ACADEMIC REGULATIONS AND SYLLABUS

M. PHARMACY PROGRAMME

HIMACHAL PRADESH TECHNICAL UNIVERSITY HAMIRPUR

HIMACHAL PRADESH TECHNICAL UNIVERSITY, HAMIRPUR

ACADEMIC REGULATIONS – M. PHARMACY PROGRAMME

INTRODUCTION

The objectives of the postgraduate programmes in Pharmacy at the H P Technical University Hamirpur (HP) are:

- To ensure high level of performance in teaching, research and practice.
- To develop the scientific and technical manpower of the highest quality to cater the needs of the industry.
- To provide a broad grasp of the fundamental principles of the sciences and scientific and Technological methods through its curriculum
- To provide a deep understanding of the area of specialization
- To provide an innovative ability to solve new problems
- To provide a capacity to learn continually and interact with multidisciplinary groups
- To develop the students with a capability for:
    - Free and objective enquiry
    - Courage and integrity
    - Awareness and sensitivity to the needs and aspirations of society

With these objectives in mind, the postgraduate programmes are designed to include courses of study, seminars and project/thesis through which a student may develop his/her concepts and intellectual skills. The procedures and requirements stated in this manual embody the philosophy of the postgraduate education and ensure a high standard of performance at the Institute. To ensure uniform system of higher education, system and duration of post graduate programme, eligibility criteria for admissions, credits among courses, system of examination and other related aspects, following academic rules and regulations are recommended.

POST GRADUATE PROGRAMMES

1. PRELIMINARY DEFINITIONS AND NOMENCLATURE

In these Regulations, unless the context otherwise requires:

i. "**Programme**" means Degree Programme. i.e. M.Pharmacy Degree Programme

ii. "**Specialization**" means the discipline of the Post Graduate Degree Programme i.e. Pharmaceutics, Pharmaceutical chemistry. Pharmaceutical Analysis and Quality Assurance, etc.

iii. "**Course**" means a Theory or Practical subject that is normally studied in a semester, like Advanced Pharmaceutical Instrumental Analysis, Pharmaceutical Formulation technology, etc.

iv. "**Controller of Examinations**" means the Authority of the University who is responsible for all activities of the University Examinations.

v. "**University**" means Himachal Pradesh Technical University, Hamirpur.

2. PROGRAMMES OFFERED, MODE OF STUDY AND ADMISSION REQUIREMENTS

2.1 Programmes Offered

Himachal Pradesh Technical University offers Master of Pharmacy (M.Pharmacy) course in the following specializations.

2.1.1. Pharmaceutics

2.1.2. Pharmaceutical Chemistry

2.1.3. Pharmaceutical Analysis and Quality Assurance

A Candidate shall be offered one of the branches of study from these approved specializations.

2.2 Mode of Study

2.2.1. Candidates shall be admitted only under 'Full-Time 'basis. He/she should be available in the departments during the entire duration of working hours (From Morning to Evening) for the curricular, co-curricular and extra-curricular activities.

2.2.2. The candidates should not attend any other Full-time programme(s)/course(s) or take up any Full-Time job / Part-Time job in any Institution or company during the period of programme. Violation of the above rules will result in cancellation of admission.

2.3 Duration of Programme

The programme is for a period of two years. Each year shall consist of two semesters, viz. Odd and Even semesters. Odd semesters shall be from June/ July to October / November and Even semesters shall be from November/December to April / May. There

shall be not less than 90 working days for each semester (exclusive of the days for the conduct of University end-semester examinations).

A student shall ordinarily be expected to complete the Programme in 4 semesters (two academic years). The maximum duration in any case shall not be more than 8 Semesters (4 academic years).

2.4. Admission Requirements

2.4.1. Candidate who possesses Bachelor Degree in Pharmacy from AICTE and PCI approved institute with 50 percent marks shall be eligible for admission. Students with valid GPAT score shall be given preference over other candidates.

2.4.2. In general, the admission would be made on the combined merit of the GPAT and combined entrance test (CET) conducted by the HP Technical University.

2.4.3. In order to give preference to GPAT qualified students, the combined merit shall be worked out giving a weightage of 70% to GPAT score and 30% weightage to CET score

2.4.4. Admission against the unutilized seats of M. Pharmacy Programme shall also be made on the basis of merit in the Entrance Test conducted by the University/College affiliated to Himachal Pradesh Technical University with the approval of the Vice Chancellor.

2.4.5. The Academic council of the University may decide to restrict admission in any particular year to candidates having the subset of qualifications prescribed at the time of admission.

3. SYSTEMAND STRUCTURE OF THE P.G.PROGRAMMES

3.1 The Semester system of education shall be followed across the Himachal PradeshTechnical University affiliated colleges at post Graduate level in Pharmacy. Eachsemester will be at least of 90 working days duration. Every enrolled student shall be required to fulfill the specified load of course work in the chosen specialization of specialization including dissertation.

The following is the course module suggested for the PG programmes:

Courses	No of courses
I Semester	
Common course for all the specialization	1
Specialization Core Courses (SCC)	2
Elective Course (EC)	1
II Semester	
Specialization Core Courses (SCC)	3
Common Course for all the specialization (CC)	1
III Semester	
Dissertation-Phase-I	
Research Supportive Course (RSC)	1
IV Semester	
Dissertation-Phase-II	1

3.2 Programme structure and Credits

3.2.1. A student admitted to a program shall study the courses and earn credits specified in the course structure.

3.2.2. The Curriculum and Syllabi of all the P.G. Programmes shall be approved by the Academic Council of HPTU.

3.2.3. The number of credits to be earned for the successful completion of the Programme shall be as specified in the Curriculum of the respective specialization of the P.G Programmes.

3.2.4. The Head of the Institution shall ensure that every teacher imparts instruction as per the number of periods specified in the syllabus and that the teacher teaches the full content of the specified syllabus for the course (Subject) being taught.

End-semester Examination shall be scheduled after the last working day of the semester as noted in the academic calendar

3.2.5. The Curriculum of P.G. Programmes shall be so designed that the prescribed credits required for the award of the degree shall be within the limits as following.

a. One credit for each lecture period allotted per week
b. One credit for each tutorial period allotted per week
c. Three credits for each practical sessions designed per week
d. Three credits for RSC in III semester
e. Other credits as assigned in the curriculum mentioned in each respective specialization

The total minimum number of credits for completing a PG programme is 70.

3.2.6. One elective course should be chosen from the pool of electives course provided, with the approval of the Head of the institutions concerned. To give an elaborative knowledge of the progressive research a common Research Supportive Course (RSC) shall be conducted in the III semester to all the specialization.

4. DISSERTATION WORK

4.1.1 The dissertation work for M. Pharmacy programme consists of Phase – I and Phase – II. The phase– I during III semester and Phase – II, which is a continuation of Phase – I at IV semester shall be followed.

4.1.2. Dissertation work shall be carried out under the supervision of faculty member in the Department concerned and the work progress to be maintained in the prescribed work dairy and log book. The work diary and log book shall be verified and certified by the Head of the Department and Head of the institution. The certification of satisfactory progress is based on the work diary and log book.

4.1.3. A candidate shall submit the choice of the research area and topic with title of the dissertation immediate after the second semester for the approval by the department head and head of the institutions.

4.1.4. A candidate may, however, in certain cases, be permitted to work on projects in and industrial/Research Organization, on the recommendations of the Head of his/her Department. In such cases, the Project work shall be jointly supervised by a supervisor of the department and an expert-as a joint supervisor from the organization.

4.1.5. The Project Report prepared according to approved guidelines and duly signed by the supervisor(s) and the Head of the Department shall be submitted to the Head of the Institution.

5. FACULTY ADVISER

5.1.1. A faculty adviser to a group of students may be assigned by the head of the department to help the students in planning their courses of study and general advice on the academic Programme throughout the period of study

5.1.2. The Faculty Advisor shall advise the students in regard to the minimum and the maximum number of total credits and lecture credits in the context of his/her past performance, backlog of courses, SGPA/CGPA and individual interest. Maintain all records pertaining to his function.

6. POST GRADUATE ACADEMIC COMMITTEE (PGAC)

6.1.1. A Class Committee shall be formed which includes the concerned teachers, student Representatives, Faculty Advisor and a chairperson (Head of the institutions) for the overall goal of improving the teaching-learning process.

6.1.2. The functions of the PGAC shall include clarifying the regulations of their degree Programme and the details of rules therein informing the student representatives "the academic schedule" including the number of assessments, the dates and the syllabus for each assessment period.

6.1.3. Informing the details of regulations regarding the weightage used for each assessment. In the case of practical courses (laboratory/project work/ seminar etc.,), the breakup of marks for each experiment/exercise/module of work should be clearly discussed in the class committee meeting and informed to the students through the class representatives.

6.1.4. Analyzing the performance of the students of the class after each test and finding the ways and means of improving the students' performance.

7. ATTENDANCE

All activities prescribed under these regulations and listed by the course faculty members are compulsory for all students pursuing the M. Pharmacy Programme.Ideally, every student is expected to attend all classes and earn 100% attendance. Candidate having deficient attendance on account of illness, participation in academic seminars, conferences, Inter Institute Tournaments/ NCC/ NSS camp/ Mountaineering skiing course/competitive examinations or any other genuine ground can be given attendance consideration to the maximum extent of 25% of the total classes held in each course during the semester for the period of his/her absence by the Principal on the recommendation of the concerned departments. Candidates having less than 75% attendance (including the attendance benefits as prescribed above) shall not be allowed to appear in the examination and will be awarded I.

8. END-SEMESTER EXAMINATIONS

The examinations shall ordinarily be conducted as per the HPTU calendar of events.

9. EVALUATION

The performance of every student in each course will be evaluated as follows:

9.1.1. Internal evaluation is based on continuous assessment, for 40% of the marks for the all the theory course and 50% for practical.

9.1.2. End semester examination shall be conducted by the Himachal Pradesh Technical University through written paper or practical test and viva-voce/presentation by the student or a combination of any two or more of these, for 60% of the marks for the theory course and 50% for practical course.

9.1.3. The duration of Technical examination by Himachal Pradesh Technical University shall be conducted for 3 hours for theory and as per Course requirement for practical's examinations with not less than 3 hours.

9.1.4. The evaluation of the Project work in Phase - I & Phase - II shall be based on the project report submitted in each of the Phase – I & Phase - II semesters and a Viva-Voce Examination by a team consisting of the supervisor, a common internal examiner (other than the supervisor) and a common External Examiner for each programme.

9.1.5. The common internal examiner and the external examiner shall be appointed by the University for Phase – I and Phase – II evaluation.

9.1.6. A copy of the approved project report after the successful completion of viva-voice examinations shall be kept in the library of the college / institution and a copy in university library.

9.1.7. A student who has passed all the courses prescribed in the curriculum for the award of the degree shall not be permitted to re-enroll to improve his/her marks in a course or the aggregate marks / CGPA.

10. PASSING REQUIREMENTS

10.1.1. If a candidate fails to secure a pass in a particular course, it is mandatory that he / she shall register and reappear for the examination in that course during the next semester when examination is conducted in that course; he / she should continue to register and reappear for the examination till he / she secures a pass.

10.1.2. The question paper shall contain questions based on the chapter weightage with short and essay type questions.

The distribution of weightage of the various components of evaluation for each course shall be as follows:

a. Curriculum Works

Hours spent on reference work, seminar, quizzes and relative curriculum works should be not less than 8 hours in a week.

b. Theory

Class seminars, quizzes, assignments and regularity	5%
Attitude and Discussions	5%
At least two periodical tests each of 2 hours duration	30%
End Semester examination of not less than 3 hours duration	60%
Total	***100%***

c. Practicals

Practical, assignments and regularity	5%
Attitude and Discussions	5%
Day to day activity	20%
Record and internal viva-voce	20%
Practical university examination	50%
Total	***100%***

d. Dissertation (Phase-I)

Progress ascertainment	30%
Seminars	10%
Research progress Evaluation	60%
Total	***100%***

e. Dissertation (Phase-II)

Progress ascertainment	30%
Seminars	10%
Dissertation Open Defense and Evaluation	60%
Total	***100%***

11. GRADING SYSTEM

11.1 All assessments of a course will be done on relative marks basis. However, for thepurpose of reporting the performance of a candidate, letter grades, each carrying certain points, will be awarded as per the range of total marks obtained by the candidate.

The following Table gives the correspondence between the ‘grade,’ ‘merit’ and ‘grade point.’

Letter grade	Merit	Grade point
A1	Outstanding	10
A2	Excellent	9
B1	Very Good	8
B2	Good	7
C1	Average	6
C2	Fair	5
P	Pass	4
U	Unsuccessful	<4
I	Require reappearance	0
W	Withdrawal	0

At the end of a semester, based on the evaluation report,a student shall be awarded a letter grade in each course. A student is deemed to have passed and acquired the corresponding credits in a particular course if he/she obtainany one of the following grades (A1,A2, B1, B2, C1, C2 and P).

"**U**" denotes 'Unsuccessful' grade which requires Reappearance (RA) in the examination for that particular course. (RA will figure in Result sheets & Grade sheets).

"**I**" denotes inadequate attendance and hence prevention from writing the End Semester Examination.

"**W**" denotes withdrawal from the course.

11.2 Guidelines for the Award of Grades

"A teacher is the best judge in awarding the grades". However, he/she has to be impartial, logical and maintain complete transparency while awarding grades. The institute will normally follow relative grading system.

The following are the general guidelines for the award of grades:

1. All evaluations of different components of a course announced in the course plan shall be done in marks for each student.
2. The marks of various components shall be added to get total marks secured on a 100-point scale for theory courses and laboratory courses.
3. For any course, the statistical method (Table) shall be used for the award of grades with or without marginal adjustment for natural cut off.
4. The teacher will ensure coverage of all the contents of a course taught during the semester. The end semester examinations question paper shall be within the prescribed syllabus. At the end of the semester a teacher will submit a complete course file having following documents.

a. Course Plan
b. Attendance record
c. Tutorial sheets/Assignment sheets
d. Question papers of periodical/minor exams
e. Quizzes
f. Complete details of marks with final grades

5. In case a student repeats a particular course during summer term or along with his/her juniors, he/she will be awarded only up to a maximum of A2 grade as per his/her performance and with respect to his/her earlier class.
6. The statistical method shall invariably be used with marginal adjustment for the natural cut off. The mean and the standard deviation (σ) of marks obtained of all the students in a course shall be calculated and the grades shall be awarded to a student depending upon the marks and the mean and the standard deviation as per the Table given below.

Table: Statistical Method for Grading

Lower Range of Marks	Grade	Upper Range of Marks
	A1	≥Mean + 3 σ
Mean + 2 σ ≤	A2	< Mean + 3 σ
Mean + σ ≤	B1	< Mean + 2 σ
Mean ≤	B2	< Mean + σ
Mean – σ ≤	C1	< Mean
Mean – 2 σ ≤	C2	< Mean – σ
Mean – 3 σ ≤	P	< Mean - 2 σ
	U	< Mean - 3 σ

$$\sigma = \sqrt{\frac{\sum_{i=1}^{n}(x_i - \bar{x})}{(n-1)}}$$

Where x_i = marks of the student, $\bar{x}$ = arithmetic mean value and n = the number of students

12. DECLARATION OF RESULTS AND PROMOTION

The academic performance of a student shall be evaluated on the basis of his or her grade in each course, semester grade point average (SGPA) and cumulative grade point average (CGPA). These two are calculated as shown below:

- At the end of a semester examination, a student shall be awarded a Grade Card showing the grades obtained by him or her in each Course, the semester grade point average (SGPA) and the cumulative grade point average (CGPA), the former (SGPA) being the average of the grade points awarded to a student in the semester, which shall be calculated as follows:

$$SGPA = \frac{Sum\ of\ [Credits\ X\ Grade\ points]}{Sum\ of\ Credits\ of\ all\ the\ courses\ of\ each\ semester}$$

- The cumulative grade point average (CGPA) shall be calculated in a manner similar to that used for calculating SGPA, however, now taking into account all the courses of all the semesters so far completed by the student. "U", "I" and "W" grades will be excluded for calculating GPA and CGPA.
- The Grade Card shall also show the result of the student as "Semester Course Passed/ Failed," as the case may be.
- The Grade Card issued at the end of IV Semester, in addition, shall show the final result of the student; "M. Pharmacy Course Passed in ___ Class with Honors" or "M. Pharmacy Course Failed".
- If equivalence between the SGPA/ CGPA and the percentage of marks needs to be drawn for the purpose of informing the results of a student to external agencies, the following conversion formula shall be used: X = 10 Y, *where X is the equivalent percentage of marks and Y is the SGPA/ CGPA*.
- For passing I and II Semesters, a student must obtain a Grade of A1, A2, B1, B2, C1, C2 and P in each course and an SGPA of 5.00 or more.
- For passing III Semester, a student must obtain a Grade of A1, A2, B1, B2, C1, C2 and P in 'seminar on dissertation' as well as in 'dissertation - interim evaluation'.
- For passing IV Semester, a student must obtain a Grade of (A1, A2, B1, B2, C1, C2 and P in 'dissertation - open defense' as well as in 'dissertation - evaluation.'

The final result of the Master's Degree Examination shall be declared on the basis of CGPA after IV Semester examination, as follows:

CGPA	CLASS
8.00 and above	Distinction
6.00 and above and below 8.00	First Class
5.00 and above and below 6.00	Second Class
Below 5.00	Unsuccessful

- A student, who appears more than once in any Course of any examination forming a part of the course or does not submit dissertation within the period of 24 months from the date of commencement of classes shall not be ranked at the examination of that course of study irrespective of his or her performance.
- A student appearing in a supplementary examination due to not obtaining a passing grade in any Course(s) but securing the minimum SGPA in a semester examination shall appear in the Course(s) in which he or she has failed and/or failed to appear. However, a student who fails to secure the minimum SGPA for passing a semester shall appear in the supplementary examination of the concerned semester in the Course(s) in which he or she has failed and/ or failed to appear and in addition, he or she can opt for appearing in any number of theory Courses in the concerned semester, in which he or she has obtained grade 'P'.
- A student admitted to I Semester examination shall be promoted to II Semester irrespective of whether he or she passes, fails or fails to appear on genuine medical grounds, in the examination.
- A student shall be promoted to III Semester only after he or she passes I Semester and shall be allowed for submission of dissertation only after completing the II semester.
- A student shall be allowed to repeat those courses (if available) in which the letter grade P is secured if his/her CGPA/SGPA drops below the prescribed minimum 5.0 & 4.0 respectively and is likely to improve above prescribed minimum by crediting courses in which the student has got P grade.
- During III and IV semesters student shall enter to research of his choice from the field of specialization with approval from guide, HOD and head of the institute after submitting the proposal and approval for carrying out the research.
- Every student entering research shall maintain a prescribed log book.
- The log book shall be supervised and signed by the Guide and head of the institutes.
- The log book should be maintained until the completion of the research work.

