# MASTERS DEGREE IN PHARMACY (M.Pharm)

## ACADEMIC REGULATIONS

### 1. Duration of the course

The duration of the M.Pharm course shall be of two academic years (four semesters). The course of study for M.Pharm shall include first semester, second semester, third semester and final semester, each of 15 weeks duration (excluding days spent in examination).

### 2. Eligibility for admission

2.1 A candidate who has passed B.Pharm with at least 55% marks (Aggregate of 4 years / 3 years for lateral entry admission) (for SC/ST candidates, the pass percentage at the qualifying examination) from an institution approved by PCI and AICTE.

2.2 Preference will be given to GATE qualified candidates.

2.3 For sponsored candidates

A Pharmacy Graduate, fulfilling conditions mentioned in section 2.1 and having 2 years of full time professional experience in a registered pharmaceutical company/ educational and/ or research institution/ any government organization shall be eligible for admission under sponsored category.

Sponsored candidates shall have to submit a sponsorship letter from their employer along with the application form for admission. The letter must also mention the length of candidate's employment with the sponsor and the undertaking that the sponsorship shall not be withdrawn before the completion of the course.

Sponsored candidates shall not be eligible to receive scholarship, even if they are admitted on the basis of GATE score.

2.4 There will be no age restriction. However, candidates below 45 years of age shall be preferred.

2.5 Admissions will be made in order of merit. For preparing merit, equal weightage shall be given to aggregate percentage of marks obtained in B.Pharm and GATE.

Reservations will be made as per State Govt. / University rules. In case of non availability of reserved category candidate(s), the reserved seat(s) shall be filled up by general category candidate(s).

### 3. Scheme of Study & Examination

3.1 The medium of instruction and examination shall be English.

3.2 Candidates for the M.Pharm course shall be instructed and examined as per the Teaching and Examination Scheme and Course Content of respective specializations.

### 4. Eligibility for appearing in the examination

4.1 Attendance Requirement: In order to be eligible for University examination, a student must be present in not less than 75 % of theory and practical classes of each subject.

4.2 A candidate who has attended a regular course of study for the first semester in an academic institution shall be eligible to appear at the M.Pharm first semester examination of the University.

4.3 A candidate who has been promoted to second semester as per the provisions for conditions of passing and has attended a regular course of study in an academic institution for the second semester shall be eligible to appear at second semester examination for M.Pharm.

4.4 A candidate who has been promoted to third semester in an academic institution as per the provisions for conditions of passing and has completed the dissertation research work up to the satisfaction of the supervisor as prescribed under the relevant regulations for third semester shall be eligible to appear at the third semester examination for M.Pharm.

4.5 At the beginning of M.Pharm. third semester, for each candidate, a dissertation supervisor shall be appointed by the head of the institution. The candidate shall choose a topic for dissertation in consultation with the supervisor, carry out literature survey on the proposed dissertation topic and submit a dissertation synopsis including plan of work duly signed by the supervisor to the Head of the institution for approval. The candidate shall then carry out the dissertation research work on the approved dissertation topic at the institute running the course under the guidance of respective supervisor. A candidate may also perform his/ her dissertation work at any other institute/ laboratory/ industry as per the requirement of the subject

on approval of the supervisor and the head of the institution. If the appointed supervisor leaves the college/ is likely to be absent for a long period, the head of the institution shall appoint another supervisor. The candidate shall continue the dissertation work on the topic approved earlier.

4.6 A candidate who has been promoted to final semester as per the provisions for conditions of passing and has completed the dissertation research work up to the satisfaction of the supervisor as prescribed under the relevant regulations for the final semester shall be eligible to appear at the final semester examination for M.Pharm. During M.Pharm. final semester, candidate shall continue the dissertation research work of the third semester.

**5. Sessional (Internal assessment)**

5.1 Theory sessional (25 marks):

| | | | |
|---|---|---|---|
| Written test | : | 15 marks |
| Seminar and/or assignment | : | 10 marks |
| Total | : | 25 marks |

(i) Written test (15 marks):
At least two written tests of 15 marks each in every theory subject shall be conducted by the institute at regular interval during each semester. The average of best two performances shall be taken into consideration for the purpose of computation of theory sessional marks. Duration of each written test shall be of one hour.

(ii) Seminar and/ or assignment (10 marks):
Every student shall present a subject seminar and/or submit assignment on the topic assigned by the subject teacher.

5.2 Practical sessional (25 marks):

| | | |
|---|---|---|
| Practical test | : | 15 marks |
| Day-to-day practical work | : | 10 marks |
| Total | : | 25 marks |

(i) Practical test (15 marks):
At least two practical tests of 15 marks each in every practical subject shall be conducted by the institute at regular interval during each semester. The average of best two performances shall be taken into consideration for the purpose of computation of practical test marks. The duration of each practical test shall be of 6 hours. Each practical test may be conducted in different parts viz. synopsis/ spotting, exercise/ experiment and viva-voce etc.

(ii) Day-to-day practical work/ experiments performed (10 marks):
The concerned teacher shall evaluate the day-to-day practical work/ experiments performed in the laboratory on the basis of the performance of the student, viva-voce and maintenance of practical record.

5.3 Professional practice:
The students shall carry out professional work as allotted by the head of the institution in M.Pharm. first and second semesters. The professional work shall include performance of lab. duties, analysis of samples etc.

5.4 Dissertation sessional (50 marks):
For M.Pharm. third and final semester dissertation sessional, the candidate shall submit a copy of dissertation progress report printed or type written, containing the results of his/her dissertation research work duly signed by the supervisor and forwarded to the head of the institution, on or before the prescribed date.

The evaluation shall be on the basis of seminar and dissertation progress report, presentation and viva-voce and shall be done by a board consisting of dissertation supervisor and one teacher of the subject of specialization (to be appointed by the head of the institution). The average of the marks awarded by the board members shall be considered for the purpose of computation of dissertation sessional marks.

5.5 The record of marks of sessional examination for each student shall be maintained by the academic institution and must be submitted to the University before the commencement of University examination.

5.6 A candidate failing in any of the subjects shall have a chance to improve his /her sessional marks in theory, practical and dissertation by appearing in one additional sessional examination. The aggregate of best two performances from all the sessionals shall form the basis of calculating the average for computation of improved sessional marks. Marks for day-to-day assessment in the practicals cannot be improved unless a candidate attends a regular course of study again.

**6. University examination**

6.1 University examinations for all the four semesters are to be held twice in a year, as per the Teaching and Examination Scheme and Course Content, in the months of May/June and Nov./Dec. or on such dates as may be fixed by the University.

6.2 University examination in each theory subject shall be of three hours duration. There shall be 7 questions carrying equal marks, out of which 5 questions shall have to be attempted.

6.3 University examination in each practical subject shall be of 6 hours duration and shall comprise of synopsis / spotting, exercise / experiment and viva-voce etc. The head of the institution shall send the awards to the University, on or before the prescribed date.

**7. Dissertation**

7.1 For M.Pharm. third semester University examination, the candidate shall submit four copies of dissertation report, printed or type written, in spirally bound form, containing the results of his/ her dissertation work duly signed by the supervisor and countersigned by the head of the institution.

The evaluation shall be on the basis of dissertation report, presentation and viva voce and shall be done by a Board consisting of dissertation supervisor, external examiner appointed by the University and the Head of the institution who shall be the chairman of the board.

The chairman shall then send the awards to the University, on or before the prescribed date.

7.2 For M.Pharm final semester University examination, the candidate shall submit four copies of dissertation thesis printed or type written, in bound form, containing the results of his/ her research work. The dissertation thesis shall bear a certificate from the supervisor countersigned and duly forwarded by the Head of the institution, on or before the prescribed date, certifying that:

*(i) the work has been undertaken and completed and the dissertation has been written under his/ her supervision and guidance and meets the requirements of the course;*

*(ii) the dissertation is a bonafide record of the original work carried out by the candidate and the dissertation work has not formed the basis of award of any other degree or diploma etc. of this or any other University.*

The evaluation shall be done on the basis of dissertation thesis, presentation and viva voce and shall be done by a Board consisting of dissertation supervisor, external examiner appointed by the University and the Head of the institution who shall be the chairman of the board.

The chairman shall then send the awards to the University, on or before the prescribed date.

**8. Conditions of passing**

8.1 A candidate shall be declared to have passed in a subject when he/ she has secured 50% of the maximum marks in the sessional and University examination marks put together separately in each theory and practical subjects and dissertation sessional and dissertation university examination.

8.2 A candidate who fails to obtain 50% marks in any subject(s) (Theory and practical counted as separate subject) in first or second semester examination, shall be eligible for promotion to second/ third semester. Such candidate shall have to appear again in failing subject(s) in the subsequent examination.

8.3 No candidate will be eligible for submitting the dissertation thesis unless he/ she has passed in all subjects of first/ second semester.

8.4 A candidate, who has failed in M.Pharm third semester examination, shall be furnished by the Board [Point 6(c)] with a clear statement of reasons for failure and suggestions for improvement. He/ she shall not be allowed to pursue course for M.Pharm final semester. He/ she shall revise and resubmit the dissertation report after pursuing research work as suggested by the board on the same dissertation topic. Such a candidate will have to reappear as an ex-student in the next M.Pharm third semester University examination.

8.5 A candidate, who has failed in M.Pharm final semester examination, shall be furnished by the Board [Point 6(d)] with a clear statement of reasons for failure and suggestions for improvement. He/ she shall revise and resubmit the dissertation thesis after incorporating suggestions made by the board on the same dissertation topic. Such a candidate will have to reappear as an ex-student in next M.Pharm final semester University examination.

8.6 In no case shall a candidate, who has not passed finally after six academic years from the date of enrolment, be allowed to continue the course.

The Vice-chancellor in consultation with the Head of the institution may waive this limit of six academic years. The reasons for waiving the limit shall be recorded in writing. Such extension shall not exceed one year.

8.7 A candidate who is unable to appear at any examination in any subject(s) due to any reason whatsoever shall be considered as having failed in that subject(s).

**9. Award of Degree, Division and Rank**

9.1 On satisfactory completion of the course and after passing all the semester examinations, a candidate shall be awarded degree of M.Pharm in the respective branch.

9.2 No division shall be awarded at the end of M.Pharm first, M.Pharm second and M.Pharm third semester examinations. The division to a successful candidate shall be awarded on the basis of aggregate of marks obtained by him/ her in M.Pharm first semester, M.Pharm second semester, M.Pharm third semester and M.Pharm final semester examinations regardless of the number of attempts, as shown below:

| ***Percentage of marks*** | ***Division*** |
|---|---|
| 75% or above | Honours |
| 60% or above | First Division |
| 50% or above | Second Division |

9.3 A candidate will be said to have passed a paper with distinction if he/ she secure 75% or more marks in the concerned paper.

9.4 The actual marks (and not the passing marks) as obtained by a candidate in a supplementary/attempt examination shall be counted for award of division.

9.5 Rank and university gold medal shall be conferred to those candidates who have passed the whole examination in first attempt (without any grace) and such candidates shall be eligible for any prize or scholarship.

**Teaching & Examination Scheme**

**M.Pharm (Pharmaceutics)**

**First semester**

| Paper No. | Subject | Teaching Hours/ Week | Univ. Exam Hrs. | Marks | | |
|---|---|---|---|---|---|---|
| | | | | Sessional | Univ. Exam | Total |
| M.111T | Methods in Pharmaceutical Research, Theory | 4 | 3 | 25 | 75 | 100 |
| M.112P | Methods in Pharmaceutical Research, Practical | 6 | 6 | 25 | 75 | 100 |
| M.PH113T | Product Development, Theory | 4 | 3 | 25 | 75 | 100 |
| M.PH114P | Product Development, Practical | 6 | 6 | 25 | 75 | 100 |
| M.PH115T | Advanced Pharmaceutics & Biotechnology, Theory | 4 | 3 | 25 | 75 | 100 |
| | Professional Practice | 12* | | - | - | - |
| | **Total** | **36** | | **125** | **375** | **500** |

* These hours will not be counted as workload of Teacher.

