BHARATI VIDYAPEETH UNIVERSITY PUNE

Faculty of Pharmaceutical Sciences

Master of Pharmacy (M.Pharm.)

CHOICE-BASED CREDIT AND GRADING SYSTEM 2012 -13

INTRODUCTION

Bharati Vidyapeeth, the parent body of Bharati Vidyapeeth University was established on 10th May, 1964, by Dr. Patangrao Kadam with the objective of bringing intellectual awakening and all sided development of the people of our country through dynamic education.

Bharati Vidyapeeth is a leading educational institution in the country, which has created a history by establishing within a span of 48 years, 171 educational institutions imparting education from the pre-primary stage to post graduate stage. Our institutions of higher education impart education in different disciplines including Medicine, Dentistry, Ayurved, Homemopathy, Nursing, Arts, Science, Commerce, Engineering, Pharmacy, Management, Social Sciences, Law, Environmental Science, Architecture, Hotel Management and Catering Technology, Physical Education, Computer Science, Library Science, Information Technology, Biotechnology and Agriculture.

The Department of Human Resource Development, Government of India on the recommendation of University Grants Commission accorded the status of University initially to twelve units of Bharati Vidyapeeth. Subsequently, 17 additional colleges/ institutes were brought within the ambit of Bharati Vidyapeeth University vide various notifications of the Government of India. Bharati Vidyapeeth University commenced its functioning on 26th April 1996.

Constituent Units of Bharati Vidyapeeth Deemed University

1. BVDU Medical College,Pune
2. BVDU Dental College & Hospital, Pune
3. BVDU College of Ayurved,Pune
4. BVDU Homoeopathic Medical College, Pune
5. BVDU College of Nursing, Pune
6. BVDU Yashwantro Mohite College of Arts, Science and Commerce, Pune
7. BVDU New Law College, Pune
8. BVDU Social Sciences Centre (M.S.W.) Pune
9. BVDU Poona College of Pharmacy, Pune
10. BVDU College of Engineering, Pune
11. BVDU Institute of Management Enterprenurship Development, Pune
12. BVDU Yashwantrao Chavan Institute of Social Sciences Studies & Research, Pune.
13. BVDU Research and Development Centre in Pharmaceutical Science & Applied Chemistry, Pune
14. BVDU College of Physical Education, Pune
15. BVDU Institute of Environmental Education & Research, Pune
16. BVDU Rajiv Gandhi Institute of Information Technology and Biotechnology, Pune
17. BVDU Interactive Research School in Health Affairs (IRSHA), Pune
18. BVDU Research and Development Centre in Pharmaceutical Sciences & Applied Chemistry, Pune
19. BVDU Institute of Management and Research, New Delhi
20. BVDU College of Architecture, Pune
21. BVDU Institute of Hotel Management and Catering Technology, Pune.
22. BVDU Yashwantrao Mohite Institute of Management, Kolhapur
23. BVDU Institute of Management & Rural Development Administration, Sangli.
24. BVDU Abhijit Kadam Institute of Management and Social Sciences, Solapur

25. BVDU Medical College & Hospital, Sangli
26. BVDU Dental College & Hospital, Mumbai.
27. BVDU Dental College & Hospital, Sangli
28. BVDU College of Nursing, Sangli
29. BVDU College of Nursing, Navi Mumbai

ACCREDITATION:

The National Assessment and Accreditaion Council (NAAC) have Re-accreditated Bharati Vidyapeeth University and all its constituent units with A grade.

Poona College of Pharmacy

Poona College of Pharmacy was established in 1981. This college has got approval and recognition of All india Council of Technical Education, New Delhi, and Pharmacy Council of India, New Delhi. Earlier the college was permanently affiliated to University of Pune. Now it is a constituent unit of Bharati Vidyapeeth University. The college conducts B.Pharm, M.Pharm (Pharmaceutics, Pharm. Chemistry, Pharmacology, Pharmacognosy, Pharmaceutical Biotechnology, Quality Assurance Techniques and Pharmaceutical Regulatory Affairs), Pharm.D, Pharm.D (Post Baccalaurate) and Ph. D. programs. The college is housed in beautiful building and located in our bewitching educational complex at Erandvane, Pune. The excellence which this college has achieved during these years in pharmacy education is mainly due to its experienced and qualified teaching faculty and the insfrastructural facilities of high quality provided in the college. The college has excellent library with modern books on pharmacy. The college also provides hostel facilities on a limited scale to our students both boys and girls.

As soon as the college came under the ambit of Bharati Vidyapeeth University, the syllabus of B.Pharm and M.Pharm. Courses was revised and upgraded with the help of the eminent experts in the pharmacy field and the same was approved by the University authorities. While doing so the guidelines given by UGC, AICTE, Pharmacy Council of India, and the societal needs have been taken into consideration.

Accreditation

In appreciation of it's academic excellence, availability of excellent infrastructural facilities and the potential it has for further growth, the National Board of Accreditation (NBA) has re accreditated the B.Pharm. program of this college. Similarly, the National Assessment and Accreditaion Council (NAAC) has also re-accreditated Bharati Vidyapeeth University, and this college.

Receiving the re- accreditation from both the accrediting national authorities is a remarkable achievement of this college.

GUIDELINES FOR CHOICE-BASED CREDIT AND GRADING SYSTEM:

The University Grants Commission (UGC), the National Assessment and Accreditation Council (NAAC), the Distance Education Council (DEC) and even the National Knowledge Commission (NKC) have time and again come out with recommendations for improving the quality and effectiveness of higher education provisions in the country. The ministry of Human Resource Development at the Central level and the Ministry of Higher & Technical Education, Govt. of Maharashtra have also repeatedly stressed on the need for universities to adopt measures to improve the quality of education imparted by the universities. Thus the need to develop a Choice-Based Credit System (CBCS) in tune with global trends and the adoption of a sound grading system for reflecting learner performance.

Advantages of the Credit System

- Represents a much-required shift in focus from teacher-centric to learner-centric education since the workload estimated is based on the investment of time in learning, not in teaching.
- Helps to record course work and to document learner workload realistically since all activities are taken into account - not only the time learners spend in lectures or seminars but also the time they need for individual learning and the preparation of examinations etc.
- Segments learning experience into calibrated units, which can be accumulated in order to gain an academic award.
- Helps self-paced learning. Learners may undertake as many credits as they can cope with.
- Affords more flexibility to the learners allowing them to choose inter-disciplinary courses, programmes, etc.
- Respects 'Learner Autonomy'. Allows learners to choose according to their own learning needs, interests and aptitudes.
- Makes education more broad-based. One can take credits by combining unique combinations.
- Facilitates learner mobility. Offers the opportunity to study at different times and in different places. Credits earned at one institution can be transferred to another.
- Is beneficial for achieving more transparency and compatibility between different educational structures.

ACADEMIC REGULATIONS FOR MASTER OF PHARMACY (M. Pharm.) PROGRAMME

Bharati Vidyapeeth University, Pune offers Master of Pharmacy (M.Pharm.) course at the Poona College of Pharmacy, Pune in the following specializations:

1) Pharmaceutics
2) Pharmaceutical Chemistry
3) Pharmacology
4) Pharmacognosy
5) Quality Assurance Techniques
6) Pharmaceutical Biotechnology
7) Pharmaceutical Regulatory Affairs.

1.0 Duration :

The duration of Master of Pharmacy (M.Pharm.) course will be of 24 months, divided into four semesters, each semester of 6 months duration.

2.0 Eligibility for admission to M.Pharm. course :

The candidate seeking admission to M.Pharm. course must have :

1) Passed B.Pharm. degree examination of any statutory/recognized University with atleast 60% of aggregate marks or equivalent grade (55 % for S.C./S.T., teacher and sponsored candidates.
2) As per the AICTE guideline, few seats are reserved for the candidates having qualified GPAT score and atleast 60% marks at the B.Pharm. examination.
3) The candidate must have appeared at All India Entrance Test conducted by Bharati Vidyapeeth University.

3.0 Admission to M.Pharm. course :

The admissions to this course will be given strictly on the basis of merit obtained by the candidates in the relevant categories in the All India Entrance Test conducted by Bharati Vidyapeeth University.

4.0 Annual intake and allotment of seats :

A. The annual intake for each specialization is as follows :

1.	Pharmaceutics	-	18
2.	Pharmaceutical Chemistry	-	18
3.	Pharmacology	-	10
4.	Pharmacognosy	-	10
5.	Quality Assurance Techniques	-	18
6.	Pharmaceutical Biotechnology	-	10
7.	Pharmaceutical Regulatory Affairs.	-	10

B. The seats will be allotted to the different categories (that is SC/ST/GPAT etc.) of the candidates as per the rules of AICTE & Bharati Vidyapeeth University.

5.0 A.I.C.T.E. fellowship :

Only those candidates who have a qualified GPAT score and who have obtained atleast 60 % marks at B.Pharm. examination will be considered eligible for A.I.C.T.E. fellowships.

6.0 Fees:

The tuition fees, other fees and deposits like library and laboratory deposits will be as prescribed by the University from time to time.

7.0 Grant of terms :

The student who have satisfactorily completed the prescribed requirements of the course, appeared in all the internal assesements and has kept at least 75 % attendance at theory classes and practicals (if any) separately for each subject will be granted terms.

8.0 Syllabus :

The syllabii of the subjects for Semester-I and II are given as **Annexure II.**

9.0 Structure of the M. Pharm Programme

9.1 Each academic year consists of two semesters. Every branch of the M.Pharm. programme has a curriculum and course content (syllabii) for the subjects recommended by the Board of Studies, Faculty of Pharmaceutical Sciences and approved by the Academic Council.

9.2 The programme details are as follows:

I. First semester programme containing theory & practical subjects which are as per the respective specialization.

II. The core subjects in the semester are based on the respective specializations.

III. An assignment on the research paper or patent on the subjects related to the field of specialization shall be allotted to the students to develop research and analytical skills to analyze various facets of the given research topic.

IV. The candidate has to present seminar on the chosen/ allotted topics during the 1st, 2nd 3rd and 4th semesters.

V. 3rd & 4th semester shall be devoted for the project work for the respective specialization.

VI. During the 3rd semester a candidate has to present an seminar and assignment on research paper and patent.

VIII. The 4th semester consists of seminar followed by submission of project dissertation and viva-voce.

9.3 Project dissertation has to be submitted by each student individually. The general guidelines for evaluation of M. Pharm. thesis/ project work shall include the following:

I. Whether the objectives of the project work has been clearly identified and defined.

II. Whether it is relevant to the respective field.

III. Whether it is likely to make a significant contribution to the advancement of the knowledge or its usefulness from commercial viability.

IV. Whether the investigator possesses the necessary expertise to accomplish the work.

V. Whether the investigator has published/ submiited and presented any papers in the relevant field.

10.0 CREDIT BASED SYSTEM

The studies and examinations of the M. Pharm course shall be on the basis of Marks cum Credit system but semester -wise and final evaluation shall be by grading system.

10.1 The course content of the individual subjects (theory and practicals) is expressed in terms of a specified number of credits. The number of credits assigned to a subject depends on the number of contact hours per week.

10.2 In general, credits are assigned to the subjects based on the following contact hours per week per semester.

One credit for each Lecture hour.

One credit for two hours of practical.

10.3 The curriculum of M. Pharm programme is designed to have a total of 100 credits for the award of M. Pharm degree. A student is to have successfully completed a particular semester's programme of study when he / she earns all the credits of that semester i.e., he /she has no 'F' grade in any subject of that semester.

11.0 MEDIUM OF INSTRUCTION

The medium of instruction (including examinations and project reports) shall be English.

12.0 REGISTRATION

Every student has to register himself/herself for each semester individually at the time specified by the College / University.

13.0 Scheme of Examination: CONTINUOUS ASSESSMENT AND EXAMINATIONS (ANNEXURE I)

13.1 The assessment of the student's performance in each course will be based on continuous internal evaluation and semester-end examination. The marks for each of the component of assessment are based on the assessment procedure shown in the Table 1.

Scheme of examination for M.Pharm is as given in Annexure I.

Table 1: Assessment Procedure

S. No.	Component of assessment	Marks allotted	Type of Assessment	Scheme of Examination
1	Theory	40	Continuous evaluation	(i) Two mid semester examinations shall be conducted for 15 marks each. (ii) 10 marks are allotted for assignments.
		60	Semester end evaluation	The semester-end examination in theory subjects will be for a maximum of 60 marks.
	Total	100		
2	Practicals	40	Continuous evaluation	(i) 10 marks are allotted for record work , day to day performance and viva voce of the student in each lab throughout the semester. (ii) One examination for a maximum of 30 marks shall be conducted at the middle of the semester
		60	Semester end evaluation	The semester-end practical examination will be for a maximum of 60 marks.
	Total	100		
3	Seminars	50	Seminar	**Seminar 1:** During the 1st semester the candidate has to present end semester seminar on selected topics which shall be evaluated by the departmental committee. **Seminar 2:** During the 2nd semester the candidate shall present the end semester seminar on proposed project work, literature survey and methodology of the project work which shall be evaluated by the departmental committee. **Seminar 3:** During the 3rd semester the candidate shall present the end semester seminar on progress of project work which shall be evaluated by the departmental committee. **Seminar 4 :** During the 4th semester the candidate shall present the end semester seminar on the dissertation work of the project This shall be evaluated by the departmental committee.
4	Project work	550	Project evaluation	**Viva Voce** The dissertation work of the project shall be evaluated on the basis of the performance and presentation skills on parameters like Preface, Objectives, general introduction, Drug profile, Review of literature, Plan of work, Methodology/experimental work and investigations, Interpretation and analysis of data, Results and Discussion.The candidate has to present the seminar before the committee comprising of External and Internal Examiners* on the project work which shall be followed by viva voce which shall be evaluated for a maximum marks of 550.

* BVDU shall appoint examiners for conduct of the examination.

14.0 REAPPEARANCE

14.1 A student who has secured 'F' Grade in any theory course / Practicals of any semester shall have to reappear for the semester end examination of that course / Practicals.

14.2 A student who has secured 'F' Grade in Project work shall have to improve his report and reappear for viva – voce Examination of project work at the time of examination to be conducted as scheduled by the University.

15.0 ATTENDANCE REQUIREMENTS

15.1 A student whose attendance is less than 75% in all the courses put together in any semester will not be permitted to attend the end - semester examination and he/she will not be allowed to register for subsequent semester of study. He /She has to repeat the semester subsequently.

16.0 GRADING SYSTEM

16.1 Based on the student performance during a given semester, the final letter grade will be awarded at the end of the semester in each course. The letter grades and the corresponding grade points are as given in Table 2.

Table 2: Grades & Grade Points

Grade	Grade points	Absolute marks
O	10	91 and above
A+	9	81- 90
A	8	71-80
B+	7	61-70
B	6	51- 60
C	5	50 only
F	-	Less than 50

16.2 A student who earns a minimum of 5 grade points (C grade) in a course is declared to have successfully completed the course, and is to have earned the credits assigned to that course. However, a minimum of 50 marks is to be secured at the semester end examination of theory / practical courses in order to pass in the theory / practical course.

16.3 Seminar :

The student will have to give one seminar in each Semester.

Evaluation of Performance in Seminar :

The performance of student in seminars will be evaluated for 50 marks each by the Seminar Evaluation committee.

The student will be considered to have passed in seminar provided he/she has obtained atleast 25 Marks. The failed candidate will have to give the seminar again in the same semester. If a student fails to secure minimum 25 Marks in the seminar at the second attempt, he/she will be required to give the seminar again in the next semester.

18.0 GRADE POINT AVERAGE

18.1 A Semester Grade Point Average (GPA) for the semester will be calculated according to the formula:

$$SGPA = \frac{\sum [C \times G]}{\sum C}$$

Where,

C = number of credits for the course,

G = grade points obtained by the student in the course.

18.2 Semester Grade Point Average (SGPA) is awarded to those candidates who have passed in all the subjects of the semester.

18.3 To arrive at Cumulative Grade Point Average (CGPA), a similar formula is used considering the student's performance in all the courses taken in all the semesters completed up to the particular point of time.

$$CGPA = \frac{\sum [C \times G]}{\sum C}$$

Where,

C = total number of credits for the course,

G = grade points obtained by the student in the entire course.

18.4 The requirement of CGPA for a student to be declared to have passed on successful completion of the M. Pharm programme and for the declaration of the class is as shown in Table 3.

Table 3: CGPA required for award of class

Distinction	**8.0 and above**
First class	**7.0 and above, but less than 8.0**
Second class	**6.0 and above, but less than 7.0**
Pass	**5.0 and above, but less than 6.0**

19.0 **ELIGIBILITY FOR AWARD OF THE M. Pharm. DEGREE**

19.1 **Duration of the programme**:

A student is ordinarily expected to complete the M Pharm. programme in four semesters of two years. However a student may complete the programme in not more than four years including study period.

19.2 However the above regulation may be relaxed by the Vice Chancellor in individual cases for cogent and sufficient reasons.

19.3 Project dissertation has to be submitted on or before the last day of the course. However, it can be extended up to a period of 6 months maximum, with the written permission of the concerned supervisor.

19.4 A student shall be eligible for award of the M. Pharm degree if he / she fulfil all the following conditions.

a) Registered and successfully completed all the courses and projects.

b) Successfully acquired the minimum required credits as specified in the curriculum corresponding to the branch of his/her study within the stipulated time.

c) Has no dues to the Institute, hostels, Libraries etc, and

d) No disciplinary action is pending against him / her.

19.5 The degree shall be awarded after approval by the Academic Council.

RULES

1. With regard to the conduct of the end-semester examination in any of the practical courses of the programme, the University shall appoint one examiner from the institute in addition to an external examiner in the said subject.
2. In respect of all theory examinations, the paper setting shall be done by an internal and external paper setter having a minimum of five years of PG teaching experience. The panel of paper setters for each course is to be prepared by the Board of Studies and approved by the Academic Council.
3. The theory papers of end-semester examination will be evaluated by two examiners, internal and external.
4. Panel of examiners of evaluation for each course is to be prepared by the Board of Studies and approved by the Academic Council.
5. The examiner for evaluation should possess post graduate qualification and a minimum of five years PG teaching/ industrial experience.
6. Project work shall be evaluated by three examiners at the semester end examination. One examiner shall be internal and the two shall be external.
7. **Exemption :**

   A student who has obtained atleast 50 % marks in theory paper/s and/or practicals shall be exempted at his/her option from appearing for the same. The benefit of the exemption so earned will be available for 2 consecutive years only, since his/her first appearance at that examination.
8. **A.T.K.T.**

   A student will be promoted from First Semester to Second Semester and from Second Semester to Third Semester irrespective of number of subjects in which he/she failed in the First and Second Semester examination.