13. AWARD OF DEGREE

Every student of the programme who fulfills the following criteria will be eligible for the award of the degree.

- He/She should have earned at least minimum required credits as prescribed in course structure.

- He/She should have cleared all external and overall evaluation components in every course.
- He/She should have secured a minimum CGPA of 5.0 at the end of the programme.
- In addition to above, the student has to complete the required formalities as per the regulatory bodies, if any.
- The student who fails to satisfy minimum requirement of CGPA will be allowed to improve the grades so as to secure a minimum CGPA for award of degree. Only latest grade will be considered.

14. REVALUATION

A candidate can apply for revaluation of his/her semester examination answer paper in a theory course, within two weeks from the declaration of results, on payment of a prescribed fee through proper application to the Controller of Examinations through the Head of institutions. The Controller of Examination will arrange for the revaluation and the results will be intimated to the candidate concerned through the Head of the institutions. Revaluation is not permitted for practical courses, seminars, practical training and for project work.

15. TRANSCRIPT

The transcript issued to the student at the time of leaving the University will contain a consolidated record of all the courses taken, credits earned, grades obtained, SGPA, CGPA, class obtained, etc.

16. DISCIPLINE

Every student is required to observe disciplined and decorous behavior both inside and outside the college and not to indulge in any activity which will tend to bring down the prestige of the University / College.

17. REVISION OF REGULATION AND CURRICULUM

The University may from time to time revise, amend or change the Regulations, scheme of examinations and syllabi and if necessary the same brought to the Academic Council.

18. GENERAL

Notwithstanding anything contained in this Manual, all categories of students/candidates shall be governed by the Rules & Regulations framed by the Academic Council in this behalf and in force from time to time.

19. INTERPRETATIONS

Any doubt or dispute arising about the interpretations of the Rules & Regulations shall be referred to the Chairman Academic Council whose decision shall be the final.

20. SCHEME OF EVALUATION

S. No	Course	Theory Awards			Practical Awards		
		University	Internal	Total	University	Internal	Total
1	Common Course for all the specialization-I	90	60	150	75	75	150
2	Specialization Core Course-I	90	60	150	75	75	150
3	Specialization Core Course -II	90	60	150	75	75	150
4	Elective Course	60	40	100	-	-	-
5	Specialization Core Course -III	90	60	150	75	75	150
6	Specialization Core Course -IV	90	60	150	75	75	150
7	Specialization Core Course -V	90	60	150	75	75	150
8	Common Course for all the specialization-II	60	40	100	-	-	-
9	Research Supportive Course	60	40	100	-	-	-
10	Dissertation - Interim evaluation				60	40	100
11	Dissertation evaluation				120	80	200
					Total Theory Marks		**1200**
					Total practical Marks		**900**
					Total Dissertation Marks		**300**
				Overall Total Marks (Theory/Practical/Dissertation)			**2400**

SYLLABUS

Master of Pharmacy Programme

PHARMACEUTICS

(SPECIALIZATION-1)

HIMACHAL PRADESH TECHNICAL UNIVERSITY
HAMIRPUR

SPECIALIZATION-1: PHARMACEUTICS

SCHEME OF TEACHING

First Semester

S. No	Courses	Course code	Theory / Practical	Contact hrs / week	Credits
1	Advanced Pharmaceutical Instrumental Analysis	**MP-011**	Theory	3	3
			Practical	5	3
2	Pharmaceutical Formulation Technology	**MP-111**	Theory	3	3
			Practical	5	3
3	Biopharmaceutics	**MP-112**	Theory	3	3
			Practical	5	3
4	Elective*	**MP-012 to 018**	Theory	2	2
	Total of First Semester			**26**	**20**

*Any one from the list of elective courses provided

Second Semester

S. No	Courses	Course code	Theory / Practical	Contact hrs / week	Credits
1	Advanced Pharmaceutics	**MP-121**	Theory	3	3
			Practical	5	2
2	Industrial Pharmacy	**MP-122**	Theory	3	3
			Practical	5	2
3	Pharmacokinetics	**MP-123**	Theory	3	3
			Practical	5	2
4	Intellectual Property Rights & Drug Regulatory Affairs	**MP-021**	Theory	2	2
	Total of Second Semester			**26**	**20**

Third Semester

S. No	Courses	Course Code	Theory / Practical	Contact hrs / week	Credits
1	Research Methodology and Statistics	**MP-030**	Theory	3	3
2	Dissertation work	**MP-D01**	Practical	24	12
	Total of Third Semester			**27**	**15**

Fourth Semester

S. No	Courses	Course Code	Theory / Practical	Contact hrs / week	Credits
1	Dissertation work (continued from previous semester)	**MP-D01**	Practical	24	12
2	Publication / Conference Presentation*				3
	Total of Fourth Semester			**24**	**15**

Total credits - 70

*One paper in national/ international indexed journal or presentation in a national level conference or at least acceptance letter from the editorial board of journal is compulsory for getting credits. The publication/ Conference presentation shall have names of guide and institution.

SCHEME OF EVALUATION

S. No	Course	Course code	Theory Awards			Practical Awards		
			University	Internal	Total	University	Internal	Total
SEMESTER-I								
1	Advanced Pharmaceutical Instrumental Analysis	MP-011	90	60	150	75	75	150
2	Pharmaceutical Formulation Technology	MP-111	90	60	150	75	75	150
3	Biopharmaceutics	MP-112	90	60	150	75	75	150
4	Elective*	MP-012 to 018	60	40	100	-	-	-
SEMESTER-II								
5	Advanced Pharmaceutics	MP-121	90	60	150	75	75	150
6	Industrial Pharmacy	MP-122	90	60	150	75	75	150
7	Pharmacokinetics	MP-123	90	60	150	75	75	150
8	Intellectual Property Rights & Drug Regulatory Affairs	MP-021	60	40	100	-	-	-
SEMESTER-III								
9	Research Methodology and Statistics	MP-030	60	40	100	-	-	-
10	Dissertation - Interim evaluation	MP-D01				60	40	100
SEMESTER-IV								
11	Dissertation evaluation	MP-DO1				120	80	200
							Total Theory Marks:	**1200**
							Total Practical Marks:	**900**
							Total Dissertation Marks:	**300**
							Overall Total Marks:	**2400**

* Any one from the list of elective courses provided

M. PHARMACY SPECILIZATION-1 (PHARMACEUTICS)

Semester- I

Name of Course	**ADVANCED PHARMACEUTICAL INSTRUMENTAL ANALYSIS**			
Course Code	MP-011		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objective of the Course

To make students familiar with the principles of modern analytical techniques and application of analytical instruments in pharmacy.

Student Learning Outcomes/Objectives

At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques, which is important for qualitative as well as quantitative analysis of drug substances and drug product.

Instructional Methods and Pedagogy

Faculty member/s shall explain in a class room using black board and multimedia projector.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each, only three are to be answered by candidate and out of 9 short questions carrying 5 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. UV-Visible spectroscopy (6 Hrs)

Brief review of electromagnetic spectrum, UV-Visual range, Interaction of electro-magnetic radiation (UV-Vis) and matter and its effects, principle, shifts, instrumentation, absorption spectra of organic compounds illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs.

2. Infra-Red Spectroscopy (6 Hrs)

Nature of Infra-red radiation, Interaction of IR radiation with organic molecules and effects on bonds, principle, brief outline of classical IR instrumentation, sample preparation for spectroscopy and qualitative interpretation of IR Spectra, FT-IR and applications.

3. Nuclear Magnetic Resonance Spectroscopy (8 Hrs)

Principles of NMR (Magnetic Properties of nuclei, applied field and precessional frequency, absorption and transition frequency), relaxation process, chemical shift concept, shielding, de-shielding effect and brief outline of interpretation of spectra.

4. Mass Spectrometry (5 Hrs)

Principle and brief outline of instrumentation, mass spectrum, types of peaks and its characteristics, interpretation of spectra and applications.

5. Thermal Methods of Analysis: (3 Hrs)

Theory, instrumentation and Applications of thermo gravimetric analysis (TGA), Differential Thermal Analysis (DTA) and Differential Scanning Calorimetry (DSC).

6. Electron Microscopy (3 Hrs)

Application of Transmittance Electron Microscopy (TEM) and Scanning Electron Microscopy (SEM).

7. Chromatographic Techniques (12 Hrs)

- High Performance Thin Layer Chromatography (HPTLC): Principle, adsorbents, instrumentation, qualitative and quantitative analysis of drugs.
- High performance Liquid Chromatography (HPLC): Principle, stationary and mobile phase, instrumentation, qualitative and quantitative analysis of drugs.
- Gas Chromatography: Introduction, principles, mobile phase and & stationary phase, instrumentation and identification of substances.
- Electrophoresis: Principle, techniques and applications of Paper electrophoresis and Gel electrophoresis.
- Principles, applications of ion exchange chromatography, affinity chromatography and size exclusion chromatography.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments shall be designed by the faculty

Experiments

1. Simultaneous estimation of drugs in combination formulations (1 expt)
2. UV Visible spectrum scanning of drugs absorption and correlation of structure (1expt)
3. HPLC estimation of drugs in formulation (1 expt)
4. Comparison of three different analytical techniques for the estimation of any suitable drug (1 expt)

5. Gradient elution technique in column chromatography (1 expt)
6. FT-IR spectrum scanning of drugs-absorption and correlation of structure (1 expt)

RECOMMENDED BOOKS

1. "Contemporary practice of chromatography" by Poole, Colin F. and SheilaA.Schuette.
2. Practical HPLC method development by L. R. Snyder Willey Interscience, Second Ed.
3. Aldrich FT-IR Spectral Library. "Pharmaceutical Analysis" by DavidC.LeeBlackwell Publisher.
4. British Pharmacopoeia, 2004 The british pharmacopoeia commission office, Market Tower, 1 Nine Elms Lane, London.
5. Chromatographic Analysis of Pharmaceuticals, A. John, Adamovics, Cytogan Corporation, Princeton, NJ.
6. Ewing's Analytical Instrumentation Handbook, edited by JackCazes, CRC press.
7. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P.D.Sethi, CBS Publishers and Distributers, New Delhi.
8. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography, 2nd Edition, P.D.Sethi, CBS Publishers and Distributers, New Delhi.
9. Indian Pharmacopoeia-2007, Indian pharmacopoeia commission, Sector-23, Raj Nagar, Ghaziabad.
10. Instrumental Methods of Analysis, Willard, Merritt, Dean and Settle, CBS publishers and Distributers, Delhi.
11. Instrumental Methods of Chemical Analysis, G. W. Ewing, McGraw Hill Book Co, NY.
12. Modern Methods of Pharmaceutical Analysis,Vol 1,2, RE Schirmer, Franklin Book Co
13. NMR spectroscopy (Basic Principles, concepts and application in Chemistry) Herald Gunther, (JohnWiley and Sons), NY.
14. Pharmaceutical Analysis – Modern Methods – Part A, Part B, J. W. Munson, MarcelDekker, NY.
15. Principles of Instrumental Analysis, Skoog, Hollar and Nieman, Philadelphia.
16. Remington's Pharmaceutical Sciences, J.P.Remington, MackPub. Co.,Pennsylvania.
17. Spectroscopic identification of organic compounds. JohnDyer, Willy, NY.
18. Spectroscopic identification of organic compounds. R.M.Silverstein, G.C.Bassler, T.C. Morrill Pub: John Wiley and Sons, NY.
19. United States Pharmacopoeia- United State of Pharmacopoeial convention, INC, 12601 Twin brook Parkway, Rockville, MD 20852.

M. PHARMACY SPECILIZATION-1 (PHARMACEUTICS)

Semester- I

Name of Course	PHARMACEUTICAL FORMULATION TECHNOLOGY			
Course Code	MP-111		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objectives of the course

To inculcate formulation technology of pharmaceutical dosage forms.

Students learning outcomes/objectives

To develop the ability to effectively apply knowledge of excipients, dosage forms, production, quality improvements, safety and production management and optimization of pharmaceutical products and drug delivery systems.

Instructional Methods and Pedagogy

Through class-room teaching & discussions. Performing experiments related to Product development studies.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each only three are to be answered by candidate and out of 9 short questions carrying 5 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Preformulation Studies **(6 Hrs)**

- Objectives of Preformulation, Preformulation parameters and drug excipients compatibility
- Excipients used in pharmaceutical dosage forms
- Selection criteria for various excipients like surfactant, viscosity improvers, diluents, coating materials, plasticizers, preservatives, flavors and colours
- Solubility and Solubilization Techniques
- pH and Partition Coefficient, Log P Values, theoretical computation using Hansnch and Leo/Rekker method
- Solid state Pharmaceutics, Rheology, Complexation

2. Formulation Development: (20 Hrs)

- **Solid Dosage Forms:**
  - Improved production techniques for tablets: New materials process, equipments improvements, high shear mixers, compression machines, coating machines, coating techniques in tablet technology for product development, physics of tablet compression, computerization for in process quality control of tablets, types of tablets and their manufacture.
  - Formulations, production and evaluation of hard and soft gelatin capsules.
  - Powder dosage forms: Formulation development and manufacture of powder dosage form for internal and external use including inhalations dosage forms.
- **Liquid And Semi-Solid Dosage Forms:** Recent advances in formulation aspects and manufacturing of monophasic dosage forms. Recent advances in formulation aspects and manufacturing of suspensions, dry syrups and semi-solid dosage forms.
- **Parenteral Dosage Forms:** Advances in materials and production techniques, filling machines, sterilizers and aseptic processing.Manufacturing of small and large volume parenterals and quality control.
- **Aseptic Processing Operation:** Introduction, contamination control, microbial environmental monitoring, microbiological testing of water, Microbiological air testing, characterization of aseptic process, media and incubation condition, theoretical evaluation of aseptic operations.
- **Aerosols:** Advances in propellants, metered dose inhaler designs, selection of containers and formulation aspects in aerosol formulation, Manufacture and quality control.

3. Good Manufacturing Practices and Regulatory Requirements (8 Hrs)

- Knowledge of the legal/regulatory standards/systems governing products: National and International.
- Product claims, claims substantiation, consumer research in cosmetic products.
- Knowledge of the various raw materials including colours etc. allowed/not allowed for use in the industry.
- Documentation requirements.

4. Stability of Drug and Dosage Forms (9 Hrs)

Physicochemical and biological factors affecting stability of drugs, Degradation of drug in solid state & solid dosage forms, stabilization methods, ICH guidelines, importance of stability indicating assay in stability evaluation, stability evaluation of disperse systems.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Preformulation, compression and evaluation of tablets (2 expts)
2. Stability studies of a drug in dosage forms based on Arrhenius approach (1 expt)
3. Sterility testing of injections as per IP (1 expt)
4. Preparation and evaluation of gels containing two different gel bases (1 expt)
5. Preparation and comparative evaluation with marketed products for efficiency of neutralizing property of antacid suspension (1 expt)

RECOMMENDED BOOKS

1. How to Practice GMPs, PPSharma, 2nd edition, Vandana Publications, Agra
2. Pharmaceutical Process Validation, Edited by Berry and Nash, 2nd edition
3. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total Quality Control, Edited by Sydney H Willig & James R Shoher, 3rd edition
4. Applied production and Operations Management, Evans, Anderson, Sweeney and Williams, 3rd edition, West Publishing company Ltd. St Paul
5. Management (Task, Responsibility and Practices), PeterF.Drucker, Allied Publication, Bangalore

M. PHARMACY SPECILIZATION-1 (PHARMACEUTICS)

Semester- I

Name of Course	**BIOPHARMACEUTICS**			
Course Code	MP-112		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objective of the Course

- To make students familiar with the fundamental principles of drug absorption, distribution, metabolism and excretion of drugs.
- To emphasize on bioavailability study and application of biopharmaceuticals.

Student Learning Outcomes

- On completion of the course the student would understand the drug absorption, distribution, metabolism, and elimination.
- Basic mechanisms and concepts of absorption, distribution, metabolism, and elimination.
- How to predict the fate of drugs in the body given all the physiological, chemical and physical parameters of the drug and the patient

Instructional Methods and Pedagogy

Faculty member/s shall explain in a class room using black board and multimedia projector.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each only three are to be answered by candidate and out of 9 short questions carrying 5 marks each only seven are to be answered by candidate.

THEORY **Total 43 hours**

1. Basic concepts of Biopharmaceutics (4 Hrs)

Definition, Fundamental principles of Biopharmaceutics, Concept of bioavailability, Determination of bioavailability, Absolute bioavailability and Relative bioavailability.

2. Drug Absorption from Gastro-intestinal Tract (9 Hrs)

Anatomic and physiologic considerations; Physicochemical factors influencing drug absorption from the GIT; Drug dissolution constant (pka) and lipid solubility; Dissolution rate of drugs (Particle size and Surface area, Crystal form, Polymorphism, Solvation, Salt forms, Complexation, Solid solutions, Adsorption, Eutectics, Surfactants); Chemical stability of drugs in the GIT; Physiological factors influencing drug absorption from the GIT; Surface area of the GI absorption sites, pH of the G.I. fluids, Gastric emptying, Intestinal motility; Dosage form factors influencing drug absorption from the GIT.

3. Drug Absorption via Buccal and Other Routes of Administration (6 Hrs)

Drug absorption via buccal, sublingual, pharyngeal and nasogastric mucosa; Rectal drug absorption, Ophthalmic drug absorption, Parenteral drug absorption, Inhalation drug delivery systems, Percutaneous drug absorption.

4. Disposition Factors Influencing Drug Activity (8 Hrs)

Drug distribution, Binding to blood components, Tissue distribution, Membrane transport (pH partition, uptake into CSF), Drug metabolism, Principles and pathways of biotransformation, Factors affecting drug biotransformation, Drug excretion-Renal excretion (Glomerular filtration, Active tubular secretion, Passive tubular reabsorption), Non-renal excretion (Biliary, Salivary, Mammary, Pulmonary, Skin, Genital).

5. Considerations in Drug Evaluation (6 Hrs)

In vivo and *In vitro* evaluation of drug dosage forms.

7. Regulatory Requirements (5 Hrs)

Role of biopharmaceutics and pharmacokinetics in the NDA and ANDA submissions.

