoparticles, proteins and peptides, implants, loaded erythrocytes.

UNIT II

B) TECHNOLOGY- Manufacturing of Parenterals

6. Layout of parenteral facilities, FFS and BFS technology for parenterals.
7. Environmental control: Temperature and humidity control, air handling systems and their validation.
8. Industrial sterilization: Large-scale sterilization processes, process selection, specifications, development and validation of process and equipment.
9. Parenteral devices such as syringes, cannula, catheters.
10. Guidelines: Overview of GMP and regulatory guidelines.
11. Hazards associated with parenteral therapy

Recommended Books:

1. K. E. Avis, H. A. Liebermann and Lachman; Pharmaceutical dosage forms: Parenteral Medications: Vol. 1,2,3, Marcel Dekker.
2. S. J. Turco Sterile Dosage Forms: their preparation and clinical application; Lee and Febiger.
3. N. K. Jain; Controlled and Novel drug delivery: CBS Publication.
4. J. R. Robinson and H. L. Lee; Controlled drugs delivery: Fundamentals and Applications; Marcel Dekker.
5. F. J. Carleton and J. P. Agalloco: Validation of aseptic pharmaceutical processes: Marcel Dekker.
6. L. A. Trissel: Handbook on injectable drugs; American Society for Hospital Pharmacist Publication.
7. N. A. Halls; Achieving sterility in medical and pharmaceutical products; Marcel and Dekker.

(E.1.5) ACTIVE PHARMACEUTICAL INGREDIENTS (APIS)
MANUFACTURING TECHNOLOGY
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

Introduction to basic pharmaceutical and fine chemical chemistry: Definitions of basic pharmaceuticals, intermediates, fine chemicals, heavy chemicals. Technology involved in manufacturing of pharmaceuticals. Unit processes in synthesis, biochemical processes in synthesis.

UNIT II

Unit processes: Study of the following chemical processes (with references to reagents, mechanisms, equipments and manufacture of drugs given below): Acylation, esterification, alkylation, amination, halogenation, hydrolysis, nitration, oxidation and reduction.

UNIT III

Industrial processes & scale up techniques

Industrial manufacturing methods and flow charts of Sulphamethoxazole, Ciprofloxacin, Benzocaine, Adrenaline, Rifampicin, Aspirin and Pentothal sodium.

UNIT IV

Bioethics and Bio-Safety

Health hazards in manufacturing facility, The forms of Atmospheric contaminants, Chemical mixtures, Detection and sampling, Atmospheric contamination, industrial noise, criteria for hearing damage, Noise measuring instruments, effects of sound and ultrasound, the control of noise, vibration, Radiation Hazards, Radiation detection and measurement, personal protection, eye protection, Types of eye protection equipment. Finger & Arm protection, Foot & leg protection. Environmental protection laws related to industry.

Reference

1. M.G. Larians: Fundamentals of Chemical Engineering Operations.
2. W. L. Badger and Banchemo: Introduction to Chemical Engineering.
3. L. Lachman-The Theory and Practice of Industrial Pharmacy.
4. Ganderton G.: Unit Processes in Pharmacy.
5. Groggin P. K.: Unit Processes in Organic Synthesis.
6. Marshall Sitting: Organic Chemical Processes.
7. Dryden C. L.: Outlines of Chemical Technology.

(E.1.6) CLINICAL TRIALS
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1. Introduction to clinical Trial

History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments

2. Regularly affairs in clinical trials

IND, NDA, ANDA- Parts and contents, Safety monitoring boards, FDA in various countries including India

3. Ethical issues in clinical trials

Principal, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), Protection of participants, The Nuremberg Code, The Declaration of Helsinki, The Belmont Report Clinical trial design

UNIT II

4. Designs used in clinical trials with their advantages and disadvantages, hypothesis, risks and benefits, subject selection, inclusion and exclusion criteria, randomization, blinding and controls

5. Clinical trial protocol Development

Required Documentation including Investigator's Brochure, Case Report Forms, Serious Adverse Event (SAE) Reports, Laboratory Certification, data collection and quality control of data, closing out of clinical trial

6. Good Clinical Practice

UNIT III

7. Concept, importance, and GCP guidelines including ICH guidelines

Management of Clinical trials

8. Role and responsibilities of Stakeholders of clinical trials (FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient), monitoring of clinical trials, Publications of clinical trials

9. Bioavailability, bioequivalence and Therapeutic Drug Monitoring

Concept, organization, advantages, special issues, applications, bioequivalence

10. Data analysis issues in Clinical Trials

Monitoring of data, computer applications, statistical tests used, interpretation, survival analysis, sub-group analysis, Quality control of clinical trials

Recommended Books:

1. Dipiro, Joseph L.; Pharmacotherapy: A Pathophysiological Approach, Elsevier
2. Davidson's Principles of Internal Medicine, Vol-I And II, 14th Edition, Mc Graw-Hill
3. Harrison's Principle And Practice Of Medicine, 18th Edition, Churchill, Livingston, London
4. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London
5. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics
6. Tussle, T.G.: Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall, New York

(E.1.7) SAFETY PHARMACOLOGY
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1. Definition and scope of safety pharmacology
2. Regulatory requirements for the new drug safety assessment: ICH, OECD, USFDA, EMEA, Japan, MHW guidelines

UNIT II

3. Principals and study design of safety evaluation
 - a) Acute toxicity- rodent and non-rodent
 - b) Repeated dose studies (sub acute and chronic)
 - c) Analysis of safety pharmacological data
4. Preclinical safety pharmacology: In vitro and in vivo studies including genotoxicity, mutagenicity, carcinogenicity, reproductive and ocular toxicity, Safety testing for dermatological product

UNIT III

5. Clinical Safety pharmacology: definition, data collection, reporting methods and assessment and analysis of adverse event (AE) monitoring during clinical trials
6. Pharmacovigilance: Definition, collection of data, reporting, assessment of Post marketing surveillance, periodic safety update reports, Risk-benefit assessment

Recommended Books:

1. Sogliero-Gilbert, G., Drug safety assessment in clinical trials. Statistics, textbooks and monographs. 1993, New York: Dekker. x, 437 p.
2. Marx, U. and V. Sandig, Drug testing in vitro : breakthroughs and trends in cell culture technology. 2007, Weinheim: Wiley-VCH. xix, 298 p.