   A candidate is allowed to continue his/her research work and submit the dissertation in accordance with the relevant regulation, but the result of the dissertation will not be declared until he/she has cleared the First , Second and Third Semester Examinations.

   A candidate who has failed to pass M.Pharm. Fourth Semester Examination is required to keep minimum one fresh Semester and resubmit the revised dissertation, give a seminar and appear for viva-voce examination.
9. **Dissertation :**

   Every student before appearing for the M.Pharm. Fourth Semester Examination is required to submit 5 typewritten copies of the dissertation duly certified by the Supervisor to the University for evaluation through the Principal of the College. The topic for the dissertation shall be assigned to him/her by the Supervisor.

   The student will be allowed to submit his/her dissertation not before 23 months since his registration. However he/she will submit the same within a period of one month after the end of the Fourth Semester.
10. **Extra Credits:**

    A student can enrol for extra credits over and above the total 100 credits prescribed for the course with following options:

    a. Attend and appear for the examination of the opted extra credits.
    b. Only attend the classes for the opted extra credit.

    The extra credit course can be selected from within the institute or any other Faculty of Bharati Vidyapeeth University offering courses for Faculty of Pharmaceutical Sciences.

ANNEXURE I

SCHEME OF INSTRUCTION : M.PHARM

SEMESTER-I

Sr.No	Theory	No.of hours/week	Credits
1	Advanced Pharmaceutical Analysis	04	04
2	Research Methodology and Bioscreening	04	04
3	Advanced Core subject-I	04	04
4	Elective-I	04	04
	Total	**16**	**16**
Sr.No	**Practicals**	**No.of hours/week**	**Credits**
1	Advanced Pharmaceutical Analysis Practical	06	03
2	Advanced Core subject-I Practical	06	03
3	Seminar- I	-	03
	Total	**12**	**09**
	Grand Total	**28**	**25**

SEMESTER-II

Sr.No	Theory	No.of hours/week	Credits
1	Advanced Core Subject -II	04	04
2	Advanced Core Subject -III	04	04
3	Elective-II	04	04
4	Elective-III	04	04
	Total	**16**	**16**
Sr.No	**Practicals**	**No.of hours/week**	**Credits**
1	Advanced Core Subject -II Practical	06	03
2	Seminar-II	-	06
	Total	**06**	**09**
	Grand Total	**22**	**25**

SEMESTER-III

Sr.No	Theory	No.of hours	Credits
1	Seminar-III	-	06
2	Assignment on Research Paper/Patent	--	06
	Total	**-**	**12**

SEMESTER-IV

Sr.No	Theory	No.of hours	Credits
1	Seminar-IV	-	06
2	Dissertation work	-	22
3	Viva-voce	-	10
	Total	**-**	**38**

SEMESTER WISE DISTRIBUTION OF CREDITS FOR M. PHARM

Semester	Theory		Practical/ Seminar/ Assignment/ Dissertation Work Credits		Total Credits
	Hours	Credits	Practical Hours	Credits	
M. Pharm. I Semester	16	16	12	09	25
M. Pharm. II Semester	16	16	06	09	25
M. Pharm. III Semester	–	–	–	12	12
M. Pharm. IV Semester	–	–	–	38	38
	Total				**100**

SCHEME OF EXAMINATION FOR MASTER OF PHARMACY (M.PHARM) PHARMACEUTICS

SEMESTER I -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Advanced Pharmaceutical Analysis	30	10	60	100
2	Research Methodology and Bioscreening	30	10	60	100
3	Advanced Pharmaceutics-I	30	10	60	100
4	Elective-I	30	10	60	100
	Total				**400**

SEMESTER I –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Advanced Pharmaceutics-I	10	30	60	100
3	Seminar I	-	-	50	50
	Total				**250**
	Grand Total Semester I (Theory+ Practical)				**650**

SEMESTER II -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Advanced Pharmaceutics-II	30	10	60	100
2	Advanced Pharmaceutics-III	30	10	60	100
3	Elective-II	30	10	60	100
4	Elective-III	30	10	60	100
	Total				**400**

SEMESTER II –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutics-II	10	30	60	100
2	Seminar II(Seminar on proposed Project Work, Literature Survey , Plan of Work, Methodology)	-	-	50	50
	Total				**150**
	Grand Total Semester II (Theory+ Prtactical)				**550**

SEMESTER III

S.No	Name of the Subject	End sem	Grand Total
1	Seminar III (Seminar on progress of Project Work)	50	50
2	Assignment on Research Paper / patent	50	50
	Total		100

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand Total
1	Seminar-IV	50	-	50
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology/ experimental work and investigations, interpretation and analysis of data, results and discussions, publications/ abstracts,mode of presentation)		300	300
3	Viva – Voce		250	250
	Total			**600**
Grand Total Semester I to IV = 650 + 550 + 100 + 600 = 1900				

SCHEME OF EXAMINATION FOR MASTER OF PHARMACY (M.PHARM) PHARMACEUTICAL CHEMISTRY

SEMESTER I -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1.	AdvancedPharmaceutical Analysis	30	10	60	100
2.	Research Methodology and Bioscreening	30	10	60	100
3.	Advanced Pharmaceutical Chemistry -I	30	10	60	100
4.	Elective-I	30	10	60	100
	Total				**400**

SEMESTER I –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Advanced Pharmaceutical Chemistry-I	10	30	60	100
3	Seminar I	-	-	50	50
	Total				**250**
	Grand Total Semester I (Theory+ Practical)				**650**

SEMESTER II -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Advanced Pharmaceutical Chemistry-II	30	10	60	100
2	Advanced Pharmaceutical Chemistry-III	30	10	60	100
3	Elective-II	30	10	60	100
4	Elective-III	30	10	60	100
	Total				**400**

SEMESTER II –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutical Chemistry-II	10	30	60	100
2	Seminar II (Seminar on proposed Project Work, Literature Survey , Plan of Work, Methodology)	-	-	50	50
	Total				**150**
	Grand Total Semester II (Theory+ Prtactical)				**550**

SEMESTER III

S.No	Name of the Subject	End Sem	Grand Total
1	Seminar III (Seminar on Progress of Project Work	50	50
2	Assignment on Research Paper	50	50
	TOTAL		**100**

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand total
1	Seminar-IV	50	–	50
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology/ experimental work and investigations, interpretation and analysis of data, results and discussions, publications/ abstracts mode of presentation)		300	300
3	Viva – Voce		250	250
	Total			**600**
	Grand Total Semester I to IV = 650+550+100+600 = 1900			

SCHEME OF EXAMINATION FOR MASTER OF PHARMACY (M.PHARM) PHARMACOLOGY

SEMESTER I -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Advanced Pharmaceutical Analysis	30	10	60	100
2	Research Methodology and Bioscreening	30	10	60	100
3	Advanced Pharmacology-I	30	10	60	100
4	Elective-I	30	10	60	100
	Total				**400**

SEMESTER I –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Advanced Pharmacology - I	10	30	60	100
3	Seminar I	-	-	50	50
	Total			**250**	
	Grand Total Semester I (Theory+ Practical)				**650**

SEMESTER II -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Advanced Pharmacology -II	30	10	60	100
2	Advanced Pharmacology -III	30	10	60	100
3	Elective-II	30	10	60	100
4	Elective-III	30	10	60	100
	Total				**400**

SEMESTER II –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmacology -II	10	30	60	100
2	Seminar II (Seminar on proposed Project Work, Literature Survey , Plan of Work, Methodology)	-	-	50	50
	Total				**150**
	Grand Total Semester II (Theory+ Prtactical)				**550**

SEMESTER III

S.No	Name of the Subject	End Sem	Grand Total
1	Seminar III (Seminar on Progress of Project Work	50	50
2	Assignment on Research Paper	50	50
	TOTAL		**100**

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand Total
1	Seminar-IV	50	––	50
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology/ experimental work and investigations, interpretation and analysis of data, results and discussions, publications/ abstracts mode of presentation)		300	300
3	Viva – Voce		250	250
	Total			**600**
	Grand Total Semester I to IV =650 + 550 + 100 + 600 = 1900			

SCHEME OF EXAMINATION FOR MASTER OF PHARMACY (M.PHARM) PHARMACOGNOSY

SEMESTER I -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Advanced Pharmaceutical Analysis	30	10	60	100
2	Research Methodology and Bioscreening	30	10	60	100
3	Advanced Pharmacognosy - I	30	10	60	100
4	Elective-I	30	10	60	100
	Total				**400**

SEMESTER I –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Advanced Pharmacognosy-I	10	30	60	100
3	Seminar I	-	-	50	50
	Total				**200**
	Grand Total Semester I (Theory+ Practical)				**600**

SEMESTER II -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Advanced Pharmacognosy-II	30	10	60	100
2	Advanced Pharmacognosy-III	30	10	60	100
3	Elective-II	30	10	60	100
4	Elective-III	30	10	60	100
	Total				**400**

SEMESTER II –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmacognosy-II	10	30	60	100
2	Seminar II (Seminar on proposed Project Work, Literature Survey , Plan of Work, Methodology)	-	-	50	50
	Total				**150**
	Grand Total Semester II (Theory+ Prtactical)				**550**

SEMESTER III

S.No	Name of the Subject	End Sem	Grand Total
1	Seminar III (Seminar on Progress of Project Work	50	50
2	Assignment on Research Paper	50	50
	TOTAL		**100**

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand total
1	Seminar-IV	50	––	50
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology/ experimental work and investigations, interpretation and analysis of data, results and discussions, publications/abstracts mode of presentation)		300	300
3	Viva – Voce		250	250
	Total			**600**
	Grand Total Semester I to IV = 650 + 550 + 600 = 1900			

SCHEME OF EXAMINATION FORMASTER OF PHARMACY (M.PHARM) QUALITY ASSURANCE

SEMESTER I -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Advanced Pharmaceutical Analysis	30	10	60	100
2	Research Methodology and Bioscreening	30	10	60	100
3	Advanced Quality Assurance Techniques -I	30	10	60	100
4	Elective-I	30	10	60	100
	Total				**400**

SEMESTER I –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand Total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Advanced Quality Assurance Techniques -I	10	30	60	100
3	Seminar I	-	-	50	50
	Total				200
	Grand Total Semester I (Theory+ Practical)				**600**

SEMESTER II -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Quality Assurance Techniques -II	30	10	60	100
2	Advanced Quality Assurance Techniques -III	30	10	60	100
3	Elective-II	30	10	60	100
4	Elective-III	30	10	60	100
	Total				**400**

SEMESTER II –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand Total
1	Advanced Quality Assurance Techniques -II	10	30	60	100
2	Seminar II (Seminar on proposed Project Work, Literature Survey , Plan of Work, Methodology)	-	-	50	50
	Total				**150**
	Grand Total Semester II (Theory+ Prtactical)				**550**

SEMESTER III

S.No	Name of the Subject	End Sem	Grand Total
1	Seminar III (Seminar on Progress of Project Work	50	50
2	Assignment on Research Paper	50	50
	TOTAL		**100**

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand total
1	Seminar-IV	50	––	50
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology / experimental work and investigations, interpretation and analysis of data, results and discussions, publications/abstracts mode of presentation)		300	300
3	Viva – Voce		250	250
	Total			**600**
	Grand Total Semester I to IV = 650 + 550 + 100 + 600 = 1900			

SCHEME OF EXAMINATION FOR MASTER OF PHARMACY (M.PHARM)
PHARMACEUTICAL BIOTECHNOLOGY

SEMESTER I -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Advanced Pharmaceutical Analysis	30	10	60	100
2	Research Methodology and Bioscreening	30	10	60	100
3	Advanced Pharmaceutical Biotechnology-I	30	10	60	100
4	Elective-I	30	10	60	100
	Total				**400**

SEMESTER I –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Advanced Pharmaceutical Biotechnology -I	10	30	60	100
3	Seminar I	-	-	50	50
	Total				**250**
	Grand Total Semester I (Theory+ Practical)				**650**

SEMESTER II -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Advanced Pharmaceutical Biotechnology-II	30	10	60	100
2	Advanced Pharmaceutical Biotechnology-III	30	10	60	100
3	Elective-II	30	10	60	100
4	Elective-III	30	10	60	100
	Total				**400**

SEMESTER II –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutical Biotechnology-II	10	30	60	100
2	Seminar II (Seminar on proposed Project Work, Literature Survey , Plan of Work, Methodology)	-	-	50	50
	Total				**150**
	Grand Total Semester II (Theory+ Prtactical)				**550**

SEMESTER III

S.No	Name of the Subject	End Sem	Grand Total
1	Seminar III (Seminar on Progress of Project Work	50	50
2.	Assignment on Research Paper	50	50
	TOTAL		**100**

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand total
1	Seminar-IV	50	––	50
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology/experimental work and investigations, interpretation and analysis of data, results and discussions, publications/abstracts mode of presentation)		300	300
3	Viva – Voce		250	250
	Total			**600**
	Grand Total Semester I to IV =650 + 550 +100 + 600 = 1900			

CREDIT BASED SYSTEM FOR M. PHARM IN PHARAMCEUTICAL REGULATORY AFFAIRS (PRA)

SEMESTER I -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Advanced Pharmaceutical Analysis	30	10	60	100
2	Research Methodology and Bioscreening	30	10	60	100
3	Pharmaceutical Regulatory Affairs I	30	10	60	100
4	Elective-I	30	10	60	100
	Total				**400**

SEMESTER I –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutical Analysis	10	30	60	100
2	Pharmaceutical Regulatory Affairs I	10	30	60	100
3	Seminar I	-	-	50	50
	Total				**250**
	Grand Total Semester I (Theory+ Practical)				**650**

SEMESTER II -THEORY

S.No.	Name of the Subject	2 Mid Sem tests	Assignment / MCQ / Quiz	End Sem	Grand Total
1	Pharmaceutical Regulatory Affairs II	30	10	60	100
2	Pharmaceutical Regulatory Affairs III	30	10	60	100
3	Elective-II	30	10	60	100
4	Elective-III	30	10	60	100
	Total				**400**

SEMESTER II –PRACTICAL

S.No.	Name of the Subject	Day to day Assessment	Mid sem exam	End sem	Grand total
1	Advanced Pharmaceutical Biotechnology-II	10	30	60	100
2	Seminar II (Seminar on proposed Project Work, Literature Survey , Plan of Work, Methodology)	-	-	50	50
	Total				**150**
	Grand Total Semester II (Theory+ Prtactical)				**550**

SEMESTER III

S.No	Name of the Subject	End Sem	Grand Total
1	Seminar III (Seminar on Progress of Project Work	50	50
2.	Assignment on Research Paper	50	50
	TOTAL		**100**

SEMESTER IV

S.No.	Name of the subject	Mid term exam	End sem	Grand total
1	Seminar-IV	50	–	50
2	Project dissertation (Preface, objectives general introduction, drug profile, review of literature, plan of work, methodology/experimental work and investigations, interpretation and analysis of data, results and discussions, publications/abstracts mode of presentation)		300	300
3	Viva – Voce		250	250
	Total			**600**
	Grand Total Semester I to IV =650 + 550 +100 + 600 = 1900			

ANNEXURE II

RESEARCH METHODOLOGY AND BIOSCREENING

Theory 4 hours/week

CREDITS 04

UNIT I

i. Meaning of research, purpose of research, types of research (educational, clinical, experimental historical descriptive, basic applied and patent oriented research)- Objective of research

ii. Literature survey: Use of library, books and journals- Medline-Internet, getting patents and reprints of articles as source for literature survey.

iii. Selecting a problem and preparing research proposal for different types of research mentioned above.

UNIT II

i. Methods and tools used in research.

ii. Qualitative studies, Quantitative studies

iii. Sample data organization, Descriptive data analysis.

iv. Limitations and source of error.

v. Inquiries in form of questionnaire, opinioaire or by interview.

vi. Technical report writing/ paper writing/thesis writing. Plagiarism.

vii. Quality By Design: Basic concepts, Process Analytical Techniques.

UNIT III

i. Guidelines and techniques for experiments with animals. Regulatory bodies like CPCSEA, BS, OECD, LD_{50}, ED_{50} determination, Bioassays, Handling of biological waste, handling of radioactive materials.

ii. Bioscreening of following category of drugs:

   a. Cardiovascular System- Antihypertensives, antiarrythmics, antiatherosclerotic.

   b. Central nervous system-Anti psychotics, antidepressants, antiparkinsonian, nootropics, anticonvulsants.

   c. Pain pathways: Analgesics, antiinflammatory.

UNIT IV

i. Biostatistics: Probability distribution, binomial polynomial, distribution, continuous data distribution, probit and logit analysis, linear regression and correlation, significance of correlation and regression, Parametric tests, testing hypothesis, types of errors, Test of significance for correlation co efficient. Non parametric tests, Experimental design (randomization, completely randomized and latin square designs, cross over and parallel design and factorial designs.)

RECOMMENDED BOOKS:

1. Anderson J. Thesis and Assignment writing.
2. Best JV, Kahn JV. Research in education. 7th Ed. Prentice Hall of India. New Delhi.1999
3. Brown L. Effective Business Report Writing.
4. Das P and Das G. Protection of industrial property rights.
5. Davis R M. Thesis project in Science and Engineering.
6. Day R A. How to write and publish a research paper. 5th Ed. ISI Press. Philadelphia. 2006.
7. Furmess E. Spelling for the millions.
8. Halton M. Presentation skills Indian Society for Institute Education.
9. Mcfariane G. A practical introduction to copy right.
10. Menzel D. Writing a technical paper.
11. CPCSEA guidelines WWW.CPCSEA.COM
12. CPCSEA guidelines for laboratory animal facility Indian Journal of Pharmacology. 2003; 35: 257-274.
13. OECD guidelines.
14. Bolton S; Pharmaceutical statistics; Marcel Dekker.
15. Rao NSN, Murthy NS Applied statistics in health care. Jaypee Brothers Medical Publishers. New Delhi.
16. Juran J.M. and Godfrey A.B. Juran's quality handbook; McGraw Hill.
17. Vogel H. G. and Vogel W. H.: Drug Discovery and Evaluation: Pharmacological Assays, Springer, New York.