8. Bioequivalence (5 Hrs)

Definition and concept, Bioequivalence requirements and design, Bioequivalence studies, Methods of documenting bioequivalence and therapeutic equivalence.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 06; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Improvement of dissolution characteristics of slightly soluble drugs by various solid dispersion techniques and solvent deposition systems (3 expts)
2. Comparison of dissolution of two different marketed products / brands (2 expts)
3. Influence of polymorphism on solubility and dissolution (1 expt)

RECOMMENDED BOOKS

1. Clinical Pharmacokinetics - concept & application - MalcolmRowland&ThomasN.Tozer, Lea & Febiger book.
2. Applied Biopharmaceutics & Pharmacokinetics – LeonShargel.
3. Biopharmaceutics & Pharmacokinetics - Milo Gibaldi , Lea & Febiger book publication
4. Biopharmaceutics & Pharmacokinetics - an introduction - RobertE.Notary.
5. Biopharmaceutics - Swarbrick, Lea & Febiger book publication
6. Biopharmaceutics & Pharmacokinetics. A treatise - D. M. Brahmankar S B. Jasiwal
7. Biopharmaceutics & Pharmacokinetics - P.L.Madan
8. Introduction to Biopharmaceutics. - G.P. -Shriwastav
9. Textbook of Applied Biopharmaceutics and Pharmacokinetics by Shargel.
10. Biopharmaceutics and Clinical Pharmacokinetics by John and Wagner.
11. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
12. Biopharmaceutics and Pharmacokinetics-A Treatise by D.M.Brahmankar and S.B.Jaiswal, VallbahPrakash, New Delhi.
13. Biopharmaceutics by Swabeic.

M. PHARMACY SPECILIZATION-1 (PHARMACEUTICS)

Semester-II

Name of Course	**ADVANCED PHARMACEUTICS**			
Course Code	MP-121		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objectives of the course

To get acquainted with formulation, methods of preparation, evaluation and applications of New Drug Delivery Systems.

Students learning outcomes/objectives

Students can select research based project in subsequent semesters for specific type of delivery systems. The knowledge gained by the students during the study of this course can also help them in research projects and in Pharma industry.

Instructional methods and pedagogy

Through discussion in a class-room, and performing related experiments.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each only three are to be answered by candidate and out of 9 short questions carrying 5 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Introduction (4 Hrs)

Fundamental concepts of controlled release including Biopharmaceutical consideration of controlled release dosage forms.

2. Modified Release Oral Drug Delivery Systems (5 Hrs)

Principle, formulation, in-vivo evaluation of drug delivery systems,osmotic pumps, membrane permeation, pH controlled, ion exchange controlled, gel diffusion controlled, hydrodynamically balanced system, modulation of gastrointestinal transit time.

3. Mucosal Drug delivery (5 Hrs)

Mechanism of mucoadhesion.Bioadhesive polymers, penetration enhancers.Development of buccal, nasal, pulmonary, rectal and vaginal drug delivery system.In vitro, ex-vivo and in-vivo evaluation techniques.

4. Ocular Drug Delivery (5 Hrs)

Ocular delivery mechanism, factors affecting ocular drug absorption and development of ocular drug delivery systems, mucoadhesive polymers, ocular inserts, iontophoresis, delivery of peptides and proteins.

5. Transdermal Drug Delivery (5 Hrs)

Permeation through skin, physicochemical factors in drug permeation, permeation enhancers, iontophoresis drug delivery, approaches and technologies for developing transdermal drug delivery systems and their evaluation.

6. Advanced Drug Delivery Systems (15 Hrs)

Implantable Devices: Types, release mechanism,fabrication, biocompatibility and performance evaluation.

Targeted Drug Delivery: Pulsatile, colon specific, intra-arterial, non-corneal drug delivery systems

Liposomes and Niosomes: Methods of preparation, characterization, stability, applications and evaluation techniques.

Resealed Erythrocytes: Methods of drug entrapment, characterization of loaded erythrocytes, stability, storage and release from the system. Applications and immunological,consideration.

Microspheres and Nanopartilces: Polymers used,Method of preparation, characterization, evaluation and pharmaceutical applications.

7. Optimization Techniques in Pharmaceutical Formulation and Processing (4 Hrs)

Concept of optimization, optimization parameters,classical optimization, statistical design and optimization methods.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Preparation and evaluation of albumin microspheres (1 expt)
2. Preparation and evaluation of matrix tablets using various polymers (1 expt)
3. Preparation and in vitro evaluation of buccal mucoadhesive formulations (tablets/ films) (2 expts)
4. Preparation and evaluation of hydrodynamically balanced tablets (1 expt)
5. Preparation and evaluation of ocular films (1 expt)

RECOMMENDED BOOKS

1. P.Tyle; Drug Delivery Devices, fundamental applications, MarcelDekker.
2. MortonRosoff; Controlled release of drugs, VCH Publishers.
3. D.W.Osborne, A.H.Amann; Topical drug delivery formulations, MarcelDekker.
4. P.Tyle; Drug Delivery Devices, fundamental applications, MarcelDekker.
5. Barry; Dermatological Formulation, MarcelDekker.
6. Robinson; Novel Drug Delivery systems. MarcelDekker.
7. N. K. Jain; Novel and Drug Delivery systems, CBS Publishers, New Delhi.
8. P.Johnson and J.G. lioyd- Jones; Drug Delivery Systems, VCH Publishers.
9. P.Tyle and B. P. Ram; Targetted Therapeutic systems, MarcelDekker.
10. C. G.Wilson and N. Washington; Physiological Pharmaceutics, Ellis Horwood Limited.
11. H. S.Bean, A.H.Becket and J. E. Carless; Advances in Pharmaceutical Sciences, Vol. 5, Academic Press.
12. R. O.Potts and R.H.Guy; Mechanism of Transdermal Drug Delivery,MarcelDekker.
13. T. J.Roseman and S.Z.Mansdorf; Controlled release delivery Systems, MarcelDekker.
14. J. Hickey; Pharmaceutical Inhalation Aerosol Technology, MarcelDekker.
15. J.Kreuter; Controlled Drug Delivery Systems, MarcelDekker.
16. K.S.E.Su and S.F.Chang; Nasal Systemic Drug Delivery, MarcelDekker.
17. F.Kydonieus; Controlled Release Technologies, methods, theory and applications, Vol. I and II, CRC Press Inc.
18. Y. W.Chein; Transdermal Controlled Systemic Medication, MarcelDekker.
19. P. B.Deasy; Micro encapsulation and release drug processes, MarcelDekker.

M. PHARMACY SPECILIZATION-1 (PHARMACEUTICS)

Semester- II

Name of Course	**INDUSTRIAL PHARMACY**			
Course Code	MP-122		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objectives of the course

To get acquainted with production planning, scheduling and forecasting and Production Management.

Students learning outcomes/objectives

Students can select research based project in subsequent semesters for specific type of delivery systems. The knowledge gained by the students during the study of this course can also help them in research projects and in Pharma industry.

Instructional methods and pedagogy

Through discussion in a class-room, and performing related experiments.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each only three are to be answered by candidate and out of 9 short questions carrying 5 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Compaction and Compression (7 Hrs)

Compaction of powders with a particular reference to distribution and measurement of forces within the powder mass undergoing compression.Effect of particle size, moisture content, lubrication etc on strength of tablets.A brief study on formulation aspects of tablets such as sublingual, buccal chewable and medicated lozenges.

2. Production Planning, Scheduling and Forecasting (7 Hrs)

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

3. Production Management and Documentation (8 Hrs)

ISO 9000 series, Total quality management, Guide to pharmaceutical manufacturing facilities, Productivity, GMP considerations, Quality assurance and process control, stress on documentation practices, validation for tablets and parenterals, validation aspects. Regulatory guidelines for Sustained / Controlled release products.

4. Pilot Plant Scale Up Techniques (7 Hrs)

Significance of pilot plant scale up phase to effect an orderly setup from laboratory procedures and formulations to routine production procedures. Pilot study of some important dosage forms such as tablets, capsules, injections and liquid orals and discussion on important parameters such as formula and equipment, product uniformity and stability. Raw materials and process, physical layouts, personnel requirements and reporting responsibilities.Input specifications and in process & finished product specifications.

5. Structure of Pharmaceutical Industry (3 Hrs)

Structure of pharmaceutical Industry, structure of each division, and work procedure

6. Industrial Safety (5 Hrs)

Detailed study of different Industrial hazards, precautions,Monitoring and preventive systems. Industrial effluent testing and treatment. Discussion on Industrial accident case studies, Environment and pollution Acts

7. Veterinary Dosage Forms Including Herbal Drugs (6 Hrs)

Tablet and bolus, Feed additives, Drinking water medication, Oral pastes & gel, Drenches & tubing product, Topical dosage forms, USFDA requirements for animal drugs.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Comparison of tablet manufacturing using wet granulation, dry granulation and direct compression (3 expts)
2. Study of effects of various excipients on tablet properties (1 expt)
3. Preparation and evaluation of herbal tablet / capsule (2 expts)

RECOMMENDED BOOKS

1. Applied production and Operations Management, Evans, Anderson, Sweeney and Williams, 3rd edition, West Publishing company Ltd. St Paul
2. Avis, Leon Lachman and Herbert A. Lieberman (Editors), Marcel Dekker, NY.
3. Bentley's Text Book of Pharmaceutics - E. A. Roawlins.
4. Drug Formulation Manual by Kohli, P.S., Eastern Publishers, New Delhi.
5. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total Quality Control, Edited by Sydney H Willig & James R Shoher, 3rd edition
6. How to Practice GMPs 2nd ed. by Sharma P. P., Vandana Publishing, New Delhi. GMP by M.L. Mehra, The Universal Book Agency, Allahabad.
7. Leon Lachman and Joseph B. Schwartz (Editors), Marcel Dekker, NY.
8. Lieberman, Martin M. Rieger and Gilbert (Editors), Marcel Dekker, NY.
9. Management (Task, Responsibility and Practices), Peter F. Drucker, Allied Publication, Bangalore
10. Modern Pharmaceutics by Banker, G.S and Rhodes, C.T. (Eds.), Marcel Dekker, NY.
11. Parenteral Products by Groves. Physical Pharmacy by Martin, Lea and Febiger, Philadelphia..
12. Pharmaceutical Dosage Forms - Tablets, Volumes 1 to 3. by Herbert A. Lieberman,
13. Pharmaceutical Dosage Forms and Drug Delivery Systems by Howard C. Ansel., Lea and Febiger, Philadelphia.
14. Pharmaceutical Dosage Forms-Disperse Systems, Volume 1 and 2 by Herbert A.
15. Pharmaceutical Dosage Forms-Parenteral Medications, Volume 1 and 2 by Kenneth E.
16. Pharmaceutical Preformulation by Wells, J.I., Ellis Horwood Ltd., NY, 1988.
17. Pharmaceutical Process Validation, Edited by Berry and Nash, 2nd edition
18. Sterile Dosage Forms by Salvatore Turco and Robert E. King. Lea and Febiger, Philadelphia.
19. The Theory and Practice of Industrial Pharmacy by Lachman, L., Lieberman and Kanig, J.L, KM Varghese Company, Mumbai.

M. PHARMACY SPECILIZATION-1 (PHARMACEUTICS)

Semester- II

Name of Course	**PHARMACOKINETICS**			
Course Code	MP-123		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objectives of the Course

- To study the time course of drug absorption, distribution, metabolism and excretion and their relationship with the pharmacological, therapeutic or toxicological response in human beings.
- To make students familiar with the fundamental principles of drug absorption, distribution, metabolism and excretion of drugs.

Student Learning Outcomes

- On completion of the course the student would understand the drug absorption, distribution, metabolism, and elimination.
- Basic mechanisms and concepts of absorption, distribution, metabolism, and elimination.

Instructional Methods and Pedagogy

Faculty member/s shall explain in a class room using black board and multimedia projector.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each only three are to be answered by candidate and out of 9 short questions carrying 5 marks each only seven are to be answered by candidate.

THEORY **Total 43 hours**

1. Introduction **(7 Hrs)**

Definitions of Pharmacokinetic, Pharmacodynamic, Clinical pharmacokinetics, Toxi-pharmacokinetics, Kinetic concepts of drug absorption, Compartments and models, Rates and order of kinetics.

2. Basic Concepts (7 Hrs)

Definition & introduction to absorption rate constant, bio-availability, volume of distribution, elimination half-life, elimination rate constant, clearance, extraction ratio, area under curve, protein binding and tissue binding.

3. Basic Pharmacokinetics (8 Hrs)

One compartment and two compartments open model: i.v. bolus administration, i.v. infusion, extra vascular administration. Multicompartment model

4. Pharmacokinetics of Multiple Dosing (8 Hrs)

Adjustment of dosage in renal & hepatic impairment, individualization of therapy, therapeutic drug monitoring, Kinetics of sustained release

5. Non-linear Pharmacokinetics (6 Hrs)

Causes of non-linearity, estimation of various parameters and bioavailability of drugs that follow non-linear kinetics ,Protein Binding of Drugs

6. Application of Pharmacokinetics (6 Hrs)

New drug development, Design of dosage forms and novel drug delivery systems, Case studies based on pharmacokinetic principles.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Bioavailability studies of Paracetamol by salivary data (1 expt)
2. Calculation of Ka, Ke, t½, Cmax and Tmax for two sets of data (2 expts)
3. Calculation of bioavailability from given urinary excretion data for one / two drugs (1 expt)
4. Calculation of AUC and bioequivalence from given data for two drugs (2 expts)

RECOMMENDED BOOKS

1. Applied Biopharmaceutics & Pharmacokinetics – Leon Shargel.
2. Biopharmaceutics & Pharmacokinetics - an introduction - Robert E. Notary.
3. Biopharmaceutics & Pharmacokinetics - Milo Gibaldi , Lea & Febiger book publication
4. Biopharmaceutics & Pharmacokinetics - P. L. Madan
5. Biopharmaceutics & Pharmacokinetics. A treatise - D. M. Brahmankar S B. Jasiwal
6. Biopharmaceutics and Clinical Pharmacokinetics by John and Wagner.
7. Biopharmaceutics and Clinical Pharmacokinetics by Milo Gibaldi.
8. Biopharmaceutics and Pharmacokinetics by Robert E. Notari.
9. Biopharmaceutics and Pharmacokinetics-A Treatise by D.M. Brahmankar and S.B. Jaiswal, Vallbah Prakash, New Delhi.
10. Clinical Pharmacokinetics - concept & application - Malcolm Rowland & Thomas N. Tozer, Lea & Febiger book.
11. Encyclopedia of Pharmaceutical Technology.
12. Handbook of clinical Pharmacokinetics - Gibaldi & Pancot
13. Pharmacokinetics - Milo Gibaldi & Donald Perrier
14. Remington's Pharmaceutical Sciences by Mack Publishing Company, Pennsylvania.
15. Textbook of Applied Biopharmaceutics and Pharmacokinetics by Shargel.

M. PHARMACY SPECILIZATION-1 (PHARMACEUTICS)

Semester- II

Name of Course	**INTELLECTUAL PROPERTY RIGHTS & DRUG REGULATORY AFFAIRS**			
Course Code	MP-021		Contact hours/week	T-2, P-0
Credits	2+0=2		Total teaching hours required = 30	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	**-**

Objective of the Course

To make students familiar with the fundamental principles of IPR and Drug regulatory affairs

Student Learning Outcomes

On completion of the course the student would understand the principle and importance if IPR and Drug regulatory affairs in the competitive world

Instructional Methods and Pedagogy

Faculty member/s shall explain in a class room using black board and multimedia projector.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each only three are to be answered by candidate and out of 9 short questions carrying 3 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 30**

1. Intellectual Property-Concepts and Fundamentals (5 Hrs)

The emergence and growth of the concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); economic importance, mechanism for protection of intellectual property-patents.

2. Trade Related Aspects of Intellectual Property Right (4 Hrs)

Intellectual property and international trade, concept behind WTO (World Trade Organization), WIPO (World Intellectual Property Organization), GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trades in Services), status in India and other developing countries.

3. Patenting (5 Hrs)

Copyright and trade mark protection, criteria for patentability, Indian patent act. 1970: WTO and modifications under TRIPS, filing of a patent application, precautions before patenting-disclosures/non-disclosures, publication-article/ thesis, prior art search – published patents search, internet search patent sites, specialized service search requests, costs, patent application forms and guidelines, fee structure, time frames, jurisdiction aspects, types of patent application- provisional, non-provisional, PCT and convention patent applications, international patenting requirement procedures and costs.

4. Technology Development/Transfer Commercialization Related Aspects (4 Hrs)

Technology development: Meaning, drug related technology development, toxicological studies, bioequivalence (BU), clinical trials Phase I, Phase II and Phase III.

5. Ethics and Values in IP (3 Hrs)

IP and ethics, positive and negative aspects of IPP, social responsibility, avoiding unethical practices, eco-responsibility–economic, social and environmental benefits of modern biotechnology.

6. Drug Regulatory Affairs (9 Hrs)

- Regulation on manufacture of drugs in India.
- Drug regulatory controls and authorities.
- Requirements of GMP, CGMP, GLP.
- Guidelines of WHO, inputs of international bodies, national agencies, harmonization.
- Preparation and submission of marketing application of India, US and Europe.
- Approval and appeals present and issues of confidentiality.
- ISO 9000 series.
- Drugs and cosmetics acts and rules.
- Important regulations related to import and export of drugs.

BOOKS RECOMMENDED

1. Treece DJ. Managing Intellectual Capital: Organizational, Strategic and Policy Dimension. Oxford University Press, England. Latest Edition.
2. Wadedhra BL. Law Relating to Patents, Trademarks, Copyright Design and Geographical Indications. Universal Law Publishing, New Delhi. Latest Edition.
3. Bansal P. IPR Handbook for Pharma Students and Researchers, Pharma Book Syndicate, Hyderabad. Latest Edition.
4. Copyright Protection in India [website: http:copyright.gov.in].
5. Information on Orange Book [website: www.fda.gov/cder/ob/default.htm].
6. World Trade Organization [website: www.wto.org].
7. Trivedi PR. Encylcopedia of Intellectual Property Rights. Jnanada Prakashan, New Delhi. Latest Edition.

M. PHARMACY SPECILIZATION-1 (PHARMACEUTICS)

Semester- III

Name of Course	**RESEARCH METHODOLOGY AND STATISTICS**			
Course Code	MP-030		Contact hours/week	T-3, P-0
Credits	3		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	-

Objectives of the Course

- To make the student familiar with systematic research methodology and computer applications in development of proper research methodology.
- To make the student familiar with different pharmaceutical and statistical tools required for carrying out systematic research.