**Second semester**

| Paper No. | Subject | Teaching Hours/ Week | Univ. Exam Hrs. | Marks | | |
|---|---|---|---|---|---|---|
| | | | | Sessional | Univ. Exam | Total |
| M.121T | Advances in Pharmaceutical Sciences including Biostatistics, Theory | 4 | 3 | 25 | 75 | 100 |
| M.122P | Advances in Pharmaceutical Sciences including Biostatistics, Practical | 6 | 6 | 25 | 75 | 100 |
| M.PH123T | Novel Drug Delivery System, Theory | 4 | 3 | 25 | 75 | 100 |
| M.PH124P | Novel Drug Delivery System, Practical | 6 | 6 | 25 | 75 | 100 |
| M.PH125T | Biopharmaceutics and Pharmacokinetics, Theory | 4 | 3 | 25 | 75 | 100 |
| | Professional Practice | 12* | | - | - | |
| | **Total** | **36** | | **125** | **375** | **500** |

* These hours will not be counted as workload of Teacher.

**Third semester**

| Paper No. | Subject | Teaching Hours/ Week | Marks | | |
|---|---|---|---|---|---|
| | | | Sessional | Univ. Exam | Total |
| | Dissertation Synopsis | 36 | To be submitted | | |
| M.PH212D | Dissertation (Report, Presentation & Viva-voce) | | 50 | 150 | 200 |

**Final semester**

| Paper No. | Subject | Teaching Hours/ Week | Marks | | |
|---|---|---|---|---|---|
| | | | Sessional | Univ. Exam | Total |
| M.PH221D | Dissertation (Thesis, Presentation & Viva-voce) | 36 | 50 | 150 | 200 |

## M.Pharm (Pharmaceutical Chemistry)

**First semester**

| Paper No. | Subject | Teaching Hours/ Week | Univ. Exam Hrs. | Marks | | |
|---|---|---|---|---|---|---|
| | | | | Sessional | Univ. Exam | Total |
| M.111T | Methods in Pharmaceutical Research, Theory | 4 | 3 | 25 | 75 | 100 |
| M.112P | Methods in Pharmaceutical Research, Practical | 6 | 6 | 25 | 75 | 100 |
| M.PC113T | Advanced Medicinal Chemistry-I (Chemistry of Synthetic Drugs with Biochemical Approach), Theory | 4 | 3 | 25 | 75 | 100 |
| M.PC114P | Advanced Medicinal Chemistry-I (Chemistry of Synthetic Drugs with Biochemical Approach), Practical | 6 | 6 | 25 | 75 | 100 |
| M.PC115T | Drug Discovery and Development (CADD, QSAR & Receptor Based Drug Design), Theory | 4 | 3 | 25 | 75 | 100 |
| | Professional Practice | 12* | - | - | - | |
| | **Total** | **36** | | **125** | **375** | **500** |

* These hours will not be counted as workload of Teacher.

**Second semester**

| Paper No. | Subject | Teaching Hours/ Week | Univ. Exam Hrs. | Marks | | |
|---|---|---|---|---|---|---|
| | | | | Sessional | Univ. Exam | Total |
| M.121T | Advances in Pharmaceutical Sciences including Biostatistics, Theory | 4 | 3 | 25 | 75 | 100 |
| M.122P | Advances in Pharmaceutical Sciences including Biostatistics, Practical | 6 | 6 | 25 | 75 | 100 |
| M.PC123T | Advanced Pharmaceutical Chemistry (Organic Name Reactions, Reaction Mechanism & Stereochemistry), Theory | 4 | 3 | 25 | 75 | 100 |
| M.PC124P | Advanced Pharmaceutical Chemistry (Organic Name Reactions, Reaction Mechanism & Stereochemistry), Practical | 6 | 6 | 25 | 75 | 100 |
| M.PC125T | Advanced Medicinal Chemistry-II (Chemistry of Natural Products), Theory | 4 | 3 | 25 | 75 | 100 |
| | Professional Practice | 12* | - | - | - | |
| | **Total** | **36** | | **125** | **375** | **500** |

* These hours will not be counted as workload of Teacher.

**Third semester**

| Paper No. | Subject | Teaching Hours/ Week | Marks | | |
|---|---|---|---|---|---|
| | | | Sessional | Univ. Exam | Total |
| | Dissertation Synopsis | 36 | To be submitted | | |
| M.PC212D | Dissertation (Report, Presentation & Viva-voce) | | 50 | 150 | 200 |

**Final semester**

| Paper No. | Subject | Teaching Hours/ Week | Marks | | |
|---|---|---|---|---|---|
| | | | Sessional | Univ. Exam | Total |
| M.PC221D | Dissertation (Thesis, Presentation & Viva-voce) | 36 | 50 | 150 | 200 |

## M.Pharm (Quality Assurance)

**First semester**

| Paper No. | Subject | Teaching Hours/ Week | Univ. Exam Hrs. | Marks | | |
|---|---|---|---|---|---|---|
| | | | | Sessional | Univ. Exam | Total |
| M.111T | Methods in Pharmaceutical Research, Theory | 4 | 3 | 25 | 75 | 100 |
| M.112P | Methods in Pharmaceutical Research, Practical | 6 | 6 | 25 | 75 | 100 |
| M.QA113T | Standardization & Stabilization Methods (Drugs & Formulations including Herbal Products, Food & Cosmetics), Theory | 4 | 3 | 25 | 75 | 100 |
| M.QA114P | Standardization & Stabilization Methods (Drugs & Formulations including Herbal Products, Food & Cosmetics), Practical | 6 | 6 | 25 | 75 | 100 |
| M.QA115T | Total Quality Management-I, Theory | 4 | 3 | 25 | 75 | 100 |
| | Professional Practice | 12* | - | - | - | |
| | **Total** | **36** | | **125** | **375** | **500** |

* These hours will not be counted as workload of Teacher.

**Second semester**

| Paper No. | Subject | Teaching Hours/ Week | Univ. Exam Hrs. | Marks | | |
|---|---|---|---|---|---|---|
| | | | | Sessional | Univ. Exam | Total |
| M.121T | Advances in Pharmaceutical Sciences including Biostatistics, Theory | 4 | 3 | 25 | 75 | 100 |
| M.122P | Advances in Pharmaceutical Sciences including Biostatistics, Practical | 6 | 6 | 25 | 75 | 100 |
| M.QA123T | Advanced Pharm. Analysis-Method Development, Theory | 4 | 3 | 25 | 75 | 100 |
| M.QA124P | Advanced Pharm. Analysis-Method Development, Practical | 6 | 6 | 25 | 75 | 100 |
| M.QA125T | Total Quality Management-II, Theory | 4 | 3 | 25 | 75 | 100 |
| | Professional Practice | 12* | - | - | - | |
| | **Total** | **36** | | **125** | **375** | **500** |

* These hours will not be counted as workload of Teacher.

**Third semester**

| Paper No. | Subject | Teaching Hours/ Week | Marks | | |
|---|---|---|---|---|---|
| | | | Sessional | Univ. Exam | Total |
| | Dissertation Synopsis | 36 | To be submitted | | |
| M.QA212D | Dissertation (Report, Presentation & Viva-voce) | | 50 | 150 | 200 |

* These hours will not be counted as workload of Teacher.

**Final semester**

| Paper No. | Subject | Teaching Hours/ Week | Marks | | |
|---|---|---|---|---|---|
| | | | Sessional | Univ. Exam | Total |
| M.QA221D | Dissertation (Thesis, Presentation & Viva-voce) | 36 | 50 | 150 | 200 |

**M.Pharm (Pharmacology)**

**First semester**

| Paper No. | Subject | Teaching Hours/ Week | Univ. Exam Hrs. | Marks | | |
|---|---|---|---|---|---|---|
| | | | | Sessional | Univ. Exam | Total |
| M.111T | Methods in Pharmaceutical Research, Theory | 4 | 3 | 25 | 75 | 100 |
| M.112P | Methods in Pharmaceutical Research, Practical | 6 | 6 | 25 | 75 | 100 |
| M.PL113T | Systemic Pharmacology-I, Theory | 4 | 3 | 25 | 75 | 100 |
| M.PL114P | Systemic Pharmacology-I, Practical | 6 | 6 | 25 | 75 | 100 |
| M.PL115T | Advanced Pharmacology, Theory | 4 | 3 | 25 | 75 | 100 |
| | Professional Practice | 12* | - | - | - | |
| | **Total** | **36** | | **125** | **375** | **500** |

* These hours will not be counted as workload of Teacher.

**Second semester**

| Paper No. | Subject | Teaching Hours/ Week | Univ. Exam Hrs. | Marks | | |
|---|---|---|---|---|---|---|
| | | | | Sessional | Univ. Exam | Total |
| M.121T | Advances in Pharmaceutical Sciences including Biostatistics, Theory | 4 | 3 | 25 | 75 | 100 |
| M.122P | Advances in Pharmaceutical Sciences including Biostatistics, Practical | 6 | 6 | 25 | 75 | 100 |
| M.PL123T | Methods in Drug Evaluation, Theory | 4 | 3 | 25 | 75 | 100 |
| M.PL124P | Methods in Drug Evaluation, Practical | 6 | 6 | 25 | 75 | 100 |
| M.PL125T | Systemic Pharmacology-II, Theory | 4 | 3 | 25 | 75 | 100 |
| | Professional Practice | 12* | - | - | - | |
| | **Total** | **36** | | **125** | **375** | **500** |

* These hours will not be counted as workload of Teacher.

**M.Pharm (Pharmacology)**

**Third semester**

| Paper No. | Subject | Teaching Hours/ Week | Marks | | |
|---|---|---|---|---|---|
| | | | Sessional | Univ. Exam | Total |
| | Dissertation Synopsis | 36 | To be submitted | | |
| M.PL212D | Dissertation (Report, Presentation & Viva-voce) | | 50 | 150 | 200 |

**M.Pharm (Pharmacology)**

**Final semester**

| Paper No. | Subject | Teaching Hours/ Week | Marks | | |
|---|---|---|---|---|---|
| | | | Sessional | Univ. Exam | Total |
| M.PL221D | Dissertation(Thesis, Presentation & Viva-voce) | 36 | 50 | 150 | 200 |

## M.Pharm (Pharmaceutical Management and Regulatory Affairs)

**First semester**

| Paper No. | Subject | Teaching Hours/ Week | Univ. Exam Hrs. | Marks | | |
|---|---|---|---|---|---|---|
| | | | | Sessional | Univ. Exam | Total |
| M.111T | Methods in Pharmaceutical Research, Theory | 4 | 3 | 25 | 75 | 100 |
| M.112P | Methods in Pharmaceutical Research, Practical | 6 | 6 | 25 | 75 | 100 |
| M.PMRA113T | Pharmaceutical Management-I (General, & Personnel), Theory | 4 | 3 | 25 | 75 | 100 |
| M.PMRA114T | Total Quality Management, Theory | 4 | 3 | 25 | 75 | 100 |
| M.PMRA115T | Drug Regulatory Affairs-I (National Regulatory Aspects), Theory | 4 | 3 | 25 | 75 | 100 |
| | Case Studies | 2 | - | - | - | |
| | Professional Practice | 12* | - | - | - | - |
| | **Total** | **36** | | **125** | **375** | **500** |

* These hours will not be counted as workload of Teacher.

**Second semester**

| Paper No. | Subject | Teaching Hours/ Week | Univ. Exam Hrs. | Marks | | |
|---|---|---|---|---|---|---|
| | | | | Sessional | Univ. Exam | Total |
| M.121T | Advances in Pharmaceutical Sciences including Biostatistics, Theory | 4 | 3 | 25 | 75 | 100 |
| M. 122P | Advances in Pharmaceutical Sciences including Biostatistics, Practical | 6 | 6 | 25 | 75 | 100 |
| M.PMRA123T | Pharmaceutical Management-II (Production & Marketing), Theory | 4 | 3 | 25 | 75 | 100 |
| M.PMRA124T | Pharmaceutical Management-III (Finance, Project), Theory | 4 | 3 | 25 | 75 | 100 |
| M.PMRA125T | Drug Regulatory Affairs–II (Including International Regulatory Aspects), Theory | 4 | 3 | 25 | 75 | 100 |
| | Case Studies | 2 | - | - | - | - |
| | Professional Practice | 12* | - | - | - | - |
| | **Total** | **36** | | **125** | **375** | **500** |

* These hours will not be counted as workload of Teacher.