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ADVANCED PHARMACEUTICAL ANALYSIS

Theory 4 hours/week

CREDITS 04

UNIT I

1. Spectroscopic methods - Introduction, applications and structure elucidation using UV, IR, NMR, Mass spectrometry with examples. (14h)

UNIT II

2. Separation techniques - Theory, instrumentation, applications of GLC, HPLC, HPTLC, GC-MS, LC-MS, LC-MS-MS. (14h)

UNIT III

3. a. Chiral chromatography, ion pair chromatography, super critical fluid chromatography. (8h)

   b. Immunochemical techniques - Immunoelectrophoresis, immunoprecipitation, ELISA, radioimmuno assays. (6h)

UNIT IV

4. a. Thermal analysis - Theory, instrumentation and applications of thermogravimetric analysis, differential thermal analysis, differential scanning calorimeter. (9h)

   b. XRD techniques: theory, instrumentation and applications (5h)

ADVANCED PHARMACEUTICAL ANALYSIS

Practical 6 hours/week

CREDITS 03

1) Experiments based on UV, FT-IR, HPLC, GC and DSC (10 experiments)
2) ELISA test/ LAL test
3) Estimation of drugs in biological fluids.
4) Validation of analytical methods (2 experiments)

RECOMMENDED BOOKS :

1) Skoog : Principles of Instrumental Analysis (Saunders College Publishing Philadelphia)
2) M. Orchin and H. H. Jaffe - Theory and applications of ultra violot spectroscopy (John Wiley and Sons, N.Y.)
3) Silverstein, Basseler, Morril - Spectrometric identification of organic compounds (John Wiley and Sons, N.Y.)
4) Willard, Merritt, Dean - Instrumental Methods of Analysis (CBS Publishers and Distributors, Delhi)
5) J. R. Dyer - Applications of Absorption Spectroscopy of Organic compounds (Prentic Hall, London)
6) C. N. R. Rao - Chemical applications of Infra-red spectroscopy (Academic press, N.Y.)
7) Higuchi : Instrumental Methods of Analysis
8) Analytical Chemistry by open learning series
9) R. J. Hamilton-Introduction to High Performance Liquid chromatography, (Chapman and Hall, London).
10) Ewing : Instrumental Methods of Chemical Analysis (McGraw Hill Book Co. New York)

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ADVANCED PHARMACEUTICS- I

Theory 4 hours/week

CREDITS 04

UNIT I

1. Preformulation studies:

   Physicochemical factors influencing formulation

   Principles and applications of characterization Techniques

   Drug Excipient Compatibilty studies

2. Stability Studies: Basic concepts, Kinetics and ICH guidelines for stability evaluation

UNIT II

3. Statistical Designs including Factorial and other approaches

4. Dissolution : Theory of dissolution, concept of drug release. Dissolution test apparatus: different designs, factors affecting dissolution rate. Dissolution of different dosage forms: solids, suspensions, topicals, suppositories and controlled release systems.

   Comparison of dissolution profile by model independent (f1 & f2 analysis) and dependant methods IVIVC

UNIT III

5. Solids : Handling of solids, pharmaceutical granulation, compression and compaction properties of binary mixtures, lubricant sensitivity, characterization of granules and compacts.

6. Pharmaceutical aspects of solubilization and solubilized systems : Solubilization of drugs by following approaches: use of surfactants for solubiliaztion; solid dispersions, cyclodextrin inclusion complexes, cosolvency etc.

UNIT IV

7. Surfactant System: 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

8. Polymer Science : Types and applications of polymers, methods of polymerization and characterization of polymers. Polymers for controlled release Bioadhesive polymers, stimuli sensitive polymers. Biodegradable polymers, Biodegradation of polymers, enzymatically degradable bonds in synthetic polymers, dendrimers

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ADVANCED PHARMACEUTICS-I

Practical 6 hours/week

CREDITS 03

Experiments based on following concepts :

1) Solids :

   a) Particle size analysis by microscopy and laser diffraction techniques

   b) Compression and compaction : Heckel plot studies, Tensile strength

   c) Mechanical properties of granules

2) Solubilization

   a) Effect of dielectric constant on solubility

   b) Complexation

   c) Ternary phase diagram

   d) Solid dispersions: Preparation and characterization of amorphous and crystalline forms.

3) Polymer science : Rheological and Thermal characterization of polymers.

4) Preparation and characterication of different mesophases of surfactant/ polymers.

5) Dissolution studies of various dosage forms

Recommended books :

1) N.G. Stanley - Wood, Enlargement and compaction of particle solids; Butterworths
2) D. M. Parikh, Handbook of Pharmaceutical Granulation Technology; Marcel Dekker.
3) H.G. Brittain; Physical Characterization of Pharmaceutical solids; Marcel Dekker.
4) A. Kitahard and A.Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
5) J.T.Carstensen; Drug stability; Marcel Dekker
6) G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
7) A. Martin, P.Bustamante and A.H. Chun; Physical Pharmacy; Waverly
8) Lieberman, Rieser and Banker; Pharmaceutical dosage forms; Disperse system; Marcel Dekker.
9) M.N. Rubinstein, Pharmaceutical Technology, Drug Stability, John Wiley and Sons.
10) Martin Rhodes, Principles of Powder Technology, John Wiley and Sons
11) James J.Wells, Pharmaceutical Preformulation, Ellis Horwood Ltd.
12) P.J.Tarcha, Polymers for Controlled Drugs Delivery, CRC Press.
13) P.H.List and P.C. Schmidt; Pharmaceutical technology, CRS press.
14) Robinson, Novel Drug Delivery System, Marcel Dekker.

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ADVANCED PHARMACEUTICS- II

Theory 4 hours/week

CREDITS 04

Design, development, manufacture and evaluation of the following novel drug delivery systems:

UNIT I

1. Oral Drug Delivery Systems: Osmotic DDS, Ion exchange controlled DDS, Hydrodynamically balanced DDS
2. Mucosal DDS: Physiological basis of mucosal delivery with reference to oral mucosal, nasal, vaginal and rectal routes. Bioadhesion and bioadhesive polymers, DDS for mucosal administration. In-vitro, ex-vivo and in-vivo evaluation techniques.
3. Microspheres: Methods to obtain microcapsules/ microspheres, their evaluation and applications.

UNITII

4. Transdermal DDS: Percutaneous absorption and penetration enhancers, development of transdermal gels, patches with reference to components and evaluation. Iontophoretic and Sonophoretic DDS.
5. Ocular DDS –Design of CR ophthalmic DDS including gels, inserts, novel DDS and evaluation.
6. Parenteral DDS: CR Injectables, implants etc. development and evaluation

UNIT III

7. Colloidal DDS: Specialized DDS like micro / nano emulsions, SMEDDS, Multiple emulsions, liposomes, niosomes, polymeric micelles and other vesicular DDS, their design and development into final dosage forms, issues and consideration
8. Nanoparticulate systems such as lipid nanoparticles and polymeric nanopartciles: Methods of preparation, characterization and applications
9. Peptide and protein based DDS: Chemistry and special features of peptide and protein molecules, stability, Challenges in protein/ peptide delivery, Formulation approaches and evaluation of peptide and protein delivery; Routes of delivery, Toxicity, immunogenicity, vaccines and gene based DDS

UNIT IV

10. Pulmonary DDS – Physiological basis and formulation considerations. Design of Pressurized aerosols, Dry powder DDS, Devices for administration and evaluation.
11. Targeted DDS: Concept of drug targeting, need for drug targeting , basis for drug targeting both active and passive. Ligands for targeted delivery, Monoclonal antibodies in targeted delivery, design of targeted DDS for cancer and infectious diseases, brain targeting, Colon targeting approaches and DDS
12. Intrauterine Devices, Intravaginal drug delivery systems

ADVANCED PHARMACEUTICS-II

Practical 6 hours/week

CREDITS 03

Experiments based on follwing concepts.

1) Formulation and evaluation of sustained release tablet formulation.
2) Preparation and characterization of Microcapsules/ Microspheres : at least 2 methods.
3) Preparation and evaluation transdermal films/patches and gel formulation
4) In-vitro permeation studies across skin and nasal mucosa
6) Formulation design and evaluation of

   a) Liposomes b) Multiple emulsion c) Niosomes d) nanosuspension
   e) Osmotic pump f) Ocular insert

RECOMMENDED BOOKS :

1) P. Tyle, drug Delivery Devices, fundamental and applications, Marcel Dekker.
2) Morton rosoff, Controlled release of drugs, VCH Publishers.
3) D.W. Osborne, and A.H. Amann, topical drug delivery formulations, Marcel Dekker.
4) P. Tyle Drug delivery devices, Marcel Dekker
5) Barry, Dermatological formulation, Marcel Dekker
6) Robinson, Novel Drug Delivery systems, Marcel Dekker
7) N.K. Jain, Controlled and Novel Drug delivery, CBS Publisher, New Delhi.
8) P. Johnson and J.G. Lloyd – Jones, Drug Delivery Systems, VCH Publisher
9) P. Tyle and B.P. Ram, Targeted Therapeutic systems, Marcel Dekker
10) C.G. Wilson and N. Washington, Physiological Pharmaceutics, Ellis Horwood Limited
11) H.S. Bean, A.H. Beckett, and J.E. Carless, Advances in Pharmaceutical Sciences vol. 5 Academic Press.
12) R.O. Potts, and R.H. Guy, Mechanisms of Transdermal Drug delivery, Marcel Dekker.
13) T.J. Roseman and S.Z. Controlled release delivery systems, marcel Dekker.
14) A.J. Hickey, Pharmaceutical Aerosol Technology, Marcel Dekker.
15) J. Kreuter, Controlled drug delivery systems, Marcel Dekker
16) K.S.E. Su and S.F. Chang, Nasal systemic drug delivery, Marcel Dekker
17) A.F.Kydonieus, Controlled release technologies : methods, theory and applications vol. I & II, CRC Press inc.
18) Y.W. Chein, Trasdermal controlled systemic medication, Marcel Dekker
19) P.B. Deasy, Microencapsulation and related drug processes, Marcel Dekker.

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ADVANCED PHARMACEUTICS - III

Theory 4 hours/week

CREDITS 04

UNIT I

1. Absorption: Cell membrane, absorption mechanisms, oral drug absorption, pH-partition hypothesis. Factors affecting: physico-chemical, dosage form related, patient related. Drug absorption through other routes, transdermal, nasal, buccal, ocular, and sublingual. In-vitro, in-situ and in-vivo models for drug absorption studies. ABC transporters. Animal Tissue culture Technique for drug absorption studies.
2. Distribution: Tissue permeability of drugs, barriers to distribution of drugs. Factors affecting drug distribution, physicochemical properties of drugs, volume of distribution, Drug - protein binding, drug tissue binding, factors affecting protein drug binding. Kinetics of drug protein binding significance of drug tissue binding.

UNIT II

3. Metabolism :Drug metabolism organs and enzymes, chemical pathways Phase-I and Phase-II reactions. First pass effect, factors affecting metabolism
4. Excretion:Renal and nonrenal routes of drug excretion, concept of clearance. Factors affecting excretion mainly renal excretion.

UNIT III

5. Pharmacokinetics : Pharmacokinetics in drug discovery and development, Pharmacokinetics models, Laplace transformations and concept of compartment modeling.
   1) One compartment model : intravenous injection, intravenous infusion, First order absorption (Urinary and plasma data)
   2) Multicompartment models. Intravenous injection, intravenous infusion, first order absorption, multidosing data.
   3) Non-linear Pharmacokinetics Michaelis- Menten kinetics, estimation of K_m and V_m, Area under curve, enzyme induction.
   4) Non compartmental analysis - statistical moment theory
6. Integration of Kinetics: Interrelationships between pharmacokinetics parameters and physiological variables.

UNIT IV

7. Application of Pharmacokientic: Multiple dosing, controlled release dosage form, dose adjustment in renal failure, haemodialysis, individualization, monitoring drug therapy, chronipharmacokientics.
8. Bio-availability and Bioequivalence: Study design, protocols and regulatory requirements and statistical consideration in data analysis

RECOMMENDED BOOKS :

1. J.B.Blanchard, R.J. Sawchul and B.B.Brodie, Principle and Perspectives in Drug bioavailability, K. Karger Publication.
2. M. Gibald and Perrier, Pharmacokientices, Marcel Dekker.
3. M.Rawland and T.N. Tozer, Clinical Pharmacokinetics, Waverly Publications
4. P.Jenner and B. Testa, Concepts in drug metablism, Marcel Dekker
5. D.M. Brmhankar and S.B.Jaiswal, Biopharmaceutics and pharmacokientis A Treatise, Vallabh Prakashan.
6. Jean - Pierre Labaune, Hand book of pharmacokinetics, John Wiley & sons.
7. B. Testa, Advances in drug research, Vol. 19, Academic Press.
8. R.E. Notari; biopharmaceutics and clinical Pharmacokinetics; Marcel Dekker.
9. P.G. Welling and F.L.S. Tse; Pharmacokinetics, regulatory- Industrial Academic perspectives, Marcel Dekker.

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ADVANCED PHARMACEUTICAL CHEMISTRY-I

Theory 4 hours/week

CREDITS 04

UNIT I

1. Protective groups for –OH, -NH_2, -COOH. Special protective groups for aldehyde / ketone such as oxazolines [A. I. Meyer's reagent] & 1,3- dithianes. Methods for the deprotection of the above groups. Concept of "Umplong". reactions of 1, 3-dithiane.
2. Homogeneous & heterogeneous reductions / hydrogenations. Metal - ammonia / amines reductions.
3. Catalyzed reactions-: General concept of catalysis, Distinction between catalysis and Induction, Base catalysis, Transition metal catalysis, Catalysis by Enzymes, Enzymes and chiral recognition, Artificial enzymes.

UNIT II

4. Name reactions:

Hoffmann degradation, Beckmann rearrangment, Michael addition. Claisen- Schmidt, MPV reduction, Oppanaur Oxidation, Bayer- Villiger reaction, Wolf- Kishner reaction, Clemmenson's reaction, Fries reaction, Mannich reaction, Stobbe reaction, Wiitig reaction, Pinacol-pincolone rearrangment, Benzil-benzillic acid rearrangment, Curtius rearrangment.

5. Fluorinating agents & their use in drug synthesis.
6. Regio- & stereoselective & stereospecific formation of enolate anions, their nucleoplillic & addition reactions. Role of Li, Na, K, Mg, & B metal ions in the regio- & stereoselective & stereospecific formation of enolate anions.

UNIT III

7 Chemistry of active methylene compounds.

8 Different methods for the preparation of á-methylene lactones & similar functionalities.

9 Pericyclic reactions. HOMO & LUMO. Conservation of orbital symmetry. Woodward rules for allowed & disallowed motions. Stereo specificity of these reactions.

UNIT IV

10 Heterocyclic Chemistry : IUPAC Nomenclature and name reactions such as Knorr and Paal-Knorr pyrrole synthesis, Fischer indole synthesis, Modelung indole synthesis, Reissert indole synthesis, Hinsberg thiophene synthesis, Claisen isoxazole synthesis, Robinson- Gabriel synthesis, Guareshi-Thorpe pyridine synthesis, The Zincke Reaction.

11 Stereochemistry & it's importance in medicinal chemistry.. Nomenclature & stereochemistry of spiro-compounds. Stereochemistry of allenes & biphenyls.

12 Dynamic stereochemistry, conformations & reactivity in open chain & cyclic systems. Weinstein, Curtin – Hammet principle. Cram's rule & Prelog modification. Topicity & it's significance in dynamic stereochemistry.

ADVANCED PHARMACEUTICAL CHEMISTRY-I

Practical 6 hours/week

CREDITS 03

1. Clemmenson reduction
2. Lithium aluminium hydride reduction
3. Sodium borohydride reduction
4. Claisen-schmidt condensation
5. Oxidation of sulphide to sulfoxides and sulfones with hydrogen peroxide & peracid.
6. Preparation of Wittig reagent & reaction with aldehyde and ketone

7. Resolution of a acidic and basic racemic mixture by diasteriomer formation
8. Synthesis of thiazide & hydrothiazide derivative in a multi step process.
9. Diel's Alder reaction for preparing bicyclo [2.2.1] system.
10. Synthesis of any tripeptide from amino acids.
11. Fischer Indole Synthesis
12. Grignard reaction.
13. Pinacolone – synthesis

Recommended books:

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

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ADVANCED PHARMACEUTICAL CHEMISTRY-II

Theory 4 hours/week

CREDITS 04

UNIT I

1) Enzyme Inhibition -

a. Enzyme structure : Primary, secondary, tertiary and quarternary.

b. Enzyme kinetics

c. Enzyme inhibitors - Reversible, Irreversible, Kcat inhibitors, Transition state analogs.

d. Enzyme Inhibitors as drugs - ACE, leukotrienes, Lipoxygenase, Cycloxygenase, Aromatase, Xanthine oxidase, HMG-Co- A , MAO and Cytochrome P-450 Inhibitors.

2) Drugs binding to nucleic acid :

a. DNA intercalating agents

b. DNA binding and nickling agents

c. Agents interfering with DNA enzymes

d. Inhibitors of the transcribing enzymes

e. Agents interacting with ribosomal RNA and interfering with its function.

Above agents with reference to Antimalarial, anti-cancer, antiviral.

UNIT II

3) Design and application of prodrugs concept

a. Prodrug concept, hard and soft drugs

b. Classification of prodrugs.

c. Prodrugs of various functional groups like carbonyl, hydroxy, amide, amines.

d. Application of prodrug approach to: pharmaceutical, pharmacokinetic and pharmacodynamic applications.

e. Limitations and drawbacks of prodrug concept

f. Macromolecular carries for drug targetting : types of carries used, methods of drug release, active and passive targetting, polymeric prodrugs and their applications.

g. Twin drugs/Hybrid drugs.

UNIT III

4) Synthon Approach

a. Definition of terms- disconnection, synthon, functional group interconversion (FGI).

a. Basic rules in disconnection

b. Use of synthon approach in synthesis of following compounds:

Trimethoprim, Terfenadine, Ibuprofen, Propanolol, Fentanyl, Ciproflaxacin, Cimetidine, Piroxicam, Rosiglitazone, Diclofenac, Captopril, Nifedipine.

UNIT IV

5) Drug Discovery

a. Historical perspective, Drug discovery strategies in direct drug design (structure based) and indirect drug design, Target selection and lead identification (Natural product sources, Fermentation / Microbial sources, Synthetic).

b. Drug discovery strategies in structure based drug design: Molecular drug Targets—Introduction, Enzymes, Membrane Transportes,,Voltage- Gated Ion channels, Non- selective cation channels, Direct Ligand –gated Ion channels as drug targets.

c. Lead compound discovery strategies: Introduction, Analog Design, Systematic screening, Exploitation of Biological information, Planned Reasearch and rational approaches.

d. Primary Exploration of Structure –Activity relationship : Molecular variations in homologous series; Molecular variations based on isosteric replacements, Ring transformations.

e. Homo and Heterodimer Ligands: The twin drug approach: Introduction; Homodimers and symmetrical ligands; Heterodimer and dual acting ligands Dimer and symmetrical ligands; Hybrid molecules as ligands of two different receptors., Hybrids as enzyme inhibitors, Hybrids acting at one receptor and one enzyme.