Student Learning Outcomes

On completion of the course the student would understand the principle and importance if IPR and Drug regulatory affairs in the competitive world

Instructional Methods and Pedagogy

Faculty members shall explain in a class room using black board or a multimedia projector.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each only three are to be answered by candidate and out of 9 short questions carrying 3 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Literature Survey **(2 Hrs)**

Accessing required information in a systematic manner from abstracts, books, journals, proceedings of conferences, theses and dissertations, CD ROMs, internet and such other sources.

2. Scientific Writing **(5 Hrs)**

Writing of papers, articles and thesis; preparation of title, abstracts, introduction, methodology, results and discussion, summary-conclusion; preparation of tables and figures using software like MS Office, Open Office, etc; organization of dissertations and thesis; conventions adopted in writing; citing references; preparation of oral presentations and posters.

3. Data Collection (8 Hrs)

The population – sample; measures of describing the center of data distributions; measurement of spread of data; binomial and normal distributions – their significance.

4. Statistical Inference (10 Hrs)

Statistical estimation – confidence intervals; tests for statistical significance – T-test, F-test, analysis of variance (ANOVA); Chi-square test; linear regression and correlation.

5. Non-parametric tests (10 Hrs)

Data characteristics suitable to non-parametric procedures; Sign test, Wilcoxon signed rank test, Wilcoxon rank sum test; Kruskal Wallis test; Runs test for randomness; contingency tables.

6. Statistical software (8 Hrs)

Introduction to statistical software such as SPSS, GraphPad, SigmaStat, MS Excel; open source software for statistical analysis.

BOOKS RECOMMENDED

1. Bolton, Pharmaceuticals Statistics- Practical & Clinical Applications, Marcel & Dekker, New York.
2. Fisher, R.A., Statistical Methods for Research Works, Oliver & Boyd, Edinburgh.
3. Chow, Statistical Design and Analysis of Stability Studies, Marcel Dekker, New York.
4. Buncher, Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.
5. Finney, D.J., Statistical Methods in Biological Assays, Hafner, New York.
6. Montgomery, D.C., Introduction to Statistical Quality Control, Willy.
7. Khan, Irfan A., Biostatistics for Pharmacy.
8. Khan, Irfan, A., Fundamentals of Biostatistics.
9. Gauthaman, Biostatistics for Pharmacy students.
10. Lipschutz, Introduction to Probability and Statistics.
11. Liwan Po, Statistics for Pharmacist.
12. William E. Fassett, Computer Application in Pharmacy.
13. Ekins, S., Computer Application in Pharmaceutical Research & Development, Wiley.
14. Nageswara Rao and Tiwari, Biostatistics and Computer Applications.
15. Robert A Day., How to write and publish a scientific paper, 4th edition, Cambridge University Press.

SYLLABUS

Master of Pharmacy Programme

PHARMACEUTICAL CHEMISTRY

(SPECIALIZATION-2)

HIMACHAL PRADESH TECHNICAL UNIVERSITY
HAMIRPUR

SPECIALIZATION-2: PHARMACEUTICAL CHEMISTRY

SCHEME OF TEACHING

First Semester

S. No	Courses	Course code	Theory / Practical	Contact hrs / week	Credits
1	Advanced Pharmaceutical Instrumental Analysis	**MP-011**	Theory	3	3
			Practical	5	3
2	Advanced Pharmaceutical Chemistry-I	**MP-211**	Theory	3	3
			Practical	5	3
3	Advanced Medicinal Chemistry	**MP-212**	Theory	3	3
			Practical	5	3
4	Elective*	**MP-012 to 018**	Theory	2	2
	Total of First Semester			**26**	**20**

*Any one from the list of elective courses provided

Second Semester

S. No	Courses	Course code	Theory / Practical	Contact hrs / week	Credits
1	Advanced Pharmaceutical Chemistry - II	**MP-221**	Theory	3	3
			Practical	5	2
2	Advances in Chemistry of Natural Products	**MP-222**	Theory	3	3
			Practical	5	2
3	Dug Design	**MP-223**	Theory	3	3
			Practical	5	2
4	Intellectual Property Rights & Drug Regulatory Affairs	**MP-021**	Theory	2	2
	Total of Second Semester			**26**	**20**

Third Semester

S. No	Courses	Course Code	Theory / Practical	Contact hrs / week	Credits
1	Research Methodology and Statistics	**MP-030**	Theory	3	3
2	Dissertation work	**MP-D01**	Practical	24	12
	Total of Third Semester			**27**	**15**

Fourth Semester

S. No	Courses	Course Code	Theory / Practical	Contact hrs/week	Credits
1	Dissertation work (continued from previous semester)	**MP-D01**	Practical	24	12
2	Publication / Conference Presentation*				3
	Total of Fourth Semester			**24**	**15**

Total credits - 70

*One paper in national/ international indexed journal or presentation in a national level conference or at least acceptance letter from the editorial board of journal is compulsory for getting credits. The publication/ Conference presentation shall have names of guide and institution.

SCHEME OF EVALUATION

S. No	Course	Course code	Theory Awards			Practical Awards		
			University	Internal	Total	University	Internal	Total
SEMESTER-I								
1	Advanced Pharmaceutical Instrumental Analysis	MP-011	90	60	150	75	75	150
2	Advanced Pharmaceutical Chemistry-I	MP-211	90	60	150	75	75	150
3	Advanced Medicinal Chemistry	MP-212	90	60	150	75	75	150
4	Elective*	MP-012 to 018	60	40	100	-	-	-
SEMESTER-II								
5	Advanced Pharmaceutical Chemistry-II	MP-221	90	60	150	75	75	150
6	Advances in Chemistry of Natural Products	MP-222	90	60	150	75	75	150
7	Dug Design	MP-223	90	60	150	75	75	150
8	Intellectual Property Rights & Drug Regulatory Affairs	MP-021	60	40	100	-	-	-
SEMESTER-III								
9	Research Methodology and Statistics	MP-030	60	40	100			
10	Dissertation - Interim evaluation	MP-D01				60	40	100
SEMESTER-IV								
11	Dissertation evaluation	MP-DO1				120	80	200
							Total Theory Marks:	**1200**
							Total Practical Marks:	**900**
							Total Dissertation Marks:	**300**
							Overall Total Marks:	**2400**

* Any one from the list of elective courses provided

M. PHARMACY SPECILIZATION-2 (PHARMACEUTICAL CHEMISTRY)

Semester- I

Name of Course	**ADVANCED PHARMACEUTICAL INSTRUMENTAL ANALYSIS**			
Course Code	MP-011		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objective of the Course

To make students familiar with the principles of modern analytical techniques and application of analytical instruments in pharmacy.

Student Learning Outcomes/Objectives

At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques, which is important for qualitative as well as quantitative analysis of drug substances and drug product.

Instructional Methods and Pedagogy

Faculty member/s shall explain in a class room using black board and multimedia projector.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each, only three are to be answered by candidate and out of 9 short questions carrying 5 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. UV-Visible spectroscopy (6 Hrs)

Brief review of electromagnetic spectrum, UV-Visual range, Interaction of electro-magnetic radiation (UV-Vis) and matter and its effects, principle, shifts, instrumentation, absorption spectra of organic compounds illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs.

2. Infra-Red Spectroscopy (6 Hrs)

Nature of Infra-red radiation, Interaction of IR radiation with organic molecules and effects on bonds, principle, brief outline of classical IR instrumentation, sample preparation for spectroscopy and qualitative interpretation of IR Spectra, FT-IR and applications.

3. Nuclear Magnetic Resonance Spectroscopy (8 Hrs)

Principles of NMR (Magnetic Properties of nuclei, applied field and precessional frequency, absorption and transition frequency), relaxation process, chemical shift concept, shielding, de-shielding effect and brief outline of interpretation of spectra.

4. Mass Spectrometry (5 Hrs)

Principle and brief outline of instrumentation, mass spectrum, types of peaks and its characteristics, interpretation of spectra and applications.

5. Thermal Methods of Analysis: (3 Hrs)

Theory, instrumentation and Applications of thermo gravimetric analysis (TGA), Differential Thermal Analysis (DTA) and Differential Scanning Calorimetry (DSC).

6. Electron Microscopy (3 Hrs)

Application of Transmittance Electron Microscopy (TEM) and Scanning Electron Microscopy (SEM).

7. Chromatographic Techniques (12 Hrs)

- High Performance Thin Layer Chromatography (HPTLC): Principle, adsorbents, instrumentation, qualitative and quantitative analysis of drugs.
- High performance Liquid Chromatography (HPLC): Principle, stationary and mobile phase, instrumentation, qualitative and quantitative analysis of drugs.
- Gas Chromatography: Introduction, principles, mobile phase and & stationary phase, instrumentation and identification of substances.
- Electrophoresis: Principle, techniques and applications of Paper electrophoresis and Gel electrophoresis.
- Principles, applications of ion exchange chromatography, affinity chromatography and size exclusion chromatography.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments shall be designed by the faculty

Experiments

1. Simultaneous estimation of drugs in combination formulations (1 expt)
2. UV Visible spectrum scanning of drugs absorption and correlation of structure (1expt)
3. HPLC estimation of drugs in formulation (1 expt)
4. Comparison of three different analytical techniques for the estimation of any suitable drug (1 expt)

5. Gradient elution technique in column chromatography (1 expt)
6. FT-IR spectrum scanning of drugs-absorption and correlation of structure (1 expt)

RECOMMENDED BOOKS

1. "Contemporary practice of chromatography" by Poole, Colin F. and Sheila A. Schuette.
2. Practical HPLC method development by L. R. Snyder Willey Interscience, Second Ed.
3. Aldrich FT-IR Spectral Library. "Pharmaceutical Analysis" by David C. Lee Blackwell Publisher.
4. British Pharmacopoeia, 2004 The british pharmacopoeia commission office, Market Tower, 1 Nine Elms Lane, London.
5. Chromatographic Analysis of Pharmaceuticals, A. John, Adamovics, Cytogan Corporation, Princeton, NJ.
6. Ewing's Analytical Instrumentation Handbook, edited by Jack Cazes, CRC press.
7. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi, CBS Publishers and Distributers, New Delhi.
8. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography, 2nd Edition, P. D. Sethi, CBS Publishers and Distributers, New Delhi.
9. Indian Pharmacopoeia-2007, Indian pharmacopoeia commission, Sector-23, Raj Nagar, Ghaziabad.
10. Instrumental Methods of Analysis, Willard, Merritt, Dean and Settle, CBS publishers and Distributers, Delhi.
11. Instrumental Methods of Chemical Analysis, G. W. Ewing, McGraw Hill Book Co, NY.
12. Modern Methods of Pharmaceutical Analysis,Vol 1,2, RE Schirmer, Franklin Book Co
13. NMR spectroscopy (Basic Principles, concepts and application in Chemistry) Herald Gunther, (John Wiley and Sons), NY.
14. Pharmaceutical Analysis – Modern Methods – Part A, Part B, J. W. Munson, Marcel Dekker, NY.
15. Principles of Instrumental Analysis, Skoog, Hollar and Nieman, Philadelphia.
16. Remington's Pharmaceutical Sciences, J. P. Remington, Mack Pub. Co.,Pennsylvania.
17. Spectroscopic identification of organic compounds. John Dyer, Willy, NY.
18. Spectroscopic identification of organic compounds. R.M. Silverstein, G.C. Bassler, T.C. Morrill Pub: John Wiley and Sons, NY.
19. United States Pharmacopoeia- United State of Pharmacopoeial convention, INC, 12601 Twin brook Parkway, Rockville, MD 20852.

M. PHARMACY SPECILIZATION-2 (PHARMACEUTICAL CHEMISTRY)

Semester- I

Name of Course	**ADVANCED PHARMACEUTICAL CHEMISTRY-I**			
Course Code	MP-211		Contact hours/week	T-3, P-5
Credits	3+3=6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objectives of the Course

To inculcate knowledge of basics of organic chemistry, reaction mechanisms, techniques of organic synthesis, and their application in drug development.

Students Learning Outcomes

To develop the ability to effectively apply knowledge of organic chemistry and reaction mechanisms in the synthesis of medicinal products.

Instructional Methods and Pedagogy

Through discussion in a class-room, and performing experiments related to different reactions important in synthetic chemistry.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each only three are to be answered by candidate and out of 9 short questions carrying 5 marks each only seven are to be answered by candidate.

THEORY **Total Hrs: 43**

1. Stereochemistry **(10 Hrs)**

Elements of symmetry: Plane of symmetry and center of symmetry, alternating axis of symmetry, simple axis of symmetry. Kinds of molecules displaying optical activity: compounds with a chiral carbon atom, compounds with other quadrivalent chiral atoms, compounds with tervalent chiral atoms suitably substituted adamantanes. Optical isomerism in compounds containing no chiral atom: biphenyls, allenes, compounds with exocylic double bonds, spiranes, chirality due to a helical shape, chirality caused by restricted rotation of other types. Cis-trans isomerism: resulting from double bonds,

monocyclic compounds, fused ring systems, out-in isomerism. Enantiotopic and diastereotopic atoms, groups and faces.Chirality and importance of chiral drugs, techniques for preparing chiral drugs (chirality pool, enzymatic transformation and assymetric synthesis).

2. Reaction Mechanisms (10 Hrs)

Aliphatic and aromatic nucleophilic substitution reactions, aliphatic and aromatic electrophilic substitutions, free radical reactions, elimination reactions, rearrangement reactions and addition to carbon-carbon multiple bonds.

3. Reactions of Synthetic Importance (7 Hrs)

Birch reduction, Mannich reaction, Diel's Alder reaction, Meerwin Pondroff's reaction, Oppeneaur oxidation, catalytic hydrogenation, Beckmann rearrangement, Grignard reaction, Hoffmann rearrangement, Ozonolysis, Friedel Craft's reaction, Michael reaction, Reformatsky reaction, Ullmann's condensation.

4. Chiral Technology (7 Hrs)

Techniques used in chiral synthesis, asymmetric synthesis of drugs such as diltiazem, timolol, vitamin C, ampicillin, dextrapropoxyphen, thienamycin, citrenalol, propranolol, atenolol, naproxen

5. Photochemistry (6 Hrs)

Introduction, Franck-Condon principle, Jablonski diagram, singlet and triplet states, photosensitization, forbidden transitions, types of excitation, photolytic cleavages. Determination of photochemical mechanisms.Application of photosensitizer and opacifiers.Reagents.

6. Green Chemistry (3 Hrs)

Water as solvent, Ionic liquids, Supercritical liquids, Supported reagents and catalysts, Solvent free reactions, Activation by microwave, ultrasound, Dry media reactions, Solid-state synthesis, Microwave synthesizer.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Diels-Alder reaction of anthracene and maleic anhydride (1 expt)
2. Beckmann rearrangement involving the synthesis of Benzanilide from Benzophenone (1 expt)
3. Friedel Craft's acylation involving the synthesis of p-methylacetophenone from toluene (1 expt)
4. Hoffmann rearrangement involving the synthesis of 3-aminopyridine from nicotinic acid (1 expt)
5. Mannich reaction involving the synthesis of dimethylaminopropiophenone from acetophenone (1 expt)
6. Use of microwave oven for chemical synthesis (1 expt)

BOOKS RECOMMENDED

1. Carey FA and Sundberg RJ. Advanced Organic Chemistry. Part B: Reactions and Synthesis. Plenum Press, London. Latest Edition
2. ErnestEI and SamuelH.Stereochemistry of Organic Compounds. John Wiley and Sons, New York. Latest Edition.
3. Lehr RE and Marchand AP. Orbital Symmetry: A problem solving approach. Academic Press, New York. Latest Edition.
4. March J. Advanced Organic Chemistry: Reactions, Mechanisms and Structures. John Wiley and Sons, New York. Latest Edition.
5. Lednicer: Organic Drug Synthesis Volume-1-5. John Wiley and Sons.
6. Comprehensive Medicinal Chemistry Series- I-VI. Academic Press.
7. Anastas PT, Warner JC. Green Chemistry: Theory and Practice, Oxford University Press, Oxford, 1998.
8. LancasterM.Green Chemistry: an Introductory Text. Royal Society of Chemistry, London, 2002.

M. PHARMACY SPECILIZATION-2 (PHARMACEUTICAL CHEMISTRY)

Semester- I

Name of Course	**ADVANCED MEDICINAL CHEMISTRY**			
Course Code	MP-212		Contact hours/week	T-3, P-5
Credits	3+3=6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objectives of the Course

To inculcate knowledge of synthetic medicinal compounds, their mechanisms of action and safety.

Students Learning Outcomes

To develop the ability to effectively apply knowledge of synthetic medicinal products in development of newer drugs, their safety and efficacy.

Instructional Methods and Pedagogy

Through discussion in a class-room, and performing experiments related to natural product isolation, efficacy and safety studies.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each only three are to be answered by candidate and out of 9 short questions carrying 5 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Drug Discovery **(10 Hrs)**

Historical perspective. Drug discovery strategies in Direct Drug Design (Structure based) and Indirect drug design. Target selection and lead identification from various sources-natural product sources, fermentation/microbial sources, synthetic. Lead optimization, objective of lead optimization, Pharmacophoric identification. Introduction to pharmacogenomics.Biotechnology and drug discovery.

2. QSAR (8 Hrs)

Objectives of QSAR, various parameters, Quantitative models- Hansch analysis, Free-Wilson Analysis, Mixed approach and other QSAR approaches.Applications of various quantitative models. Statistical methods, non-computer assited search operations-Topliss decision tree simplex method, Fibonacci search technique. CoMFA, CoMSIA.

3. Molecular Modelling in Drug Design (5 Hrs)

Introduction to Molecular Modeling- concepts and methods. Molecular Mechanics-force fields (Potential energy function). Energy minimization methods- Steepest, descent, conjugate gradients, Newton methods (Non mathematical). Conformation analysis-systematic search, Monte carlo simulations, Molecular dynamics simulation. Ligand design based on 3D structure of receptor enzyme.

4. Combinatorial Chemistry (5 Hrs)

Introduction, combinatorial approaches, chemical peptide and small molecule libraries, applications, methodologies, combinatorial organic synthesis, assays and screening of combinatorial libraries, introduction to high throughputs screening(HTS) methods, virtual (in silico) screening.

5. Chemistry of Drugs (5 Hrs)

Medicinal chemistry aspects of antineoplastic, antiviral, antihypertensive,antihyper-lipidemic, antifertility, antipsychotic and antiperkinsonism agents.Prostaglandins, narcotic and non-narcotic analgesics, peptide and protein hormones, immunomodulators.