3. Gad, S.C., Safety assessment for pharmaceuticals. 1995, New York: Van Nostrand Reinhold. xv, 496 p.
4. Turner, J.R., New drug development : design, methodology, and analysis. 2007, Hoboken, N.J.: Wiley-Interscience. xxi, 270 p.
5. Dmitrienko, A., C. Chuang-Stein, and R.B. D'Agostino, Pharmaceutical statistics using SAS : a practical guide. 2007, Cary, N.C.: SAS Institute. ix, 444 p.
6. Smith, C.G. and J. O'Donnell, The process of new drug discovery and development. 2nd ed. 2006, New York: Informa Healthcare. 668 p.
7. Bénichou, C., Adverse drug reactions : a practical guide to diagnosis and management. 1994, Chichester, West Sussex, England; New York: Wiley. xviii, 302p.
8. Mann, R.D. and E.B. Andrews, Pharmacovigilance. 2nd ed. 2007, Chichester, England ; Hoboken, NJ: John Wiley & Sons. xviii, 686 p.
9. World Health Organization., WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. 2004, Geneva: World Health Organization. vii, 18 p.
10. Cobert, B.L., Manual of drug safety and pharmacovigilance. 2007, Sudbury, Mass.: Jones and Bartlett Publishers. p.
11. Cobert, B.L. and P. Biron, Pharmacovigilance from A to Z : adverse drug event surveillance. 2002, Malden, MA: Blackwell Science. xiii, 235 p.

(E.1.8) CHEMISTRY OF MEDICINAL NATURAL PRODUCTS
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1. Primary and Secondary metabolites in plants.
2. Various metabolic pathways in plants.

UNIT II

3. General isolation and purification techniques of phytochemicals covering alkaloids, glycosides, terpenoids, carbohydrates and flavanoids.
4. (a) Detailed chemistry and properties of Alkaloids (general)
(b) Chemistry, structural elucidation by chemical and physical methods, methods of analysis for following: Alkaloids, Morphine, piperine, lobeline, atropine, caffeine, and ephedrine.

UNIT III

5. (a) Detailed chemistry and properties of plant steroids (general)
(b) Chemistry, structural elucidation by physical and chemical methods, methods of analysis for following: (1) Solasodine. (2) Diosgenin.
6. (a) Detailed chemistry and properties of Flavanoids.
(b) Detailed chemistry and properties of various plant pigments.

UNIT IV

7. Detailed chemistry and properties of terpenoids.
8. Detailed Chemistry and properties of carbohydrates – mono & disaccharides.

Recommended Books:

1. Chemistry of organic natural products, Vol I and II by O. P. Agarwal.
2. Pharmacognosy by Trease and Evans, 13th Ed. (Baillier- Tindall)
3. Phytochemistry, Vol. I, II, III by Miller.
4. Organic Chemistry, Vol I by Finar.
5. Recent Advances in Phytochemistry V.C. Runeckles (Elenum Press).
6. Chemistry of Natural Products, P.S Kalsi
7. Natural Products Chemistry - K. Nakanishi Ed. , Vol I and II

(E.1.9) TRADITIONAL SYSTEMS OF MEDICINE & AYURVEDIC FORMULATIONS
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1. Ethnopharmacognosy – General account.
2. A brief idea about Ayurveda. Chinese systems of medicine. Unani system of medicine. Homeopathy.

UNIT II

3. Comparative account of drugs used in above systems of medicine.
4. Ayurvedic dosage forms-Basic idea.

UNIT III

5. The formulation and evaluation of Ayurvedic dosage forms: Churna, Bhasma, Kwatha Asava, Arishta, Avaleha, Gutika, Vati, Rasa, Rasayana, Taila, Ghrita, Guggulu, Arka.
6. Ayurvedic Cosmetic formulations,

UNIT IV

7. Standardization of Ayurvedic dosage forms using:
 - a. Physical methods
 - b. Chemical methods
 - c. Biological methods.

Recommended Books:

1. Charaka Samhita
2. Sushrut Samhita
3. Sharangardhar Samhita

4. Ayurvedic formulary of India Govt of India.
5. Pharmacopocial standards for Ayurvedic drugs C.C.A.R.A., New delhi
6. Dravyagunavigyan
7. Homorpathic Materia medica.
8. World health W.H.O. 1977

(E.1.10) MEDICINAL PLANT BIOTECHNOLOGY
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1. Introduction to genetics & molecular biology.

- a. Structural and molecular organization of Cell.
- b. Genetic Material-DNA, RNA, Protein, Replication, Genetic Code, Regulation of Gene Expression, Structure & Complexity of Genome.
- c. Cell Cycle, Cell signaling.
- d. Mutation.
- e. Recombinant DNA Technology –Principles, Tools, Process & Applications.

2. Methods of improving quality of crops & their application.

- a. Plant Breeding.
- b. Chemodemes.
- c. Hybridization.
- d. Mutation.
- e. Polyploidy.

UNIT II

3. Tissue Culture & its Applications

- a. Types, Techniques & Application of Callus, Suspension, Haploid, Embryo, Organ and Immobilized Culture.
- b. Organogenesis, Embryogenesis, Synthetic seed & Somaclonal variation.
- c. Micropropagation.
- d. Production of Secondary metabolites – Strategies involving use of Precursor, Growth regulators & Elicitors: Production of Shikonin.
- e. Hairy Root Culture & Multiple Shoot Culture & their Applications.
- f. Protoplast culture & Protoplast fusion.
- g. Biotransformation.
- h. Bioreactors
- i. Cryopreservation and germplasm conservation

4. Germplasm Conservation.

- a. In- situ Conservation
- b. In- vitro methods of Conservation.