6) QSAR –

a. Strategies for primary strcture- activity relationship exploration: Introduction, Preliminery considerations, Hit optimization strategies; Application rules-

Minor modification rule, The biological logic rule, the structural logic rule; The right substituent rule, The easy organic synthesis rule, The pharmacological logic rule

b. Parameters - Lipophilicity, electronic, steric factors, Quantitative Models – (Hansch analysis, Free Wilson Analysis, Mixed approach) Other QSAR approaches, Applications of Hansch analysis, Free Wilson analysis.

RECOMMENDED BOOKS:

1. Burger : Medicinal Chemistry (John Wiley & Sons N.Y.)
2. Foye : Principles of Medicinal Chemistry (Varghese & Co.)
3. Ledinicer : Organic Drug synthesis Vol. 1, 2, 3, 4 (John Wiley & Sons N.Y.)
4. Ariens : Medicinal Chemistry Series
5. Ellis and West : Progress in Medicinal Chemistry Series
6. Butterworther: Progress in Medicinal Chemistry Series
7. Wilson and Gisvold - Text book of Medicinal Chemistry (J.B. Lippincoff cam)
8. Stuart Warren : Organic Synthesis – The Disconnection Approach (John Wiley & Sons)
9. Comprehensive Medicinal Chemistry - Series -I-VI (Elsevier Pergamon) by Corwin Hansch, Peter G. Sammes and John B. Taylor.
10. Contemporary Drug synthesis (wiley Interscience) by Jie-Jac Li, Douglas S. Jhonson, Drago R. Silskoric and Bruce D. Roth.
11. The Practice of Medicinal Chemistry (Academic Press, Elsevier), 2nd Edition by Camille G. Wermuth.
12. Synthesis of Drug, A synthon approach by Radhakrishnan P. Iyer & Anant v. prabhu, 1st Edition, (1985) Sevak Publications, Mumbai.
13. Hugo Kubingi - QSAR, Hansch Analysis and Related approaches Vol.1
14. Poul Krogsgaand Larsen : A text book of Drug Design and Development First Edi.
15. Thomas J. Perum, C.L.Propst - Computer Aided Drug Design
16. Pandi Veerapandian - Structure Based Drug design
17. Paul S. Charifson - Practical Applications of Computer Aided Drug Design (Murcell & Dekkar Inc. New York)
18. Paul Leff - Receptor Based Drug Design
19. Bernard Testa, Walter Fuhrer - Perspectives in Medicinal Chemistry
20. Hansch Comprehensive Medicinal Chemistry Vol-IV

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ADVANCED PHARMACEUTICAL CHEMISTRY- II

Practical 6 hours/week

CREDITS 03

1) Determination of partition coefficient
2) Determination of PKa value
3) Synthesis of drugs mentioned in the theory using basic operations like molecular distillation, fractional crystallization, purification by column chromatography & structure confirmation by spectroscopic methods.
4) Synthesis of drugs using synthon approach.
5) Asymmetric synthesis.
6) Resolution of racemic mixture.
7) Microwave assisted synthesis of drugs.
8) Application of partition coefficient, pKa, steric factors, electronic factors in QSAR studies with example, use of statistical regression analysis.

RECOMMENDED BOOKS:

1. Organic synthesis : Fieser and William Son (CBS publishers)
2. Mann and Saunders, Critical Organic Chemistry (Orient Longman)
3. A.I. Vogel, Practical Qualitative and Quantitative Organic Chemistry (Orient Longman).

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ADVANCED PHARMACEUTICAL CHEMISTRY-III

Theory 4 hours/week

CREDITS 04

UNIT I

1) Combinatorial chemistry:

Introduction, Combinatorial approaches, Chemical peptide and small molecule libraries; Applications, methodology, Combinatorial organic synthesis, Assays and screening of combinatorial libraries, Introduction to high throughputs screening (HTS)

2) Proteins and peptide drugs:

Chemistry, structure and stability. Reactivity of proteins and peptides. Different ways to synthesize these drugs-study of Insulin, Relaxin, Somatostatin, DNAse Interferon.

UNIT II

3) Chiral technology:

Introduction to chirality and techniques used: Assymmetric synthesis of Diltiazim, Timolol, Vitamins C, Ampicillin, Dextrapropoxyphen, Thienamycin, Citrenalol, Propranolol, Atenolol, Naproxen.

Enatio – selective synthesis of Atorvasation, Fluxitine, Sertraline, Zolmitriptan.

Esomeprazole, Gefitinib, Cetrizine, Fexofenadine, Linezolide, Ciprofloxacin, Risperidone, Ziprasidone. (14h)

UNIT III

4) Recent advances in drugs used in the treatment of:

Cancer, AIDS, cardiovascular disorders, diabetes, hepatitis, immunosuppression, Alzheimers, Parkinson, lipid / cholesterol lowering agents

Synthesis of two drugs from each category describing reaction conditions, mechanism and strategies involved in the synthesis.

UNIT IV

5) Molecular modeling in drug design

Introduction to Molecular Modelling : Concepts and Methods, Molecular Mechanics - force fields (Potential energy function), Energy Minimization Methods - Steepest, descent, Conjugate gradients, Newton methods (Non mathematical), Conformational analysis, Systematic search, Monte carlo simulations, Molecular dynamics simulations, Ligand design based on 3D structure of receptor/enzyme.

RECOMMENDED BOOKS:

1. Burger : Medicinal Chemistry (John Wiley & Sons N.Y.)
2. Foye : Principles of Medicinal Chemistry (Varghese & Co.)
3. Ledinicer : Organic Drug synthesis Vol. 1, 2, 3, 4 (John Wiley & Sons N.Y.)
4. Ariens : Medicinal Chemistry Series
5. Ellis and West : Progress in Medicinal Chemistry Series
6. Butterworther: Progress in Medicinal Chemistry Series
7. Wilson and Gisvold - Text book of Medicinal Chemistry (J.B. Lippincoff cam)
8. Stuart Warren : Organic Synthesis – The Disconnection Approach (John Wiley & Sons)
9. Comprehensive Medicinal Chemistry - Series -I-VI (Elsevier Pergamon) by Corwin Hansch, Peter G. Sammes and John B. Taylor.
10. Contemporary Drug synthesis (wiley Interscience) by Jie-Jac Li, Douglas S. Jhonson, Drago R. Silskoric and Bruce D. Roth.
11. The Practice of Medicinal Chemistry (Academic Press, Elsevier), 2nd Edition by Camille G. Wermuth.
12. Synthesis of Drug, A synthon approach by Radhakrishnan P. Iyer & Anant v. prabhu, 1st Edition, (1985) Sevak Publications, Mumbai.
13. Hugo Kubingi - QSAR, Hansch Analysis and Related approaches Vol.1
14. Poul Krogsgaand Larsen : A text book of Drug Design and Development First Edi.
15. Thomas J. Perum, C.L.Propst - Computer Aided Drug Design
16. Pandi Veerapandian - Structure Based Drug design
17. Paul S. Charifson - Practical Applications of Computer Aided Drug Design (Murcell & Dekkar Inc. New York)
18. Paul Leff - Receptor Based Drug Design
19. Bernard Testa, Walter Fuhrer - Perspectives in Medicinal Chemistry
20. Hansch Comprehensive Medicinal Chemistry Vol-IV

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ADVANCED PHARMACOLOGY- 1

Theory 4 hours/week

CREDITS 04

UNIT I

i. Care, handling and breeding techniques of laboratory animals.
ii. Regulations for laboratory animal care.
iii. Ethical requirements.
iv. Knowledge of CPCSEA proformas for performing experiments on animals.
v. Alternatives to animal studies.
vi. Organisation of preclinical screening programmes.
vii. Safety assessment tests, toxicity tests.
viii. OECD guidelines.
ix. Modern techniques
x. Receptor binding assay.
xi. Microarrays
xii. Patch clamp
xiii. High throughput screening

UNIT II

Preclinical evaluation of following category of drugs:

i. Sedative, hypnotics, anxiolytics.
ii. Antidepressents.
iii. Antipsychotics.
iv. Nootropics.
v. Antiparkinsonian.
vi. Analgesics- antipyretics.
vii. Anti inflammatory.
viii. Anticonvulsants.
ix. Local anaesthetics.
x. CNS stimulants.
xi. Cardiac glycosides.
xii. Antiarrhythmics.
xiii. Antihypertensives.
xiv. Antiatherosclerotics.

UNIT III

Preclinical evaluation of following category of drugs:

i. Anti ulcer agents, laxative
ii. Bronchodialators.
iii. Diuretics.
iv. Histamine antagonists.
v. Muscle relaxants.
vi. Cholinergic and anticholinergics.
vii. Adrenergic and adrenergic receptor blockers.

UNIT IV

Preclinical evaluation of following category of drugs:

i. Antidiabe tics.
ii. Antithyroid.
iii. Antifertility screening,
iv. Androgens, estrogen, progesterone.
v. *In vitro* testing of drugs.
vi. Animal cell lines and their uses.
vii. Limitation of in vitro testing of drugs.
viii. Transgenic animals and their applications.

RECOMMENDED BOOKS:

1. Ghosh M. N.: Fundamental of Experimental Pharmacology, Scientific Book Agency, Calcutta.
2. Jaju B. P., Pharmacology: A Practice Exercise Book. Japee Brothers, New Delhi.
3. Kulkarni S. K.: Hand Book of Experimental Pharmacology, VallabhPrakashan, New Delhi.
4. Lawrence D. R. and Bacharch A. L.: Evaluation of Drugs Activities, Pharmacometrics, Academic Press.
5. Perry W. L. M.: Pharmacological Experiments on Isolated Preparations, E and S, Livingston, London.
6. Sheth U. K., Dadkar N. K. and Kamat U. G.: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Mumbai.
7. Thomson E. B.: Drug Bioscreening, VCH, New York.
8. Turner R. A.: Screening Methods in Pharmacology, Academic Press, London.
9. Vogel H. G. and Vogel W. H.: Drug Discovery and Evaluation: Pharmacological Assays, Springer, New York.
10. Sambrook J, Russel D W. Molecular Cloning: A laboratory manual third edition vol. 1, 2. CSHL Press. New York. 2001.
11. CPCSEA guidelines WWW.CPCSEA.COM
12. CPCSEA guidelines for laboratory animal facility Indian Journal of Pharmacology. 2003; 35: 257-274.
13. OECD guidelines.

ADVANCED PHARMACOLOGY- I

Practical 6 hours/week

CREDITS 03

1. Prepration of vaginal smears and examination under microscope.
2. Methods of handling experimental animals.
3. Standard techniques for injection of drugs, collection of blood samples and feeding of animals.
4. Langendorff method.
5. Use of anesthetics and cannulation of veins, arteries and trachea. Working on Physiograph (Students Biopac, PowerLab) setting rat BP and rat/mouse ECG recording. Use of video tracking system.
6. Screening of Analgesics
7. Screening of Anti-inflammatory drugs.
8. Demonstrations of:

   i. Tread mill ii. Run way apparatus iii. Vogel conflict test iv. Light and dark chamber v. Elevated plus maze vi. Conditioned avoidance chamber vii. Catalepsy bar test viii.Actophotometer ix. Radial maze eight arms.

RECOMMENDED BOOKS:

1) Ghosh M. N.: Fundamental of Experimental Pharmacology, Scientific Book Agency, Calcutta.
2) Jaju B. P., Pharmacology: A Practice Exercise Book. Japee Brothers, New Delhi.
3) Kulkarni S. K.: Hand Book of Experimental Pharmacology, VallabhPrakashan, New Delhi.
4) Perry W. L. M.: Pharmacological Experiments on Isolated Preparations, E and S, Livingston, London.
5) Sheth U. K., Dadkar N. K. and Kamat U. G.: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Mumbai.
6) Thomson E. B.: Drug Bioscreening, VCH, New York.
7) Turner R. A.: Screening Methods in Pharmacology, Academic Press, London.
8) Vogel H. G. and Vogel W. H.: Drug Discovery and Evaluation: Pharmacological Assays, Springer, New York.
9) Trevor B Poole The UFAW Handbook on the care and management of laboratory animals sixth edition. Longman scientific and technical.
10) Foster H L, Small D J, Fox J G. The mouse in biomedical research Experimental biology and oncology. Academic Press.1982.
11) Suckow M A, Weisbroth S H, Franklin C. L. THE LABORATORY RAT. American Collge of laboratory animal medicine. Academic Press.Elsevier. 2006 second edition.
12) Sharp P E. C la Regina M. The laboratory rat. CRC Press. Taylor Francis.1998.
13) Rigalli A, Di Loreto V E. Experimental Surgical Models in the Laboratory Rat. CRC Press. Taylor Francis.2009.

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ADVANCED PHARMACOLOGY-- II

Theory 4 hours/week

CREDITS 04

UNIT I

i. Clinical evaluation of new drugs.
ii. Organization, ethics and protocols for clinical trials.
iii. Principles of therapeutic drug monitoring.
iv. Clinical pharmacology of drugs used in treatment of following diseases:
    a. Hypertension.
    b. Congestive cardiac failure.
    c. Angina pectoris, acute myocardial infarction.
    d. Cardiac arrhythmia.
    e. Atherosclerosis
    f. Peripheral vascular disorders.
    g. Coagulation disorders.

UNIT II

Clinical pharmacology of following class of drugs:

i. Pain management, pain pathways
ii. Opoid analgesics.
iii. NSAID analgesics.
iv. Local anaesthetics .
v. Prostaglandines.
vi. Leukotrienes.
vii. Platelet activating factor.
viii. Immunopharmacology: Current concepts in treatment and research of drug for AIDS.
ix. Drug allergy and hypersensitivity.
x. Immunostimulants and immunomodulants.
xi. In vitro & in vivo tests for immunological investigation.

UNIT III

Clinical pharmacology of drugs used in treatment of following diseases:

i. Gastrointestinal diseases
ii. Peptic ulcer
iii. Nausea vomiting
iv. Diarrhoea
v. Constipation
vi. Renal disease
vii. Acute renal failure.
viii. Chronic renal failure (drug doses in renal impairment).
ix. Respiratory diseases
x. Asthma
xi. Chronic obstructive pulmonary oedema
xii. Pulmonary embolism

UNIT IV

1. Clinical pharmacology of drugs used in treatment of following deseases.

i. Hepatic disorders:
ii. Cirrhosis
iii. Hepatitis
iv. Diabetis mellitus.
v. Infectious diseases
vi. Neoplastic disorders:

2. General guidelines for rational use of antibiotics.
3. Resistance to antibiotics.
4. General principles of cancer chemotherapy.
5. Toxicity and toxicity amelioration of anticancer drugs.

RECOMMENDED BOOKS:

1. Ananth J; Treatment of Psychiatric Disorders, Japee, New Delhi
2. Balakrishan, K.V., Komar's Manual of Medical Prescriptions, Paras Publications
3. Bennet P N, Brown M J. Clinical Pharmacology.10th Ed. Churchill Livingstone.Elsevier. London 2008.
4. Bickley, L.S., Bates's Guide to Physical Examination and History Taking, Lippincott
5. Chaudhari, Quintessence of Medical Pharmacology; Central Publishers, New Delhi
6. Davidson's Principles of Internal Medicine, Vol-I And II, 14th Edition, McGraw-Hill
7. Dipiro, Joseph L.; Pharmacotherapy: A Pathophysiological Approach, Elsevier
8. Harrison's Principle And Practice Of Medicine, 18th Edition, Churchill, Livingston, London
9. Herfindal, E.T. and Hirschman, J L.; Clinical Pharmacy and Therapeutics
10. Howland D H, Mycek M J. Lippincott's Illustrated Reviews. Pharmacology. 3rdEd.B I Publications Pvt. Ltd.2006.
11. Koda and Kimble; Applied Therapeutics: The Clinical Uses of Drugs
12. Kundu, A.K.; Bedside Clinics in Medicine, Academic Publishers, Part-I and II
13. Misbahuddin, M, Chaudhari, M.A., Jalil, A; Community Pharmacology, Japee, New Delhi
14. Oxford Textbook of Medicine, Blackwell Science
15. Panda, U.N., Textbook of Medicine, CBS publisher, New Delhi
16. Patten, J; Neurological Differential Diagnosis, 2nd Edition
17. Relevant Reviews Articles from Medical and Pharmaceutical Literature
18. Roger and Walker; Clinical Pharmacy and Therapeutics, Churchill, Livingston, London
19. Scott, L.T; Basic skills in interpreting laboratory data, American Society of Health System Pharmacist
20. Sharma H L, Sharma K K. Principles of Pharmacology. First Ed. Paras Medical Publisher. Hyderabad. 2008.
21. Tripathi K D. Essentials of Medical Pharmacology. 6th Ed. Jaypee. 2008.
22. Tussle, T.G.: Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall, New York
23. Walton, J.; Boain's Diseases of Nervous System, Tenth Edition.

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'ADVANCED PHARMACOLOGY-- II

Practical 6 hours/week

CREDITS 03

1. Screening of hypnotics, muscle relaxants.
2. Evaluation of i. local anesthetics, ii. anticonvulsants, iii.antiparkinsonian agents, iv. diuretics.v antiulcer agents vii. Mydriatic andmiotic agents.
3. LD_{50} determination.
4. Bio assays of Ach, Histamine, Oxytocin, Adrenaline, Pancuroniuum.
5. Use of HPLC, Spectrophotometer in estimation of drugs.
6. Knowledge of Modern Methods of Molecular Pharmacology like i.radioligand binding assay, ii.patch clamp, iii.ELISAiv.PCR and Gel Documentation.