6. Recent Advances and Trends (5 Hrs)

Recent trends in antineoplastic, antiviral, antihypertensive, antihyperlipidemic, antifertility, antipsychotic and antiperkinsonism agents. Prostaglandins, narcotic and non-narcotic analgesics, peptide and protein hormones, immunomodulators.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Synthesis and characterization of Clonidine (1 expt)
2. Synthesis and characterization of Tolazoline (1 expt)
3. Synthesis and characterization of Isoniazid (1 expt)
4. Synthesis and characterization of Pyrazinamide (1 expt)
5. Synthesis and characterization of Phenothiazine (1 expt)
6. Determination of partition coefficient and log P of any medicinal compound by shake flask method (1 expt)

BOOKS RECOMMENDED

1. Wolff ME. Burger's Medicinal Chemistry and Drug Discovery, Principle and Practice. John Wiley and Sons, New York. Latest Edition.
2. HugoKubingi – QSAR, Hansch Analysis and Related approaches Vol 1.
3. PaulSCharifson-Practical Applications of Computer Aided Drug Design (Marcel & Dekkar Inc. New York.
4. Pandi Veerapandian- Structure based Drug Design.
5. C. Hansch Comprehensive Medicinal Chemistry Vol-IV.
6. PoulKrogsgaandLarsen: A textbook of Drug Design and Developmet First Edi.
7. PaulLeff-Receptor Based Drug Design.
8. Foye: Principles of Medicinal Chemistry (Varghese & Co.)
9. Ledinicer: Organic Drug synthesis Vol. I-IV (John Wiley & Sons N.Y.)
10. Wilson & Gisvold: Text book of Organic & Pharmaceutical Chemistry (J.B.LippincottWilliams&Wilkins).
11. Ariens: Medicinal Chemistry Series.
12. Comprehensive Medicinal Chemistry- Series I-IV (Academic Press).
13. Ellis and West: Progress in Medicinal Chemistry Series.

M. PHARMACY SPECILIZATION-2 (PHARMACEUTICAL CHEMISTRY)

Semester- II

Name of Course	**ADVANCED PHARMACEUTICAL CHEMISTRY-II**			
Course Code	MP-221		Contact hours/week	T-3, P-5
Credits	3+3=6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objectives of the Course

To inculcate knowledge of synthetic medicinal compounds, their mechanisms of action and safety.

Students Learning Outcomes

To develop the ability to effectively apply knowledge of synthetic medicinal products in development of newer drugs, their safety and efficacy.

Instructional Methods and Pedagogy

Through discussion in a class-room, and performing experiments related to natural product isolation, efficacy and safety studies.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each only three are to be answered by candidate and out of 9 short questions carrying 5 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Drug Action **(5 Hrs)**

Receptors: Drug receptor interaction- basic forces involved in drug-receptor interactions, basic ligand concepts- agonist, antagonist, partial agonist and inverse agonist. G-protein coupled receptors, ion channel linked receptors, ligand-gated ion channels (LGICs), ligand-receptors theories: Clarks occupancy theory, rate theory, induced fit theory, macromolecular perturbation theory and activation aggregation theory.Drug binding to nucleic acid- Anti-malarial, Anti-cancer, Anti-viral and Steroidal.

2. Synthetic Strategies (10 Hrs)

Protection and deprotection of various groups. Synthetic methodologies for obtaining drugs: disconnection approach, synthons for carbon-carbon bond formation, difunctional compounds, selective functional group interconversions (FGI), retrosynthetic analysis. Synthetic approaches for attaching heterocyclic ring systems in drug molecules having five-membered and six-membered heteroaromatic rings, fused ring systems. Use of synthon approaches in synthesis of following drugs:- Ibuprofen, Aspirin, Trimethoprim, Terfenadine, Propanolol, Ciprofloxacin, Cimetidine, Piroxicam, Rosiglitazone, Captopril, Nifedipine, Losartan, Benzocaine, Sulfisoxazole, Cimetidine.

3. Prodrugs (10 Hrs)

Prodrug concept for drug design, drug targeting and antibody directed enzyme prodrug therapy (ADEPT), soft drug design, prodrugs of various functional groups like carbonyl, hydroxyl, amide, amines. Applications of various prodrug approaches.

4. Micro-organisms in Drug Synthesis and Development (10 Hrs)

Microbial conversions of drugs like steroids, prostaglandins, antibiotics, enzyme immobilization techniques.

5. Recent Advances in Medicinal Chemistry (5 Hrs)

Advances in medicinal chemistry of cardiovascular agents, antiarrhythimics, antianginal, antihypertensive, antihyperlipidemics, FDA approved drugs, new molecules under clinical trials.

6. Enzyme Inhibition for Therapy (5 Hrs)

Primary, secondary, tertiary and quaternary structure of enzymes.Enzyme kinectics.Enzyme inhibitors- reversible, irreversible, Kcat inhibitors.Transition state analogs. Enzyme inhibitors as drugs- ACE, Leukotrienes, Lipoxygenase, Cycloxygenase, Aromatase, Xanthine oxidase, DNA polymerase inhibitors, HIV-Protease/ Reverse Transcriptase, Integrase and Cytochrome P-450 Inhibitors.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08

- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Experiment to highlight the importance of Protection- and Deprotection of functional groups (2 expts)
2. Synthesis and characterization (highlighting the use of synthon approaches) of any two or three of the following drugs: a) Ibuprofen b) Trimethoprim c) Diphenhydramine d)Xylocaine (3 expts)
3. Experiment to highlight the importance of Prodrug involving various functional groups like carbonyl, hydroxyl, amide, amine etc (2 expts)

BOOKS RECOMMENDED

1. Wolff ME. Burger's Medicinal Chemistry and Drug Discovery, Principle and Practice. John Wiley and Sons, New York. Latest Edition.
2. AlnleyW and James EF. Martindale, The Extra Pharmacopoeia. Pharmaceutical Press, London. Latest Edition.
3. NogradyT. Medicinal Chemistry, A Biochemical Approach. Oxford University Press, New York. Latest Edition.
4. Monographs and relevant review articles appearing in various periodicals and journals.
5. FrankeR. Theoretical Drug Design Methods, Vol.VII. Elsevier, New York. Latest Edition.
6. Silverman RB. The Organic Chemistry of Drug Design and Action. Academic Press Inc., San Diego, USA. Latest Edition.
7. Foe: Principles of Medicinal Chemistry (Varghese & Co.)
8. Ledinicer: Organic Drug synthesis Vol. 1-5 (JohnWiley& sons)
9. Ariens : Medicinal Chemistry Series.
10. Ellis and West: Progress in Medicinal Chemistry series.
11. Bunerworther Progress in Medicinal Chemistry Series.
12. StuartWarren: Designing Organic Synthesis- A programmed introduction to the Synthon approach.
13. V. K.Ahluwalia: Green Chemistry. Anne Books Publications.
14. AnastasPaul. T. & John. C.Warner. Green Chemistry "Theory & Practice". Oxford University press publications

M. PHARMACY SPECILIZATION-2 (PHARMACEUTICAL CHEMISTRY)

Semester- II

Name of Course	**ADVANCES IN CHEMISTRY OF NATURAL PRODUCTS**			
Course Code	MP-222		Contact hours/week	T-3, P-5
Credits	3+3=6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objective of the Course

To inculcate knowledge of natural products and their medicinal applications.

Students Learning Outcomes

To develop the ability to effectively apply knowledge of natural products chemistry in development of newer drugs, excipients, their safety and efficacy, in the management of diseases.

Instructional Methods and Pedagogy

Through discussion in a class-room, and performing experiments related to natural product isolation, efficacy and safety studies.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each only three are to be answered by candidate and out of 9 short questions carrying 5 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Secondary Metabolites **(13 Hrs)**

Classification, method of isolation, chemistry and biological activity of alkaloids, terpenoids, flavonoids, coumarins, glycosides.

2. Plant Steroids **(5 Hrs)**

Study of chemistry, stereochemical aspects and pharmaceutical importance of plant derived steroids (cardiac glycosides, cholesterol, diosgenin).

3. Structure Elucidation of Natural Products (5 Hrs)

Degradation, synthetic methods, spectral techniques for structural elucidation of morphine, gingiberene, quercetin and xanthotoxin.

4. Antineoplastics from Plants (5 Hrs)

Recent advances in the chemistry of naturally occurring antineoplastic agents (catharanthus alkaloids, paclitaxel,camptothecin);antimalarials(cinchona alkaloids,artemisinin derivatives).

5. Natural Products in Drug Discovery (5 Hrs)

Importance of marine natural products in drug discovery.Current developments in the discovery and design of new drug candidates from natural product leads.

6. Natural Products as Drugs (5 Hrs)

Natural products as pharmaceuticals from Gymnema sylvestre, Pterocarpus marsupium, Swertia chirata; natural products for pest management. Natural products as templates for combinatorial libraries, carbohydrate derived small molecule libraries.

7. Natural Products for Neglected Diseases (5 Hrs)

Role of natural products in "Neglected Diseases" (dengue, protozoal diseases including leishmaniasis, trypanosomiasis, schistosomiasis, tuberculosis, leprosy).

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Isolation and characterization of Piperine from black pepper (1 expt)
2. Isolation and characterization of Hesperidin from orange peel (1 expt)
3. Isolation and characterization of Strychnine from Nux vomica seeds (1 expt)
4. Isolation and characterization of Curcumin from turmeric powder (1 expt)
5. Isolation and characterization of Lycopene from tomatoes (1 expt)
6. Degradation and characterization of degradation products of any one or two of the following compounds: a) Piperine b) Atropine and c) Caffeine (2 expts)

BOOKS RECOMMENDED

1. Cordell GA. Introduction to Alkaloids. John Wiley and Sons, New York. Latest Edition.
2. Fieser LF and Fieser M. Steroids. Reinhold Publishing Co., New York. Latest Edition.
3. Wickery ML and Wickery B. Secondary Plant Metabolism. Mcmillan Press Ltd. London. Latest Edition.
4. Torseel KBG. Natural Product Chemistry. John Wiley and Sons, New York. Latest Edition.
5. HarborneJB. Phytochemical Methods. Chapman and Hall, London. Latest Edition.
6. Finar IL. Organic Chemistry. The English Language Book Society, London. Latest Edition.
7. Wolff ME. Burger's Medicinal Chemistry and Drug Discovery, Principle and Practice. John Wiley and Sons, New York. Latest Edition.
8. Mitscher LA and Baker WR. A Search for Novel Chemotherapy Against Tuberculosis Amongst Natural Products. Pure and Applied Chemistry (1998) , Vol. 70, No.2, pp 365-371.
9. Wermuth CG. The Practice of Medicinal Chemistry. Academic Press, Jordon Hill, Oxford. Latest Edition.
10. Boldi AM. Combinatorial Synthesis of Natural Product Based Libraries. Taylor and Francis, London. Latest Edition.
11. Monographs and relevant review articles appearing in various periodicals and journals.

M. PHARMACY SPECILIZATION-2 (PHARMACEUTICAL CHEMISTRY)

Semester- II

Name of Course	**DRUG DESIGN**			
Course Code	MP-223		Contact hours/week	T-3, P-5
Credits	3+3=6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objective of the Course

To inculcate knowledge of various software used for synthetic medicinal products

Students Learning Outcomes

To develop the ability to effectively apply knowledge of synthetic medicinal products in development of newer drugs, their safety and efficacy.

Instructional Methods and Pedagogy

Through discussion in a class-room, and performing experiments related to drug synthesis, efficacy and safety studies.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each only three are to be answered by candidate and out of 9 short questions carrying 5 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Physicochemical Properties and Drug Design (5 Hrs)

General study of co-relation of physico-chemical properties, and stereochemistry and drug action. Isosteriem and bio-isosterism as guides to structural variations, metabolite, antagonism and theory of drug action.

2. Conventional Methods of Drug Design (5 Hrs)

Lead, discovery of lead, lead optimization, objective of lead optimization, pharmacophoric identification and analog approach of drug designing.

3. Approaches to Drug Design (5 Hrs)

An overall treatment of the approaches to drug design, including the method of variation, study of the use of biochemical and physiological information in evolving new drugs and basis of design.

4. Basis of Design and Recent Advances (14 Hrs)

The basis of drug design and recent advances in development of the following categories of drugs:

- Antihypertensive agents.
- Antineoplastic drugs.
- Anti-AIDS agents.
- Antipsychotic agents.
- GABA-nergic agents.
- Chemistry of Beta-lactam antibiotics.
- Anti-diabetic agents.

5. Molecular Modeling in Drug Design (6 Hrs)

Molecular mechanics, Quantum mechanics. Known receptors sites- defination, characterization of sites, design of ligands, manually assisted three dimentional databases & calculation of affinity. Unknown receptor sites- searching for similarity, pharmacophore models, molecular comparisons, finding common patterns.

6. Rational Design of Enzyme Inhibitors (4 Hrs)

Introduction- enzyme inhibitors in medicine, enzyme inhibitors in basic research.Rational Design of Non-covalently & covalently binding Enzyme inhibitors. Rapid reversible inhibitors, slow & tight binding inhibitors, transition state analogs, multisubstrate inhibitors.

6. Endorphins and Peptidomimetics (4 Hrs)

Discovery and recent advances in the design of enkephalins, endorphins and peptidomimetics.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Demonstration of ligand-receptor binding/docking using AutoDock or any other software (2 expts)
2. Use of packages such as ISIS / ChemDraw or any other software for drawing chemical structures and mechanisms (1 expt)
3. Advanced in-vivo & in-vitro pharmacological techniques employed to evaluate various classes of drugs (1 expt)
4. Experimental Toxicology: Calculations of LD50 values and therapeutic index (2 expts)

BOOKS RECOMMENDED:

1. Ariens- Drug Design Vol-II
2. Annuals Reports in medicinal chemistry (Academic press Inc).
3. Smith-William – Introduction to principles of drug design.
4. Woodridge- Progress in pharmaceutical research.
5. Medicinal Chemistry- Monographs series (Academic Press).
6. Buegers- Medicinal Chemistry & Drug Discovery.

M. PHARMACY SPECILIZATION-2 (PHARMACEUTICAL CHEMISTRY)

Semester- II

Name of Course	**INTELLECTUAL PROPERTY RIGHTS & DRUG REGULATORY AFFAIRS**			
Course Code	MP-021		Contact hours/week	T-2, P-0
Credits	2+0=2		Total teaching hours required = 30	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	-

Objective of the Course

To make students familiar with the fundamental principles of IPR and Drug regulatory affairs

Student Learning Outcomes

On completion of the course the student would understand the principle and importance if IPR and Drug regulatory affairs in the competitive world

Instructional Methods and Pedagogy

Faculty member/s shall explain in a class room using black board and multimedia projector.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each only three are to be answered by candidate and out of 9 short questions carrying 3 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 30**

1. Intellectual Property-Concepts and Fundamentals (5 Hrs)

The emergence and growth of the concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); economic importance, mechanism for protection of intellectual property-patents.

2. Trade Related Aspects of Intellectual Property Right (4 Hrs)

Intellectual property and international trade, concept behind WTO (World Trade Organization), WIPO (World Intellectual Property Organization), GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trades in Services), status in India and other developing countries.

3. Patenting (5 Hrs)

Copyright and trade mark protection, criteria for patentability, Indian patent act. 1970: WTO and modifications under TRIPS, filing of a patent application, precautions before patenting-disclosures/non-disclosures, publication-article/ thesis, prior art search – published patents search, internet search patent sites, specialized service search requests, costs, patent application forms and guidelines, fee structure, time frames, jurisdiction aspects, types of patent application- provisional, non-provisional, PCT and convention patent applications, international patenting requirement procedures and costs.

4. Technology Development/Transfer Commercialization Related Aspects (4 Hrs)

Technology development: Meaning, drug related technology development, toxicological studies, bioequivalence (BU), clinical trials Phase I, Phase II and Phase III.

5. Ethics and Values in IP (3 Hrs)

IP and ethics, positive and negative aspects of IPP, social responsibility, avoiding unethical practices, eco-responsibility–economic, social and environmental benefits of modern biotechnology.

6. Drug Regulatory Affairs (09 Hrs)

- Regulation on manufacture of drugs in India.
- Drug regulatory controls and authorities.
- Requirements of GMP, CGMP, GLP.
- Guidelines of WHO, inputs of international bodies, national agencies, harmonization.
- Preparation and submission of marketing application of India, US and Europe.
- Approval and appeals present and issues of confidentiality.
- ISO 9000 series.
- Drugs and cosmetics acts and rules.
- Important regulations related to import and export of drugs.

BOOKS RECOMMENDED

1. Treece DJ. Managing Intellectual Capital: Organizational, Strategic and Policy Dimension. Oxford University Press, England. Latest Edition.
2. Wadedhra BL. Law Relating to Patents, Trademarks, Copyright Design and Geographical Indications. Universal Law Publishing, New Delhi. Latest Edition.
3. Bansal P. IPR Handbook for Pharma Students and Researchers, Pharma Book Syndicate, Hyderabad. Latest Edition.
4. Copyright Protection in India [website: http:copyright.gov.in].
5. Information on Orange Book [website: www.fda.gov/cder/ob/default.htm].
6. World Trade Organization [website: www.wto.org].
7. Trivedi PR. Encylcopedia of Intellectual Property Rights. Jnanada Prakashan, New Delhi. Latest Edition.

M. PHARMACY SPECILIZATION-2 (PHARMACEUTICAL CHEMISTRY)

Semester- III

Name of Course	**RESEARCH METHODOLOGY AND STATISTICS**			
Course Code	MP-030		Contact hours/week	T-3, P-0
Credits	3+0=3		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	-

Objectives of the Course

- To make the student familiar with systematic research methodology and computer applications in development of proper research methodology.
- To make the student familiar with different pharmaceutical and statistical tools required for carrying out systematic research.

Student Learning Outcomes

On completion of the course the student would understand the principle and importance if IPR and Drug regulatory affairs in the competitive world

Instructional Methods and Pedagogy

Faculty members shall explain in a class room using black board or a multimedia projector.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each only three are to be answered by candidate and out of 9 short questions carrying 3 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Literature Survey **(2 Hrs)**

Accessing required information in a systematic manner from abstracts, books, journals, proceedings of conferences, theses and dissertations, CD ROMs, internet and such other sources.

2. Scientific Writing **(5 Hrs)**

Writing of papers, articles and thesis; preparation of title, abstracts, introduction, methodology, results and discussion, summary-conclusion; preparation of tables and figures using software like MS Office, Open Office, etc; organization of dissertations and thesis; conventions adopted in writing; citing references; preparation of oral presentations and posters.

3. Data Collection (8 Hrs)

The population – sample; measures of describing the center of data distributions; measurement of spread of data; binomial and normal distributions – their significance.

4. Statistical Inference (10 Hrs)

Statistical estimation – confidence intervals; tests for statistical significance – T-test, F-test, analysis of variance (ANOVA); Chi-square test; linear regression and correlation.