UNIT III

5. Gene Transfer in Plants.

- a. (i) Using vectors of *Agrobacterium*.
- (ii) DNA Mediated gene transfer – Electroporation, Microprojectile, Macro & Microinjection, Liposomes, Ultrasonication & Chemical mediated gene transfer.
- b. Localization of transferred gene in genetically modified plants:
 - i Nucleic acid Hybridization.
 - ii Use of Radioisotopes & Molecular Markers.
 - Auto Radiography.
 - Electrophoresis.

6. Applications of Transgenic Plants.

- a. Resistance of herbicide.
- b. Resistance to insect, fungus, & virus.
- c. Resistance to Physiological stress.
- d. Production of Phytopharmaceuticals.
- e. Edible vaccine.

UNIT IV

7. Gene Mapping & Molecular Maps of Plant Genomes.

- a. Plant Chromosome Analysis.
- b. Uses of PCR in gene mapping.
- c. Molecular Maps-RFLP, RAPD.
- d. Physical maps using in- situ hybridization.

8. Enzymes

- a. Types & Properties of enzymes.
- b. Isolation & Purification of enzymes.
- c. Immobilization of enzymes & its applications.
- d. Enzyme reactors.
- e. Detailed study of Plant enzymes – Papain & Bromelain.

Recommended Books:

1. Pharmaceutical biotechnology S.P. Vyas and V.K. Dixit, CBS Publishers and Distributors, 2001
2. Advanced methods in plant breeding & biotechnology by David R. Murray. CAB International Panima book distributors.1991.

3. Plant tissue culture by Dixon IRL Press Oxford Washington DC, 1985.
4. Role of Biotechnology in Medicinal and Aromatic Plants Vol I & II By Irfan A Khan and Atiya Khanum Ukaoz Publications.1998
5. Plant Chromosome analysis, manipulation and engineering by Arun And Archana Sharma 1st Edition Harwood Academic Publishers 1999
6. Comprehensive Biotechnology by Murray Moo-Young Vol I- IV Pergamon Press LTD, 1985.
7. Transgenic Plants by R Ranjan Agrobotanica.1999

Recommended Journals:

1. Journal of plant biochemistry and biotechnology
2. Current Science

(E.1.11) NATURAL PRODUCTS MANAGEMENT

(Theory 3 Hrs/Week)

CREDITS 03

UNIT I

I) Farm Analysis & Farm Planning

- Management exercise before farm planning / analysis.
- Appraisal of farm resources, capital resources, management factor, land resources, Enterpreural aspects
- Management of resources: land, labour, machinery & equipment.
- Farm planning & budgeting.
- Application of research in farm management.

II) Marketing

- Demand & Supply: Meaning, factors affecting demand & supply.
- Market: Meaning process of a agricultural marketing.
- Processing practice & industries in India.
- Study of co-operative processing / efforts among collectors & growers to store, transport & market the natural products.
- Processing of cocoa and oil seeds.
- Mechanization / Modernization of natural products market.

UNIT II

III) Prioritized Medicinal Plant of India

- Protocols for cultivation & quality control.
- State wise natural habitat of prioritized species.
- Cultivation economics / project proposal for few prioritize species.
- Ex-situ / in-situ cultivation & conservation.
- National & International Trade of prioritized species.

IV) Concerned ministers / Departments / Organization / State / UT Government on policy matters

- Relating to scheme & programmers for development of medicinal plants in India.

UNIT III

V) Study of General Requirement to establish extraction unit based on herbs/ Herbal products.

VI) Patent Right & IPR in relation to medicinal herbs and herbal products.

UNIT IV

VII) Import – export of natural Products –

Legal requirement & processing / techniques for marketing of raw material & value-added products (Medicine, food supplements, herbal cosmetics)

VIII) Review of Trade of herbs, phytoconstituents, Nutraceuticals & other. National medicinal products in national & international market.

Recommended Books:

1. Text Book of Agricultural Business Management, Kalyani Publisher, New Delhi, Broadway A C.
2. Acharya S.S. and Agrawal N.N. Agriculture Marketing in India, Oxford IDH Publication, New Delhi.
3. Memoria C.B. and Joshi Principal and Marketing in India, Kitab Mahal Agency, New Delhi.
4. Das Dilipkumar, Introductory Soil Science Kalyani Publisher, New Delhi.
5. Chaudhary – Herbal Industries
6. Kapoor & Attal – Cultivation and Utilization of Medicinal Plants.
7. Kapoor & Attal – Cultivation and Utilization of Aromatic Plants.
8. Chopra – Indigenous Drugs.

9. Wealth of India NISCAIR Publication, New Delhi.
10. www.nmpb.nic.in.
11. Official Journals, Periodicals, Magazines, Bulletin, Newspapers & Website be referred.

(E.1.12) QUALITY ASSURANCE TECHNIQUES IN HERBAL PRODUCTS
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1. Quality Management – Change as per following
 - a. Introduction to GMP
 - b. Elements of QA
 - c. Information on various regulatory bodies like US FDA, MHRA, TGA, MCC, ICH
 - d. Outsourcing
 - e. Quality Audits
2. GMP Requirements for herbal medicinal products, Ayurvedic and other Drug of traditional origin - overview and reference to various regulations - Drug and Cosmetic Act and Rules, , Australian/EMEA guidelines for herbal products, WHO Guidelines for Herbal Medicines
3. Surrounding, Building, and Facility – Design for processing of herbal products – Cleaning, pulverization and processing of herbal extracts/ products etc.

UNIT II

4. Equipment URS, and qualifications
5. Standardization of herbal products with reference to WHO and cGMP guidelines
6. Quality control and standardization of medicinal plant, plant based products, nutraceuticals and cosmetics.