RECOMMENDED BOOKS:

1) Ghosh M. N.: Fundamental of Experimental Pharmacology, Scientific Book Agency, Calcutta.
2) Jaju B. P., Pharmacology: A Practice Exercise Book. Japee Brothers, New Delhi.
3) Kulkarni S. K.: Hand Book of Experimental Pharmacology, VallabhPrakashan, New Delhi.
4) Perry W. L. M.: Pharmacological Experiments on Isolated Preparations, E and S, Livingston, London.
5) Sheth U. K., Dadkar N. K. and Kamat U. G.: Selected Topics in Experimental Pharmacology, Kothari Book Depot, Mumbai.
6) Thomson E. B.: Drug Bioscreening, VCH, New York.
7) Turner R. A.: Screening Methods in Pharmacology, Academic Press, London.
8) Vogel H. G. and Vogel W. H.: Drug Discovery and Evaluation: Pharmacological Assays, Springer, New York.
9) Trevor B Poole The UFAW Handbook on the care and management of laboratory animals sixth edition. Longman scientific and technical.
10) Foster H L, Small D J, Fox J G. The mouse in biomedical research Experimental biology and oncology. Academic Press.1982.
11) Suckow M A, Weisbroth S H, Franklin C. L. THE LABORATORY RAT. American Collge of laboratory animal medicine. Academic Press.Elsevier. 2006 second edition.
12) Sharp P E. C la Regina M. The laboratory rat. CRC Press. Taylor Francis.1998.
13) Rigalli A, Di Loreto V E. Experimental Surgical Models in the Laboratory Rat. CRC Press. Taylor Francis.2009.

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ADVANCED PHARMACOLOGY- III

Theory 4 hours/week

CREDITS 04

UNIT I

i. Molecular mechanisms of drug action.
ii. Receptor occupancy and cellular signalling system.
iii. G proteins
iv. Cyclic nucleotide
v. Phosphatidyl inositol.
vi. Cytokines
vii. Neuropeptides and their modulation
viii. Neurosteroids
ix. Endothelium derived vascular substances, nitric oxide
x. Phosphodiesterase and protein kinase c enzymes
xi. Arachidonic acid metabolites, COX-2 regulators and their role in inflammation
xii. Pharmacology of atrial peptides
xiii. Reactive oxygen intermediates
xiv. Antioxidants and their therapeutic implications.

UNIT II

Recent trends on different classes of receptors and drugs acting on them:

i. Adrenergic receptors
ii. Cholinergic receptors
iii. Serotonin receptors
iv. Dopamine receptors
v. Histamine receptors
vi. Opiate receptors
vii. Purinergic receptors
viii. Angiotensin receptors
ix. GABA receptors
x. Excitatory amino acid glutamate, aspartate
xi. Kinin

UNIT III

Recent trends on different classes of receptors:

i. Hormone receptors
ii. Gluccocorticoid
iii. Mineralocorticoid
iv. Oestrogen
v. Progesterone
vi. Androgen
vii. Insulin.
viii. Ion channels and their modulators
ix. Calcium
x. Potassium
xi. Sodium
xii. Chloride

UNIT IV

i. Apoptosis- Pharmacological and clinical implications
ii. Adhesion therapy- cardiac and vascular remodelling
iii. Basic concept of chronopharmacology and their implications to drug therapy
iv. Concept of gene therapy and recent developments in the in the treatment of various hereditary diseases
v. Human genome mapping and its potential in drug research.

RECOMMENDED BOOKS:

1. Avery, G.S., Drug Treatment, Adis Press, Sydney
2. Bacq Z.M., Cepek, Fundamentals of Biochemical Pharmacology
3. Barar, F.S.K., Essentials of Pharmacotherapeutics; S.Chand and Company, New Delhi
4. Bowman, W.C. and Rand, M.J.; Textbook of Pharmacology, Blackwell, Oxford
5. Craig, C.R. and Stitzel, B.E.; Modern Pharmacology, Little Brown And Co, Boston
6. Drill, V.A.; Pharmacology in Medicine, McGraw Hill, New York
7. Foreman J C, Johansen T Text book of receptor pharmacology CRC Press New York 1996
8. Goodman and Gilman; Pharmacological Basis of Therapeutics, McGraw Hill
9. Grollman Pharmacology and Therapeutics, Lea and Tebiger, Philadelphia
10. Katzung, B.G; Basic and Clinical Pharmacology, Lange Medical Publisher, USA
11. Melmon, K.L., and Morelli; Clinical Pharmacology: Basic Principle of Therapeutics, McMillan, New York
12. Rang, H.P., Dale, M.N., Pharmacology, Churchill Livingston, UK.

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ADVANCED PHARMACOGNOSY – I

Theory 4 hours/week

CREDITS 04

UNIT I

Study of information retrieval methods of natural products & herbal data base.

Phytochemical & Pharmacological literature review of:

Gymnema sylvestre
Azadirachta indica
Adathoda vasica
Asparagus racemosus
Commiphora mukul
Podophyllum hexandrum
Ocimum sanctum
Canscora decussate
Tylophora asthmatica

UNIT II

Cultivation of medicinal plants; *ex-situ* & *in-situ* cultivation, biodiversity law, WTO & TRIPS agreement. Plant breeders right, Indian & International Patent law applicable to natural products.

UNIT III

Nutraceuticals

Overview- Relationship of Food, Nutrition, Health and Disease, Current status on Relationship of Nutrition and Health Dietary Guidelines/ Food guide Pyramid/Food vs. Drugs; Defining functional Foods, Nutraceuticals and Dietary Supplement, Weight control Products and Medicinal Foods.

Antioxidants & phytochemicals & their role in prevention of specific diseases.

Nutrition laws & regulation; FDA, FPO, MPO, BIS AGMARK.

UNIT IV

Marine Drugs:

- Methods of Isolation
- Different activities reported
- New advances

RECOMMENDED BOOKS:

1. Introduction to spices, plantation crops, medicinal and aromatic plants: N. Kumar et al, Oxford & IBH Publishing Co. Pvt Ltd., New Delhi, 1997.
2. Herbal Drug Industry: R.D. Chaudhary, Eastern Publishers, New Delhi 1996.
3. Wealth of India, CSIR, New Delhi (Related Volumes).
4. Cultivation & Utilization of medicinal plants: Atal & Kapoor, RRL Jammu.
5. Cultivation & Utilization of aromatic medicinal plants: Atal & Kapoor, RRL Jammu.
6. Various Research Journals on Medicinal Natural Products.
7. Barrett, S. and Herbert, V. 1994. The Vitamoin Pushers. Prometheus Books, Amherst, N. Y.
8. Barrett, S. and Jarvis, W.T. 1993. The health Robbers. Prometheus Books, Amherst, N.Y.
9. G. Gibson and C, Williams Editors 2000 Functional foods woodhad publishers. Co. London.
10. Goldberg, I. Functional foods. 1994. Chapman and Hill, New York.
11. Tyler, V. E. 1993. The Honest herbal. Pharmaceutical Products Press, New York.
12. Shils, ME, Olson, JA, Shike, M. 1994. Modern Nutrition in health and Disease. Eighth edition. Lea and Febiger.
13. Drug & Cosmetic Act, (With latest amendments including Ayurvedic GMP), Govt. Of India.

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ADVANCED PHARMACOGNOSY – I

Practical 6 hours/week

CREDITS 03

1. Thin Layer Chromatography: Identification of alkaloids, flavonoids, steroids
2. HPLC and HPTLC: Separation of some Phytopharmaceuticals: Demonstration
3. Pharmacognostic Evaluation of crude drugs
4. Extractive value Determination
5. Volatile oil extraction – Mentha oil, eucalyptus oil, rose oil
6. Determination of heavy metals, mycotoxins, pesticidal residues
7. Spectroscopic analysis of isolated compounds
8. Flourimetric analysis of isolated compounds
9. Monograph analysis of crude drugs as per Ayurvedic Pharmacopoeia
10. Evaluation and standardization of extracts based on WHO guidelines
11. Evaluation and standardization of herbal formulations

RECOMMENDED BOOKS:

1. Quality Control of Herbal Drugs by Pulok K. Mukharjee, 1st edition, Business Horizons Pharmaceutical Publishers, New Delhi 2002.
2. Indian Herbal Pharmacopoeia Volume 1 and 2, RRL, IDMA, 1998, 2000.
3. Standardization of Botanicals by V. Rajpal, Volume 1 Eastern Publishers New Delhi 2002.
4. PDR for Herbal Medicine 2nd Edition Medicinal Economic Company New Jersey , 2000.
5. Natural Products: a lab guide by Raphael Ikan 2nd Edition Academic Press 1991.
6. Botanicals of Phytocosmetic Desk Ref by Frank S D Amelio Sr CRC Press 1999.
7. Herbal Drug Industry by R. D. Chaudhary, 1st Edition, Eastern Publisher, New Delhi 1996.
8. Trease and Evans Pharmacognosy by WC Evans 15th Edition W.B. Saunders Edinburgh New York.

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ADVANCE PHARMACOGNOSY II

Theory 4 hours/week

CREDITS 04

UNIT I

Methods of extraction: Types of extracts and standardization

Natural products as lead for new drugs: Approaches to discovery and development of natural products as potential new drugs, selection and optimization of lead compounds for further developments with suitable examples from CNS, anti-cancer, antibiotics and cardiovascular. Stereochemistry, SAR, structural modifications.

UNIT II

Steriods and Flavonoids:

Steroids: Sources, Uses and structural elucidation of cholesterol, ergosterol and stigmasterol.

Phenolics and Flavonoids: Sources, Uses, Chemistry and General methods of structural determination (chemical and spectral analysis) of quercetin, Gymnemic acid, Hesperidine.

UNIT III

Terpenoids and carotenoids:

Terpenoids: Sources, Uses, Chemistry and General methods of structural determination of Terpenoids, Structural elucidation by chemical and spectral analysis of Menthol, Curcumin, Artemisinin and Taxol.

Carotenoids: Sources, Uses, Chemistry and General methods of structural determination of Carotenoids. Structural elucidation by chemical and spectral analysis of Vitamin-A. Chemistry and sources of Lycopene, Bixin and Chlorophyll.

Alkaloids:

General method for structure elucidation. Spectral analysis and structure determination of atropine, morphine, lysergic acid, quinine and camptothecin.

UNIT IV

Biosynthetic studies on the following:

Shikimic acid pathway: Atropine and Morphine.

Acetate pathway: Anthraquinone glycosides.

Mevalonic acid pathway: Steroids, Terpenoids and Cardiac glycosides.

Methods of extraction and instrumental elucidation of phytocontituents a general idea.

RECOMMENDED BOOKS:

1. Research in education: John W.Best and James V.Kahn, Prentice Hall of India Pvt. Ltd.New Delhi,1996.
2. Quality Control of Herbal Drugs by Pulok K. Mukharjee,1st edition, Business horizons Pharmaceutical Publishers, New Delhi, 2002.
3. Standardization of Botanicals by V. Rajpal, Vol.1, Eastern publishers, New Delhi,2002.
4. Indian Herbal Pharmacopoeia, Vol.1 and 2, RRL, IDMA, 1998,2000.
5. Cultivation and Utlilzation of medicinal plants: Atal and Kapoor, RRL, Jammu.
6. Cultivation and Utlilzation of aromatic plants: Atal and Kapoor, RRL, Jammu.
7. Various Research Journals on Medicinal Natural Products.
8. PDR for Herbal Medicines. 2nd edition. Medicinal Economic, New Jearsy,2000.
9. Wealth of India, CSIR, New Delhi (Related Volumes).

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ADVANCED PHARMACOGNOSY II

Practical 6 hours/week

CREDITS 03

1. Phytochemical screening of plant extracts and drugs.
2. Isolation, separation, purification and identification of important phytoconstituents belonging to different classes:
   a) Starch, Amylose and Amylopectin
   b) Myristicin and trimyristicin from Nutmeg
   c) Eugenol from Clove
   d) Genistein from Soyabean
   e) Lycopene from Tomato
   f) Curcumin from Turmeric
   g) Sennosides from Senna
   h) Glycyrrhizin from Glycyrrhiza
   i) Strychnine and Brucine or quinine or nicotine or piperine or hesperidine.
3. Antimicrobial screening of plant extracts and drugs.
4. Screening of drugs for microbial counts.

RECOMMENDED BOOKS:

1. Cultivation of medicinal and aromatic crops, 1st edition by A.A. Farooqui and B.S. Sreeramu, University Press 2001.
2. Medicinal Plants of India, 1st edition by S.N. Yoganarsimhan, Interline Publishing Pvt, LTD 2000.
3. Medicinal Natural Products (a biosynthetic approach) 1st edition by Paul M. Dewick, John Wiley and Sons Ltd England 1998.
4. Pharmacopoeial methods for Ayurvedic Formulation CCRAS, Govt. of India
5. Ayurvedic pharmacopoeia, Govt. of India
6. Indian Herbal Pharmacopoeia: Both volumes, IDMA

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ADVANCED PHARMACOGNOSY III

Theory 4 hours/week

CREDITS 04

UNIT I

Plant Extract Types, preparation and their importance, methods of standardization of various extracts. Use of chemical and biological markers for standardization.

Isolation and Estimation of phytopharmaceuticals.

UNIT II

Regulatory guidelines for herbal drugs. (Indian and international)

Different methods (including Industrial) for isolation estimation of phytoconstituents from the following drugs (with special emphasis on HPLC and HPTLC)

1. *Acorus calamus*
2. *Aloe barbadensis* - Aloin
3. *Adhatoda vasica* –Vasicin
4. *Andrographis paniculata* – Andrographolide
5. *Azadirachta indica*
6. *Bacopa monieri* – Bacosides
7. *Curcuma longa* –Curcuminoids
8. *Garcinia cambogia* α *– hydroxyl citric acid*
9. *Glycyrrhiza glabra* – Glycyrrhzinic Acid, Derivatives
10. *Gymnema sylvestre* – Gymnemic Acid
11. *Mucuna pruriens* – L Dopa
12. *Phyllanthus amarus* – Phyllanthin
13. *Piper nigrum/ longum* – Piprrine
14. *Picrorrhiza kurroa* – Kutkin
15. *Polygala senga/ tennuifolia/ chinesis* – total triterpenoid Saponins
16. *Psoralea corylifolia* – Psoralin
17. *Tinospora cardifolia* - Cordifolioside
18. *Tribulus terestris* – Total saponins
19. *Valeriana walichii* – Valepotriates
20. *Withania somnifera*- Withanolides
21. *Zingiber officinalis*- Gingerol
22. *Coleus forskolii*- Forskolin
23. *Commiphora mukul*- Guggulosterone
24. *Trigonella foenum graceum*- Saponins
25. *Ocimum sanctum*- Ursolic acid

Shelf life studies, Protocol to study stability of herbal based products, Approaches for both physical, Physicochemical and chemical parameters of assessment at different stages.

UNIT III

Herbal Cosmetics

Raw materials of herbal origin used in cosmetics, oils, waxes, gums, hydrophilic colloids, perfumes, protective agents, bleaching agents, preservatives, anti oxidants.

Formulation aspects of incorporating herbal extracts in various preparations like skin care creams, deodorants, hair care preparations.

UNIT IV

Herbal Based Industry

Study of infrastructure, staff requirement, project profile, plant and equipment, processing research and development.

Drug herb interaction, types of interaction examples quality of evidence and significance.

Examples and case study of herbal listed above.

Standardization of ayurvedic formulations.

RECOMMENDED BOOKS:

1. Ayurvedic Formulary of India, Govt. of India, 1962
2. Pharmacognosy : Trease W. C.,Evans G. E. Bailliere & Tindall, London, 14th edition
3. Natural Products :A Lab guide by Raphael Ikhan 2ndEdition academic Press,1991.
4. Botonicals A Phytocosmetic Desk by Frank S D 'Amelio Sr CRC Press, 1999.
5. Indian Herbal Pharmacopoeia, Vol. 1 & 2, RRL, IDMA, 1998, 2000.
6. Quality Control of Herbal Drugs by Pulok K. Mukherjee, 1st edition, Business Horizons Pharmaceutical Publishers, New Delhi 2002.
7. PDR for Herbal Medicines, 2nd Edition, Medicinal Economic Company, New Jersey 2000.
8. Wealth of India, CSIR, New Delhi (Related Volumes).
9. British Herbal Pharmacopoeia, (Vol., 1,2,3) Her Majesty's Services, UK.
10. Various Research Journals on Medicinal Natural products.

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ADVANCED QUALITY ASSURANCE TECHNIQUES I

Theory 4 hours/week

CREDITS 04

UNIT I

I. Personnel :

1. Qualification, Experience and Training.
2. Key Persons and their responsibilities.
3. Personnel Hygiene and clothing.
4. Legal Aspects and Consultants.

II. Buildings and Facilities :

1. Manufacturing facilities and surrounding areas.
2. Plumbing and drainage systems.
3. Sewage,refuge and disposal of waste.
4. Washing and toilet facilities.
5. Sanitation and maintenance of sanitation system.

III. Equipment :

1. Design,site location and construction.
2. Cleaning,Operation and maintenance of equipments.

UNIT II

I. Materials :

1. Purchasing
2. RM/PM/Int./Bulk and Finishing Products
3. Reference and working standards.
4. Miscellaneous and waste materials.

II. Outsourcing :

1. Outsourcing of manufacturing operations.
2. Outsourcing of analytical services.
3. Outsourcing of other services.

UNIT III

I. Quality Management :

1. Concepts of QA/QC/cGMP.
2. Key activities in quality management function as per cGMP guidelines.

II. Post Operational Activities :

1. Distribution :
2. Recalled, Returned Rejected and Recovered Products
3. Product Complaints.

III. Inspection :

WHO guidelines on inspection of Pharma MFG. Facilities.

UNIT IV

I. Manufacturing Operations and Control :

1. Sanitation of Manufacturing Premises.
2. Control of Mix-ups and Cross Contamination.
3. Processing of in process and bulk products.

4. Packaging and labeling operations
5. I.P.Q.C. activities
6. Release of finished products.
7. Process Deviations.
8. Charge in of components.
9. Time Limitation on production.
10. Drug Product Inspections.
11. Expiration dating.
12. Calculation of yields.

II. Sterile Pharmaceutical Activities :

Manufacturing and Q.A. aspects of sterile Pharmaceutical Products.

III. CGMP guidelines for biological products :

Manufacturing and Q.A. aspects of Biological Products.

RECOMMENDED BOOKS :

1. Pharmaceutical Quality Assurance by M.A.Potdar Nirali Prakashan, Pune
2. Current Good Manufacturing Practices for Pharmaceuticals by Prof.M.A.Potdar B.S.Publications Hydrabad.
3. Good Manufacturing Practices by S.H.Wills and J.R.Stoker Marcker and Dekker Incorporations.
4. Selected International, GMP guidelines of various countries like UK, USA, Australia, South Africa.WHO.India. & ICH guide lines.