5. Non-parametric tests (10 Hrs)

Data characteristics suitable to non-parametric procedures; Sign test, Wilcoxon signed rank test, Wilcoxon rank sum test; Kruskal Wallis test; Runs test for randomness; contingency tables.

6. Statistical software (8 Hrs)

Introduction to statistical software such as SPSS, GraphPad, SigmaStat, MS Excel; open source software for statistical analysis.

BOOKS RECOMMENDED

1. Bolton, Pharmaceuticals Statistics- Practical & Clinical Applications, Marcel & Dekker, New York.
2. Fisher, R.A., Statistical Methods for Research Works, Oliver & Boyd, Edinburgh.
3. Chow, Statistical Design and Analysis of Stability Studies, Marcel Dekker, New York.
4. Buncher, Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.
5. Finney, D.J., Statistical Methods in Biological Assays, Hafner, New York.
6. Montgomery, D.C., Introduction to Statistical Quality Control, Willy.
7. Khan, Irfan A., Biostatistics for Pharmacy.
8. Khan, Irfan, A., Fundamentals of Biostatistics.
9. Gauthaman, Biostatistics for Pharmacy students.
10. Lipschutz, Introduction to Probability and Statistics.
11. Liwan Po, Statistics for Pharmacist.
12. William E. Fassett, Computer Application in Pharmacy.
13. Ekins, S., Computer Application in Pharmaceutical Research & Development, Wiley.
14. Nageswara Rao and Tiwari, Biostatistics and Computer Applications.
15. Robert A Day., How to write and publish a scientific paper, 4th edition, Cambridge University Press.

SYLLABUS

Master of Pharmacy Programme

PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

(SPECIALIZATION-3)

HIMACHAL PRADESH TECHNICAL UNIVERSITY
HAMIRPUR

SPECIALIZATION-3: PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE

SCHEME OF TEACHING

First Semester

S. No	Courses	Course code	Theory / Practical	Contact hrs / week	Credits
1	Advanced Pharmaceutical Instrumental Analysis	**MP-011**	Theory	3	3
			Practical	5	3
2	Pharmaceutical, Cosmetic and Herbal Drug Analysis	**MP-311**	Theory	3	3
			Practical	5	3
3	Quality Assurance	**MP-312**	Theory	3	3
			Practical	5	3
4	Elective*	**MP-012 to 018**	Theory	2	2
	Total of First Semester			**26**	**20**

*Any one from the list of elective courses provided

Second Semester

S. No	Courses	Course code	Theory / Practical	Contact hrs / week	Credits
1	Quality Management	**MP-321**	Theory	3	3
			Practical	5	2
2	Chemical and Biological Evaluation	**MP-322**	Theory	3	3
			Practical	5	2
3	Drug and Excipient Analysis	**MP-323**	Theory	3	3
			Practical	5	2
4	Intellectual Property Rights & Drug Regulatory Affairs	**MP-021**	Theory	2	2
	Total of Second Semester			**26**	**20**

Third Semester

S. No	Courses	Course Code	Theory / Practical	Contact hrs / week	Credits
1	Research Methodology and Statistics	**MP-030**	Theory	3	3
2	Dissertation work	**MP-D01**	Practical	24	12
	Total of Third Semester			**27**	**15**

Fourth Semester

S. No	Courses	Course Code	Theory / Practical	Contact hrs / week	Credits
1	Dissertation work (continued from previous semester)	**MP-D01**	Practical	24	12
2	Publication / Conference Presentation*				3
	Total of Fourth Semester			**24**	**15**

Total credits - 70

*One paper in national/ international indexed journal or presentation in a national level conference or at least acceptance letter from the editorial board of journal is compulsory for getting credits. The publication/ Conference presentation shall have names of guide and institution.

SCHEME OF EVALUATION

S. No	Course	Course code	Theory Awards			Practical Awards		
			University	Internal	Total	University	Internal	Total
SEMESTER-I								
1	Advanced Pharmaceutical Instrumental Analysis	MP-011	90	60	150	75	75	150
2	Pharmaceutical, Cosmetic and Herbal Drug Analysis	MP-311	90	60	150	75	75	150
3	Quality Assurance	MP-312	90	60	150	75	75	150
4	Elective*	MP-012 to 018	60	40	100	-	-	-
SEMESTER-II								
5	Quality Management	MP-321	90	60	150	75	75	150
6	Chemical and Biological Evaluation	MP-322	90	60	150	75	75	150
7	Drug and Excipient Analysis	MP-323	90	60	150	75	75	150
8	Intellectual Property Rights & Drug Regulatory Affairs	MP-021	60	40	100	-	-	-
SEMESTER-III								
9	Research Methodology and Statistics	MP-030	60	40	100			
10	Dissertation - Interim evaluation	MP-D01				60	40	100
SEMESTER-IV								
11	Dissertation evaluation	MP-DO1				120	80	200
							Total Theory Marks:	**1200**
							Total Practical Marks:	**900**
							Total Dissertation Marks:	**300**
							Overall Total Marks:	**2400**

* Any one from the list of elective courses provided

M. PHARMACY SPECILIZATION-3

(PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE)

Semester- I

Name of Course	**ADVANCED PHARMACEUTICAL INSTRUMENTAL ANALYSIS**			
Course Code	MP-011		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objective of the Course

To make students familiar with the principles of modern analytical techniques and application of analytical instruments in pharmacy.

Student Learning Outcomes/Objectives

At the end of the course, the student will be able to understand the fundamental concept of modern analytical techniques, which is important for qualitative as well as quantitative analysis of drug substances and drug product.

Instructional Methods and Pedagogy

Faculty member/s shall explain in a class room using black board and multimedia projector.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 25 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 10 marks each, only three are to be answered by candidate and out of 9 short questions carrying 5 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. UV-Visible spectroscopy (6 Hrs)

Brief review of electromagnetic spectrum, UV-Visual range, Interaction of electro-magnetic radiation (UV-Vis) and matter and its effects, principle, shifts, instrumentation, absorption spectra of organic compounds illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs.

2. Infra-Red Spectroscopy (6 Hrs)

Nature of Infra-red radiation, Interaction of IR radiation with organic molecules and effects on bonds, principle, brief outline of classical IR instrumentation, sample preparation for spectroscopy and qualitative interpretation of IR Spectra, FT-IR and applications.

3. Nuclear Magnetic Resonance Spectroscopy (8 Hrs)

Principles of NMR (Magnetic Properties of nuclei, applied field and precessional frequency, absorption and transition frequency), relaxation process, chemical shift concept, shielding, de-shielding effect and brief outline of interpretation of spectra.

4. Mass Spectrometry (5 Hrs)

Principle and brief outline of instrumentation, mass spectrum, types of peaks and its characteristics, interpretation of spectra and applications.

5. Thermal Methods of Analysis: (3 Hrs)

Theory, instrumentation and Applications of thermo gravimetric analysis (TGA), Differential Thermal Analysis (DTA) and Differential Scanning Calorimetry (DSC).

6. Electron Microscopy (3 Hrs)

Application of Transmittance Electron Microscopy (TEM) and Scanning Electron Microscopy (SEM).

7. Chromatographic Techniques (12 Hrs)

- High Performance Thin Layer Chromatography (HPTLC): Principle, adsorbents, instrumentation, qualitative and quantitative analysis of drugs.
- High performance Liquid Chromatography (HPLC): Principle, stationary and mobile phase, instrumentation, qualitative and quantitative analysis of drugs.
- Gas Chromatography: Introduction, principles, mobile phase and & stationary phase, instrumentation and identification of substances.
- Electrophoresis: Principle, techniques and applications of Paper electrophoresis and Gel electrophoresis.
- Principles, applications of ion exchange chromatography, affinity chromatography and size exclusion chromatography.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments shall be designed by the faculty

Experiments

1. Simultaneous estimation of drugs in combination formulations (1 expt)
2. UV Visible spectrum scanning of drugs absorption and correlation of structure (1expt)
3. HPLC estimation of drugs in formulation (1 expt)

4. Comparison of three different analytical techniques for the estimation of any suitable drug (1 expt)
5. Gradient elution technique in column chromatography (1 expt)
6. FT-IR spectrum scanning of drugs-absorption and correlation of structure (1 expt)

RECOMMENDED BOOKS

1. "Contemporary practice of chromatography" by Poole, Colin F. and Sheila A. Schuette.
2. Practical HPLC method development by L. R. Snyder Willey Interscience, Second Ed.
3. Aldrich FT-IR Spectral Library. "Pharmaceutical Analysis" by David C. Lee Blackwell Publisher.
4. British Pharmacopoeia, 2004 The british pharmacopoeia commission office, Market Tower, 1 Nine Elms Lane, London.
5. Chromatographic Analysis of Pharmaceuticals, A. John, Adamovics, Cytogan Corporation, Princeton, NJ.
6. Ewing's Analytical Instrumentation Handbook, edited by Jack Cazes, CRC press.
7. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi, CBS Publishers and Distributers, New Delhi.
8. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography, 2nd Edition, P. D. Sethi, CBS Publishers and Distributers, New Delhi.
9. Indian Pharmacopoeia-2007, Indian pharmacopoeia commission, Sector-23, Raj Nagar, Ghaziabad.
10. Instrumental Methods of Analysis, Willard, Merritt, Dean and Settle, CBS publishers and Distributers, Delhi.
11. Instrumental Methods of Chemical Analysis, G. W. Ewing, McGraw Hill Book Co, NY.
12. Modern Methods of Pharmaceutical Analysis,Vol 1,2, RE Schirmer, Franklin Book Co
13. NMR spectroscopy (Basic Principles, concepts and application in Chemistry) Herald Gunther, (John Wiley and Sons), NY.
14. Pharmaceutical Analysis – Modern Methods – Part A, Part B, J. W. Munson, Marcel Dekker, NY.
15. Principles of Instrumental Analysis, Skoog, Hollar and Nieman, Philadelphia.
16. Remington's Pharmaceutical Sciences, J. P. Remington, Mack Pub. Co.,Pennsylvania.
17. Spectroscopic identification of organic compounds. John Dyer, Willy, NY.
18. Spectroscopic identification of organic compounds. R.M. Silverstein, G.C. Bassler, T.C. Morrill Pub: John Wiley and Sons, NY.
19. United States Pharmacopoeia- United State of Pharmacopoeial convention, INC, 12601 Twin brook Parkway, Rockville, MD 20852.

M. PHARMACY SPECILIZATION-3

(PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE)

Semester- I

Name of Course	**PHARMACEUTICAL, COSMETIC AND HERBAL DRUG ANALYSIS**			
Course Code	MP-311		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objectives of the Course

To provide an overall understanding related to the Qualitative/Quantitative analysis of Pharmaceutical, Cosmetic & Herbal Drugs and excipients.

Student Learning Outcomes

After undergoing this course, the student will be in a position to carryout method-development related to the analysis of pharmaceutical, cosmetic & herbal drugs.

Instructional Methods and Pedagogy

Faculty member(s) shall engage regular class-room lectures using blackboard and/or audio-visual aids, and perform experiments related to the class-room teaching.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each, only three are to be answered by candidate and out of 9 short questions carrying 3 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Titrimetric Analysis (4 hrs)

Classification of reactions in titrimetric analysis, standard solutions, preparation of standard solutions, primary and secondary standard substances.Theory of acid-base titration.Neutralisation indicators, mixed and universal indicators, neutralization curves and displacement titrations. Non-aqueous titrations involving Primary, secondary and tertiary amines, Halogenated salts of bases, Acidic substances, Assays of official drugs in IP 1996 by non-aqueous titrimetry. Aquametry - determination of water by Karl Fischer reagent.

2. Redox Titrations (2 hrs)

Principles and pharmaceutical applications of redox titrations involving: Potassium lodate/bromate titrations, Ceric ammonium sulphate titrations, Titanus chloride titration, Examples of assays of official drugs in IP 1996.

3. Complexometric Titrations (2 hrs)

Principles and pharmaceutical applications of cornplexometric titrations involving: Direct titration of polymetalic system with sodium editate, Back titration with sodium editate, Titration involving the displacement of one complex by another, pM indicators, Examples of assays of official drugs in IP 1996.

4. Gravimetry (3 hrs)

Principles and procedures involved in gravimetric and argentimetric analysis with examples official in IP 1996, Diazotization titrations, Principles and methodology in thermogravimetric analysis and Differential thermal analysis.

5. Electroanalytical Methods (7 hrs)

Principles and pharmaceutical applications of electroanalytical methods: Potentiometry, pH measurements, Polarography, Amperometry, High frequency titrations, Conductometric titrations.

6. Analysis of Excipients and Finished Products (9 hrs)

Identification and quantitative determination of preservatives, antioxidants.colouring materials, emulsifiers and stabilisers in pharmaceutical formulations. Quality control of tablets, capsules, liquid dosage forms, parenteral preparations, ointments and creams, suppositories and controlled release products. Quality control of containers, closers, caps and secondary packing materials like paper and board for pharmaceuticals.

7. Analysis of Cosmetics (7 hrs)

Quality control of cosmetic products - Hair care products, skin care products. colour cosmetics, baby care products, Ethnic products, Dental products, Personal hygiene products, colour makeup preparations, Lipstics, hair setting lotions and eye shadows. Safety and legislation for cosmetic products.

8. Analysis and Quality Control of Crude drugs (10 hrs)

Significance of Important Techniques in Establishing Identity, Purity and Quality of Plant Drugs as described in various Pharmacopoeias, documents of WHO and EMEA: Organoleptic methods including gross morphology, sampling, preliminary examination and foreign matter; General and Quantitative microscopy: Lycopodium spore method, palisade ratio, stomatal number, stomatal index, vein islet number and veinlet termination number. Physico-chemical methods of quality control such as solubility, specific gravity, optical rotation, specific rotation, refractive index, melting point, swelling index, foaming index and bitterness value, moisture content, Ash and extractive values, Qualitative and quantitative chemical tests including acid value, iodine value, saponification value, ester value, unsaponifiable matter and acetyl value. Markers: choice of active/analytical marker, sources of markers, marker analysis/fingerprinting by HPLC/HPTLC/GC/fluorimetry/spectroscopy.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Assay of any one of the following: (1 expt)
    a. Ibuprofen tablets, IP 1996
    b. Bisacodyl suppositories, IP 1996
    c. Sodium diatrizoate injection, IP 1996
    d. Ferrous sulphate tablets. IP 1996
2. Determination of moisture-content of any one of the following drugs using Karl-Fischer Reagent (1 expt)
    a. Ampicillin Trihydrate
    b. Fructose
    c. Gentamycin sulphate
    d. Calcium lactate or gluconate/emetin dihydrochloride
3. Detection and quantitative determination of preservatives (1 expt)
4. Detection and quantitative determination of antioxidants (1 expt)
5. Detection and quantitative determination of colouring materials (1 expt)
6. Determination of ash values and extractive values of crude drugs (1 expt)

RECOMMENDED BOOKS

1. A.H. Beckett and J.B. Stenlake: Practical Pharmaceutical Chemistry, Part-I and II, 3rd Edition, 1997, CBS Publishers and Distributors, New Delhi.
2. G.H. Jeffery, J. Basselt, J. Mendham, R.C. Denny (Rev. by): Vogel's Text Book of Quantitative Chemical Analysis, 5th Edition, 1989, ELBS.
3. The Controller of Publications; New Delhi, Govt. of India: Indian Pharmacopoeia, Vol. I and II, 1996.
4. Lachmann: Theory and Practice of Industrial Pharmacy, 3rd Edition, Varghese Publishing House, Bombay.
5. W.A. Poucher: Poucher's Perfumes, Cosmetics and Soaps. Vol. 3, 9th Edition, Chapman and Hill, London.
6. J.B. Wilkinson and R.J. Moore: Herry's Cosmeticology. Longman Scientific and Technical Publishers, Singapore.
7. P.D. Sethi: Quantitative Analysis of Drugs in Pharmaceutical formulations, 3rd Edition, 1997, CBS Publishers and Distributors, New Delhi, India.
8. Chatwal and Anand: Instrumental Methods of Chemical Analysis, 7th Edition, 1992, Himalaya Publishing House, New Delhi.
9. Alfonso and Gennaro: Remingtons Pharmaceutical Sciences, Lippincott, Williams and Wilkins A. Wolters Kluwer Company, Philadelphia.
10. Rhodes and Banker: Modern Pharmaceutics, 2nd Edition, Marcel Dekker Inc., New York.
11. E.G. Thomssen: Modern Cosmetics, 1985, Universal Publishing Corporation, U.K.
12. Guidelines for the Assessment of Herbal Medicines- WHO Report, Geneva, 1991, Fitoterapia Vol. LXIII, 105-110.

M. PHARMACY SPECILIZATION-3

(PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE)

Semester- I

Name of Course	**QUALITY ASSURANCE**			
Course Code	MP-312		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objectives of the course

To provide an overall understanding related to the Qualitative/Quantitative analysis of drugs.

Students learning outcomes/objectives

After undergoing this course, the student will be in a position to carryout method-development related to the analysis of pharmaceutical products.

Instructional methods and pedagogy

Faculty member(s) shall engage regular class-room lectures using blackboard and/or audio-visual aids, and perform experiments related to the class-room teaching.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each, only three are to be answered by candidate and out of 9 short questions carrying 3 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Introduction **(4 Hrs)**

An understanding of the concepts of Quality Assurance, Good Manufacturing Practice and Quality Control as applied to the pharmaceutical Industry.

2. Materials Selection **(4 Hrs)**

Raw material, purchase specifications, stores selection of vendors, controls on raw materials.

3. Manufacture- and Control of Dosage Forms **(6 Hrs)**

Manufacturing documents, Master formula, Batch formula records, standard operating procedures. Quality audits of manufacturing processes and facilities.

4. Process Quality Control (7 Hrs)

In process quality controls on various dosage forms sterile and non-sterile. Standard operating procedures for various operations like cleaning, filling, drying, compression, costing disinfection, fumigation, sterilisation, membrane, filtration etc.

5. Packaging (3 Hrs)

Packing and labeling controls, line clearance, reconciliation of labels, cartons and other packaging material.

6. Laboratory Practices (8 Hrs)

Quality control laboratory, responsibilities and laboratory practices: Routine controls on instruments, reagents, sampling plans, standard test procedures and protocols, non-clinical testing. Quality control documentation, retention, samples, records. Audits of quality control facilities.

7. Validation (8 Hrs)

Qualification validation and calibration of equipment, Aseptic Validation, Analytical and Bioanalytical method validation, Personnel validation, Process Validation, Validation of water system, Validation and security measures for electronic data processing and Cleaning validation.