**Third semester**

| Paper No. | Subject | Teaching Hours/ Week | Marks | | |
|---|---|---|---|---|---|
| | | | Sessional | Univ. Exam | Total |
| | Dissertation Synopsis | 36 | To be submitted | | |
| M.PMRA211D | Dissertation (Report, Presentation & Viva-voce) | | 50 | 150 | 200 |

**Final semester**

| Paper No. | Subject | Teaching Hours/ Week | Marks | | |
|---|---|---|---|---|---|
| | | | Sessional | Univ. Exam | Total |
| M.PMRA221D | Dissertation (Thesis, Presentation & Viva-voce) | 36 | 50 | 150 | 200 |

## COURSE CONTENT

### M.Pharm (Pharmaceutics, Pharmaceutical Chemistry, Quality Assurance, Pharmacology, Pharmaceutical Management and Regulatory Affairs)

**COMMON SUBJECTS**

**First semester**

| M.111T | Methods in Pharmaceutical Research, Theory | 60 Hrs. |
|---|---|---|

UV–Visible spectroscopy: Brief review of electromagnetic spectrum, UV-Visible range, energy–wavelength–color relationships. Interaction of electro–magnetic radiation (UV-Vis) and matter and its effects, chromophores and their interaction with E.M.R. Absorption spectra of organic compounds and complexes illustrating the phenomenon and its utilization in qualitative and quantitative studies of drugs, shifts and their interpretations (including solvent effects); photo-acoustic spectroscopy.

Infra-Red spectroscopy: Nature of I.R. radiation, interaction of I.R. radiation with organic molecules and effects on bonds, molecular or infra-red spectra, brief outline of classical I.R. instrumentation and interpretation of spectra including sample preparation for spectroscopy, qualitative interpretation of I.R. spectra, quantitative methods and recent advances in I.R. spectroscopy including FTIR, ATR, etc.

Nuclear Magnetic Resonance spectroscopy: Fundamental principles of NMR (magnetic properties of nuclei: applied field and precession: absorption and transition frequency), chemical shifts concept, factors affecting chemical shift, isotopic nuclei, reference standards; Proton magnetic spectra, their characteristics, presentation, terms used in describing spectra and their interpretation (number position and intensity of signal), brief outline of instrumental arrangements and some practical details, signal multiplicity phenomenon in high resolution PMR; Spin-spin coupling, application of signal splitting and coupling constant data to interpretation of spectra, proton exchange reactions, decoupling and shift reagent methods.

Brief outline of principles of FT-NMR with reference to $^{13}$C-NMR: Spin-spin and spin-lattice relaxation phenomenon, free induction decay (FID), proton noise decoupling, signal averaging time domain and frequency domain signals, nuclear overhauser enhancement; $^{13}$C-NMR spectra; their presentation, characteristics, interpretation, examples and applications.

Brief indication of application of magnetic resonance spectral data of other nuclei by modern NMR instruments, introduction to 2-D NMR techniques.

Mass Spectrometry: Basic principles and brief outline of instrumentation, ion formation and types; molecular ions, meta stable ions, fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups, relative abundances of isotopes and their contribution to characteristic peaks, mass spectrum; its characteristics, presentation and interpretation, chemical ionization mass spectrometry, GC-MS including recent advances in MS, Fast atom bombardment mass spectroscopy; analysis of drugs in biological samples by combined GC- MS.

Chromatography: Basic principles, instrumentation, methodological techniques and quantitative analysis of drugs and their metabolites using column chromatography, paper chromatography, TLC, ion exchange chromatography, GC, GLC, HPLC and HPTLC.

Electrophoresis: Moving boundary electrophoresis, zone electrophoresis, iso-tachophoresis. iso-electric focusing and continuous electrophoresis.

Flourimetry and chemilumniscence: Principles, instrumentation and applications; electro-chemiluminescence, resonant ionization and Laser-enhanced ionization.

X-ray crystallography, thermal methods of analysis, DSC, SEM etc.

| M.112P | Methods in Pharmaceutical Research, Practical | 90 Hrs. |
|---|---|---|

Experiments based on calibration and validation of analytical instruments.

Qualitative and quantitative analysis of pharmaceutical preparations and dosages having single component or in combination of following categories: (biological and microbiological methods excluded).

i) Alkaloids ii) Antibiotics iii) Steroidal hormones iv) Vitamins v) Barbiturates vi) Sulfa drugs.

U.V./ Visible spectrum scanning of certain organic compounds, absorption and correlation of structures, comparison e.g., chloramphenicol, analgin, paracetamol, sulphadiazine, Ibuprofen etc., effect of pH and solvent on UV spectrum of certain drugs.

Estimation of single drug (raw material/ formulations) by colorimetry involving different reagents.

Determination of UV cut off wavelength for different solvents.

Estimation of single drug (raw material/ formulations) by UV spectrophotometry.

Simultaneous estimation of paracetamol and ibuprofen and other combination formulations by UV spectrophotometry using simultaneous equations/ derivative spectroscopy/ multiwavelength spectroscopy etc.

Comparison of three different analytical methods for salbutamol or other drugs.

Calibration of IR spectrophotometer using polystyrene film and checking the performance of the instrument.

Recording IR spectra for known drugs and comparing with that of Pharmacopoeia, estimation of drugs using IR.

IR spectra of simple molecules and interpretation of the same.

Estimation of drugs by flourimetry.

Estimation of drugs by flame photometry.

Structural elucidation of at least 5 unknown compounds using UV, IR, NMR and Mass spectral data.

**Second semester**

| M.121T | Advances in Pharmaceutical Sciences including Biostatistics, Theory | 60 Hrs. |
|---|---|---|

Biostatistics: The application of the following in pharmacy shall be covered.
Mean, median and mode, standard deviation and coefficient of variation, students t-test, one way ANOVA, chi-square test, probability, frequency distribution, regression analysis, bioavailability-cross-over study, Wilcoxon signed rank test, introduction to control charts.

Pharmainformatics: Introduction to information resources available on the internet for the various subjects in pharmacy.

Experimental Designs: Introduction to full factorial designs, central composite designs, evolution of full and reduced mathematical models in experimental designs, applications of the experimental designs for the subjects mentioned under pharmainformatics, introduction to contour plots.

Patents: Definition, need for patenting, types of patents, conditions to be satisfied by an invention to be patentable, introduction to patent search.

The essential elements of patent; Guidelines for preparation of laboratory notebook, non obviousness in patent, drafting of patent claims, important patent related web-sites, brief introduction to trademark protection and WTO patents.

Introduction to 'The Patent Act 1970' as amended in 1999, 2002 & 2005 and the rules made there under, with special emphasis on the forms to be submitted along with a patent application.

Biological evaluation of the following classes of drugs: analgesics, anti-inflammatory agents, tranquilizers, hypoglycemic agents and diuretic agents.

Introduction to various stages in process of drug development, scope and aims of preclinical and clinical trials for drugs and dosage forms.

Pharmacopoeial methods for evaluation of crude drugs, mono or polyherbal formulations by F.O.M. determination, L.O.D., ash values, extractive value, phytomorphology, microscopial methods, quantitative microscopy, qualitative analysis, pesticide analysis, microbial content determination and evaluation by other advanced methods like UV, IR, GLC, HPLC, TLC, & HPTLC etc.; automated analysis - Computer aided Analysis.

Drug Stability: Solution stability, solid stability, parameters for physical stability testing, protocol for physical stability testing program, accelerated studies and shelf life assignment.

| M.122P | Advances in Pharmaceutical Sciences including Biostatistics, Practical | 90 Hrs. |
|---|---|---|

Animal experiments for determination of activity, potency and toxicity of drug substance and dosage forms.

Parameter studies for physical stability of drugs.

Shelf life study of formulations.

Evaluation of crude drugs.

Evaluation/ standardization of extracts based on WHO guidelines.

Isolation, separation, purification and identification of important phytoconstituents.

Practical exercises based on Student ‘t’ test, one-way ANOVA, Chi–square test, first and second order equations, calculation of Rf value, mean, median, mode, standard deviation, Stoke’s linear trapezoidal rule.

Cumulative percentage drug release, linear regression, and other simple programs of pharmaceutical interest.

Practical exercises based on biostatistics and statistics in clinical research.

Preparing protocols on various validation requirements.

## M.Pharm (Pharmaceutics)

**First semester**

| M.PH.113T | Product Development, Theory | 60 Hrs. |
|---|---|---|

Fundamental Aspects of Product Development: Studies of wettability, solubility, dissolution, partition and absorption, surfactant and hydrocolloids and their role in drug delivery and targeting.

Designing of Oral Pharmaceuticals: Formulation, evaluation, stability studies and recent advances in dosage forms; tablet, capsule, suspension, emulsion; microencapuslation, advances in coating techniques.

Development of Parenterals: Concepts, formulation, evaluation of large and small volume parenterals, environmental control and quality assurance in manufacturing.

Ophthalmic Preparations: Introduction, physiology of eye, formulation considerations and evaluation of ophthalmic products (ointments, suspension, eye drops, contact lenses, occuserts etc.), containers and closures.

Pulmonary Preparations: DPI, Aerosols: Basic preparation and type of preparations, formulation and evaluation, containers, recent developments of pressurized dosages forms.

Suppositories: Selection of suppository bases, characteristics of bases, formulation, preparation, evaluation and packaging of suppositories, stability studies and recent development.

Dermatological Preparations: Anatomy and physiology of skin, mechanism of absorption through skin including mathematical treatment, formulation and evaluation of ointments, creams, paste, gels including herbal cosmetic creams.

Stability Studies: Basic concepts, consideration of physical and chemical stability studies, determination of shelf life, problems encountered during storage of dosages forms.

| M.PH.114 P | Product Development, Practical | 90 Hrs. |
|---|---|---|

Validation of dissolution test apparatus.
Determination of molecular weight of the given polymer.
Enhancement of solubility of the given drug by solid dispersion technique.
Performance of powder glass test on different type of glasses.
Performance of water attack on treated soda lime glass container.
Formulation and evaluation of matrix tablet of given drug.
Formulation and characterization of topical gels of some anti-inflammatory drugs.
Comparison of release rate profile of conventional and sustained release tablets.
Preparation of microcapsules by different techniques and their evaluation.
Determination of shelf life of aspirin by accelerated stability studies.
Evaluation of spherical crystallization as a particle size enlargement technique for aspirin.
Formulation and evaluation of ophthalmic dosage forms.
Performance of physical stability and dissolution studies of the suspension of given drug.
Formulation and evaluation of suppositories of given drug.
Determination of the effect of process variables on physico-chemical characteristics and in-vitro release profile of microcapsules.

| M.PH.115T | Advanced Pharmaceutics & Biotechnology, Theory | 60 Hrs. |
|---|---|---|

Formulation Considerations: Preformulation studies in development of solid, oral liquid and parenteral dosage forms; solubility, dissolution rate, Pka, partition coefficient, stability etc., In-vivo evaluation techniques.

Production Management and Documentation: ISO 9000 series, intellectual property rights, total quality management, GMP and quality assurance, validation for tablets and parenterals, practice of WHO GMP.

Pilot Plant Scale up Techniques: Significance of pilot plant scale up phase, laboratory procedure and formulations, routine production procedure, discussion on important parameters such as formulation, equipments etc, pilot study of dosage forms such as tablets, capsules and oral liquid.

Pharmaceutical Packaging Technology: Selection and evaluation of pharmaceutical packaging materials, containers and closures, problems of container-product interactions, pharmacopoeial specifications, test and standards for packaging materials.

Industrial Safety: Industrial hazards and their prevention, fire, accidents, mechanical and electrical equipments, industrial effluent testing and treatment.

Biotechnology: Introduction, importance and application of pharmaceutical biotechnology, enzyme kinetics, enzyme inhibition, pharmaceutical applications of enzymes, immobilization of cells and enzymes, application of immobilization, immobilization in design of novel drug delivery systems and drug targeting.