ADVANCED QUALITY ASSURANCE TECHNIQUES I

Practical 6 hours/week

CREDITS 03

Designing of the following key documents :

1. Site master file
2. SOP on SOP
3. MPCR/BPCR (for sterile and non sterile products)
4. Change control format
5. Product complaint document
6. Internal audit document
7. Product recall document
8. I.P.Q.C document
9. Warehousing documents
10. System suitability test document

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ADVANCED QUALITY ASSURANCE. TECHNIQUES II

Theory 4 hours/week

CREDITS 04

UNIT-I

I. Introduction to Pharmaceutical Validation:

a) F.D.A guidelines.
b) Definition of process validation and its importance.
c) Scale up of process validation.
d) Organisation of process validation.

II. Master Plans:

a) Validation Master Plan.
b) Calibration Master Plan.

III. Validation of solid dosage forms, tablets and capsules.

UNIT-II

1. Vendor certification.
2. Cleaning validation.
3. Computer system validation.
4. Validation of sterilization process & Injectable formulations.

UNIT- III

1. Prospective, retrospective, concurrent and revalidation.
2. Analytical method validation.
3. Validation of equipment and facilities, HVAC and water systems.

UNIT- IV

1. Process validation and Quality assurance.
2. Validation in contract manufacturing.
3. Harmonization, cGMP and validation.

RECOMMENDED BOOKS:

1. Pharmaceutical process validation by Robert Nash and A.H Wacther Marcel and Dekker Inc. Vol. 129
2. Validation of pharmaceutical process (sterile products) by F.J Carleton and J.P Agalloco Marcel and Dekker Inc.
3. Pharmaceutical Q.A by Professor M.A Potdar Nirali Prakashan, Pune.
4. Current good manufacturing practices by Professor M.A Potdar B.S publications, Hyderabd.

ADVANCED QUALITY ASSURANCE TECHNIQUES II

Practical 6 hours/week

CREDITS 03

A. Validation of following equipment

1. Autoclave
2. Hot air oven
3. Powder mixer (dry)
4. Tablet compression machine
5. Fluidised bed drier

B. Validation of processing area

(developing room description chart and unfolded room diagrams)

C. Cleaning validation of an equipment and facility.

D. Validation of any two analytical instruments.

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ADVANCED QUALITY ASSURANCE TECHNIQUES III

Theory 4 hours/week

CREDITS 04

UNIT I

I. Basic concepts of Quality

(1) Historical background
(2) Definitions of Quality
(3) The quality function
(4) Managing quality

II. Quality improvement and cost reduction

(1) Sporadic and chronic problems
(2) Product by Product approach
(3) Introduction to six sigma improvement
(4) Concepts of continuous improvement

UNIT II

I. Quality Control

(1) Definitions of Control
(2) Measurement
(3) Self Control
(4) Six step control procedure

II. Organization for Quality

(1) Evolution of organization for Quality
(2) Co-ordination of Quality activities
(3) Role of upper management and quality director
(4) Role of middle management and workfoce
(5) Concept of teams in organizing quality
(6) Quality project management

UNIT III

I. Developing quality culture

(1) Technology and Culture
(2) Motivation theories of MASLOW and McGregor
(3) Corporate quality culture
(4) Quality goals and their management
(5) Self development and empowerment

II. Quality Assurance

(1) Defination of Q.A.
(2) Quality audits
(3) Human relations in auditing
(4) Reporting audit results and taking corrective actions.

III. Quality in Manufacturing

(1) Lean manufacturing and value stream management
(2) Initial planning for quality
(3) Automated manufacturing
(4) Manufacturing planning
(5) Quality management in manufacturing operations

UNIT IV

I. Inspection test and measurement

(1) Inspection planning
(2) Seriousness Classification
(3) Automated inspection and inspection accuracy
(4) Acceptance sampling and quality indexes
(5) Sampling plan

II. Statistical Process Control

(1) Definitions and advantages of SPC
(2) Statistical control charts
(3) Pre- control
(4) Process capability
(5) Measuring process performance
(6) SPC and quality improvement

RECOMMENDED BOOKS

(1) Quality planning and analysis. By J. M. Juran and F.M. Gryna Tata Mcgraw Hill India. 5th Edition
(2) Improving quality through planned experimentation By Moen.Tata Mcgraw Hill India.
(3) Statistical Process Control By Grant. Tata Mcgraw Hill India.

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ADVANCED PHARMACEUTICAL BIOTECHNOLOGY I

Theory 4 hours/week

CREDITS 04

UNIT I

Molecular and genetic mechanisms, Genes and Chromosomes

Nucleic acids and their structure, DNA replication, Central Dogma of Molecular Biology, Sequencing methods; Enzymatic DNA sequencing; Chemical sequencing of DNA; Automated DNA sequencing; Transcription-structure of mRNA and tRNA, Splicng-translation-post transcriptional modifications. Chromosomal organization and morphology in eukaryotes and prokaryotes, exons and introns, mobile and organelle DNAs, nucleosome-structure and spatial organization, histones, transposons

UNIT II

Tools of Genetic Engineering

Restriction Enzymes; DNA ligase, Klenow enzyme, T4 DNA polymerase, Polynucleotide kinase, Alkaline phosphatase; Cohesive and blunt end ligation; Linkers; Adaptors; Labeling of DNA: Hybridization techniques: Northern, Southern and Colony hybridization, Fluorescence *in situ* hybridization; DNA-Protein Interactions-Electromobility shift assay, Cloning Vectors: Plasmids; Bacteriophages; M13 vectors; PUC19 and Bluescript vectors, Phagemids; Lambda vectors; Insertion and Replacement vectors; Cosmids; Artificial chromosome vectors (YACs; BACs); Animal Virus derived vectors-SV-40; vaccinia/bacculo & retroviral vectors; Expression vectors; pMal; GST; pET- vectors; Protein purification; His-tag; GST-tag; MBP-tag etc.; Intein-based vectors; Inclusion bodies; Methodologies to reduce formation of inclusion bodies; Baculovirus and Pichia vectors syste

UNIT III

Cloning Methodologies

Insertion of foreign DNA into host cells; Transformation; Construction of libraries; Isolation of mRNA and total RNA; cDNA and genomic libraries; cDNA and genomic cloning; Expression cloning; Yeast two hybrid system; Phage display; PCR: Primer design; Taq DNA polymerases; Proof reading enzymes; Types of PCR – multiplex, nested, reverse transcriptase, real time PCR, touchdown PCR, hot start PCR, colony PCR, cloning of PCR products; PCR in molecular diagnostics;

UNIT IV

Applications of Genetic Engineering

Site specific mutagenesis; rDNA technology for the production of therapeutic protins, production of recombinant insulin, Blood products: Erythropoietin, human serum albumin, Recombinant vaccice: Hepatitis B surface antigen, Regulatory proteins: growth hormones, interferon, Stability of rDNA procucts

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ADVANCED PHARMACEUTICAL BIOTECHNOLOGY I

Practical 6 hours/week

CREDITS 03

Experiments: Recombinant DNA Technology lab

1. Analysis of DNA by agarose gel electrophoresis,
2. Isolation of plasmid DNA by Alkali lyses method
3. Isolation of mammalian DNA form blood
4. Restriction enzyme digestion Isolation of genomic DNA from bacteria/animal tissue (to show partial and complete digestion).
5. Isolation of total RNA /poly A mRNA
6. DNA amplification through Polymerase Chain Reaction using random and gene specific primers
7. DNA ligation

RECOMMENDED BOOKS:

1. Lenin's Genesx. Kreb JE, Goldstein E.S., Kilpatrick S.T. (2011) Jores and Bartlett Pyblishers, M.A., USA, Ol 1776
2. Watson J and Stephen (2004) Molecular Biology of the Gene, Dorling Kindersley (India) Pvt. Ltd. New Delhi Tylor and French group New York.
3. Cooper G.M. and Hausman R.E.(2004).The Cell: A Molecular approach, Sinauer Associates, Inc. ASm Press, Washington D.C.

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ADVANCED PHARMACEUTICAL BIOTECHNOLOGY II

Theory 4 hours/week

CREDITS 04

UNIT I

Fundamental concepts of the immune system

Basics of Immunology. Components of cell mediated and humoral immunity. Components of innate and acquired immunity; MHC genes, Antigen processing and presentation; MHC and immune responsiveness and disease susceptibility, different MHC molecules Phagocytosis; Complement and Inflammatory responses; Haematopoesis; maturation of different immune cells. Antigens - immunogens, haptens; Active and passive immunization

UNIT II

Molecular basis of Immune response

Immunoglobulins, class, sub-class and structure, Immunoglobulin superfamily, affinity, avidity. Allotype, Idiotype, Isotype, Antibody genes and antibody diversity, monoclonal and polyclonal antibody, Precipitation, agglutination, opsonization and complement mediated immune reactions; Different immunological techniques - RIA, ELISA, Western blotting, ELISPOT assay, immunofluorescence, and flow cytometry, recombinant DNA and protein based vaccines, adjuvants

UNIT III

Enzyme technology

Dynamics of enzyme activity, enzyme kinetics, sources of enzymes, Pharmaceutical, therapeutic and clinical applications of enzymes. Protein engineering in enzyme improvements, Immobilization of enzymes, methods of immobilizaion, whole cell immobilization and its applications

UNIT IV

Bioprocess Engineering:

Kinetics of cell/microbial growth, substrate utilization and product formation; Simplestructured models; Sterilization of air and media; Batch, fed-batch and continuous processes; Aeration and agitation; Mass transfer in bioreactors; Rheology of fermentation fluids; Scale-up concepts; Design of fermentation media; Various types of microbial and enzyme reactors; Instrumentation in bioreactors.

RECOMMENDED BOOKS:

1. Kuby, RA Goldsby, Thomas J. Kindt, Barbara, A. Osborne Immunology, 6th Edition, Freeman, 2002.
2. Brostoff J, Seaddin JK, Male D, Roitt IM., Clinical Immunology, 6th Edition, Gower Medical Publishing, 2002.
3. Janeway et al., Immunobiology, 4th Edition, Current Biology publications., 1999.
4. Paul, Fundamental of Immunology, 4th edition, Lippencott Raven, 1999.

ADVANCED PHARMACEUTICAL BIOTECHNOLOGY II

Practical 6 hours/week

CREDITS 03

Experiments:

1. cDNA amplification by RT-PCR, form isolated RNA
2. Preparation of competent cells for transformation
3. Bacterial transformation, Selection of recombinant colonies
4. Detection of SNPs in specific DNAs
5. Bacterial fermentation for production of recombinant protein
6. Basic Bioinformatic tools
7. *In silico* analysis of DNA sequences

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ADVANCED PHARMACEUTICAL BIOTECHNOLOGY III

Theory 4 hours/week

CREDITS 04

UNIT I

Control of gene expression and epigenetics

Introduction of DNA into mammalian cells; Transfection techniques; Gene silencing techniques; Introduction to siRNA technology; Micro RNA; Construction of siRNA vectors; Principle and application of gene silencing; Gene knockouts and Gene Therapy; Creation of knockout mice; Disease model; Somatic and germ-line therapy- *in vivo* and *ex-vivo*; Suicide gene therapy; Gene replacement; Gene targeting; Transgenics; cDNA and intragenic arrays; Differential gene expression and protein array.

UNIT II

Introduction to the human genome project and Pharmacogenomics

Physical mapping and sequencing of the genome; Sequence analysis, comparative homologies; Evolutionary changes and single nucleotide polymorphism; Expression: analysis of expressed genes

UNIT III

Animal cells and culture techniques

Characteristics of animal cells: Metabolism, regulation and nutritional requirements for mass cultivation of animal cellcultures; Kinetics of cell growth and product formation and effect of shear force; Product and substrate transport; Micro & macro-carrier culture; Genetic engineering in animal cell culture; Animal cell preservation.

UNIT IV

Bioinformatics:

Introduction to Human genome and bioinformatics resources (NCBI, EBI, ExPASy); Sequence and structure of the databases; Sequence analysis (biomolecular sequence file formats, sequence alignment, phylogeny); Online tools and their application, ORF finder, BLAST etc. Genomics and Proteomics (Large scale genome sequencing strategies; Comparative genomics; Understanding DNA microarrays and protein arrays); Molecular modeling and simulations (basic concepts including concept of force fields).

RECOMMENDED BOOKS :

a). Watson J and Stephen (2004) Molecular Biology of the Gene, Dorling Kindersley (India) Pvt. Ltd. New Delhi Tylor and French group New York.

b) Freshney R. Ian, "Culture of animal cells: A manual of Basic Technique", Willey-Liss Publisher, 5th edition (2005). Morgan, Animal Cell Culture-Biotol Series,1993

c) Voet D, Voet JG & Pratt CW, Fundamentals of Biochemistry, 2nd Edition. Wiley 2006

Brown TA, Genomes, 3rd Edition. Garland Science 2006

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PHARAMCEUTICAL REGULATORY AFFAIRS – I

Theory 4 hours/week

CREDITS 04

UNIT I

Overview of GMP guidelines with specific reference of World health organization (WHO), Medicines and Healthcare products Regulatory Agency (MHRA), Medicines control council (MCC), Therapeutic goods administration (TGA) and ANVISA Brazil guidelines and Japanese regulation.

UNIT II

International organization for standardization (ISO): Fundamentals of quality management system.

Pharmaceutical management, Material management, Documentation control, Market Complaints and recalls, GMP audits, Pharmaceutical Total Quality System (Quality by Design (QBD).

UNIT III

ICH Guidelines, overview of QSEM classification and related guidance. Detailed study of stability, analytical validation, impurities, pharmacopeias, specification, quality risk management and pharmaceutical development.

UNIT IV

Preparation of Common technical document (CTD) as per ICH guidelines, electronic documentation and e-filing (e-CTD).

Guidelines for reporting adverse drug reaction in various countries.

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.

PHARAMCEUTICAL REGULATORY AFFAIRS – I

Practical 6 hours/week

CREDITS 03

1. Preparation stability protocol and stability report.
2. Accelerated stability studies of marketed products as per ICH Guidelines.
3. Dossier preparation as various countries guidelines.
4. Preparation of SOP's for operation of manufacturing and analytical equipments.

RECOMMENDED BOOKS AND REFERENCES :

1. Willing, Tuckerman and Hitchings, Good Manufacturing Practices for Pharmaceuticals
2. Common Technical documents (ICH guidelines).
3. ISO Guidelines
4. The Gazettes of India. The Drug and Cosmetics Act and Rules and its Latest amendments.
5. The Gazettes of India. The Patent Act 1970 and its Latest amendments.
6. WHO GMP guidelines
7. www.ich.org
8. www.anvisa.gov.
9. www.picscheme.org
10. www.mhra.gov.uk
11. www.tga.gov.au
13. www.mccza.com
14. www.who.int
15. www.ep.espace.net

PHARAMCEUTICAL REGULATORY AFFAIRS – II

Theory 4 hours/week

CREDITS 04

UNIT I

Requirements of cGMP with specific reference of USFDA (21 CFR part 210 and 211), European Medicines Agency (EMEA) guidelines.

UNIT II

Requirements for registration of pharmaceutical products into USA with emphasis on para I, II, III & IV filing. Preparation of documents for approval of IND, NDA, ANDA, BLA applications and export registration (USFDA 21 CFR part 310, 312, 314, 320). Biowaivers. Understanding the FDA 505(b)(2) Regulatory Approval Pathway, Hatch-Waxman act.

UNIT III

Brief Guidance for Industry: CMC related to all dosage forms and Scale - Up and Post approval Changes (SUPAC)-Chemistry, Manufacturing and Controls, In Vitro Release Testing, and In Vivo Bioequivalence Documentation.

UNIT IV

Registration of product in European market: New drug product and generic product.
Preparation of dossier of Drug product and Drug master file.

In vitro BA/BE Clinical

Brief Guidance for Industry: Dissolution testing of immediate release solid oral dosage forms.
Guidance for Industry: Extended release oral dosage forms: Development, evaluation and application of In Vitro/In Vivo Correlations.
Guidance for Industry: Waiver of In Vivo Bioavailability and Bioequivalence Studies for
Immediate-Release Solid Oral Dosage Forms Based on a Biopharmaceutics Classification System

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PHARAMCEUTICAL REGULATORY AFFAIRS – II

Practical 6 hours/week

CREDITS 03

1. Comparison of dissolution profiles and calculation of F1 and F2 values of tablets of innovator/standard and generic manufacturers.
2. Comparison of In-vitro release and calculation of F1 and F2 values of semisolid preparations of innovator/standard and generic manufacturers.
3. Preparation dossier of a pharmaceutical product.
4. Preparation of MFR, BPR and packaging record for manufacturing of various dosage forms.
5. Dossier preparation for US and European market a) Product without BA and BE, b) Products with clinical data.
6. Evaluation of some Orange Book (OB) patents from PARA IV filing prospective.

References Recommended:

www.emea.europa.eu
www.fda.gov

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PHARMACEUTICAL REGULATORY AFFAIRS - III

Theory 4 hours/week

CREDITS 04

UNIT I

The Drugs and Cosmetics act, 1940 and Rules with emphasis on Good laboratory practices and requirements of premises and equipments (Schedule L-I), Good manufacturing practices for pharmaceutical products (Schedule M), Good manufacturing practices for homeopathic medicines (Schedule M-I), Requirements of factory premises for manufacture of cosmetics (Schedule M-II), Good manufacturing practices for Ayurvedic, Siddha and Unanni medicines (Schedule T). Regulatory requirements for nutraceuticals. ISI standards of cosmetics.

UNIT II

Requirements for registration of pharmaceutical products into India. Preparation of dossier for product registration as per Indian legislative requirements**.**

UNIT III

Documentation: Master formula record (MFR), Master formula card (MFC), Batch processing record (BPR), Packaging records, Standard operating procedure (SOP), Site master file, specifications, Certificate of analysis (COA), Material safety data sheet (MSDS), Method of Analysis (MOA), Annual product review, validation protocols, Stability protocol, T- License, forms, maintenance of records in Pharmaceutical industry.

UNIT IV

Regulatory requirements and guidelines for permission to import and/or manufacture of new drugs for sale or to undertake clinical trials (schedule Y).

Regulatory requirements for packaging material– Pharmacopoeial requirements, D & C act & rules, Weight & Measure acts, DCGI / DPCO guidelines, FDA guidelines and various other foreign regulatory guidelines.

Books and References Recommended:

1. Vijay Malik, Law relating to Drugs & Cosmetics.
2. The Gazettes of India. The Drug and Cosmetics Act and Rules and its Latest amendments.
3. The Gazettes of India. The Patent Act 1970 and its Latest amendments.