UNIT III

7. Analytical methods development guidelines for materials and products/ formulations of herbal/natural origin viz. extracts, herbal formulations, isolated compounds, modern herbal formulations etc.
8. Study of compendial methods for evaluation of crude drug and herbal formulation
9. Stability issues guidelines for studies related to herbal formulations, extracts, fractions and natural products/isolated compounds.

UNIT IV

10. Safety issues related to herbals products and storage of herbal raw materials and herbal products.
11. Pharmacovigilance for herbal products
12. Packaging development: Types of packages, Flexible packaging, primary, secondary & tertiary, quality evaluation as applicable to packages, Child resistant, tamper evident, advancement in packaging.
13. Cleaning and sanitization of plant and equipment. Cleaning validation

Reference Books:

1. Mukherjee Pulok K., **Quality Control of Herbal Drugs: An Approach to Evaluation of Botanicals**. Business Horizons, 2002. ISBN 8190078844.
2. Prof. Dr. Robert Verpoorte and Dr. Pulok K. Mukherjee **GMP for Botanicals**
3. Standardization of Botanicals by V. Rajpal, Vol. I and Vol II, Eastern Publishers, New Delhi.
4. G. Sudesh Kumar **Regulatory Roadmap for Herbal Medicines**
5. Peter Houghton , Pulok Mukherjee **Evaluation of Herbal Medicinal Products**
6. Willow J.H. Liu, **Traditional Herbal Medicine Research Methods**
7. Jian-guo Zeng, Man-liang Tan, Xuan Peng, and Qi Luo, **Standardization and Quality Control of Herbal Extracts and Products**
8. John Sharp, **Good Pharmaceutical Manufacturing Practice Rationale And Compliance**
9. J.T. Carstensen, **Drug Stability**, Marcel Dekker, New York.
10. **WHO Guidelines: Good manufacturing practices: guidelines for the manufacture of herbal medicines**
11. **Quality Assurance of Medicinal Herbs (Eddie Pang) RIRDC Publication No. 11/093**

(E.1.13) TOXICOLOGY
(Theory 3Hrs/Week)
CREDITS 03

UNIT I

1. Principles of Toxicology:
 - a) Tolerance, addiction, habituation, idiosyncrasy, allergy, hypersensitivity, antagonism, synergism, potentiation, tachyphylaxis,
 - b) Types of Toxicology (General Toxicology, Mechanistic Toxicology, Regulatory Toxicology, Descriptive Toxicology and Clinical Toxicology).
- c) Classification and sources of Toxic Agents.
2. Preclinical toxicology:
 - a) Preclinical toxicological requirements for biological and biotechnological products, safety analysis, problems specific to recombinant products, toxicokinetics.
 - b) Principles of GLP as per OECD/ICH etc. guidelines for conducting preclinical toxicity studies.

UNIT II

3. Single dose and repeat dose toxicity:
 - a) Factors influencing such studies such as species, sex, size, route, dose level.
 - b) Data evaluation and regulatory requirements.
 - c) Determination of Maximum Tolerated Dose (MTD) and LD50 as per revised OECD guidelines.
 - d) Allergenicity testing, dermal toxicity immunotoxicology and in situ methods of toxicology
4. Toxic Responses to Xenobiotics:
 - a) Molecular Changes
 - b) Subcellular Changes
 - c) Cellular Changes
 - d) Allergic or Sensitization of Reactions
 - e) Idiosyncrasy

UNIT III

- 06 Target Organ Toxicity and management:
 - a) Ocular toxicity, Neuronal and Behavioural toxicity, renal toxicity, pulmonary toxicity, cardiotoxicity, hepatotoxicity, genetic toxicity, Mutagenicity, Carcinogenesis and reproductive toxicity.
 - b) Environmental and industrial toxicology.

- c) Management of toxicity reaction in humans.
- 07 Biochemical and Molecular techniques in toxicology
 - a) Cell culture techniques
 - b) Molecular cloning
 - c) cDNA and Genomic libraries
 - d) PCR, Northern and southern Blot analysis
 - e) Immunochemical techniques.
- 08 Applications of Toxicology:
 - a. Research, Academic and Industrial Applications.
 - b. Regulatory Toxicology, Forensic Toxicology, Clinical Toxicology.

Recommended Books:

1. Ernest Hodgson. A Textbook of Modern Toxicology, Third Edition.
2. Michael J. Derelanko and Mannfred A. Hollinger, Handbook of Toxicology, second edition, 2002, Taylor & Francis.
3. Frank A. Barile. Principles of Toxicology Testing. CRC press, Taylor & Francis group.
4. Dipiro, Joseph L. Pharmacotherapy: A Pathophysiological Approach, Elsevier.
5. Davidson's Principles of Internal Medicine, Vol-I and II, 14th Edition, Mc Graw-Hill.
6. Harrison's Principle and Practice Of Medicine, 18th Edition, Churchill, Livingston, London.

(E.1.14) SAFETY PHARMACOLOGY
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

- 01 Definition and scope of safety pharmacology
- 02 Regulatory requirements for the new drug safety assessment: Important guidelines such as ICH, OECD, USFDA, EMEA, Japan MHW

UNIT II

- 03 Principals and study design of safety evaluation:
 - a. Acute toxicity- rodent and non-rodent

b. Repeated dose studies (sub acute and chronic)

c. Analysis of safety pharmacological data

04 Preclinical safety pharmacology:

In vitro and in vivo studies including genotoxicity, mutagenicity, carcinogenicity, reproductive and ocular toxicity, Safety testing for dermatological product

05 Application of In vitro techniques in drug safety assessment

UNIT III

06 Clinical Safety pharmacology:

definition, data collection, reporting methods and assessment and analysis of adverse event (AE) monitoring during clinical trials

07 Pharmacovigilance:

Definition, collection of data, reporting, assessment of Post marketing surveillance, periodic safety update reports, Risk-benefit assessment.