Tissue Culture: Introduction, types of culture, micropropogation, protoplast microinjection, plant tissue culture, animal cell culture, pharmaceutical applications of plant and animal tissue culture, production of commercially useful compounds by plant cell culture, bio-transformation by higher plant cell culture, growth of cell in bioreactor and production of active principles, bioreactor, tissue culture based pharmaceutical industries.

Recombinant DNA Technology and Genetics: Basic concepts of DNA, protein synthesis and targeting, genetic recombination, gene transfer methods in prokaryotes and eukaryotes, techniques of genetic engineering, applications of recombinant DNA technology in proteins, vaccines, hormones production, genetic disorders and gene therapy.

**M.Pharm (Pharmaceutics)**

**Second semester**

| M.PH.123T | Novel Drug Delivery System, Theory | 60 Hrs. |
|---|---|---|

Polymers and their Applications in Development of NDDS: Introduction, basic properties of biodegradable and non biodegradable polymers and their uses.

Sustained Release Drug Delivery System: Principle involved, advantages and disadvantages, dose considerations, physical–chemical and biological properties of drugs relevant to sustained release formulation, micro encapsulation, evaluation and stability studies of SRDF.

Oral Controlled Drug Delivery Systems: Principle involved, basic concept, osmotic pressure controlled, membrane permeation controlled, pH independent, ion exchange, controlled gel diffusion, controlled and hydro dynamically balanced systems, evaluation.

Mucosal Drug Delivery System: Introduction, anatomy and physiology of oral mucosal, mechanism of transmucosal permeation and mucous membrane models, buccal, nasal, pulmonary, rectal, vaginal, drug delivery systems, delivery of peptides based pharmaceuticals.

Transdermal Drug Delivery System: Fundamentals of transdermal permeation and factors affecting it, permeation enhancers, development of transdermal drug delivery systems, evaluation and recent developments.

Targeted Drug Delivery Systems: Principles of targeting, method of targeting preparation and evaluation of vesicular carrier systems such as liposomes, aquasomes, niosomes, pharmacosomes, dendrimers and particulate carrier systems such as nano particles, micro spheres, modified micro spheres, solid lipid nano particles (SLN), liquid crystals, resealed erythrocytes, monoclonal antibodies, interaction of colloidal delivery systems with biological environment, surface modification of colloidal drug delivery systems.

Parenteral Drug Delivery System: Basic concepts and approaches to parenterals, controlled release of drugs, formulation of parenteral controlled release, implants.

Intravaginal and Intrauterine Drug Delivery System: Introduction, vaginal contraceptive ring, medicated IUD, copper IUD, hormone releasing IUD.

| M.PH.124 P | Novel Drug Delivery System, Practical | 90 Hrs. |
|---|---|---|

Characterization of given polymer such as viscosity, molecular weight and glass transition temperature.
Evaluation of drug free polymeric films.
In-vitro characterization of transdermal patches of given drug.
Development and evaluation of ocular inserts of given drug.
Formulation and evaluation of floating microspheres.
Formulation and evaluation floating tablets.
Preparation and evaluation of buccal films of some cardiovascular drugs.
Taste abatement of some bitter drugs by ion-exchange resins.
Preparation and physico-chemical characterization of microcapsules of given drug.
Development and evaluation of osmotically controlled drug delivery system.
Study of effect of solubility enhancers on diffusion of poorly water soluble drugs.
Preparation and evaluation of muco-adhesive microspheres.
Preparation and characterization of wax embedded microspherules of given drugs.
Preparation and characterization of – (a) liposomes (b) niosomes (c) nanoparticles

| M.PH.125T | Biopharmaceutics and Pharmacokinetics, Theory | 60 Hrs. |
|---|---|---|

Drug Absorption: Gastrointestinal absorption of drugs, mechanism of drug absorption, physico-chemical, biological factors influencing absorption, buccal absorption, salivary excretion of drugs.

Drug Distribution, Biotransformation and Excretion: Factors affecting drug distribution, volume of distribution, protein binding, mechanism of biotransformation and factors affecting it, renal and non-renal excretion, concept of clearance and kinetics.

Bioavailability and Bioequivalence: Introduction, factors influencing bioavailability methods to determine bioavailability, designing the study for assessment of bioavailability and bioequivalence, in-vitro and in–vivo correlation of bioavailability, methods to enhance bioavailability, statistical concepts.

Pharmacokinetics: Basic consideration of one, two and multiple compartment models including IV- bolus, IV infusion and extra vascular administration, kinetics of multiple dosing, dosage regimen (loading and maintenance dosages)

Clinical Pharmacokinetics: Concepts, absorption, distribution and renal excretion, hepatic clearance and elimination, disposition and absorption kinetics, therapeutic regimen, therapeutic response and toxicity, dosage regimen, clinical based studies.

Physiologic Pharmacokinetic Models: Basic concepts, physiologic pharmacokinetic model with binding, blood flow–limited versus diffusion limited model, application and limitations of physiologic pharmacokinetic models, mean residence time (MRT), mean absorption time (MAT) and mean dissolution time (MDT), statistical moment theory (SMT).
Non-Linear Pharmacokinetics : Recognition of non-linearity, one and two compartment open model with Michaelis–Menton Kinetics, determination of km, Vmax. nonlinear tissue binding constants.

Applications of Computer: Introduction, application of computers in pharmacokinetics and biostatistics.

**M.Pharm (Pharmaceutical Chemistry)**

**First semester**

| | | |
|---|---|---|
| **M.PC113T** | **Advanced Medicinal Chemistry-I (Chemistry of Synthetic Drugs with Biochemical Approach), Theory** | **60 Hrs.** |

Survey of recent advances in following areas, brief chemistry, and synthetic approach to marketed drugs, mode of action, SAR, of following classes of drugs:

Cardiovascular (antihypertensives, antiarrythmics, antianginals, cardiotonics), CNS (anesthetics, sedative–hypnotics, anticonvulsants, antipsychotics and CNS stimulants), immunosuppressants, immunostimulants, antibacterials, antivirals, antineoplastics, drugs for tropical diseases and malaria, tuberculosis, leprosy, amoebiasis, and leishmania, radio protectives and drugs against ageing, diuretics, antihistaminics, cholinergic and anticholinergics.

Microorganism in Drug Synthesis: Introduction, theoretical and practical aspects of microbial transformation, microbial conversion of antibiotics.

| | | |
|---|---|---|
| **M.PC114P** | **Advanced Medicinal Chemistry-I (Chemistry of Synthetic Drugs with Biochemical Approach), Practical** | **90 Hrs.** |

Synthesis; determination of $R_f$ value and purity by thin layer chromatography; spectral analysis and M.P. determination of following drugs/ drug intermediates and other drugs related to theory syllabus.

Synthesis of caprolactam from cyclohexanone.
Synthesis of isatin from phthalimide.
Synthesis of antipyrin.
Synthesis of dibenzal acetone from benzaldehyde.
Synthesis of coumarins from resorcinol.
Synthesis of pinacol from acetone.
Synthesis of sulphanilamide from acetanilide.
Synthesis of phenobarbitone.
Synthesis of diketopiperazine.
Synthesis of nifedipine.
Synthesis of propranolol.
Synthesis of xylocaine.
Synthesis of dimethoxy benzaldehyde.
Synthesis of mefenemic acid.
Synthesis of phenytoin.
Synthesis of para amino phenol.
Synthesis of atleast 4 compounds from journal of repute.

| | | |
|---|---|---|
| **M.PC115T** | **Drug Discovery and Development (CADD, QSAR & Receptor Based Drug Design), Theory** | **60 Hrs.** |

General Introduction, importance of physicochemical and steric properties (including isosteric modifications) in new drug discovery, influence of formulations on drug bioavailability.

Metabolism: Introduction, different phases, metabolic pathways of different drugs, importance in drug design.

Drug Design: Various approaches used in drug design, electronic aspects of design, molecular size, shape, molecular orbital approach and quantitative drug design.

Tools for Rational Drug Design: QSAR; introduction, methods of QSAR, aims, object, limitations, applications, Hansch's LFER model, various physicochemical parameters used in drug design and their practical determination, free Wilson mathematical model,

Molecular connectivity, Electro topological state atom indices (ETSAI), Computational chemistry, Combinatorial chemistry, bioinformatics and High Throughput Screening as tools for new drug discovery.

Molecular Modeling: Structure based drug design. 3D–QSAR (COMFA); Computer Aided Drug Design.

Pharmacokinetic Studies in New Drug Discovery: Introduction, relation of drug metabolism to drug design structure, absorption-distribution relationship- significance for drug design.

Prodrug concept in new drug discovery.

**M.Pharm (Pharmaceutical Chemistry)**

**Second semester**

| M.PC123T | Advanced Pharmaceutical Chemistry (Organic Name Reactions, Reaction Mechanism & Stereochemistry), Theory | 60 Hrs. |
|---|---|---|

Structure of Organic Molecules: Atomic and molecular structures, use of resonance, hydrogen bond, bond energy, bond lengths in resonance hybrids, electronegativity, hyper conjugation, dipole moment, acids, bases, electrophiles, nucleophiles.

Reaction Mechanism: Kinetics, inductive, resonance and steric effects upon reactivity of molecules, nucleophilic substitution reactions in aliphatic systems: $SN_1$, $SN_2$. Reaction of carboxylic acids and esters: BAC2, AAC2, BAL2, BAL1, AAL1.

Claisen condensation, decarboxylation, carbanions, enolization, keto-enol equlibria, organometallic compounds.

Aromaticity, electrophilic & nucleophilic substitution in aromatic systems, E1, E2 mechanisms, Hofmann and Saytzeff elimination, competition between elimination and substitution, intramolecular elimination, addition reactions, Markownikovs rule, nucleophilic additions, hydride transfer reactions, Crams rule, participation of neighboring groups in transannular rearrangements.

Transannular rearrangements, Pinacol and related rearrangements, Beckmann rearrangements, Hofmann rearrangements, free radical displacements, additions and rearrangements of free radicals.

Stereochemistry: Molecular dissymmetry, compounds with one or two or more unequal asymmetric carbon atoms, configurations, absolute, relative, racemic modifications, optically active compounds, cyclohexane, six membered heterocyclic rings, stereoisomerism of allenes and related compounds.

Study of Individual Reactions: Allylic rearrangement, Arndt Eistert synthesis, Baeyer, Villiger reaction, Baker-Venkataraman reaction, benzidine rearrangement, benzilic acid rearrangement, Buchner method of ring enlargement, Carrol reaction, Curtius rearrangemet, Dimoth rearranement, Fries rearrangement, Lossen & Schmidt rearrangement, Pinner reaction, Reformatsky reaction, Robinson, Annelation reaction, Witting reaction, Diels-Alder reaction, use of diazonium salt, diazomethane and peracids in synthesis.

Pericyclic reactions, principle of cycloadditions, electrocyclic reactions and sigmatropic rearrangements reactions.

Photochemistry: Theory, energy transfer, characteristics of photoreactions and typical photoreactions.

| M.PC124P | Advanced Pharmaceutical Chemistry (Organic Name Reactions, Reaction Mechanism & Stereochemistry), Practical | 90 Hrs. |
|---|---|---|

Following unit processes as applied to drugs and drug intermediates are to be performed:

Nitration, amination by catalytic and chemical reduction, diazotization, halogenation, sulphonation, oxidation, hydrogenation, esterification, hydrolysis, polymerization and other name reactions.

Synthesis of atleast 4 hetrocyclic rings containing nitrogen, sulphur and/or oxygen.

| M.PC125T | Advanced Medicinal Chemistry-II (Chemistry of Natural Products), Theory | 60 Hrs. |
|---|---|---|

Carbohydrates: Disaccharides, determination of structures, sucrose, maltose, lactose, polysaccharides, cellulose, starch, introduction to lignin, pectin, pectic substances.

Fats, oils, waxes, lipoproteins; their general classification and chemistry.

Amino acids: Polypeptides; introduction, classification, synthesis of amino acids, polypeptides. Synthesis of naturally occurring proteins, structure of polypeptides, amino and carboxyl terminal determination. Proteins; classification, composition, structure, chemistry of oxytocin, insulin, angiotensin and peptides of medicinal importance. Purines and nucleic acids.