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ELECTIVES

1. STERILE PRODUCT FORMULATION AND TECHNOLOGY

Theory 4 hours/week

CREDITS 04

UNIT I

1. **Preformulation:** Physico-chemical properties of materials used in parenteral formulations, selection of polymeric components, selection of packaging components.
2. **Formulation of SVP and LVP:** Requirement, components, materials, Pharmacopoeial requirements, special types of parenterals such as suspensions, emulsions, dried forms, sterile diagnostics and radiopharmaceuticals.

UNIT II

3. **Ophthalmic Products:** Ocular anatomy and physiology relevant to ocular drug delivery, ocular pharmacokinetics, conventional ophthalmic products, ocular inserts.
4. **Sustained Release Parenterals:** Liposomes, and niosomes, polymeric nanoparticles, lipid nanoparticles, implants, loaded erythrocytes.

   Delivery systems for Proteins and peptides

UNIT III

5. Environmental Control: Temperature and humidity control, air handling systems and their validation.
6. Industrial sterilization: large scale sterilization processes, process selection, specifications, development and validation of process and equipments.

UNIT IV

7. Guidelines: Overview of GMP and regulatory guidelines.

RECOMMENDED BOOKS :

1) K.E. Avis, H. A. Liberman 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 Deker.
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.

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2. NOVEL DRUG DELIVERY SYSTEMS

Theory 4 hours/week

CREDITS 04

Design, development, manufacture and evaluation of the following novel drug delivery systems:

UNIT I

a. Oral Drug Delivery Systems: Osmotic DDS, Ion exchange controlled DDS, Hydrodynamically balanced DDS

b. Mucosal DDS: Physiological basis of mucosal delivery with reference to oral mucosal, nasal, vaginal and rectal routes. Bioadhesion and bioadhesive polymers, DDS for mucosal administration. In-vitro, ex-vivo and in-vivo evaluation techniques.

c. Microspheres: Methods to obtain microcapsules/ microspheres, their evaluation and applications.

UNIT II

d. Transdermal DDS: Percutaneous absorption and penetration enhancers, development of transdermal gels, patches with reference to components and evaluation. Iontophoretic and Sonophoretic DDS.

e. Ocular DDS –Design of CR ophthalmic DDS including gels, inserts, novel DDS and evaluation.

f. Parenteral DDS: CR Injectables, implants etc. development and evaluation

UNIT III

g. Colloidal DDS: Specialized DDS like micro / nano emulsions, SMEDDS, Multiple emulsions, liposomes, niosomes, polymeric micelles, and other vesicular DDS, their design and development into final dosage forms, issues and consideration

h. Nanoparticulate systems such as lipid nanoparticles and polymeric nanopartciles: Methods of preparation, characterization and applications

i. Peptide and protein based DDS: Chemistry and special features of peptide and protein molecules, stability, Challenges in protein/ peptide delivery, Formulation approaches and evaluation of peptide and protein delivery; Routes of delivery, Toxicity, immunogenicity, vaccines and gene based DDS

UNIT IV

j. Pulmonary DDS – Physiological basis and formulation considerations. Design of Pressurized aerosols, Dry powder DDS, Devices for administration and evaluation.

k. Targeted DDS: Concept of drug targeting, need for drug targeting , basis for drug targeting both active and passive. Ligands for targeted delivery, Monoclonal antibodies in targeted delivery, design of targeted DDS for cancer and infectious diseases, brain targeting, Colon targeting approaches and DDS

RECOMMENDED BOOKS :

1) P. Tyle, drug Delivery Devices, fundamental and applications, Marcel Dekker.

2) Morton rosoff, Controlled release of drugs, VCH Publishers.

3) D.W. Osborne, and A.H. Amann, topical drug delivery formulations, Marcel Dekker.

4) P. Tyle Drug delivery devices, Marcel Dekker

5) Barry, Dermatological formulation, Marcel Dekker

6) Robinson, Novel Drug Delivery systems, Marcel Dekker

7) N.K. Jain, Controlled and Novel Drug delivery, CBS Publisher, New Delhi.

8) P. Johnson and J.G. Lloyd – Jones, Drug Delivery Systems, VCH Publisher

9) P. Tyle and B.P. Ram, Targeted Therapeutic systems, Marcel Dekker

10) C.G. Wilson and N. Washington, Physiological Pharmaceutics, Ellis Horwood Limited

11) H.S. Bean, A.H. Beckett, and J.E. Carless, Advances in Pharmaceutical Sciences vol. 5 Academic Press.

12) R.O. Potts, and R.H. Guy, Mechanisms of Transdermal Drug delivery, Marcel Dekker.

13) T.J. Roseman and S.Z. Controlled release delivery systems, marcel Dekker.
14) A.J. Hickey, Pharmaceutical Aerosol Technology, Marcel Dekker.
15) J. Kreuter, Controlled drug delivery systems, Marcel Dekker
16) K.S.E. Su and S.F. Chang, Nasal systemic drug delivery, Marcel Dekker
17) A.F.Kydonieus, Controlled release technologies : methods, theory and applications vol. I & II, CRC Press inc.
18) Y.W. Chein, Trasdermal controlled systemic medication, Marcel Dekker
19) P.B. Deasy, Microencapsulation and related drug processes, Marcel Dekker.

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3. BIOPHARMACEUTICS AND PHARMACOKINETICS

Theory 4 hours/week

CREDITS 04

UNIT I

1. Absorption: Cell membrane, absorption mechanisms, oral drug absorption, pH-partition hypothesis. Factors affecting: physico-chemical, dosage form related, patient related. Drug absorption through other routes, transdermal, nasal, buccal, ocular, and sublingual. In-vitro, in-situ and in-vivo models for drug absorption studies. ABC transporters. Animal Tissue culture Technique for drug absorption studies.
2. Distribution: Tissue permeability of drugs, barriers to distribution of drugs. Factors affecting drug distribution, physicochemical properties of drugs, volume of distribution, Drug - protein binding, drug tissue binding, factors affecting protein drug binding. Kinetics of drug protein binding significance of drug tissue binding.

UNIT II

3. Metabolism :Drug metabolism organs and enzymes, chemical pathways Phase-I and Phase-II reactions. First pass effect, factors affecting metabolism
4. Excretion:Renal and nonrenal routes of drug excretion, concept of clearance. Factors affecting excretion mainly renal excretion.

UNIT III

5. Pharmacokinetics:Pharmacokinetics in drug discovery and development, Pharmacokinetics models, Laplace transformations and concept of compartment modeling.
6. One compartment model : intravenous injection, intravenous infusion, First order absorption (Urinary and plasma data)
7. Multicompartment models. Intravenous injection, intravenous infusion, first order absorption, multidosing data.
8. Non-linear Pharmacokinetics Michaelis- Menten kinetics, estimation of K_m and V_m, Area under curve, enzyme induction.
9. Non compartmental analysis - statistical moment theory Integration with Kinetics : Interrelationships between pharmacokinetics parameters and physiological variables.

UNIT IV

10. Application of Pharmacokientic: Multiple dosing, controlled release dosage form, dose adjustment in renal failure, haemodialysis, individualization, monitoring drug therapy, chronipharmacokientics.
11. Bio-availability and Bioequivalence: Study design, protocols and regulatory requirements and statistical consideration in data analysis

RECOMMENDED BOOKS :

10. J.B.Blanchard, R.J. Sawchul and B.B.Brodie, Principle and Perspectives in Drug bioavailability, K. Karger Publication.
11. M. Gibald and Perrier, Pharmacokientices, Marcel Dekker.
12. M.Rawland and T.N. Tozer, Clinical Pharmacokinetics, Waverly Publications
13. P.Jenner and B. Testa, Concepts in drug metablism, Marcel Dekker
14. D.M. Brmhankar and S.B.Jaiswal, Biopharmaceutics and pharmacokientis A Treatise, Vallabh Prakashan.
15. Jean - Pierre Labaune, Hand book of pharmacokinetics, John Wiley & sons.
16. B. Testa, Advances in drug research, Vol. 19, Academic Press.
17. R.E. Notari; biopharmaceutics and clinical Pharmacokinetics; Marcel Dekker.
18. P.G. Welling and F.L.S. Tse; Pharmacokinetics, regulatory- Industrial Academic perspectives, Marcel Dekker.

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4. INDUSTRIAL PHARMACY AND PRODUCTION MANAGEMENT

Theory 4 hours/week

CREDITS 04

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 acquizition, 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 Wiely 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.Will 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(I) Pvt. Ltd.

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5. PACKAGING TECHNOLOGY

Theory 4 hours/week

CREDITS 04

UNIT I

1. **S**tatus and scope in Pharmaceutical Industry
2. **Elements of packaging :** Purpose, types of packaging material: primary and secondary and special types, functions of packaging.
3. Primary Packaging Material:
   a. Glass containers (ampoules, vails and bottles) metals (tins for consmetic powders, tubes for skin and ophthalmic ointments, Aluminium containers and foils), Fibers board and paperboard for bulk packaging in containers and drums).
   b. Containers and laminations of the metal containers Films and Foils- including AL, PVC, used ins trip packaging and blister packaging of tablets, cellulosics and cellophone.
   c. Plastic- polymers and copolymers, electrosetting and thermoforming (Medium and high density polystyrene PET)
   d. Equipment in primary packaging including strip packing, blister packing powder filling , liq filling, aerosol filling, snap on closures.
   e. Sterilization of primary packaging material by gamma irradiation.

UNIT II.

4. a. Secondary Packaging Materials: Folding cartons and set of boxes, Materials of construction, design and specifications-corrugated fiberboard, Packaging inserts- specifications and test methods and quality control.
   b. Cushioning–Cushioning materials, applications for impact, vibrations, temperature and humidity closures, applicatures fasteners and adhesives- cap threads, cap liners, aluminium bands, shrink brands, stoppers and plugs, tapes, adhesives.
   c. Shrink Warp Process

UNIT III

5. Specifications, quality control tests and methods and evaluation of packaging of materials.
6. Labels and labeling
   a. Direct printing heat transfer, ordinary labels, adhesives
   b. Standards and Quality Control test including dimensions printing and lists such as folding test, gluing, ageing, block vibration and shock for the boxes
   c. Toxicity and safety of printing inks

UNIT IV

7. Sterilization of containers:

   Different methods of sterilization for containers (primary) including autoclaving, dry heat, gas sterilization, ionizing and non-ionizing radiations

8. Quality Control, Stability, Safety and Environmental consideration.

   Law and regulation governing packaging

RECOMMENDED BOOKS:

1. J. F.Hanlon; Handbook of Package Engineering; Mc-Graw Hill book Company.
2. Lockhart H; Packaging pharmaceutical and health care.
3. K. Harburn;Quality Control of Packaging Materials in the Pharmaceutical Industry;. Marcel Dekker.

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6. COSMETICOLOGY

Theory 4 hours/week

CREDITS 04

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 V.C. 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.

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7. IMMUNOPHARMACOLOGY AND IMMUNOASSAYS

Theory 4 hours/week

CREDITS 04

UNIT I

1) Basic Principles :
   - i. Cells of the immune system.
   - ii. Non specific immunity
   - iii. The specific immunologic response Antigens and antigen-body binding
   - iv. Immunologlobulines
   - v. The humoral immune response
   - vi. The cellular immune response
   - vii. The control of immune response
   - viii. The complement system
2) Pharmacological aspects of clinical conditions involving immunological mechanism
   - i. Hypersensitivity
   - ii. Delayed hypersensitivity
   - iii. Immunomodulators

UNIT II

i. Current concepts in therapy and research of drugs for :
ii. Acquired Immuno Deficiency Syndrome (AIDS)
iii. Tissue transplantation (Immunosuppresants and immunoenhancers)
iv. Cancer
v. Vaccines and sera
vi. Antifertility drugs and vaccine
vii. Drug allergy

UNIT III

i. Methods for (invitro and invivo) evaluation of influencing immune system drugs
ii. Biochemical tests used in immunology laboratory
iii. Radio immunoassays (RIA), Enzyme multiplied Immuno assay techniques (EMIT)
iv. Fluoroscencepolarisation Immunoassay (FPIA)
v. Enzyme linked Immunosorbent Assay (ELISA)
vi. Apoenzyme - Reactivation Immunoassay (NIIA)
vii. Substrate labeled flouroscence immunoassay (SLFIA)
viii. Prosthetic group labeled Immunoassay (PGLI)
ix. Immunomodulators of Indigenous origin (plants)

UNIT IV

Fc Receptors

i. Introduction, structure and function of antibodies, conformation of antibodies, FcR family.
ii. Proteins, transcripts and genes: Gene, structure and actions of high affinity Fc receptor for immunoglobulin E.
iii. Fc - receptor mediated killing
iv. Fc- receptor on T and B lymphocytes
v. Immunoglobulin binding factors

RECOMMENDED BOOKS :

1) Kirkwood E and Catriona L. Understanding Medical Immunology (John Wiley and Sons, New Yord)
2) Humphrey J.H. and White R.G. Immunology for students of Medicine (Blackwell Scientific Publication London)
3) Goodman and Gilmans. The pharmacological Basis of Therapeutics (9th Ed.)McGraw Hill 1996.

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8. TOXICOLOGY

Theory 4 hours/week

CREDITS 04

UNIT I

I) Fundamental Principles :

i. Introduction, Toxicological Evidence, Common household poisons, description of sub disciplines of toxicology, qualitative and quantitative aspects of toxic effects.

ii. Biotransformation : detoxication and bioactivation

iii. Absorption, distribution and elimination of xenobiotics

iv. Toxicokinetics : quantitative aspect Dose time - effect relationships

II) Molecular aspects of toxicology

i. Cytotoxicity - Molecular Mechanism of cell death, Genetic toxicology

ii. Introduction to carcinogenesis

UNIT II

Organ toxicology

i. Cytopathology general response patterns and Morphological aspects Necrosis and apoptosis: Irreversibility of cell damage and cell death.

ii. Dermatotoxicology: Toxicological, pathology and methodological aspects Respiratory toxicology: toxicological, pathology and methodological aspects.

iii. Respiratory toxicology; pathophysiology, toxicological pathology and mechanisms of toxicity

iv. Gastrointestinal toxicology: toxicological pathology and source of intestinal toxicity

v. Hepatotoxicology : Mechanisms of liver toxicity and methodology aspects

vi. Nephotoxicology : toxicological pathology and biochemical toxicology

vii. Cardiovascular toxicology: Toxicological pathology and methodological aspects

viii. Toxicology of blood: Pathophysiology, Toxicological pathology and mechanism of toxicity

UNIT III

i. Immunotoxicology:determination of immunotoxic effects and immunotoxicity mechanisms

ii. Endocrine toxicology

iii. General reproductive toxicology

iv. Functional neurotoxicology

v. Neurobehavioural toxicology

vi. Food, nutritional toxicology

UNIT IV

i. Medical and clinical toxicology

ii. Ecotoxicology

iii. Occupational toxicology

iv. Carcinogenicity mutagenicity; Teratogenicity

RECOMMENDED BOOKS :

1) Niesink R.J.M. de Vries J and Hollingers M.A. Toxicology, Principles and Applications, CRC Press 1996

2) Amdur M.O. Doul J and Klassen C.D. Casarett and Doull's toxicology

3) Gupta P.K. and Salunkhe D.K. Modern toxicology Vol-I, II and III (Metropolitan, New Delhi).

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9. PHARMACOKINETICS AND THERAPEUTIC DRUG MONITORING

Theory 4 hours/week

CREDITS 04

UNIT I

Therapeutic Drug Monitoring

Introduction, Necessity of TDM, Criteria for valid TDM, Essentials for effective TDM, Organization of a TDM service, information requirements for TDM, effectiveness of TDM.

UNIT II

Drug selection, Dosage regimen design, Pharmacokinetics of the Drug, Patient compliance, Evaluation of pateint's response, Measurement of serum drug concentrations, Monitoring serum drug concentrations, Design of dose regimens. Conversion from i.v. infusion to oral dosing. Determination of dose frequently, dosing of drugs in elderly.

UNIT III

Analytical aspects of TDM, Uses of HPLC and Immunoassays in TDM

UNIT IV

TDM of selected individual drugs - Aminoglycosides, Carbamazepine, Theophulline Digoxin, Methotrexate, Phenytoin, Aspirin, Lithium, Valproic acid.

RECOMMENDED BOOKS :

1) Applied Biopharmaceutics and Pharmacokinetics by Leon Shargel and B.C. Andrew
2) Therapeutic Drug Monitoring and Clinical Biochemistry by Mike Halworth and Nigel Capps.
3) Biopharmaceutics and Pharmacokinetics by RobertE. Notari.
4) Principles and Prescriptives in Drug Bioavailability by S.Karger.
5) Pharmaceutics and Pharmacy Practice by Gilbert S.Banker
6) Remington's Pharmaceutical Sciences
7) Dissolution, bio-availability and bio-equivalence by Abdou
8) Pharma Review by Leon Shargel
9) Current concepts in Pharmaceutical Sciences by James Swarbrick
10) Drug Disposition and Pharmacokientics by Stephen H. Curry
11) Pharmacokinetics by MiloGilbaldi and Donald Perrier 2nded Marcel Dekker Inc. New York 1982.
12) Drug Level monitoring, Analghical Techniques, metabolism and pharmacokinetics.
13) Simkin : Handbook of TDM.
14) Goodman & Gilman's The pharmacological Basis of Therapeutics Ed. J.G. Hardman, L.E. Limbird, P.B. Molinoff and R.W. Ruddon. International Edition.MicGraw Hill.
15) Principles of drug action the basis of pharmacology by goldstein A., Arrow L. and Kalman S.M. 2nd ed. John Wiley & sons. Inc.New York 1974.
16) Clinical pharmacokinetics. Concepts and Applications by rowland M and Tozert.N. 3rd ed. Lea and Febiger Philadelphia, 1995.
17) Pharmacokinetics for pharmaceutical scientists Wagner J.G. Technomic. Inc. Lancaster PA 1993.
18) Integration of pharmacokinetics, pharmacodynamics and Toxico kinetics in Rational Drug Development Plenum, New York, 1993.
19) Applied Pharmacokinetics, Principles of Therapeutic Drug monitoring, by Evans W.E., Schentag J.J. and Jusko W.J. (Eds). 3rd ed. Applied Therapeutics Inc. Vancouvers HA. 1992.

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10. AGROTECHNOLOGY

Theory 4 hours/week

CREDITS 04

UNIT I

1. Significance/importance of cultivation of Medicinal and Aromatic plants.

Export potential of Medicinal and Aromatic plants and their derivatives from India.