Recommended Books:

1. Sogliero-Gilbert G. Drug safety assessment in clinical trials. Statistics, textbooks and monographs. New York: Dekker.
2. Marx U and Sandig V. Drug testing in vitro: breakthroughs and trends in cell culture technology. 2007, Weinheim: Wiley-VCH.
3. Gad SC. Safety assessment for pharmaceuticals. 1995, New York: Van Nostrand Reinhold.
4. Turner JR. New drug development: design, methodology, and analysis. 2007, Hoboken, N.J.: Wiley-Interscience.
5. Smith CG and O'Donnell J. The process of new drug discovery and development. 2nd ed. 2006, New York: Informa Healthcare.
6. Benichou C. Adverse drug reactions: a practical guide to diagnosis and management. 1994, Chichester, West Sussex, England; New York: Wiley.
7. World Health Organization. WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems. 2004, Geneva: World Health Organization.
8. Cobert BL. Manual of drug safety and pharmacovigilance. 2007, Sudbury, Mass. Jones and Bartlett Publishers.

9. Cobert BL and Biron P. Pharmacovigilance from A to Z: adverse drug event surveillance. 2002, Malden, MA: Blackwell Science.

(E.1.15) CLINICAL TRIALS
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

- 01 Introduction to clinical Trial :

History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments.

- 02 Clinical Research Organizations in India and Schedule “Y” as per D&C Rules.

UNIT II

- 03 Regularly affairs in clinical trials:

IND, NDA, ANDA- Parts and contents, Safety monitoring boards, FDA in various countries including India.

- 04 Ethical issues in clinical trials:

Principal, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), Protection of participants, The Nuremberg Code, The Declaration of Helsinki, The Belmont Report.

UNIT III

- 05 Clinical trial design:

Designs used in clinical trials with their advantages and disadvantages, hypothesis, risks and benefits, subject selection, inclusion and exclusion criteria, randomization, blinding and controls.

- 06 Clinical trial protocol Development

Required Documentation including Investigator's Brochure, Case Report Forms, Serious Adverse Event (SAE) Reports, Laboratory Certification, data collection and quality control of data, closing out of clinical trial.

UNIT IV

07 Good Clinical Practice:

Concept, importance, and GCP guidelines including ICH guidelines

02 Management of Clinical trials:

Role and responsibilities of Stakeholders of clinical trials (FDA, CRO, Sponsor, Physicians, Nurses, Health professionals, Hospitals, Patient), monitoring of clinical trials, Publications of clinical trials.

UNIT V

09 Bioavailability, bioequivalence and Therapeutic Drug Monitoring:

Concept, organization, advantages, special issues, applications, bioequivalence.

10 Data analysis issues in Clinical Trials:

Monitoring of data, computer applications, statistical tests used, interpretation, survival analysis, sub-group analysis, Quality control of clinical trials.

Recommended Books:

1. Dipiro Joseph L. Pharmacotherapy: A Pathophysiological Approach, Elsevier
2. Davidson's Principles of Internal Medicine, Vol-I And II, 14th Edition, Mc Graw-Hill
3. Harrison's Principle And Practice Of Medicine, 18th Edition, Churchill, Livingston, London
4. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London
5. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics
6. Tussle, T.G.: Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall, New York

(E.1.16) CLINICAL PHARMACOKINETICS AND PHARMACODYNAMICS

(Theory 3 Hrs/Week)

CREDITS 03

UNIT I

- 1 Basic considerations: Therapeutic relevance, fundamental concepts and terminology
- 2 Exposure and response after a single dose: Kinetics following intravenous bolus dose, Membranes and distribution, elimination, kinetics following an extra vascular dose, absorption, response following a single dose

UNIT II

- 3 Therapeutic regimens: Therapeutic window, constant rate input, multiple drug regimen
- 4 Individualization: Variability, genetics, age, weight and gender, disease, non-linearities, drug interactions, initiating and managing therapy

UNIT III

- 5 Distribution Kinetics: One compartment model, Plasma concentration data, clearance and half life associated with elimination
- 6 Metabolites and Drug response

UNIT IV

- 7 Protein Drugs
- 8 Prediction and refinement of human kinetics from in vitro preclinical and early clinical data
- 9 Principles, Calculations and Basic Assessments: AUC, ionization and pH partition hypothesis, distribution of drugs extensively bound to plasma proteins, plasma to blood concentration ratio, Well-stirred model of hepatic clearance, absorption kinetics, Wagner-Nelson method, Mean residence time, amount of the drug in the body on accumulation to plateau

Recommended Books:

1. Malcolm Rowland and Thomas N. Tozer. Clinical Pharmacokinetics and Pharmacodynamics: Concept and Application, Lippincott Williams & Wilkins
2. Wolfgang A. Ritschel and Gregory L. Kearns. Handbook of Basic Pharmacokinetics including Clinical Applications, American Pharmacist Association
3. Michael E. Winter. "Basic Clinical Pharmacokinetics".2010, Lippincott Williams &Wilkins.
4. Robert E. Notari. Biopharmaceutics and Clinical Pharmacokinetics, Marcel Dekker Inc. New York
5. Larry Bauer and P.B. Bauer Larry, Clinical Pharmacokinetics. Mc-Graw Hil New Delhi .
6. Leon Shargel, Susanna Wu-Pong and Andrew B. C. Yu, Applied Biopharmaceutics and Pharmacokinetics, Mc-Graw Hill. New Delhi
7. Milo Gibaldi and Donald Perrier, Pharmacokinetics. Marcel Dekker. Inc.
8. V. Venkateshwarlu, Biopharmaceutics and Pharmacokinetics. 2008, Pharm Med Press
9. Ronald Schoenwald. Pharmacokinetic Principles of Dosing Adjustments. CRC press, New York

(E.1.17) CLINICAL IMMUNOLOGY AND ENZYMOLOGY
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

1 General Considerations:

Basics of Immunology- Innate Immunity, Specific Acquired Immunity, The Recognition of antigen, antibody, membrane receptors of antigen and their interactions.