Alkaloids: General methods of isolation and structure determination, study the structural elucidation of atropine, morphine, ergotamine, reserpine, colchicine, vinca, podophyllum alkaloids.

Glycosides: Cardiac, saponins, anthraquinones, etc.

Steroids: Stereochemistry, conformational studies of steroidal nucleus, chemistry of cholesterol, stereochemistry of side chain at C-17, cholic acid, vitamin $D_3$, cortisone and aldosterone.

Anthrocyanins: Introduction, general nature, synthesis, structure of anthrocyanins, flavones, isoflavones, depsides

Selected Synthesis: Stereochemical aspects of ascorbic acid, vitamin A, cholesterol, cortisone, progesterone-dihydroabietic acid, coenzyme A, β-carotene, estrone, prostaglandins F2 and E2.

## M.Pharm (Quality Assurance)

**First semester**

| M.QA113T | Standardization & Stabilization Methods-Drugs & Formulations including Herbal Products, Food & Cosmetics, Theory | 60 Hrs. |
|---|---|---|

Biological standardization, general principles, scope and limitation of bioassays, procedures involved in the biological assay of some official drugs and vaccines.

Pyrogens: Production, chemistry and properties of bacterial pyrogens and endo-toxins, pyrogen testing of IP compared to that of BP and USP, LAL test.

Pre-Clinical drug evaluation; acute, sub-acute and chronic toxicity studies, LD50, ED50 determination, evaluation of compound for its biological activity, study of special toxicities like teratogenecity and mutagenecity.

Microbiological assay of antibiotics and vitamins.

Extraction, isolation, purification, identification and therapeutic importance of following markers (Phytopharmaceuticals); Artemisine, Reserpine, Vinca alkaloids, Podophyllotoxin, Ginseng Saponins, Diosgenin, Taxol, Guggulipids and Rutin.

Novel technologies used in the development of phytomedicines like polyploidy, hybridization, mutation, incorporation of plant growth regulators and tissue cultures.

Food products: Concepts of nutritional requirements at different age, sex and in different conditions of disease, pregnancy and lactation etc, different types of additives used, analysis of nutritional and other ingredients in ethical and non ethical foods.

Cosmetics: Ingredients used in various products such as creams, powders, lotions, hair products, nail polishes, lipsticks, depilatories and toiletries etc. and their analysis.

Formulation, stabilization and evaluation of tablets, capsules and liquid dosage forms, parenteral preparations, transdermal products, suppositories and controlled release products.

Containers and closures for pharmaceuticals: Types, performance, quality control tests; assuring quality of glass; types of plastics used, permeation, leaching, sorption, chemical reaction, biological tests, modification of plastics by drugs; different types of closures and closure liners; film wrapper; blister packs; bubble packs; shrink packaging; foil / plastic pouches, bottle seals, tape seals, breakable seals and sealed tubes; quality control of packaging material and filling equipment.

Flexible packaging, product package compatibility, transit worthiness of package.

| M.QA114P | Standardization & Stabilization Methods-Drugs & Formulations including Herbal Products, Food & Cosmetics, Practical | 90 Hrs. |
|---|---|---|

Sterility tests: Methodology and interpretation.

Microbiological assay of antibiotics and vitamins.

Bioassays.

Experiments involving use of microbiological techniques in analysis of drug substances, pharmaceutical aids and dosage forms.

Animal experiments for determination of activity, potency and toxicity of drug substance and dosage forms.

Animal experiments for assessing safety of packaging materials.

Pilot plant experiments.

Quality control testing for pharmaceutical containers, plastic materials, paper board, aluminum caps and rubber closures, of labels, label adhesives, of strip pack and blister pack and of corrugated boxes.

Parameter studies for physical stability of drugs.

Shelf life study of formulations.

Preparing protocols on various validation requirements.

Thin layer, paper and column chromatography.

Evaluation of crude drugs.

Evaluation/ standardization of extracts based on WHO guidelines.

Preparation and evaluation of herbal formulations and herbal cosmetics.

Isolation, separation, purification and identification of important phytoconstituents.

| M.QA115T | Total Quality Management-I, Theory | 60 Hrs. |
|---|---|---|

Concepts and philosophy of TQM, GLP, GMP (orange guide).

Drug regulatory and accrediting agencies of the world (USFDA, TGA, ICH, WHO, ISO etc.).

Good manufacturing practices.

Organization and personnel, responsibilities, training, hygiene.

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

Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP).

Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms.

Manufacture of and controls on dosage forms: Manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.

In process quality controls on various sterile and non–sterile dosage forms; standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.

Packaging and labeling control, line clearance, reconciliation of labels, cartons and other packaging materials.

Quality control laboratory: Responsibilities, good laboratory practices, routine control instruments, reagents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house.

Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities.

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

Warehousing design, construction, maintenance and sanitation, good warehousing practice, materials management.

Distribution and distribution records, handling of returned goods, recovered materials and reprocessing.

Complaints and recalls, evaluation of complaints, recall procedures, related records and documents.

Waste disposal, scrap disposal procedures and records.

**M.Pharm (Quality Assurance)**

**Second semester**

| M.QA123T | Advanced Pharmaceutical Analysis-Method Development, Theory | 60 Hrs. |
|---|---|---|

Chromatographic Techniques: HPTLC detection methods, quantitative methods in TLC; programmed multiple development techniques.

Gas Chromatography: Instrumentation, packed and open tubular column, column efficiency parameters, the Van Deemter equation, resolution, liquid stationary phases, derivatisation methods of GC including acylation, perfluoroacylation, alkylation and esterification. Detectors: FID, ECD, TCD, NPD. A critical comparison of sensitivity, selectivity and field of applications of these detectors. Examples of applications of GC in pharmaceutical analysis.

Liquid Chromatography: Comparison of GC and HPLC, instrumentation in HPLC, analytical, preparative and micro-bore columns, normal and reversed-phase packing materials, reverse-phase HPLC, HPLC–tryptic mapping, size exclusion, ion-exchange amino acid analysis, amino acid sequence analysis, hydrophobic interaction chromatography, column selection, mobile phase selection, efficiency parameters, resolution. Detectors in HPLC: refractive index, photometric and electrochemical; comparison of sensitivity, selectivity and field of applications of these detectors. HPTLC–instrumentation and applications.

Supercritical Fluid Chromatography (SFC).

X-ray Diffraction Methods: Introduction, generation of X-ray, elementary crystallography, Miller indices, X-ray diffraction, Bragg's law of X-ray powder diffraction, X-ray powder diffractometer, obtaining and interpretation of X-ray powder diffraction data.

Radiochemical Assays: Sodium iodide, cyanocobalamin and quality control of radiopharmaceuticals.

Radioimmune assays of drugs and hormones.

Immunological Assays: ELISA, immunoblotting, immumofluorescence, immunoaffinity.

Enzyme Analysis: Pepsin, papain, hyaluronidase.

Principles and procedures involved in using the following reagents in pharmaceutical analysis: 2,6–dichloroquinone chlorimide, 1,2–napthaquione-4-sulfate, 2,3,5-triphenyltetrazolium salt, 3–Methyl-1,2-benzothiazoline hydrazone hydrochloride (MBTH), Folium ciocalteu reagent, p-dimethylamino benzaldehyde/ cinnamaldehyde (PDAB), (PDMAC), Ninhydrin reagent.

Polarography: AC pulse polarography and square wave of polarography.

Thermal Methods of Analysis: Introduction, TCA, DTA and DSC theory, instrumentation of thermographs and application.

Analysis of drugs obtained from genetic engineering: Vaccines, sera and toxoids.

Electron Spin Resonance: Principle, instrumentation, interpretation of spectra and applications.

Laser: Basic principles, classification, instrumentation and application of Laser.

Reference standards: Source, preparation, characterization, usage, storage and records.

| M.QA124P | Advanced Pharmaceutical Analysis-Method Development, Practical | 90 Hrs. |
|---|---|---|

Gradient elution techniques in column chromatography.

Two dimensional paper chromatography and TLC.

Separation by electrophoresis.

Experiments using HPLC, GC, HPTLC: Determination of chromatographic parameters– capacity factor, selectivity, resolution, efficiency of column, HETP, asymmetric factor. Effect of polarity of mobile phase on retention of samples in normal/ reversed phase mode in HPLC, Estimation of single component or multicomponent drugs in formulations–using different methods of quantitative analysis (Direct comparison method, calibration curve method, internal standard method).

Experiments based on application of the following reagents in pharmaceutical analysis: 2,6– dichloroquinone chlorimide, 1, 2–napthaquione -4- sulfate, 2,3,5-triphenyltetrazolium salt, 3 – methyl -1,2- benzothiazoline

hydrazone hydrochloride (MBTH), Folium ciocalteu reagent, p-dimethylamino benzaldehyde (PDAB)/ cinnamaldehyde (PDMAC), ninhydrin reagent.

Qualitative and quantitative determination of various drugs in biological fluids (blood, urine) – barbiturates, sulpha drugs, adrenaline, amphetamine, hydantoins, morphine, pethidine, diazepam.

Case studies on Q. C. lab planning and analytical reporting of raw materials, in process and finished goods.

| M.QA125T | Total Quality Management-II, Theory | 60 Hrs. |
|---|---|---|

Validation and calibration of equipments and instruments.

Elements of validation, benefits, types of process validation, validation protocol, process characterization and optimization.

Validation of processes: Mixing, granulation, drying, compression, filtration, filling.

Validation of sterilization methods and equipments: Dry heat sterilization, autoclaving, membrane filtration, gaseous sterilization and sterilization by radiation.

Validation of system and analytical procedures (as per ICH or Pharmacopoeia).

Validation of air handling equipments and facilities in sterile and non-sterile areas, cleaning validation.

Validation of water purifying systems (demineralised water, distilled water and water for injection).

Validation and security measures for pharmaceutical data processing.

Validation of computer aided instruments.

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

Loan license (contract manufacture) auditing.

Recent amendments to Drugs and Cosmetic Act and other relevant rules.

Relevant provisions of Consumer Protection Act, Environmental Protection Act, Factories Act.

Introduction to Patent Act.

Certification and licensing procedures.

Quality, safety and legislation for cosmetic products.

Quality, safety and legislation for herbal products.

Approval of New Drug: Investigational new drug (IND) submission, format and content of IND, content of investigator brochure, clinical research protocols, objective and protocol design, FDA guidelines for clinical trials, reviews and approval of a clinical study, general consideration of the new drug approval (NDA), specific requirements, content and format of NDA, manufacturing and control requirements of NDA.

Schedule U requirements.

Product development stage documentation.

Factory Procedures: Standard operating procedures

Standard test procedures.

Manufacturing documents.

Cleaning methods.

Retention samples and records.

Quality control documentation.

Batch release documents.

Distribution records.

Complaints and recalls.

## M.Pharm (Pharmacology)

**First semester**

| M.PL113T | Systemic Pharmacology–I, Theory | 60 Hrs. |
|---|---|---|

General Pharmacology: Mechanisms of action of drugs with special emphasis on receptors, their nature and other characteristics. Dose-response relations, plasma concentration-time curves, pharmacokinetic parameters and their inter-relationships. Zero and first order pharmacokinetics. One compartment and two compartment pharmacokinetic models. Therapeutic drug monitoring.

In-depth study, including mechanism of action, pharmacodynamic actions, adverse effects, drug interactions, indications, contra-indications, important therapeutic aspects and recent advances of drugs belonging to the following categories:

Drugs Acting on ANS: Cholinergic drugs, anti-cholinesterase drugs, anti-cholinergic drugs, adrenergic drugs, adrenergic receptor and neuron blockers.

Drugs Acting on PNS: Neuro-muscular blockers, local anesthetics.

Drugs Acting on CNS: Ethanol, general anesthetics, sedatives and hypnotics, anti-epileptics, narcotic analgesics, centrally acting muscle relaxants, psychopharmacological agents.

Autacoids: Histamine, serotonin and their antagonists; eicosanoids, anti-inflammatory drugs, anti-gout drugs, drugs used in treatment of asthma.