8. Regulatory Concepts (3 Hrs)

Regulatory aspects of pharmaceutical and bulk drug manufacture, Regulatory drug analysis.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Development of standard operating procedures and validation methods for analytical instrumentation (2 expts)
2. Development of standard operating procedures and validation methods for pharmaceutical machinery (1 expt)
3. Development of standard operating procedures and validation methods for cleaning process (1 expt)
4. Development of validation method for aseptic room (1 expt)
5. Validation of UV and HPLC methods for analysis of selected drugs (2 expts)

RECOMMENDED BOOKS

1. S. Weinberg, Good laboratory practice Regulations, Marcel and Dekker.
2. J. Swarbrick Boylan, encyclopedia of pharmaceutical technology, Marcel and Dekker.
3. J.R. Berry and R.A. Nash, Pharmaceutical process validation. Marcel and Dekker.
4. S.H. Will and J.R. Stoker, good manufacturing Practices for Pharmaceutics Marcel Dekker.
5. R.F. Brewer, Design of experiments for process improvement and quality Assurance Narrosa.
6. B. Othery. ISO 14000 and ISO 9000 Gower. D.H. Stamatis, Understanding ISO 9000 and implementing the basics to quality; Marcel Dekker.

M. PHARMACY SPECILIZATION-3

(PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE)

Semester- II

Name of Course	**QUALITY MANAGEMENT**			
Course Code	MP-321		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objectives of the course

To teach the students about Concept of Total Quality Management and Qualification Validation and Calibration.

Students learning outcomes/objectives

After completing this course, the student will be in a position to perform validation and total quality management.

Instructional methods and pedagogy

Faculty member(s) shall engage regular class-room lectures using blackboard and/or audio-visual aids, and perform experiments related to the class-room teaching.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each, only three are to be answered by candidate and out of 9 short questions carrying 3 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Concept of total quality management (4 Hrs)

ISO 9000, GMPs and GLPs Guidelines.

2. Organisation and Personnel (5 Hrs)

Responsibilities, training, hygiene, personnel, records.

3. Premises (9 Hrs)

Location, design, plant layout, construction, maintenance and sanitation environmentalcontrol, utilities and services like gas water maintenance of sterile areas control of contamination.

4. Equipment (5 Hrs)

Selection, purchase specifications, preventive maintenance, clean in place and sterilize in place, method (GTP & STP).

5. Warehousing (4 Hrs)

Good warehousing practices, material management.

6. Distribution (4 Hrs)

Distribution records, Handling of returned goods, Recovered material processing.

7. Complaints and Recalls (8 Hrs)

Evaluation of complaints, recall procedures, related records and documents. Waste disposal, scrap disposal procedures and records.

8. Product Reviews (3 Hrs)

Finished products release, quality review, quality audits, batch release documents.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

The experiments involve industrial visit to study the following aspects:

(Duration of visit: 10 days)

1. Layout of manufacturing premises for tablets, oral liquids, semi-solids. (2 expts)
2. Maintenance of sterile areas and control of contamination. (1 expt)
3. Cleaning and sterilization of equipment in place. (1 expt)
4. Layout and maintenance of warehouse for raw materials and finished products. (1 expt)
5. Study of quality audit. (1 expt)
6. Study of complaint handling and product recall procedures. (1 expt)

RECOMMENDED BOOKS

1. The Theory and Practice of Industrial Pharmacy by Lachman, L., Lieberman and Kanig, J.L, KM Varghese Company, Bombay.
2. Modern Pharmaceutics by Banker, G.S and Rhodes, C.T. (Eds.), Marcel Dekker, NY.
3. How to Practice GMPs 2nd ed. by Sharma P. P., Vandana publishing, New Delhi.
4. GMP by M.L. Mehra, The Universal Book Agency, Allahabad.
5. Pharmaceutical Statistics by David Jones, The Pharmaceutical Press, London.
6. Pharmaceutical Statistics by Bolton. S, Marcel Dekker Inc., NY.
7. Parenteral Quality Control by Akers MJ and Guazoo DM (eds), Marcel Dekker Inc., NY.
8. Pharmaceutical Process Validation by Berry IR and Nash RA (eds), Marcel Dekker Inc., NY.
9. Validation of Pharmaceutical Process by Carleton FJ and Agalloco, Marcel Dekker Inc., NY.
10. Good Laboratory Practice Regulations by Weinberg, Marcel Dekker Inc., NY.

M. PHARMACY SPECILIZATION-3

(PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE)

Semester- II

Name of Course	**CHEMICAL AND BIOLOGICAL EVALUATION**			
Course Code	MP-322		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objectives of the course

To apprise the students about concepts related to Quality Control in industry, Method Validation and Assay Development and Documentation related to Bio-pharmaceutical products.

Students learning outcomes/objectives

After getting exposed to this course, the student will be in a position to understand quality control aspects, carryout validation protocols and perform various assays as per industry requirements.

Instructional methods and pedagogy

Faculty member(s) shall engage regular class-room lectures using blackboard and/or audio-visual aids, and perform experiments related to the class-room teaching.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each, only three are to be answered by candidate and out of 9 short questions carrying 3 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Quality Control (9 Hrs)

Quality control, layout, responsibilities, good laboratory practices, training, calibration of instruments, sampling techniques, specifications, SOPs. Documentation review and batch release. Vendor and warehouse audit. Working reference and pharmacopoeial standards.Retention of active pharmaceutical ingredients and finished formulations and quality review.Schedule-M and WHO certification for export of pharmaceuticals. Salvaging of returned goods and reprocessing.

2. Validation (4 Hrs)

Method validation, cleaning validation, personnel validation.

3. Pharmaceutical Documentation (2 Hrs)

Development of drug information profiles.

4. Immunoassays (3 Hrs)

Enzyme immunoassay: Concepts and methodology.

5. Sterility Testing (2 Hrs)

Methodology and interpretation.

6. Preservatives (2 Hrs)

Tests for effectiveness of antimicrobial preservatives.

7. Biological Assays (12 Hrs)

Detailed study of principles and procedures following: Adsorbed Diptheria vaccine, Adsorbed Tetanus vaccine, Chorionic gonadotrophin, Diphtheria antitoxin, Gas Gangrene antitoxin, Heparin sodium, Human antihaemophilic fraction, Japanese encephalitis vaccine, Oxytocin, Pertussis vaccine, Plague vaccine, Rabies antiserum and vaccine, Streptokinase, Tetanus antitoxin, Tuberculin purified protein derivative, Urokinase.

8. Pyrogens (3 Hrs)

Production, chemistry and properties of bacterial pyrogens and endotoxins. Pyrogens testing: IP, BP and USP methods. Interpretation of data comparison with other official pyrogen tests

9. Microbial Analysis (6 Hrs)

Microbial assays for antibiotics and vitamins. Chemical and bacteriological analysis of potable water, purified water and water for injection

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Standard operating procedures (2 expts):
    (a) Analytical instrumentation
    (b) Operating pharmaceutical machinery
    (c) Cleaning process
    (d) Monograph analysis
2. Assay of following formulations (3 expts):
    (a) Amikacin sulphate injection, IP 1996
    (b) Bacitracin zinc, IP 1996

(c) Gentamycin sulphate injection,lP 1996

(d) Ofletracycline HCI, IP 1996

(e) Neomycin sulphate eye drops, IP 1996

3. Test for absence of pyrogens. (1 expt)

RECOMMENDED BOOKS

1. Kaushik Maitra and Sadhan K. Ghosh: A guide to total Quality management, Oxford Publishing House, Calcutta.
2. Sadhan K. Ghosh: Introduction to ISO 9000 and Total Quality management, Oxford Publishing House, Calcutta.
3. R.S. Iyer: Schedule M and beyond good manufacturing practices, Indian Drug Manufacturers Association, Mumbai.
4. Burn, Fininey and Godwin: Biological standardisation, 2nd Edition, OxfordUniversity: Press, London.
5. Regulation of Pharmaceuticals in developing countries legal issues and approaches by D.C. Jeering, WHO publications (1985).
6. The International Pharmacopoeia Vol. 1, 2, 3, 4: 3rd Edition, General methods of analysis and quality specifications for pharmaceutical substances, excipients, dosage forms.
7. Quality assurance of pharmaceuticals - A compendium of guidelines and related materials Vol. 1 (WHO publications).
8. Basic tests for pharmaceutical substances - WHO (1988).
9. Basic tests for Pharmaceutical. Dosage forms- WHO (1991).
10. WHO expert committee on 'Specifications for pharmaceutical preparations' 13th, 22nd, 23rd, 24th and 34th reports.
11. WHO expert committee on 'Biological standardizations' – 37th, 38th, 39th, 40th, 41st, 42nd, 43rd, 44th, 45th reports.
12. Wilmer A. Jenkins & Kenton R. Osborn: Packaging and drugs and Pharmaceuticals Technomic Publishing Company Inc., Pennsylvania.
13. H. Lookhartand, F.A. Paine: Packaging of Pharmaceuticals and Health care products.
14. M. Purkany: Quality assurance and TQM for analytical laboratories, The Royal Society of Chemistry, Cambridge, London.
15. Donald C. Singer and Ronald P. Upton: Guidelines for laboratory quality auditing (Quality and Reliability Series No. 39), 1 st Edition (1993), Marcel Dekker, New York.
16. Broton. J. Wright: Microbiological assays.

M. PHARMACY SPECILIZATION-3

(PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE)

Semester- II

Name of Course	**DRUG AND EXCIPIENT ANALYSIS**			
Course Code	MP-323		Contact hours/week	T-3, P-5
Credits	3+3 = 6		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	90	60	75	75

Objectives of the course

To teach the students about how to identify and characterize drugs in various formulations, involving standard analytical techniques and chemical methods.

Student learning outcomes

After completing this course, the student will be in a position to perform identification- and characterization of drugs in pharmaceutical formulations and other related products; be able to understand the working principles of various bio-analytical instrumental techniques.

Instructional methods and pedagogy

Faculty member(s) shall engage regular class-room lectures using blackboard and/or audio-visual aids, and perform experiments related to the class-room teaching.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each, only three are to be answered by candidate and out of 9 short questions carrying 3 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Application of Instrumental Methods in Drug Development (2 Hrs)

Introduction, product characterization for drug development.Product development, production and pharmacopoeial controls, concept of analytical method development.

2. Analysis of Drugs and Excipients in SolidState (4 Hrs)

Introduction, particle size analysis, importance of particle size in various dosage forms, methods of particle size analysis, X-ray powder diffraction.

3. Light scattering methods in quantitative analysis (3 Hrs)

Turbidometry, Nephelometry.

4. Light Emission Methods in Quantitative Analysis (3 Hrs)

Fluorimetry, Flame photometry

5. Analysis of Drugs in Pharmaceutical Dosage Forms (10 Hrs)

A detailed study of principles and procedures involved in various physico-chemical methods of analysis (including instrumental methods of analysis) of pharmaceutical dosage forms containing the following classes of drugs:

a) Sulphonamides
b) Barbiturates
c) Adrenergic drugs
d) Antitubercular drugs
e) Diuretics
f) Antimalarials
g) Local anaesthetics
h) General anaesthetics
i) Analgesics and antipyretics
j) Anthelmintics

6. Analysis of Drugs from Natural Sources (7 Hrs)

Principles and procedures involved in the analysis of pharmaceutical preparations and dosage forms containing the following groups of substances:

a) Alkaloids
b) Glycosides
c) Vitamins
d) Antibiotics
e) Steroid hormones

7. Elemental Analysis (4 Hrs)

Analysis of non-metals and metals. Principles and procedures involved in the quantitative determination of the following groups: Hydroxyl, Carboxylic acid, Aldehyde, Ketone, Methoxyl, Ester, Amine, Nitrates.

8. Use of Reagents in Pharmaceutical Analysis (5 Hrs)

Principles and procedures involved in the use of the following reagents in pharmaceutical Analysis:

a) MBTH (3-Methyl-2-benzothiazolone hydrazone) reagent
b) FC (Folin Ciocalteu) reagent
c) 2,6-Dichloroquinine monoamine reagent
d) 1,2-Naptha quinone-4-sulfonate reagent
e) 2,3,5-Triphenyltetrazolium salt
f) PDAB (Paradimethyl aminobenzaldehyde) reagent
g) PDACA (Paradimethylamino cinnamaldehyde) reagent
h) Ninhydrine reagent
i) Carr-Price reagent
j) Bratton-Marshal reagent
k) 2,6-Dichloroquinone chlorimide

9. Analytical Method Validation Parameters (3 Hrs)

Validation protocols for Spectrophotometric, HPLC and GC methods.

10. Radiopharmaceuticals (2 Hrs)

Quality Control of radiopharmaceuticals and radiochemical methods in analysis.

PRACTICALS

Note

- Minimum number of practicals to be conducted: 05; Maximum: 08
- Apart from the experiments listed below, other relevant experiments can be designed by the faculty

Experiments

1. Determination of chloride/sulphate in calcium gluconate by Nepheloturbidimetric analysis (1 expt)
2. Estimation of the following drugs by fluorimetry: Doxazosin mesylate, Riboflavin, Thiamine, Terazocin (1 expt)
3. Study of quenching effect in fluorimetry (1 expt)
4. Quantitative analysis of drugs in the following multi-component dosage forms: Ibuprofen, Paracetamol and Chlorzoxazone; Amoxycillin and Probenecid; Diazepam and Diphenhydramine HCl; Clotrimazole and Tinidazole; Cloxacillin and ampicillin (1 expt)

5. Quantitative colourimetric determination of any drug by using any one of the following reagents: paradimethyl- aminocinnamaldehyde reagent; MBTH reagent (1 expt)
6. Colourimetric estimation of Ferrous ions using 1,10- Phenanthroline

RECOMMENDED BOOKS

1. A.I. Vogel: Textbook of Inorganic chemistry 4th edition, ELBS, Publications, London.
2. Becket and Stanlake: Pharmaceutical Chemistry, 3rd Edition, Vol. I and II, CBS Publishers, New Delhi.
3. K.A. Connors: Text Book of Pharmaceutical Analysis, 3rd Edn., Wiley-inter Science Publication, New York.
4. Sidney, Siggia: Quantitative organic analysis, 4th edition, Wiley Interscience Publications, John Wiley and Sons, New York, Toronto.
5. P. D. Sethi: Quantitative analysis of drugs in Pharmaceutical formulations, 2nd Edition, CBS Publisher, New Delhi.
6. John H. Kennedy: Principles of analytical chemistry, 2nd Edition, Saunders College Publishing, New York.
7. Jorg Augstin, Barbara PKlein, Deborah Becker, Paul B: Methods of Vitamin Assay, 4th Edition, John Wiley and Sons, New York.
8. David G Watson: Pharmaceutical Analysis, Churchill Livingston, Edinburg.
9. Indian Pharmacopoeia, 1996, The Controller of Publications, Govt. of India.
10. Higuchi, Bechmman and Hassan: Pharmaceutical analysis, 2nd Edition, John Wiley and Sons, New York.

M. PHARMACY SPECILIZATION-3

(PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE)

Semester- II

Name of Course	**INTELLECTUAL PROPERTY RIGHTS & DRUG REGULATORY AFFAIRS**			
Course Code	MP-021		Contact hours/week	T-2, P-0
Credits	2+0=2		Total teaching hours required = 30	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	-

Objective of the Course

To make students familiar with the fundamental principles of IPR and Drug regulatory affairs

Student Learning Outcomes

On completion of the course the student would understand the principle and importance if IPR and Drug regulatory affairs in the competitive world

Instructional Methods and Pedagogy

Faculty member/s shall explain in a class room using black board and multimedia projector.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each only three are to be answered by candidate and out of 9 short questions carrying 3 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 30**

1. Intellectual Property-Concepts and Fundamentals (5 Hrs)

The emergence and growth of the concepts regarding intellectual property (IP), intellectual property protection (IPP) and intellectual property rights (IPR); economic importance, mechanism for protection of intellectual property-patents.

2. Trade Related Aspects of Intellectual Property Right (4 Hrs)

Intellectual property and international trade, concept behind WTO (World Trade Organization), WIPO (World Intellectual Property Organization), GATT (General Agreement on Tariff and Trade), TRIPs (Trade Related Intellectual Property Rights), TRIMS (Trade Related Investment Measures) and GATS (General Agreement on Trades in Services), status in India and other developing countries.

3. Patenting (5 Hrs)

Copyright and trade mark protection, criteria for patentability, Indian patent act. 1970: WTO and modifications under TRIPS, filing of a patent application, precautions before

patenting-disclosures/non-disclosures, publication-article/ thesis, prior art search – published patents search, internet search patent sites, specialized service search requests, costs, patent application forms and guidelines, fee structure, time frames, jurisdiction aspects, types of patent application- provisional, non-provisional, PCT and convention patent applications, international patenting requirement procedures and costs.

4. Technology Development/Transfer Commercialization Related Aspects (4 Hrs)

Technology development: Meaning, drug related technology development, toxicological studies, bioequivalence (BU), clinical trials Phase I, Phase II and Phase III.

5. Ethics and Values in IP (3 Hrs)

IP and ethics, positive and negative aspects of IPP, social responsibility, avoiding unethical practices, eco-responsibility–economic, social and environmental benefits of modern biotechnology.

6. Drug Regulatory Affairs (09 Hrs)

- Regulation on manufacture of drugs in India.
- Drug regulatory controls and authorities.
- Requirements of GMP, CGMP, GLP.
- Guidelines of WHO, inputs of international bodies, national agencies, harmonization.
- Preparation and submission of marketing application of India, US and Europe.
- Approval and appeals present and issues of confidentiality.
- ISO 9000 series.
- Drugs and cosmetics acts and rules.
- Important regulations related to import and export of drugs.

BOOKS RECOMMENDED

1. Treece DJ. Managing Intellectual Capital: Organizational, Strategic and Policy Dimension. Oxford University Press, England. Latest Edition.
2. Wadedhra BL. Law Relating to Patents, Trademarks, Copyright Design and Geographical Indications. Universal Law Publishing, New Delhi. Latest Edition.
3. Bansal P. IPR Handbook for Pharma Students and Researchers, Pharma Book Syndicate, Hyderabad. Latest Edition.
4. Copyright Protection in India [website: http:copyright.gov.in].
5. Information on Orange Book [website: www.fda.gov/cder/ob/default.htm].
6. World Trade Organization [website: www.wto.org].
7. Trivedi PR. Encylcopedia of Intellectual Property Rights. Jnanada Prakashan, New Delhi. Latest Edition.