2 Immunodeficiency:

Primary immunodeficiency states in the human, deficiency of innate immune mechanisms, primary T-cell deficiency, acquired immunodeficiency

UNIT II

3 Hypersensitivity:

General consideration of in appropriate immune response, anaphylactic hypersensitivity, antibody dependent cytotoxic hypersensitivity, immune complex mediated hypersensitivity, cell mediated hypersensitivity.

4 Transplantation:

Basic consideration of graft rejection and immunology, Genetic control of transplantation, consequences of MHC incompatibility, mechanisms and prevention of graft rejection, interference by xenobiotics.

UNIT III

5 Tumor Immunology:

Changes in the surface of tumor cell, immune response to tumors, lymphoproliferative disorders, approaches to cancer immunotherapy.

6 Autoimmune diseases-Scope and etiology:

The scope of auto immune diseases, autoreactivity, role of T-helper cells, mechanisms, pathogenic effect of humoral autoantibody, pathologic effects of complexes with autoantigens, T-cell mediated hypersensitivity, diagnostic values of autoantibodies

UNIT IV

7 Hybridoma techniques –

fusion methods for myeloma cells and B-Lymphocytes, selection and screening techniques. Production and purification of monoclonal antibodies and their applications in clinical diagnosis, immunotherapy and pharmaceutical research.

8 Enzymology:

General considerations, properties and sources of enzymes, Enzyme kinetics and regulations. Application of enzymology: biological preparations/ analytical reagents, diagnostics, therapeutics, inborn errors of enzymes, of production of important enzymes (examples), Techniques of immobilization of enzymes and their applications in industry, Biosensor technology, Immobilized Enzyme engineering, Kinetics of immobilized enzymes.

Books Recommended:

1. Jan Klein and Vaclav Horejsi, Immunology, 2nd Editions, Blackwell Science, Meldom MA, USA.
2. Dennis K. Flaherty, Immunology of Pharmacy. Elsevier, New York.
3. Ivon Roitt, Roitt's Essential Immunology. Blackwell Science, Meldom, MA, USA.
4. Jenet M. Decker, Introduction to Immunology. Blackwell Science, Meldom, MA, USA.
5. Immunology by Ivan Roitt, Jonathan Brostooff and David Male.
6. Weir DM, Stewart John. Immunology, 8th edition, Churchill Livingstone.
7. Abdul K Abbas, Andrew H Lichtman, Shiv Pillai. Cellular and molecular immunology. 6th edition. Saunders.
8. Robert K. Murray. Harper's Illustrated Biochemistry.
9. Lehninger. The foundations of biochemistry.
10. Nicholas C. Price, Lewis Stevens. Fundamentals of Enzymology: Cell and Molecular Biology of Catalytic Proteins. Oxford University Press.

(E.1.18) INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT

(Theory 3 hours/week)

CREDITS 03

UNIT I

1. Pilot plant scale - up, pilot plant design: tablets, capsules, liquid orals. parenterals, and semisolid preparations. Basis requirements for design of product, facility, equipment selection, personnel. Pharmaceutical process validation for various products.

2. Quality Assurance: GMP considerations, quality assurance and process control. Total quality management and productivity. ISO 9000 Series salient features.

UNIT II

3. Optimization Techniques: Optimization parameters, classical optimization, statistical design and applied optimization methods.

4. Production Planning: Plant site selection, layout and organization of pharmaceutical industries. Vendor development capacity (plant, machine, human resources) assessment of production rate changes, inventory management costing of product and cost controls, planning product mix.

UNIT III

5. Machinery Engineering: Introduction to mechanical, electrical and electronic parts of pharmaceutical machinery, equipments. Material handling for various pharmaceutical products.

6. Drugs and Cosmetics Act: Requirements related to manufacture and sale of drugs.

UNIT IV

7. Safety: Industrial hazards due to fire, accident, mechanical and electrical equipment, chemical and pharmaceuticals, monitoring and preventive system.

8. Effluent Testing and Treatment: For pharmaceutical industry.

9. Automation: Flexible manufacturing system, computer control systems: data acquisition, distributed control and centralized control system. Typical models for solid and liquid manufacturing.

Recommended Books:

1. P. R. Watt; Tablet machine instruments in pharmaceuticals; John Wiley and Sons.

2. B. Rothery; ISO 14000 and ISO 9000; Gower.

3. G.C. Cole; Pharmaceutical production facilities, design and applications; Taylor and Francis.

4. J.R. Berry and R.A. Nash; Pharmaceutical process validation; Marcel Dekker.

5. S. Bolton; Pharmaceutical statistics; Marcel Dekker.

6. S.H. Wili and J.R. Stoker; Good Manufacturing Practices for Pharmaceuticals; Marcel Dekker.

- 7.R. F. Brewer; Design of Experiments for process improvement and quality Assurance; Narosa.
- 8.A. Jaiswal; Management of quality control and standardisation; Kanishka Publisher, New Delhi.
- 9.D.H.Stamatis; Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.
- 10.P. Gilson, G. Green halgh and K. Kerr; Manufacturing management; Chapman and Hall.
- 11.S.S.Rao; Optimization theory and applications; Wiley Eastern Limited.
- 12.J.F. Despautz; Automation and validation of information in pharmaceutical processing; Marcel Dekker.
- 13.J.M. Juran and A..B. Godfrey; Juraris quality handbook; McGraw Hill.
- 14.S.N. Katju's; Law and drugs; Law Publishers(1) Pvt. Ltd.

(E.1.19) FERMENTATION TECHNOLOGY
(Theory 3 Hrs/Week)
CREDITS 03

UNIT I

Basic principle of Bioprocess engineering

Isolation, screening and maintenance of industrially important microbes; Strain improvement for increased yield and other desirable characteristics. Isolation and screening of industrially important microbes; Large scale cultivation of industrial microbes; Strain improvement to improve yield of selectee' compounds e.g. antibiotics. enzymes or recombinant proteins (Cellular control regulating production of microbial metabolites

- Primary and Secondary metabolite - Induced mutation technique - Analogue resistant mutant - Catabolic derepressed mutants - Genetically engineered strain - Protoplast fusion technique). Industrial microbes as cloning hosts (Streptomyces/Yeast). Recombinant protein production in microbes; Commercial issues pertaining to the production recombinant products from microbes.