Drugs Acting on Blood and Blood-forming Organs: Hematinics, anti-coagulants, haemostatic, fibrinolytics, anti-hypercholesterolemics.

Gastro-intestinal Drugs: Anti-ulcer drugs, laxatives and purgatives, emetics, anti-emetics.

Diuretics and anti-diuretics.

| M.PL114P | Systemic Pharmacology–I, Practical | 90 Hrs. |
|---|---|---|

Experiments involving action of drugs on autonomic effectors using preparations like frog/ mammalian heart, cat/ dog/ rat blood-pressure (major experiments), rat/ guinea pig/ rabbit intestine, rat uterus. The exercises should include investigations into mechanism of action of given autonomic drug.

Experiments to demonstrate/ detect the presence of the following actions in drugs: Sedation/ hypnosis, muscle relaxation, anti-convulsant action, anti-anxiety action, analgesic action, anti-inflammatory action, effect on learning/ memory, neuroleptic effect, anti-ulcer effect etc.

| M.PL115T | Advanced Pharmacology, Theory | 60 Hrs. |
|---|---|---|

Mechanisms of free-radical and oxidative injury in biological systems. Involvement of such injury in pathological processes and states.

Nitric Oxide: Generation and role in physiology and pharmacology.

Immuno-modulation: Immune response, cell-mediated and humoral immunity. Immune-deficiency states. Pharmacology of immunomodulatory agents and their applications.

Ion-Channels: Various types of ion channels. Characteristics of sodium, potassium, calcium and chloride channels. Role of various ion channels in physiology and pathological states. Regulation of ion channels and drugs modifying ion-channel function.

Role of various central neuro-transmitters in physiology and pathological states. Agents modulating neurotransmitter function in brain (with special reference to acetylcholine, dopamine, nor-adrenaline, glutamic acid, aspartic acid, GABA and glycine)

Bio-active Peptides: Source, characteristics and pathological and physiological roles of VIP, gastrin, cholecystokinin, opioid peptides, melatonin, neurokinins, plasmakinins, angiotensin, interleukins, platelet activating factor, TNF-α and interferons.

Receptor signal transduction mechanisms, role of second messengers(cAMP,$IP_3$ etc).

Introduction to stem cell, gene therapy and molecular oncology.

**M.Pharm (Pharmacology)**

**Second semester**

| M.PL123T | Methods in Drug Evaluation, Theory | 60 Hrs. |
|---|---|---|

Introduction to various stages in the process of drug development. Scope and aims of pre-clinical and clinical evaluation.

Fundamental techniques in estimation of enzymes and other endogenous substances in different tissues and body fluids.

Blind neuro-pharmacological screening and methods of determination of $LD_{50}$. Importance of $LD_{50}$.

Methods of biological evaluation of drugs of the following classes:

Autonomic drugs, local anesthetics, anticoagulants, antihypertensives, drugs acting on heart, vasodilators, bronchodilators, diuretics, skeletal muscle relaxants, drugs effecting learning and memory, psychopharmacological agents, analgesics, anti-inflammatory agents, hypnotics, anticonvulsants, anti-diabetic drugs, anti-fertility agents, anti-ulcer drugs, immunomodulators.

Bioassays: Definition, principle, advantages over other assays, graded and quantal bioassays, matching, bracketing, interpolation, three point and four point assays. Methods of bioassay of adrenaline, nor-adrenaline, acetylcholine, histamine, angiotensin, d-tubocurarine, insulin, digoxin, oxytocin, estrogen, thyroxine, corticotrophin and somatotrophin

Introduction to high-throughput screening and modern techniques like ligand-binding studies and use of tissue-culture in biological evaluation of drugs.

Clinical Trials: Aim, requirements, design, stages and outcomes.

| M.PL124P | Methods in Drug Evaluation, Practical | 90 Hrs. |
|---|---|---|

Experiments designed to familiarize the student with the process of systematic screening of unknown drugs for their pharmacological activity and mode/ mechanism of action.

Exercises in bioassays of drugs studied in theory.

Calculation of pA2 value of antagonists using isolated preparations.

| M.PL125T | Systemic Pharmacology, Theory | 60Hrs. |
|---|---|---|

In-depth study, including mechanism of action, pharmacodynamic actions, adverse effects, drug interactions, indications, contra-indications and important therapeutic aspects and recent advances of the drugs belonging to the following categories:

Drugs Acting on CVS: Cardiac glycosides, anti-anginal drugs, anti-arrhythmics, anti-hypertensives, drugs used in treatment of MI.

Hormones and Hormone Antagonists : Insulin and oral hypoglycemic agents, thyroid hormones and anti-thyroid drugs, growth hormone, oxytocin, anti-diuretic hormone, corticosteroids, gonadotrophins, estrogens, anti-estrogens, progestins, anti-progestins, testosterone and other androgens, anti-androgens, anabolic steroids.

Anti-microbial Drugs: Mechanisms of anti-microbial action and microbial resistance. Antibiotics and synthetic anti-microbial drugs. Penicillins, cephalosporins, other β-lactams, use of β-lactamase inhibitors, aminoglycosides, tetracyclines, chloramphenicol, macrolides, vancomycin, bacitracin, lincomycin, clindamycin, sulphonamides, trimethoprim and pyrimethamine, quinolones and fluoroquinolones, urinary antiseptics.

Drugs used in the treatment of malaria, amoebiasis, giardiasis, trichomoniasis, trypanosomiasis, leishmaniasis, anthelmintics, and pediculocidal agents.

Drugs used in the treatment of tuberculosis, leprosy, mycobacterium avium complex infections, syphilis, gonorrhoea, chancroid and lymphogranuloma venereum.
Anti-retroviral and other anti-viral drugs.

Anti-neoplastic agents.

Anti-fungal agents.

Drugs Modifying Immune Status: Immunostimulants and immunosupressants.

## M.Pharm Pharmaceutical Management and Regulatory Affairs

**First Semester**

| M.PMRA113T | Pharmaceutical Management-I (General & Personnel), Theory | 60 Hrs. |
|---|---|---|

Pharmaceutical Management: Meaning, Evolution-scientific, administrative and human relation approach. Process of management: Planning, organizing, staffing, directing, coordinating and controlling–a preliminary idea of concepts, processes and techniques.

Fundamental concepts of production, financial, personal, legal and marketing functions with special reference to Pharmaceutical Management. Introduction to budgeting, costing, accounting, auditing and budgetary control. Entrepreneurship development.

Understanding organizations: Meaning, process, types of organization structures and departmentation, line/staff authority, promoting organizational culture. Organizations, pharmaceutical services and functioning of hospital pharmacy, bulk drug unit, formulation unit, Ayurvedic and Unani manufacturing units and testing labs etc.

Professional Mangers; Tasks, responsibilities and skills needed. Leadership; Styles and managing change. Decision Making; Types, procedures, evaluation and selection of alternatives, decision making under various situations. Management information and decision support systems and time management.

Personnel Management: Job Analysis, recruitment, selection, orientation and training, performance appraisal and compensation. Retrenchment, lay off and discharge.

Management of Industrial Relations: Industrial disputes, settlement of disputes through various routes such as bargaining, etc.

Motivational aspects, theories of motivation, group dynamics, rewards and incentives, interpersonal skills, significance of communication, its processes, measures for effective communication, conflict management. Stress management.

| M.PMRA114T | Total Quality Management (Theory) | 60 Hrs. |
|---|---|---|

Concepts and Philosophy of TQM, GLP, GMP (orange guide).

Drug regulatory and accrediting agencies of the world (USFDA, TGA, ICH, WHO, ISO etc.).

Good manufacturing practices:

Organisation and personnel, responsibilities, training, hygiene.
Premises: Location, design, plant layout, construction, maintenance and sanitation, environmental control, utilities and services like gas, water, maintenance of sterile areas, control of contamination.

Equipments: Selection, purchase specifications, maintenance, clean-in-place, sterilize-in-place, methods (TP and STP).

Raw materials: Purchase specifications, maintenance of stores, selection of vendors, controls on raw materials and finished dosage forms.

Manufacture of and controls on dosage forms: Manufacturing documents, master formula, batch formula records, standard operating procedures, quality audits of manufacturing processes and facilities.

In process quality controls on various dosage forms; sterile and non–sterile, standard operating procedures for various operations like cleaning, filling, drying, compression, coating, disinfections, sterilization, membrane filtration etc.,

Packaging and labeling control, line clearance, reconciliation of labels, cartons and other packaging materials.

Quality Control Laboratory: Responsibilities, good laboratory practices, routine controls instruments, regents, sampling plans, standard test procedures, protocols, non-clinical testing, controls on animal house.

Data generation and storage, quality control documents, retention samples, records and audits of quality control facilities.

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

Regulatory Considerations for Pre-clinical and Clinical Evaluation: Pre-clinical requirements currently in use. Regulatory requirements of single dose and repeat dose toxicity studies. Study of specific toxicities such as

mutagenicity, carcinogenicity and teratoginicity. Animal pharmacokinetics and toxicokinetics. Regulatory requirements of clinical evaluation, pharmacokinetics in man genetic polymorphism. Design and interpretation of clinical trials.
Quality assurance standards as per ISO.

Globalization of drug industry, present status and scope of pharmaceutical industry in India.
WHO and NABL certification, ICH guidelines for manufacturing and quality assurance of drug formulation.

| M.PMRA115T | Drug Regulatory Affairs–I (National Regulatory Aspects), Theory | 60 Hrs. |
|---|---|---|

Origin, development, scope, objectives and nature of Pharmaceutical legislation in India. History and ethics of profession of Pharmacy.

A study of regulatory aspects that affect drug product design, manufacture and distribution in India with special emphasis on the detailed study of the following Acts (with latest amendments)

The Narcotics Drugs and Psychotropic Substances Act.

Medicinal and Toilet Preparations (Excise Duties) Act, 1955.

The Pharmacy Act, 1948.

The Drugs and Cosmetics Act, 1940 and Rules there under.

Drugs (Price Control) Order in force.

Introduction to Intellectual Property Rights; Copy Right Act, Trade Mark Act, Patent Act and Biodiversity Act, WTO, TRIPS and TRIMS.

The Drugs and Magic Remedies (Objectionable Advertisements) Act, 1955.

Prevention of Cruelty to Animals Act.

Schedule U requirements- Product development stage documentation, factory procedures – Standard operating procedures and standard test procedures,

Legal Environment of Business- Need for government regulations; financial regulations, SEBI, BIFR, FEMA and others, Contract Act and Sale of Goods Act, Company Act, Corporate tax laws – Direct and Indirect.

Indian Patent Law: Critical evaluation of development of Indian Patent law with necessary changes. Comparison with US and EP Patent Law.

**M.Pharm Pharmaceutical Management and Regulatory Affairs**

**Second Semester**

| M.PMRA123T | Pharmaceutical Management-II (Production & Marketing), Theory | 60 Hrs. |
|---|---|---|

Production Management: Fundamentals of production, organization, economic policy, manufacturing economics, production capacities, production lines and job balancing, visible and invisible inputs, methodology of activities. Development of efficient work methods, quality control and management of R&D.

Production planning and control, production processes - mass, job and project; plant location and lay out; work study (preliminary idea only), materials management- purchase, inventory control and store keeping. Productivity management: Concepts, problems, tools and techniques for improvement. Operation research techniques by PERT and CPM.

Considerations for design of large scale manufacturing units including intricate design criteria for units to manufacture sterile and non-sterile products with special reference to tablets, capsules, and injections.

Design and development of packaging units including recent advances in packaging techniques for various types of sterile and non-sterile dosage forms.

Warehousing design, construction, maintenance and sanitation; good warehousing practice, materials management.

Pharmaceutical Marketing: Evolution of marketing concept; production oriented, sales oriented, promotion oriented and consumer oriented (modern concept); market segmentation; concept of marketing, mix Role of 7 P's (Product, Price, Promotion, Place, Physical Evidence, Process, People) in Pharmaceutical Marketing Management, corporate planning & strategy, Pharmaceutical industrial marketing management. Pharmaceutical marketing environment. Product management. E-Pharma Marketing.