M. PHARMACY SPECILIZATION-3

(PHARMACEUTICAL ANALYSIS AND QUALITY ASSURANCE)

Semester- III

Name of Course	**RESEARCH METHODOLOGY AND STATISTICS**			
Course Code	MP-030		Contact hours/week	T-3, P-0
Credits	3		Total teaching hours required = 43	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	-

Objectives of the Course

- To make the student familiar with systematic research methodology and computer applications in development of proper research methodology.
- To make the student familiar with different pharmaceutical and statistical tools required for carrying out systematic research.

Student Learning Outcomes

On completion of the course the student would understand the principle and importance if IPR and Drug regulatory affairs in the competitive world

Instructional Methods and Pedagogy

Faculty members shall explain in a class room using black board or a multimedia projector.

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each only three are to be answered by candidate and out of 9 short questions carrying 3 marks each only seven are to be answered by candidate.

THEORY **Total Hours: 43**

1. Literature Survey **(2 Hrs)**

Accessing required information in a systematic manner from abstracts, books, journals, proceedings of conferences, theses and dissertations, CD ROMs, internet and such other sources.

2. Scientific Writing **(5 Hrs)**

Writing of papers, articles and thesis; preparation of title, abstracts, introduction, methodology, results and discussion, summary-conclusion; preparation of tables and figures using software like MS Office, Open Office, etc; organization of dissertations and thesis; conventions adopted in writing; citing references; preparation of oral presentations and posters.

3. Data Collection (8 Hrs)

The population – sample; measures of describing the center of data distributions; measurement of spread of data; binomial and normal distributions – their significance.

4. Statistical Inference (10 Hrs)

Statistical estimation – confidence intervals; tests for statistical significance – T-test, F-test, analysis of variance (ANOVA); Chi-square test; linear regression and correlation.

5. Non-parametric tests (10 Hrs)

Data characteristics suitable to non-parametric procedures; Sign test, Wilcoxon signed rank test, Wilcoxon rank sum test; Kruskal Wallis test; Runs test for randomness; contingency tables.

6. Statistical software (8 Hrs)

Introduction to statistical software such as SPSS, GraphPad, SigmaStat, MS Excel; open source software for statistical analysis.

BOOKS RECOMMENDED

1. Bolton, Pharmaceuticals Statistics- Practical & Clinical Applications, Marcel & Dekker, New York.
2. Fisher, R.A., Statistical Methods for Research Works, Oliver & Boyd, Edinburgh.
3. Chow, Statistical Design and Analysis of Stability Studies, Marcel Dekker, New York.
4. Buncher, Statistics in the Pharmaceutical Industry, Marcel Dekker, New York.
5. Finney, D.J., Statistical Methods in Biological Assays, Hafner, New York.
6. Montgomery, D.C., Introduction to Statistical Quality Control, Willy.
7. Khan, Irfan A., Biostatistics for Pharmacy.
8. Khan, Irfan, A., Fundamentals of Biostatistics.
9. Gauthaman, Biostatistics for Pharmacy students.
10. Lipschutz, Introduction to Probability and Statistics.
11. Liwan Po, Statistics for Pharmacist.
12. William E. Fassett, Computer Application in Pharmacy.
13. Ekins, S., Computer Application in Pharmaceutical Research & Development, Wiley.
14. Nageswara Rao and Tiwari, Biostatistics and Computer Applications.
15. Robert A Day., How to write and publish a scientific paper, 4th edition, Cambridge University Press.

SYLLABUS

Master of Pharmacy Programme

ELECTIVE SUBJECTS

(FOR ALL SPECIALIZATIONS)

HIMACHAL PRADESH TECHNICAL UNIVERSITY
HAMIRPUR

ALL SPECILIZATIONS

Semester-I

Name of Course	**POLYMERS IN PHARMACEUTICALS**			
Course Code	MP-012		Contact hours/week	T-2, P-0
Credits	2+0=2		Total teaching hours required = 30	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	-

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each, only three are to be answered by candidate and out of 9 short questions carrying 3 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 30**

1. Classification of Polymers (8 Hrs)

Synthesis of polymers, general methods of preparation of polymers like solution bulk, suspension and emulsions polymerizations.Properties of the following commonly used polymers; Starch, gelatin, albumin, Cellulose derivatives, acrylates and poloxamers.

2. Characterization of Polymers (8 Hrs)

Molecular weight and Molecular weight distribution of polymers, flow characteristics, crystalline, solubility and thermodynamic of polymer solutions. Biodegradability and biodegradability testing of polymers.

3. Applications of Polymers (7 Hrs)

Acrylic latex system and their applications, Biodegradable polymers and their application in parenterals, application of polymers in conventional and new drug delivery system.

4. Regulatory Issues (7 Hrs)

Food and drug administration perspective on regulation of pharmaceutical excipients

RECOMMENDED BOOKS

1. J.Brandrup, E.H.Immergur; Polymer Handbook;John wiley and Sons
2. Charles G.Gebelein. T.C.Chin and V.C.Yang; Cosmetic and

3. Pharmaceutical Applications of Polymers; Plenum Press, New work.
4. D.S.Soane; Polymer Applications for Biotechnology ; Prentice Hall Inc.
5. J.R.Robinson and V.H.Lee: Controlled Drug Delivery – Fundamentals
6. and Application; Marcel Dekker.
7. N.K.Jain;Controlled and Novel Drug Delivery; CBS publications.
8. P.J.Tarcha; Polymers for controlled Drug Delivery; CRC Press.
9. A.F.Kydonieus; Controlled Release Technologies: Methods, Theory
10. and Application, Vol-I & II; CRC Press Inc.
11. Excipient Development for Pharmaceutical, Biotechnology, and Drug Delivery Systems Edited by Ashok Katdare, Informa Healthcare USA, Inc.

ALL SPECILIZATIONS

Semester-I

Name of Course	**COSMETICOLOGY**			
Course Code	MP-013		Contact hours/week	T-2, P-0
Credits	2+0=2		Total teaching hours required = 30	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	-

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each, only three are to be answered by candidate and out of 9 short questions carrying 3 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 30**

1. Physiological Considerations in Development of Cosmetics (4 Hrs)

Skin, hair, nail and eye- in relation to cosmetic application.

2. Rheology of Cosmetics (4 Hrs)

Rheological additives in cosmetics, rheology of nail products, antiperspirants, deodorants, hair products, creams and lotions.

3. Manufacturing Techniques (3 Hrs)

Cosmetics creams, powders, compacts, sticks, liquids, foam and aerosol cosmetics.

4. Evaluation of Cosmetics (7 Hrs)

Performance, physicochemical, microbiological and psychometric evaluation of cosmetics.Design and Assessment of preservetive systems for cosmetics, valuation of preservatives in cosmetic products and factors affecting activity of preservatives. Testing of moisturizers, deodorants, antiperspirants, sunscreen and anti-aging products.

5. Clinical Safety Testing (3 Hrs)

Irritation, sensitization, photo irritation, photo allergy, ocular irritation and protocols for the same.

6. Packaging (3 Hrs)

Package development and design for cosmetics including aerosol packs.

7. Advances in Cosmeticology (6 Hrs)

Liposomes, multiple and micro emulsions, tooth pastes, hair waving, hair planting, permanent hair coloration, cosmetic surgery, contact lenses.

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; 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.

ALL SPECILIZATIONS

Semester-I

Name of Course	**PRODUCT DEVELOPMENT**			
Course Code	MP-014		Contact hours/week	T-2, P-0
Credits	2+0=2		Total teaching hours required = 30	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	-

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each, only three are to be answered by candidate and out of 9 short questions carrying 3 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 30**

1. Introduction to Biopharmaceutics and Clinical Pharmacokinetics (8 Hrs)

Absorptionmechanisms, pharmacokinetics factors influencing bioavailability.evaluation of bioavailabilityof single drug.

2. Dosage Forms (10 Hrs)

- Tablet formulation, preparation of components for compression,characterization of granulation, coating of tablets and evaluation of tablets.
- Formulation consideration and evaluation of liquid oral preparations including syrup,and dispensed vehicles.
- Formulation of topical dosage form with special reference to dermatological factors.
- Formulation consideration of Parenteral and ophthalmic preparations, Environmental control and quality assurance in Parenteral drug manufacturing.
- Current good manufacturing practice cGMP as followed in the manufacturing ofabove dosage forms.
- Pharmacokinetics aspects of structural modification in drug design.

3. Novel Drug Delivery Systems (4 Hrs)

Concept of Pro-drugs,Liposomes& Niosomes, Transdermaldrug delivery system.

4. Optimization Techniques (5 Hrs)

Optimization techniques in pharmaceutical formulations and processing, pilot plant scaleup techniques of dosage form manufacturing.

5. Packaging of Pharmaceuticals (3 Hrs)

Types of containers and closures, packaging and stabilityassessment.

BOOKS RECOMMENDED

1. N. G. Stanley – Wooed; 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. Kitahard and A. Watanabe; Electrical Phenomena at Interfaces; Marcel Dekker.
5. G. Alderborn and C. Nystrom; Pharmaceutical Powder Compaction Technology; Marcel Dekker.
6. Martin, P. Bustamante and A.H. Chun; Physical Pharmacy; Waverly.
7. Lieberman, Rieser and Banker; Pharmaceutical Dosage Forms; Disperse system; Marcel Dekker.

ALL SPECILIZATIONS

Semester-I

Name of Course	**BULK DRUG TECHNOLOGY**			
Course Code	MP-015		Contact hours/week	T-2, P-0
Credits	2+0=2		Total teaching hours required = 30	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	-

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each, only three are to be answered by candidate and out of 9 short questions carrying 3 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 30**

1. Stoichiometry **(7 Hrs)**

Unit processes, material and energy balance, mole fraction, tie substance, mole volume, primary and secondary quantities, equilibrium state, rate process, steady and unsteady state, dimensionless equations, formula and groups, types of graphical representations

2. Unit Processes **(8 Hrs)**

Study of the following chemical processes (with refefence to reagents, mechanisms, equipments and manufacture of drugs given below): Acylation, Esterification, Alkylation, Amination, Halogenation, Hydrolysis, Nitration, Oxidation, Reduction.

3. Principles and Design of Reactors **(6 Hrs)**

Factors to be considered (including material selection) construction of flow diagrams-selection of equipment.

4. Bulk Manufacturing **(6 Hrs)**

Detailed manufacturing aspects, inclusive of processes and operations involved for: Aspirin, Adrenaline, Aneurine, Barbitones, Benzocaine, Chloramphenicol, Sulphathiazole.

5. Industrial Safety and Hazards (3 Hrs)

Detailed study of different Industrial hazards, precautions, Monitoring and preventive systems.Industrial effluent testing and treatment. Discussion on Industrial accident case studies, Environment and pollution Acts.

BOOKS RECOMMENDED

1. M. Giarians: Fundamentals of Chemical Engineering operations.
2. W. J. Badger and Banchero: Introduction to Chemical Engineering (Mcgraw Hill services).
3. L. Lachman- The theory and practice of Industrial Pharmacy (Vergesse 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).

ALL SPECILIZATIONS

Semester-I

Name of Course	**CLINICAL PHARMACY**			
Course Code	MP-016		Contact hours/week	T-2, P-0
Credits	2+0=2		Total teaching hours required = 30	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	-

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each, only three are to be answered by candidate and out of 9 short questions carrying 3 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 30**

1. Introduction to Clinical Pharmacy (4 Hrs)

Scope, objectives and goals in healthcare, Practice of Clinical Pharmacy in hospitals and community.

2. Fundamentals of Diseases (7 Hrs)

Symptoms and disease identification, General Systemic effects of disease, CVS and other systemic effects of disease and injury, Endocrine and metabolic responses to disease and trauma, Nervous system involvement in disease, Communicable disease and prevention.

3. Therapeutic use of Medicines (10 Hrs)

a. Drug Selection and Administration: Problems associated with concomitant therapy, Patient sensitivities, allergies, Precautions during the use, Diet control.

b. Reasons for noncompliance: Poor standards of labeling, social isolation, complex therapeutic regimens, nature of medication, side effects, Lack of doctor / pharmacist / patient rapport, Inadequate patient education.

c. Strategies for Improving Compliance: Supplementary labeling, simplification of therapeutic regimens, patient counseling, use of warning cards, patient education, patient Package inserts.

d. *Use of drugs in specialized conditions*: Geriatric, Pediatric patients and in Pregnancy.

4. Monitoring the Patient in Health and Illness (6 Hrs)

Fluid and electrolyte imbalance, Cardio-pulmonary dysfunction, Metabolic disorders, Patient follow-up, Discharge interview for hospitalized patients, Precautions and Directions during use of medication, Pharmacological and biochemical examinations, their significance, Supervision of therapeutic success, side effects and adverse effects.

5. Drug information (3 Hrs)

Introduction to information resources available, development of drug information services, drug literature utilization, selection, evaluation and immunization.Physician - Pharmacist interaction, Pharmacist - patient interaction.

BOOKS RECOMMENDED

1. Clinical pharmacy practice; C.W. Blissit
2. Clinical pharmacy & therapeutics; Walker Edwards, Churchill Livingston
3. Textbook of clinical pharmacology; James M. Ritter, Lionel D.
4. Drugs in Pregnancy & lactation; 4th Ed; Gerald, G Briggs, Roger K. Freeman, Williams & Wilkins.
5. Pharmaceutical & Medicine Information Management; Principles & Practice; Andrew S. Robson, Churchill - Livingston.
6. Handbook of Pharmacy Healthcare Diseases & Patient Advice; Ed; R.J.Harman, Pharmaceutical Press; London.
7. Patient care in community practice; R.J. Harman; Pharmaceutical Press, London.
8. Applied therapeutics for clinical pharmacists; Koda Kimble M.N, Applied Therapeutic Inc., San Fransico.

ALL SPECILIZATIONS

Semester-I

Name of Course	**THERAPEUTIC DRUG MONITORING**			
Course Code	MP-017		Contact hours/week	T-2, P-0
Credits	2+0=2		Total teaching hours required = 30	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	-

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each, only three are to be answered by candidate and out of 9 short questions carrying 3 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 30**

1. Introduction to Therapeutic Drug Monitoring (TDM) (8 Hrs)

Definition, Introduction, Indication for TDM & clinical applications.Monitoring plasma drug levels.Role of Clinical pharmacist in TDM.Importance of TDM with respect to adverse drug reactions.

2. Techniques used in TDM (5 Hrs)

Physical methods - HPLC, HPTLC, GC; Immunoassays- RIA, ELISA, EMITH, NIIA.

3. Variation of Clinical Laboratory Tests Due to Drugs (7 Hrs)

Serum creatinine, blood urea, nitrogen, plasma, glucose, creatinine kinase, phosphatase, amylase, bilirubin, serum proteins, globulines, complete blood count, differential blood count**.**

4. Clinical Pharmacokinetics (10 Hrs)

Importance of clinical pharmacokinetics, General guidelines, sample collection, time of sample collection, clinical comments, clinical monitoring parameters, usual dosing parameters, common toxicities, adverse drug reactions and drug interaction, techniques used for estimation, importance ofDigoxin, gentamicin, lidocaine, lithium, theophylline, phenytoin, phenobarbitone, carbamazepine, valproic acid, metformin

BOOKS RECOMMENDED

1. Clinical pharmacy practice – C.W.Blissit.
2. Therapeutic drug monitoring – B. Widdop.
3. TDM & Clinical biochemistry – MikeHallworth.
4. Textbook of therapeutics, Drug & disease management – 7thedition – EricT.Herfindel, Dick. R.Gourley.
5. Recent developments in TDM & Clinical toxicology – I. Sunshine – Marcel – Dekker – 1982.
6. Handbook of TDM – Simkin.
7. TDM – Abbot.

ALL SPECILIZATIONS

Semester-I

Name of Course	**PHARMACEUTICAL INDUSTRIAL MANAGEMENT**			
Course Code	MP-018		Contact hours/week	T-2, P-0
Credits	2+0=2		Total teaching hours required = 30	
Examination	Theory		Practical	
	University	Internal Assessment	University	Internal Assessment
Maximum Marks	60	40	-	-

For paper setter: Question paper shall consist of very long and short questions uniformly distributed from whole of the syllabus. Out of two very long questions, carrying 18 marks each, only one need to be answered by candidate, out of 4 long questions, carrying 7 marks each, only three are to be answered by candidate and out of 9 short questions carrying 3 marks each, only seven are to be answered by candidate.

THEORY **Total Hours: 30**

1. Personnel (3 Hrs)

Introduction, Qualification Experience and Training, Responsibilities and Key Personnel, Personal hygiene and clothing, Legal Aspects and Consultants.

2. Surrounding, Building And Facilities (4 Hrs)

Introduction, Principal Area, Plumbing and Drainage system, Lighting, Sewage, Refuge and Disposal of Water, Washing and Toilet Facilities, Sanitation Maintenance.

3. Materials Management (3 Hrs)

Introduction, Purchasing, Raw Materials, Packaging Materials, Intermediate and Bulk Products, Finished Products, Rejected and Recovered Materials, Recalled Products, Returned goods, Reagents and Culture Media, Waste Materials, Reference standards, Miscellaneous Materials.

4. Manufacturing Operations and Control (6 Hrs)

Introduction, Sanitation of Manufacturing Premises, Mix-ups and Cross Contamination, Processing of Intermediates and Bulk product, Packaging Operations, Release of Finished Product, Process Deviations , Charge-in of Components, Time Limitations on Production, Drug product Inspection, Expiration Dating, Calculation of Yields and Production Record Review.

5. Documentation and Records (3 Hrs)

Introduction, specifications, Master Production and Control Record, Batch Production and Control Record, Important SOPs and Record, Change Control and Site Master File.

6. Outsourcing (2 Hrs)

Introduction, Manufacturing and Packaging Outsourcing, Analytical Outsourcing and Other Services- Outsourcing.

7. Post Operational Activities (3 Hrs)

Introduction, Distribution, Recall Products, Returned Products, Complaints and Adverse Effects and Drug Product Salvaging.

8. Site and Plant Security (3 Hrs)

Introduction, Security Personnel, Entry to Site, Entry to Plant Buildings, Internal Security and Current Issues.

9. Safety and Enviromental Protection (3 Hrs)

Introduction, Safety and Environmental Protection and Procedures.

RECOMMENDED BOOKS

1. MA Potdar. Pharmaceutical Quality Assurance, Nirali Prakashan, Pune.
2. M.A. Potdar, Current Good Manufacturing Practices, Pharma-Med Press, Hyderabad.
3. Sidney H. Willing, GMP for Pharmaceuticals, 5th Edition, Marcel Decker, New York.
4. Regulatory guidelines related to GMP by a. Australian code of GMP for medicinal products, 16th Aug. 2002.
5. M. S. P. Khan, Assurance of Quality, Pharmaceutical Total Quality Approach, Signet Press, Bangladesh.