2. **Cultivation :** Methods of propagation and factors (Endogenous and exogenous) affecting cultivation of Medicinal and Aromatic plants.

Endogenous Factors: Mutation, polyploidy, chemical races, hybridization etc.

Exogenous factors: Soil - physical and chemical properties, organic matter, microorganisms of soil, soil classification and soil management, soil testing.

Influences of altitude temperature, humidity, rainfall /irrigation,

Soil fertility and fertilizers - plant nutrition and their functions, maintainance of soil fertility, types of manure and fertilizers, mode and time of application of fertilizer and manure.

Weeds and weed control

Diseases and Pests of medicinal and Aromatic crops and their control.

UNIT II

3. Agroproducts marketing and storage:
4. Methodology for assessment of availability of Medicinal and Aromatic plant materials from the forest.

UNIT III

5. Scientific study of cultivation, collection and preparation for market of followings, along with their products and Byproducts :
   a) Dioscorea
   b) Senna
   c) Isapgol
   d) Neem
   e) Mentha
   f) Solanum
   g) Jasmine
   h) Spirulina

UNIT IV

6. Study of following agro based products :

   a) Starch and its derivatives
   b) Cellulose and its derivatives
   c) Activated carbon
   d) Catechu and catechin
   e) Alginate and its derivatives
   f) Plant products for insect control
   g) Cheese, butter, yoghurt from milk.

RECOMMENDED BOOKS :

1) Wealth of India : CSIR New Delhi
2) A hand book of Agriculture - ICAR, New Delhi
3) Cultivation and utilization of Medicinal plants C.K. Atal and B.M.Kapour RRL, CSIR
4) Cultivation and utulization of Aromatic plants, C.K. Atal and B.M.Kapour RRL, CSIR
5) Spices, plantation crops, Medicinal and aromatic plants. N.Kumar, J.B.M. Md. Abdul Khader, P. Rangaswami, I. Irulappan - Oxford and 1BH Publishing Co.. Pvt. Ltd., New Delhi.
6) Materia Medica: Nadkarni, Kothari.

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11. PHYTOPHARMACEUTICALS

Theory 4 hours/week

CREDITS 04

Source, phytochemistry (isolation, identification, chemical nature), and physiological activities of following phytopharmaceuticals.

UNIT I

1) Anticancer: Taxol, other taxanes, Camptothecin, vinblastine, Genistein, Etoposide

UNIT II

2) Nervous system activities: Hypericin, Valepotriates, Gingkolides

3) CVS activities: Colenol, Streptokinase

UNIT III

4) Anti-inflammatory : Curcuminoids, Guggulipids, Boswellic acid, Serratiopeptidase.

UNIT IV

5) Miscllaneous: Silymarin, Artemisinin, Omega-3 fatty acids.
Charantin and momordicosides, Resveretrol, Protamine sulphate, prostaglandins.

RECOMMENDED BOOKS :

1) Pharmacognosy : Trease and Evans, Bailliere & Tindall, 14th edth.

2) Pharmacognosy : Kokate,Purohit, Gokhale, Nirali Prakashan, Pune, 15th edtn.

3) Biochemistry : Delvin

4) Alkaloids Edited by J.R.F.Manske

5) Various Research Journals on Natural products and therapeutics.

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12. MEDICINAL PLANT BIOTECHNOLOGY

Theory 4 hours/week

CREDITS 04

UNIT I

1. Introduction to Plant tissue Culture, advantages, applications and limitations.
2. Concepts of totipotency, nutritional requirements and role of growth hormones, types of cultures. Organogenesis, Embryogenesis, Protoplast culture

UNIT II

3. Suspension culture, protocols to evaluate growth and viability of plant cells under *in vitro* conditions. Production of secondary metabolites by plant cells under *in vitro* conditions and strategies to enhance secondary metabolites.
4. Bioreactor management and its comaprision with fermention. Large scale cultivation of plant cells in bioreactor system for the production of bioactive compounds.

UNIT III

5. Gene Transfer in plants concepts and applications. Initiation of Hairy root cultures and their application in production of secondary metabolites. Electroporation, Microprejectiles, Micro and macro injection. Liposomes Ultrasonication.
6. Methods of quality improvement of plants.
   a) Chemodemes b) Hybridisation c) Mutation d) Polyploidy
   Applications of transgenic plants
   a) Resistance to hebicides, insects, fungus and virus, physiological stress
   b) Edible vaccines

UNIT IV

7. Localisation of transferred gene in genetically modified plants
   a) Gene mapping
   b) Use of markers
8. Applications of Medicinal Plant Biotechnology in Pharmacy
   a) Cell Immobilisation
   b) Biotransformation
   c) Germplasm conservation

RECOMMENDED BOOKS :

1. Medicinal Plant Biotechnology: A. G. Namdeo
2. Medicinal Plant Biotechnology: Ciddi Veersham
3. Essentials of Molecular Biology: Dovid F.A., George M.M.
4. An introduction to plant tissue culture : M.A.Razdan
5. Plant biotechnology: Samtel
6. Plant tissue culture: Narayanswamy
7. Plant tissue culture: Angela Stafford, Open University press, Buckingham, 1991.
8. Plant tissue culture: Dixon
9. Pharmaceutical Biotechnology: Vyas, Dixit, CBS Publishers, New Delhi, 1998.
10. Pharmcognosy: Trease W.C., Evans g.E., Bailliere & Tindall, 15th edth.

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13. PHARMACEUTICAL MARKETING

Theory 4 hours/week

CREDITS 04

UNIT I

1) CONCEPT OF PHARMACEUTICAL MARKETING SELLING AND ORGANIZATION STRUCTURE

1. Meaning of Pharmaceutical Marketing and selling
2. Organization structure of Pharmaceutical Marketing dept. Job responsibilities of people involved.
3. Customers in Pharmaceutical Marketing

UNIT II

2) ADVERTISING AND SALES PROMOTION IN PHARMACEUTICAL MARKETING

1. Advertising of Pharma products and Detailing concepts
2. Various sales Promotion Methods its advantages, disadvantages.
3. Medical representative and his role
4. Various strategies to sell Pharmaceutical products

UNIT III

3) DISTRIBUTOR AND RETAILER IN PHARMA BUSINESS

1. Retailer and his importance
2. Distributor and his importance
3. Retail prescription audit

UNIT IV

4) INSTITUTIONAL BUSINESS

1. Types of Institutions
2. Promotion activities at Institutions
3. Advantages of Institutional business

5) INTERNATIONAL PHARMA MARKETING MANAGEMENT :

1. International Pharma Market
2. Export Management of Pharmaceuticals

RECOMMENDED BOOKS :

1. Pharmaceutical Marketing by Subba Rao
2. The Fast Track Career- The M.R. S.S. Nadkarni

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14. IPR AND REGULATORY AFFAIRS

Theory 4 hours/week

CREDITS 04

UNIT I

Intellectual property rights: Patent, copyrights, design and trademark. Effect of GATT and WTO on commerce of pharmaceuticals. Importance of patent, Application, processing of patent, Indian Patent Act 1970 and its latest amendments, United state patent, world patent processing. Patent term extension.

UNIT II

Drugs Prices Control Order 1995, Factory Act, Labour Act, Medicinal and Toilet preparation (Excise duties) Act and Rules,

Narcotic Drugs and Psychotropic Substances Act and Rules, 1985 and latest amendments. The drug and Magic remedies (Objectionable advertisements) act and rules, 1954.

UNIT III

Inspection and quality audit: Self inspection, Internal and External audits. Procedure for inspection of pharmaceutical manufacturing plants. Audits for vendor approvals, Contract manufacturing.

Biostatistics tools techniques, data analysis and presentation.

UNIT IV

Sewage disposal and pollution control from pharmaceutical Industry: Categorization of pharmaceutical industry as per EPA, Solid waste management of the expiry and rejected materials. Biomedical waste (Management and Handling) Rules, 1998.

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15. DRUG REGULATORY AFFAIRS

Theory 4 hours/week

CREDITS 04

UNIT I

The Drugs and Cosmetics act, 1940 and Rules with emphasis on Good laboratory practices and requirements of premises and equipments (Schedule L-I), Good manufacturing practices for pharmaceutical products (Schedule M), Good manufacturing practices for homeopathic medicines (Schedule M-I), Requirements of factory premises for manufacture of cosmetics (Schedule M-II), Good manufacturing practices for Ayurvedic, Siddha and Unanni medicines (Schedule T). Regulatory requirements for nutraceuticals. ISI standards of cosmetics.

UNIT II

Requirements for registration of pharmaceutical products into USA with emphasis on para I, II, III & IV filing. Preparation of documents for approval of IND, NDA, ANDA, BLA applications and export registration (USFDA 21 CFR part 310, 312, 314, 320). Biowaivers. Understanding the FDA 505(b)(2) Regulatory Approval Pathway, Hatch-Waxman act.

Section II

UNIT III

Overview of GMP guidelines with specific reference of World health organization (WHO), Medicines and Healthcare products Regulatory Agency (MHRA), Medicines control council (MCC), Therapeutic goods administration (TGA) and ANVISA Brazil guidelines and Japanese regulation.

UNIT IV

Intellectual property rights: Patent, copyrights, design and trademark. Effect of GATT and WTO on commerce of pharmaceuticals. Importance of patent, Application, processing of patent, Indian Patent Act 1970 and its latest amendments, United state patent, world patent processing. Patent term extension.

RECOMMENDED BOOKS AND REFERENCES :

1. Vijay Malik, Law relating to Drugs & Cosmetics.
2. The Gazettes of India. The Drug and Cosmetics Act and Rules and its Latest amendments.
3. The Gazettes of India. The Patent Act 1970 and its Latest amendments.
4. Common Technical documents (ICH guidelines).
5. ISO Guidelines
6. www.ich.org
7. www.anvisa.gov.
8. www.picscheme.org
9. www.mhra.gov.uk
10. www.tga.gov.au
11. www.mccza.com
12. www.who.int
13. www.patentoffice.nic.in
14. www.ep.espace.net
15. www.uspto.gov
16. www.epa.gov
17. www.emea.europa.eu
18. www.fda.gov.

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16. PROJECT MANAGEMENT

Theory 4 hours/week

CREDITS 04

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: Tata 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

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17 PHARMACEUTICAL ADMINISTRATION

Theory 4 hours/week

CREDITS 04

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.

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18.BULK DRUG TECHNOLOGY

Theory 4 Hrs/Week

Credit 04

UNIT I

1) a) Stoichiometry and its importance in the manufacture of drugs
   b) Discussion on the following processes (reaction types in relation to manufacturing of drugs. Acetylation, Nitration, Sulphonation, Chlorosulphonation,Oxidation, Reduction, Alkylation, Halogenation, Carboxylation, Decarboxylation, Esterification, Addition, Epoxidation and important rearrangements.

UNIT II

2) UNIT processes: Study of the following chemical processes (with reference to reagents, mechanisms, equipments, and manufacture of drugs given below): acylation, esterification, alkylation, amination, halogenation, hydrolysis, nitration, oxidation, reduction.
3) Further discussion on unit operations important to drug synthesis e.g. mixing, distillation, drying, filteration and centrifugation, evaporation, crystallization, counter current extraction, effluent treatment and pollution control.

UNIT III

4) Principles and design of the reactors - Factors to be considered (including material selection) construction of flow diagrams- selection of Equipment.
5) Detailed manufacturing aspects, inclusive of processes and operations involved for : Aspirin, Adrenaline, Aneurine, Barbitones, Benzocaine, Chloramphenicol, Sulphathiazole.

UNIT IV

6) Safety and Hazards concepts.

RECOMMENDED BOOKS :

1) M.G.Larians : Fundamentals of Chemicals Engineering Operations
2) W.L.Badger and Banchero : Introduction to chemical engineering (McGraw Hill Servies)
3) L.Lachman- the theory and practice of Industrial Pharmacy (Vergaese Publishing)
4) Ganderton G ; Unit processes in Pharmacy
5) Groggin P.K.:Unit processes in Organic synthesis (McGraw Hill Publication London)
6) Marshall Sitting : Organic Chemical Processes
7) Dryden C.L.:Outlines of chemical Technology (Affiliated East-West Press Pvt. Ltd.)

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19. FERMENTATION TECHNOLOGY

Theory 4 Hrs/Week

Credits 04

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 selected 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 4 Applications of enzymes in food processing

Enzymic bioconversions e.g. starch and sugar conversion processes; High-Fructose Corn Syrup; Inter-esterified fat; Hydrolyzed protein etc. and their downstream processing; baking by amylases, deoxygenation and desugaring by glucosesoxidase, beer mashing and chill proofing; 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.

TEXT/REFERENCES :

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. Roger Harrison et al., Bioseparations 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.

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20.ANIMAL CELL CULTURE AND APPLICATIONS

Theory 4 Hrs/Week

Credits 04

UNIT 1: Cell culture Laboratory design & Equipments,

History of animal cell culture; Different tissue culture techniques; Equipments and materials for animal cell, Types of primary culture; Chicken embryo fibroblast culture; Secondary culture; Trypsinization; Cell separation; Continuous cell lines; Suspension culture; Organ culture etc.; Behavior of cells in culture conditions: division, growth pattern, estimation of cell number; Development of cell lines; Characterization and maintenance of cell lines, stem cells; Cryopreservation; Common cell culture contaminants.

UNIT 2: Media and reagents, Different types of cell cultures, scale up

Types of cell culture media; Ingredients of media; Introduction to the balanced salt solutions and simple growth medium, Physiochemical properties; CO_2 and bicarbonates; Buffering; Oxygen; Osmolarity; Temperature; Surface tension and foaming; Antibiotics, growth supplements; Foetal bovine serum; Serum free media; Trypsin solution; Selection of medium and serum; Conditioned media; Other cell culture reagents; Preparation and sterilization of cell culture media, serum and other reagents.

UNIT 3: Application of animal cell culture

Toxicological study, Measurement of viability and cytotoxicity; Biology and characterization of the cultured cells, measuring parameters of growth; cell cycle regulation study, apoptosis, drug testing, bioactivity assays. Cell cloning and micromanipulation; Cell transformation;

UNIT 4: Stem cells and applications

Stem cell cultures, embryonic stem cells and their applications; Cell culture based vaccines, Somatic cell genetics. Organ and histotypic cultures; Measurement of cell death; Apoptosis, three dimensional culture and tissue engineering.

REFERENCES:

1. Freshney R. Ian, "Culture of animal cells: A manual of Basic Technique", Willey-Liss Publisher, 5th edition (2005).
2. Morgan, Animal Cell Culture-Biotol Series,1993
3. Davis.J.M Basic Cell Culture Second Edition, Oxford University Press. (First Indian Edition, 2005)
4. Jenkins N, ed., "Animal Cell Biotechnology: Methods and Protocol", Humana Press (1999).
5. Minuth W.W., Strehl R., Schumacher K., "Tissue Engineering: Essential for Daily Laboratory Works", Willey Publisher (2005).
6. Butler, M "Mammalian Cell Biotechnology- A Practical Approach," IRL Oxford University Press (1991)

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21.GENOMICS & PROTEOMICS

Theory 4 Hrs/Week

Credits 04

UNIT I

Introduction

Structural organization of genome in Prokaryotes and Eukaryotes; Organelle DNA mitochondrial, chloroplast; DNA sequencing principles and translation to large scale projects; Recognition of coding and non-coding sequences and gene annotation; Tools for genome analysis-RFLP, DNA fingerprinting, RAPD, PCR, Linkage and Pedigree analysis Physical and genetic mapping.

UNIT II

Genome sequencing projects

Microbes, plants and animals; Accessing and retrieving genome project information from web; Comparative genomics, Identification and classification using molecular markers-16S rRNA typing/sequencing, EST's and SNP's.

UNIT III

Proteomics

Protein analysis (includes measurement of concentration, aminoacid composition, N-terminal sequencing); 2-D electrophoresis of proteins; Microscale solution isoelectricfocusing; Peptide fingerprinting; LC/MS-MS for identification of proteins and modified proteins; MALDITOF; SAGE and Differential display proteomics, Protein-protein interactions, Yeast two hybrid system.

UNIT IV

Pharmacogenomics

High throughput screening in genome for drug discovery identification of gene targets, Pharmacogenetics and drug development

TEXTS/REFERENCES:

1. Voet D, Voet JG & Pratt CW, Fundamentals of Biochemistry, 2nd Edition. Wiley 2006
2. Brown TA, Genomes, 3rd Edition. Garland Science 2006
3. Campbell AM & Heyer LJ, Discovering Genomics, Proteomics and Bioinformatics, 2nd Edition. Benjamin Cummings 2007
4. Primrose S & Twyman R, Principles of Gene Manipulation and Genomics, 7thEdition, Blackwell, 2006.
5. Glick BR & Pasternak JJ, Molecular Biotechnology, 3rd Edition, ASM Press, 1998.

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22. PHARMACEUTICAL PLANT DESIGN AND OPERATION

Theory 4 Hrs/Week

Credits 04

UNIT I (Regulatory requirements and Project management)

1. Regulatory requirements of pharma facilities with ref. to cGMP and Factory Act
2. Introduction of pharmaceutical project management.

UNIT II

(Formulation Facility Design)

3. Designing of non-sterile products facilities for tablets, hard gelatin capsules, dry syrups ointments/ creams and liquid orals.
4. Designing of sterile products facilities for liquid ampoules, liquid vials dry powder vials.
5. Designing of Q.C. Laboratory and Pilot plant
6. Designing of ware houses.

UNIT III

(Utility Design.)

7. Designing of following utility services
   - Water and stream
   - Electricity
   - Compressed air and other gases
   - Engineering workshop
8. Designing of effluent treatment plant
9. Designing of plant support services like security office, vehicle parking, fuel storage, canteen and cooking, garden and horticulture, scrap yards, Administrative block and traning centre, sports and entertainment block, resident managers bunglow, residences for essential service staff.

UNIT IV

(Operation of Plant)

10. Operation of ware housing department
11. Operation of Q.A./QC department
12. Operation of Production department
13. Operation of Personnel and HRD department
14. Operation of factory Administration department
15. Operation of Engineering department
16. Operation and Production planning and control department.

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 : Elwood Bufa Publisher: Wiley Eastern Limited (New Delhi)
4) Production planning and control by: Samuel Eilon Publisher: Universal book corporation, Mumbai.
5) Pharmaceutical Facilities: Design,Layouts,and Validation By: Dr. M.A.Potdar Publisher: PharmaMed Press, Hydrabad

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