Product Planning: Selection of product, new product development and product differentiation, pricing, promotion – personal selling; salesmanship, qualities of salesman, management of sales force, advertising, publicity and window display, channels of distribution.

Marketing Research: Definition and importance, Pharmaceutical Marketing Research techniques, marketing information system, pharmaceutical marketing research area.

Market Demands and Sales Forecasting: Major concepts in the demand measurement, estimating current demands, geo-demographic analysis, estimating industry sales, market share and future demand, sales forecasting.

| M.PMRA124T | Pharmaceutical Management- III (Finance, Project), Theory | 60 Hrs. |
|---|---|---|

Introduction to financial management, financial planning and control, working capital management, management of fixed assets.

Concepts and techniques of financial management decision, concepts in evaluation – time value of money, valuation of a firm's stock, capital assets pricing model, investment in assets and required returns, risk analysis, financing and dividend policies, capital structure decision, working capital management, management of cash, management of accounts receivable, inventory management.

Banking and finance: Service and functions of bank, finance planning and sources of finance, short, intermediate and long term financing, tools of financial analysis, financial ratio analysis, funds analysis and financial forecasting, operating and financial leverages. General principles of insurance.
Introduction to financial management, financial planning and control, working capital management, management of fixed assets.

Evaluation of investment decisions by pay back period, accounting rate of return, net present value methods, break even analysis.

Accounting & Finance: Financial accounting, GAAP, cost accounting, budgetary control, valuation of inventory and assets, modern trends, role of internal auditing, internal versus external auditing, accounting control and information systems.

Project definition, preparation of feasibility assessment and selection, project reporting, conventional project appraisal; limitations, towards a new framework. Projections, profitability, cost and benefit analysis, appraisal criteria – financial, economic and social. Risk analysis.

Institutional Finance and Project Appraisal: Framework for domestic/ international finance evaluation, project identification, feasibility, appraisal, financial and capital structures, capital market instruments, managing new

issues, negotiations with FIs, FIIs, and other market players, issue pricing, SEBI guidelines, syndication of loans including term loans, lease financing.

| M.PMRA125T | Drug Regulatory Affairs-II (Including International Regulatory Aspects), Theory | 60 Hrs. |
|---|---|---|

A detailed study of regulatory aspects that affect drug product design, manufacture and distribution in a developed country such as USA and in a developing country such as Brazil, Hatch Waxmann Act; Bolar Provisions and other FDA Regulations.

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

Loan license (contract manufacture).

Recent amendments to Drugs and Cosmetic Act and other relevant rules.

Certification and licensing procedures.

Documentation related to manufacturing, cleaning methods, retention samples and records, quality control, batch release documents, distribution records, complaints and recalls.

Quality, safety and legislation for cosmetic products and herbal products.

Approval of New Drug: Investigational new drug (IND) submission, format and content of IND, content of investigator brochure, clinical research protocols, objective and protocol design. FDA guidelines for clinical trials, reviews and approval of a clinical study, general consideration of the new drug approval (NDA), specific requirements, content and format of NDA, manufacturing and control requirements of NDA. New Chemical Entity (NCE).

International business and inland & foreign trade, procedure of exporting and importing goods. General international environment; political, legal, socio-cultural and economic factors, tax aspects, marketing factors, labour factors and economic integration. BOP analysis, foreign exchange control, governmental policies, international finance, economic community, IMF, managing multinationals/ globalization of operations.

Emerging Trends in Biotechnology Patenting.

Patent Cooperation Treaty

Strategies for effective Patent Drafting. IP Issues in contract Manufacturing. Exporting to the US and Prelitigation Consideration

## REFERENCE BOOKS (LATEST EDITION)

### M.Pharm (Pharmaceutics, Pharmaceutical Chemistry, Quality Assurance, Pharmacology, Pharmaceutical Management and Regulatory Affairs)

**Methods in Pharmaceutical Research (M.111T & M.112P )**

1. Instrumental Methods of Analysis by Scoog and West.
2. Spectrometric Identification of Organic Compounds by Silverstein et.al.
3. Instrumental Method of Analysis by Willard Dean & Merrit.
4. Text Book of Inorganic Chemistry by A.I. Vogel.
5. Pharmaceutical Chemistry, Vol. I & Vol. II by Becket and Stanlake.
6. Pharmaceutical Chemistry, Vol. I & Vol. II by L.G.Chatten.
7. Text Book of Pharmaceutical Analysis by K.A. Connors.
8. Pharmaceutical Analysis by Hiquchi, Bechmman, Hassan.
9. Methods of Drug Analysis by Gearien, Graboski.
10. Text Book of Biopharmaceutic Analysis by Robert Smith and James Stewart.
11. Pharmaceutical Analysis – Modern Methods, Part A and B by Munson James. W.
12. Quantitative Analysis of Drugs by Garrot.
13. Quantitative Analysis of Drugs in Pharmaceutical Formulations by P. D. Sethi.
14. IP/BP/USP.
15. Application of Absorption Spectroscopy of Organic Compounds by Dyer.
16. Analytical Profiles of Drug Substances by Florey [Volume 13].
17. Spectroscopy of Organic Compound by P. S. Kalsi; Wiely Eastern Ltd., New Delhi.
18. Absorption Spectroscopy of Organic Molecules by V. M. Parikh; Addision, Wesley Publishing Company, London.
19. Organic Spectroscopy by William Kemp.
20. Identification of Organic Compounds by Shriner et al.

**Product Development (M.PH113T & M.PH114P)**

1. Theory and Practice of Industrial Pharmacy by Lachmann et.al.
2. Modern Pharmaceutics by Banker G.S and I Thodes.
3. Pharmaceutics Dosage Forms & Drug Delivery System by Ansel H.C
4. Remington's Pharmaceutical Sciences.
5. Bentley's Textbook of Pharmaceutics by E.A Rawlins.
6. Physical Pharmacy by Martin.
7. Applied Production and Operation Management by Jamer R. Evans.
8. How to Practice GMP by Sharma R.P
9. Pilot Plants and Seals up of Chemical Process by W. Hoyle.
10. Pharmaceutical Packaging Technology by E.R Evans.
11. Pharmaceuticals Process Validation by Berry I.R and Nash R.A
12. Good Manufacturing Practices for Pharmaceuticals by Willing S.H and Stoker J.R
13. S.O.P Guidelines by Shah D.S

**Advanced Pharmaceutics & Biotechnology (M.PH.115T)**

1. Theory and Practice of Industrial Pharmacy by Lachmann
2. Pharmaceutical Dosage From and Drug Delivery Systems by Ansel H.C
3. Bentley's Textbook of Pharmaceutics by Ratlines E.A
4. Science of Dosage Form by Aulton.
5. Remington's Pharmaceutical Sciences.
6. Modern Pharmaceutics by Banker G.S Et. Al.
7. Physical Pharmacy by Martin.
8. Drug Formulation Manual by D.P.S Kohli.
9. Encyclopedia of Pharmaceutical Technology (Vol. I to IV) by James Swarbrick and Boylan J.C
10. Herbal Indian Perfumes and Cosmetics by Ram V.A
11. Methods for Cutaneous Investigation by Robert L. Rietschel
12. Dispensing of Medication by Robert E. King.
13. Pharmaceutical Biotechnology by S.P Vyas and V.K. Dixit
14. Plant Biotechnology by K.G Ramawat
15. Biotechnology–Secondary Metabolites by K.G Ramawat
16. Biotechnology Fundamentals and Applications by S.S Purohit and S.K Mathur

**Advances in Pharmaceutical Sciences including biostatistics (M.121T & M.122P)**

1. Pharmaceutical Statistics by Sanford Bolton; Marcel Dekker.
2. Pharmaceutical Statistics of Industrial Pharmacy by Lachman.
3. Text Book of Biopharmaceutic Analysis by Smithe, Stewart.
4. Methods in Biostatistics by Mahajan.
5. Fundamental of Applied Statistics by S. C. Gupta and C. K. Kapoor.

6. Mathematical Statistics by Kapoor and Saxena.
7. Statistics by Gofeti Radhakrishna.
8. Web Rsources in Pharmacy, In Pharma Publication, Bangalore.
9. Basic Statistics and Pharmaceutical Statistics Application by James E.De Muth; Marcel Dekker Inc.
10. Pharmaceutical Experimental Design by G.A. Lewis, D. Matheia, Roger Phan-Tan-Luu; Marcel Dekker Inc.
11. Pharmaceutical Experimental Design and Interpretation by N.A. Armstrong, L.K.C. James; Taylor & Francis.
12. Current Patent Acts of various countries.
13. Web Resources in Pharmacy by Mueen Ahmed K.K.

**Novel Drug Delivery System ((M.PH.123T & M.PH.124P)**

1. Encyclopedia of Controlled Drug Delivery, Vol. I & II Edited by Edith Mathiowitz.
2. Novel Drug Delivery Systems by Y.W Chien.
3. Targeted Therapeutic Systems by P. Tyle, B.P Ram.
4. Controlled Drug Delivery Fundamental & Applications by J.R. Robinson.
5. Drug Delivery Systems: Fundamental & Techniques by P. Johnson and J.G Lloyd.
6. Biopolymeric Controlled Released System by Donald L. Wise.
7. New Drug Delivery System by Joliano.
8. Controlled Drug Delivery, Vol. I & II by Stephen D. Bruck.
9. Microencapsulation and Related Drug Processes by Patrice B. Deasy.
10. Controlled and Novel Drug Delivery by N.K. Jain.
11. Remington's Pharmaceutical Sciences.
12. Liposomal Therapeutics by S.P Vyas and V.K Dixit
13. Interfacial Phenomena in Drug Delivery and Targeting by Graham Buckton.
14. Liposomes–A Practical Approach by H.H.C New.

**Biopharmaceutics and Pharmacokinetics (M.PH.125T)**

1. Biopharmaceutics and Clinical Pharmacokinketics by Milo Gibaldi.
2. Biopharmaceutics and Pharmacokinetics by Robert E. Notari.
3. Biopharmaceutics by Swarbrick.
4. Textbook of Applied Biopharmaceuticals and Pharmacokinetics by Shargel.
5. Biopharmaceutics and Clinical Pharmacokinetics by John and Wagner.
6. Textbook of Biopharmaceutical Analysis by Smith R.V and Stewart J.T
7. Dissolution, Bioavailability and Bioequivalence by Abdou, H.M
8. Clinical Pharmacokinetics: Concepts and Applications by Rewland M. and Tozer T.N
9. Pharmaceutical Bioequivalence by Welling P.G
10. Remington's Pharmaceuticals Sciences.
11. Advanced Pharmaceutics by Bankers and Bhods.

**Advanced Medicinal Chemistry-I (M.PC113T & M.PC114P)**

1. Medicinal Chemistry by Burger.
2. Principles of Medicinal Chemistry by Foye.
3. Organic Drug Synthesis, Vol. 1, 2 & 3 by Lednicer.
4. Annual Reports in Medicinal Chemistry by Hans, Jurgen Hess.
5. Medicinal Chemistry Series by Ariens.
6. Progress in Medicinal Chemistry Series by Ellis and West.

**Drug Discovery and Development (M.PC115T)**

1. Introduction to the Principles of Drug Design by Smith & Williams.
2. Drug Design, Vol. VII by Ariens.
3. Progress in Pharmaceutical Research by Woodridge.
4. Annual Reports in Medicinal Chemistry, Academic Press Inc.
5. Comprehensive Medicinal Chemistry, Vol. 4.
6. Burger's Medicinal Chemistry, Vol. 1

**Advances in Pharmaceutical Sciences including Biostatistics (M.121T & M.122P)**

1. Pharmaceutical Statistics by Sanford Bolton; Marcel Dekker.
2. Pharmaceutical Statistics of Industrial Pharmacy by Lachman.
3. Text Book of Biopharmaceutic Analysis by Smithe, Stewart.
4. Methods in Biostatistics by Mahajan.
5. Fundamental of Applied Statistics by S. C. Gupta and C. K. Kapoor.
6. Mathematical Statistics by Kapoor and Saxena.
7. Statistics by Gofeti Radhakrishna.
8. Web Resources in Pharmacy, In Pharma Publication, Bangalore.
9. Basic Statistics and Pharmaceutical Statistics Application by James E.De Muth; Marcel Dekker Inc.
10. Pharmaceutical Experimental Design by G.A. Lewis, D. Matheia, Roger Phan-Tan-Luu; Marcel Dekker Inc.