UNIT II

Bioreactors and Fermenter Design

Introduction to bioreactors; Batch and Fed-batch bioreactors, Continuous bioreactors; immobilized cells; Bioreactor operation; Sterilization; Aeration; Instrumentation & control,

Culture-specific design aspects: plant/mammalian cell culture reactors. Description of industrial processes. Solid substrate, surface and submerged fermentation; Fermentation media; Fermenter design, Mechanically agitated; Pneumatic and hydrodynamic fermenters; Large scale animal and plant cell cultivation and air sterilization; Upstream processing: Media formulation; Sterilization; Aeration and agitation in bioprocess; Measurement and control of bioprocess parameters; Scale up and scale down process.

UNIT III

Principles of enzyme catalysis and microbial growth

Proteins as enzymes; Michaelis-Menten kinetics; Kinetics and Statistics. Inhibition; Effect of pH and temperature; Enzymology; Immobilized enzymes: methods, mass transfer considerations; Industrial enzymes: Factors affecting microbial growth; Stoichiometry: mass balances: energy balances; Growth kinetics; Measurement of growth (an example from each group, particularly with reference to industrially useful microorganisms).

UNIT IV

Applications of enzymes in food processing

Enzymic bioconversions e.g. starch and sugar conversion process High Fructose Corn Syrup; Inter-esterified fat; Hydrolyzed protein etc. and their downstream products; baking by amylases, deoxygenation and desugaring by glucosyl oxidase, beer mashing and distillation, cheese making by proteases and various other enzyme catalytic actions in food processing. Applications of Microbes in food process operations and production: Fermented foods and beverages: Food ingredients and additives prepared by fermentation and their purification; fermentation as a method of preparing and preserving foods; producing colours and flavours. alcoholic beverages and other products; Production of Bioethanol, Biohydrogen and biopesticides.

Recommended Books:

1. Michael Shuler and Fikret Kargi, Bioprocess Engineering: Basic Concepts, 2nd Edition, Prentice Hall, Englewood Cliffs, NJ, 2002.
2. Stanbury RF and Whitaker A., Principles of Fermentation Technology, Pergamon press, Oxford, 1997.
3. Baily JE and Ollis DF., Biochemical Engineering fundamentals, 2nd Edition. McGraw-Hill Book Co., New York, 1986.
4. Pauline Doran. Bioprocess engineering principles. 1 Edition. Academic Press. 1995.
5. Colin Ratledge. Bjorn Kristiansen. Basic Biotechnology. 2nd Edition. Cambridge University Press, 2001
6. Hamson et al., Bioprocess Engineering Science and Engineering, Oxford University Press. 2003.

7. Jackson AT.. Bioprocess Engineering in Biotechnology, Prentice Hall, Engelwood Cliffs, 1991.
8. Aiba S, Humphrey AE and Millis NF, Biochemical Engineering, 2nd Edition, University of Tokyo press, Tokyo. 1973.

(E.1.20) PROJECT MANAGEMENT
(Theory 3 hours/week)
CREDITS 03

UNIT I

Pre Planning For Project Management:

1. Importance of project management
2. Organizing for project management
3. Role of project manager
4. Role of clients, customers and others
5. Setting up planning and control system

UNIT II

Project Planning Process:

1. Defining project
2. Creating work breakdown structure
3. Estimating activities
4. Sequencing activities
5. Calculating the critical path
6. Scheduling project
7. Resources planning
8. Preparing planning budgets
9. Approval of projects
10. Setting up a monitoring and control process

UNIT III

Executing the Project

1. Initiating the project
2. Controlling project objectives
3. Reporting on project objectives

4. Controlling changes in the project
5. Conducting project evaluations
6. Managing risks in project management
7. Closing the project

UNIT IV

Heading The Project Team

1. Developing project teams
2. Managing conflicts
3. Communicating effectively
4. Holding effective meetings
5. Making team decisions
6. Using sources of power wisely
7. Making changes
8. Managing performance

Recommended books:

1. Project management; step by step By Larry Richman Publisher: Prentice-Hall of India Pvt. Ltd Year of publication 2008
2. Project management: The managerial process By Clifford F. Gray and Eric W Larson Publisher: Tara Mc Graw Hill Third edition
3. Rethinking project management By Erling S. Andersen Publisher: Prentice- Hall Year of publication 2008
4. Project management By Jeffery K. Pinto Publisher: Prentice-Hall Year of publication 2007

(E.1.21) PHARMACEUTICAL ADMINISTRATION

(Theory 3 Hours/Week)

CREDITS 03

UNIT I

I. Introduction to administration

1. Concept of management and administration
2. Management social responsibility and ethics
3. Function of management

II. Planning and decision making

1. Types of plans and steps in planning

2. Planning process
3. Concept of objectives & MBO
4. Strategic planning process
5. Effective implementation and strategies
6. Process of decision making

UNIT II

I. Organising

1. Formal and informal organizations
2. Concept of span of control
3. Structure and process of organizing
4. Departmentalisation
5. Line and staff concept
6. Making organizations effective and developing positive organization culture

II. Staffing

1. Definition of staffing
2. Systems approach to human resource management and an overview of staffing function
3. Performance appraisal of staffing function
4. Manager development process and training

UNIT III

I. Leading

1. Human factors in managing
2. Human motivation theories of:-
Abraham Maslow
McClelland's needs theory
3. Communication process in organizations

II. Controlling

1. BaSIC control process
2. Critical control points and standards
3. Feedback and feed forward controls
4. Requirements for effective control

UNIT IV

I. Productivity and operations management

1. Productivity problems and measurement
2. Production and operations management
3. Controlling and improving productivity

II. Overall and preventive control

1. Control of overall performance

2.Direct control

3.Preventive control

Recommended Books:

1. Essentials of management by Dr.Herold Koontz and Heinz Weitnrich, published by McGraw Hill publishing company.
2. Managing productivity in organizations by Kopelman, published by McGraw Hill publishing company.
3. Effective supervision: A practical approach by Hodgetts, published by McGraw Hill publishing company.

(E.1.22) COSMETICOLOGY
(Theory 3 Hours/Week)
CREDITS 03

UNIT I

- 1) Physiological consideration: skin, hair, nail and eye - in relation to cosmetic application.
- 2) Rheology of cosmetics: Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, dentifrices, hair products, creams and lotions.

UNIT II

- 3) Manufacturing techniques: cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics.
- 4) Evaluation of cosmetics: Performance, physicochemical, microbiological and psychometric evaluation of cosmetics. Design and Assessment of preservative systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antiperspirants, sunscreen and antiaging products.

UNIT III

- 5) Clinical safety testing: Irritation, sensitization, photoirritation, photoallergy ocular irritation and protocols for the same.
- 6) Advances in cosmetics: Liposomes, multiple and microemulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.
- 7) Herbal cosmetics: Formulation development

UNIT IV

- 8) Packaging: Package development and design for cosmetics including aerosol packs
- 9) -Regulatory requirements: Manufacturing and sale of cosmetics

Recommended Books:

- 1) J. Knowlton and S. Rearce; Handbook of cosmetic sciences and technology; Elsevier science publisher.
- 2) J.B.Wilkinson and R.J. Moore; Harry's cosmetology; Longman Science and Technical.
- 3) S.N. Katju's; Law of Drugs; Law Publishers (India) Pvt. Ltd.
- 4) E.G.Thomssen; Modern cosmetics; Universal Publishing Corporation.
- 5) M.S.Balsam and E. Sagarin ; Cosmetics, science and technology; John Wiley and Sons.
- 6) R. L. Elder; Cosmetic Ingredients, their safety assessment; Pathotox
- 7) H.R.Moskowitz; Cosmetic Product Testing; Marcel Dekker.
- 8) W. C. Waggoner; Clinical safety and efficacy testing of cosmetics; Marcel Dekker.
- 9) C.G.Gebelein, T.C.Cheng and VC. Yang ; Cosmetic and pharmaceutical applications of polymers; Plenum.
- 10) L. Appell; The formulation and preparation of cosmetics, fragrances and flavours; Micelle Press.
- 11) w.A. Poucher; Poucher's Perfumes, cosmetics and soaps; vol. 3, Chapman and Hall
- 12) Dr. Laba; 'Rheological properties of cosmetics and toiletries; Marcel Dekker.

SEMESTER-I

- (M. 1. 1) Advanced Analytical Techniques
- (M. 1.2) Advanced Analytical Techniques (Practical)
- (M.1.3) Research Methodology
- (M.1.4) Advanced Pharmaceutics
- (M.1.5) Advanced Pharmaceutics (Practical)
- (M.1.6) Advanced Pharmaceutical Chemistry
- (M.1.7) Advanced Pharmaceutical Chemistry (Practical)
- (M.1.8) Advance Pharmacology (Preclinical Evaluation of Drugs)
- (M.1.9) Advance Pharmacology (Preclinical Evaluation of Drugs) (Practical)
- (M.1.10) Advanced Pharmacognosy
- (M.1.11) Advanced Pharmacognosy (Practical)
- (M.1.12) Advanced Quality Assurance Techniques (cGMP & Documentation)
- (M.1.13) Advanced Quality Assurance Techniques (cGMP & Documentation) (Practical)

SEMESTER-II

- (M.2.1) Drug Regulatory Affairs
- (M.2.2) Formulations & Development
- (M.2.3) Formulations & Development (Practical)
- (M.2.4) Novel Drug Delivery Systems
- (M.2.5) Advanced Medicinal Chemistry
- (M.2.6) Advanced Medicinal Chemistry (Practical)
- (M.2.7) Drug Design
- (M.2.8) Clinical Pharmacology
- (M.2.9) Clinical Pharmacology (Practical)
- (M.2.10) Molecular Pharmacology
- (M.2.11) Phytochemistry & Phytopharmaceuticals
- (M.2.12) Phytochemistry & Phytopharmaceuticals (Practical)
- (M.2.13) Industrial Pharmacognosy
- (M.2.14) Pharmaceutical Validation
- (M.2.15) Pharmaceutical Validation (Practical)
- (M.2.16) Quality Planning And Analysis

ELECTIVE SUBJECTS OF ALL SEMESTERS

- (E.1.1) Quality Control & Assurance of Pharmaceuticals
- (E.1.2) Pharmaceutical Plant Design and Operations
- (E.1.3) Biopharmaceutics and Pharmacokinetics
- (E.1.4) Sterile Products Formulation & Technology
- (E.1.5) Active Pharmaceutical Ingredients (APIs) Manufacturing Technology
- (E.1.6) Clinical Trials

- (E.1.7) Safety Pharmacology
- (E.1.8) Chemistry of Medicinal Natural Products
- (E.1.9) Traditional Systems of Medicine & Ayurvedic Formulations
- (E.1.10) Medicinal Plant Biotechnology
- (E.1.11) Natural Products Management
- (E.1.12) Quality Assurance Techniques In Herbal Products
- (E.1.13) Toxicology
- (E.1.14) Safety Pharmacology
- (E.1.15) Clinical Trials
- (E.1.16) Clinical Pharmacokinetics and Pharmacodynamics
- (E.1.17) Clinical Immunology and Enzymology
- (E.1.18) Industrial Pharmacy And Production Management
- (E.1.19) Fermentation Technology
- (E.1.20) Project Management
- (E.1.21) Pharmaceutical Administration
- (E.1.22) Cosmeticology