11. Pharmaceutical Experimental Design and Interpretation by N.A. Armstrong, L.K.C. James; Taylor & Francis.
12. Current Patent Acts of various countries.
13. Web Resources in Pharmacy by Mueen Ahmed K.K.

**Advances in Pharmaceutical Sciences including biostatistics ((M.PC123T & M.PC124P)**

1. Mechanism and Structure in Organic Chemistry by Gould.
2. A Guidebook to Mechanism in Organic Chemistry by Sykes.
3. Advanced Organic Chemistry, Reaction Mechanism and Structure by March.
4. Stereochemistry of Carbon Compounds by Eliel.
5. Principles of Ionic Organic Reactions by Alexander.
6. Reactions in Organic Chemistry by Surrey.
7. Organic Chemistry by Hendrickson.
8. Unit Processes in Organic Synthesis by Groggins.

**Advanced Medicinal chemistry-II (M.PC125T)**

1. Organic Chemistry, Vol. 2 by Finar
2. Steroids by Fieser and Fieser.
3. Organic Chemistry by Gilman.
4. Selected Organic Synthesis by Fleming.
5. Natural Product Chemistry, Vol. 1 & 2 by Nakanishi.
6. The Alkaloid, Chemistry and Physiology by Manske.
7. Medicinal Plant Glycosides by Sim.
8. Medicinal Plant Alkaloids by Sim.
9. IUPAC, Chemistry of Natural Products, International symposium.
10. Progress in the Chemistry of Organic Natural Products by Zechmeister.
11. Progress in Phytochemistry by Reinhold, Liwschitz.
12. New Natural Products and Plant Drugs with Pharmacological, Biological or Therapeutic Activity by Wagner, Wolff.
13. Organic Chemistry by Finar.
14. Modern Methods of Plant Analysis by Paech, Tracey.
15. Modern Methods of Plant Analysis by Geissman.
16. The Quantitative Analysis of Drugs by Garratt.
17. Practical Pharmaceutical Chemistry by Backett, Stenlake.
18. Symposium on Phytochemistry by Arthur.
19. Biosynthetic Pathways in Higher Plants by Pridham, Swain.
20. Metabolic Pathways by Greenbury.
21. Secondary Plant Metabolism by Margaret, Brain.
22. Pharmacognosy and Phytochemistry by Wagner, Horhammer.
23. Comparative Biochemistry of Flavonoids by Harbon.
24. Principles of Biochemistry by Lehninger.
25. Plant Biochemistry by Bonner.
26. Phytochemical Methods by Harborne.
27. The Chemical Investigation of Plants by Rosenthaler.
28. Organic Functional Group Analysis by Cheronis.

**Standardization and Stabilization Methods (M.QA113T & M.QA114P)**

1. Standardization & Stabilization Methods-Drugs & Formulations including Herbal Products, Food & Cosmetics.
2. Indian Herbal Pharmacopoeia, RRL, Jammu & IDMA, Mumbai; 1998.
3. British Herbal Pharmacopoeia, British Herbal Medicines Association; 1996.
4. Supplement to Cultivation and Utilization of Medicinal Plants, edited by Handa S.S. & Kaul, K.L.; 1996.
5. Analytical Microscopy by Wallies, T.E., J & A Churchill Ltd.
6. Plant Drug Analysis by Wagner, H. Bladt S. & Zgainski, Springer Verlog, New York.
7. Isolation and Identification of Drugs by Clark, E.C.G., The Pharmaceutics Press, London.
8. The Practical Evaluation of Phytopharmaceutics by Brain, K.R. and Turner, R.D., Wright-Scientechnics Bristol.
9. Modern Methods of Plant Analysis by Peach K. & Tracey, M.V., Narosa Publisher House, N.D.
10. Biological Standardization by Burn. Fininey and Godwin.
11. Modern Pharmaceutics by Rhodes & Banker.
12. Microbial Assays by Barton J. Wringht.
13. The International Pharmacopoeia, Vol. I, II, III, IV, 3rd Edition.
14. Basic Tests for Pharmaceutical Substances – WHO (1988)
15. Basic Tests for Pharmaceutical Dosage Forms – WHO (1991)
16. Evaluation of Drug Activities: Pharmacometrics (Vol. I & II) by D.R.Laurence.
17. Screening Methods in Pharmacology by R.A.Turner.
18. Animal and Clinical Pharmacologic Techniques in Drug Evaluation by Nodine and Siegler.

**Total Quality Management-I (M.QA115T)**

1. Quality Assurance Standards as per ISO.
2. WHO And NABL Certification, Globalization of Drug Industry, Introduction to Export of Drugs and Import Policy.
3. ICH Guidelines for Manufacturing and Quality Assurance of Drug Formulation.
4. Present Status and Scope of Pharmaceutical Industry in India.
5. Guidelines for Developing National Drug Policies, WHO Publications, 1998.
6. Quality Assurance of Pharmaceuticals – A Compendium of Guidelines and Related Materials, Vol.–1; WHO Publications.
7. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.
8. GMP by Mehra.
9. How to Practice GMP by P.P. Sharma.
10. ISO 9000 and Total Quality Management by Sadhan K. Ghosh.
11. Good Manufacturing Practices for Pharmaceuticals - A Plan for Total Quality Control by Sidney H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol. 78, Marcel Dekker Inc.
12. OPPI-Quality Assurance.
13. USP.

**Advanced in Pharmaceutical Sciences including Biostatistics (M.121T & M.122P)**

1. Pharmaceutical Statistics by Sanford Bolton; Marcel Dekker.
2. Pharmaceutical Statistics of Industrial Pharmacy by Lachman.
3. Text Book of Biopharmaceutical Analysis by Smith, Stewart.
4. Methods in Biostatistics by Mahajan.
5. Fundamental of Applied Statistics by S. C. Gupta and C. K. Kapoor.
6. Mathematical Statistics by Kapoor and Saxena.
7. Statistics by Gofeti Radhakrishna.
8. Web Resources in Pharmacy, In Pharma Publication, Bangalore.
9. Basic Statistics and Pharmaceutical Statistics Application by James E.De Muth; Marcel Dekker Inc.
10. Pharmaceutical Experimental Design by G.A. Lewis, D. Matheia, Roger Phan-Tan-Luu; Marcel Dekker Inc.
11. Pharmaceutical Experimental Design and Interpretation by N.A. Armstrong, L.K.C. James; Taylor & Francis.
12. Current Patent Acts of various countries.
13. Web Resources in Pharmacy by Mueen Ahmed K.K.

**Advanced Pharm. Analysis Methods Development (M.QA123T& M.QA123T)**

1. Advanced Pharmaceutical Analysis-Method Development.
2. Trace and Ultra Trace Analysis by HPLC by Ahuja.
3. HPLC in Pharmaceutical Analysis [2 Volumes] by Szepesi
4. HPLC Analysis of Biological Compounds, Lab. Guide Chromatography Series, Vol. 26 by Hancock and Sparrow.
5. Chromatography of Pharmaceuticals: Natural Synthetic & Recombinant Products by Ahuja.
6. HPLC–Pharma Analysis–Modern Methods Part–B, Vol.–2, Edited by James W.Munson.
7. X-Ray methods by Clive Whiston, John Wiley & Sons.
8. Jenkins Quantitative Pharmaceutical Chemistry by A. M. Khevel, F. E. Diagangi.
9. Pharmaceutical Analysis by H. Takeru.
10. Advances in Automated Analysis / Clinical Analysis.

**Systemic Pharmacology-I (M.PL113T & M.PL114P)**

1. Applied Neuromuscular Pharmacology by B. J. Pollard
2. The Pharmacological Basis of Therapeutics by Alfred Goodman and Gilman's.
3. Essentials of Pharmacotherapeutics by F.S.K. Barar
4. Pharmacological and Pharmacotherapeutics by Satoshkar and Bhandarkar
5. Clinical Pharmacology by Laurance and Bennett.
6. Essentials of Medical Pharmacology by Tripathi.
7. Basic & Clinical Pharmacology by Bertram G. Katzung
8. Lewis Pharmacology by Crossland
9. Internal Medicine by Harrison
10. Modern Pharmacology by Charls Craig
11. Fundamentals of Experimental Pharmacology by M.N. Ghosh
12. Practical in Pharmacology by R.K. Goyal
13. Practical Pharmacology by Burn.
14. A Handbook of Experimental Pharmacology by Kulkarni
15. Pharmacological Experiments on isolated preparations. Perry WLME & Livingstone S. Ltd.
16. A Manual of Adverse Drug Interactions, 1997 by J.P. Griffin
17. Pharmacological Basis of Therapeutics by Goodman & Gilman
18. Pharmacology by Rang & Dale
19. Principles of Drug Action:Basis of Pharmacology by Goldstein A,Arnow, L, Kalman S M

20. Modern Pharmacology by Charles R.Craing P.Rober, E.Stitzel (editor)
21. Principles of Pharmacology by Paul L. Munson, Rober A Mucller, George R Breese
22. Hand Book of Experimental Pharmacology by Zaimis E & Others
23. Handbook of Drug Screening by Ramkrishna Seethala and Prabhavathi B. Fernandes
24. Methods of Drug Screening by Turner
25. Textbook of Pharmacology by V.N. Sharma

**Advanced Pharmacology (M.PL115T)**

1. Lewis Pharmacology by Crossland
2. Modern Pharmacology by Charls Craig
3. The Pharmacological Basis of Therapeutics by Alfred Goodman and Gilman's.
4. Medical Pharmacology and Therapeutics by Waller, Renwick and Hiller.
5. Textbook of Medical Physiology by Guyton.
6. Harpers Illustrated Biochemistry by Harpers
7. Medical Pathology by Devidson.
8. Ion Channel Pharmacology by Bernat Soria
9. Principles of Drug Action:The Basis of Pharmacology by Goldstein A,Arnow, L, Kalman S M
10. Pharmacology by Rang & Dale

**Advances in Pharmaceutical Sciences including Biostatistics (M.121T & M.122P)**

1. Pharmaceutical Statistics by Sanford Bolton; Marcel Dekker.
2. Pharmaceutical Statistics of Industrial Pharmacy by Lachman.
3. Text Book of Biopharmaceutic Analysis by Smithe, Stewart.
4. Methods in Biostatistics by Mahajan.
5. Fundamental of Applied Statistics by S. C. Gupta and C. K. Kapoor.
6. Mathematical Statistics by Kapoor and Saxena.
7. Statistics by Gofeti Radhakrishna.
8. Web Resources in Pharmacy, In Pharma Publication, Bangalore.
9. Basic Statistics and Pharmaceutical Statistics Application by James E.De Muth; Marcel Dekker Inc.
10. Pharmaceutical Experimental Design by G.A. Lewis, D. Matheia, Roger Phan-Tan-Luu; Marcel Dekker Inc.
11. Pharmaceutical Experimental Design and Interpretation by N.A. Armstrong, L.K.C. James; Taylor & Francis.
12. Current Patent Acts of various countries.
13. Web Resources in Pharmacy by Mueen Ahmed K.K.

**Methods in Drug Evaluation (M.PL123T & M.PL124P)**

1. Drug Discovery and Drug Evaluation by Vogel
2. Hand Book of Experimental Pharmacology by Zaimis E & Others
3. Handbook of Drug Screening by Ramkrishna Seethala and Prabhavathi B. Fernandes
4. Methods of Drug Screening by Turner
5. Clinical Research in Pharmaceutical Development by Barry Bleidt and Michael Montagne
6. Screening Methods in Pharmacology. Turner R.A.
7. Evaluation of Drug Activities: Pharmacometrics by Laurance D.R.
8. Methods in Enzymology.
9. Culture of Animal Cells by Freshney
10. Clinical Trials. Bio-informatics Institute of India.
11. Methods in Bio-statistics by Mahajan B.K.
12. Fundamentals of Statistics by Gupta S.C.
13. Fundamentals of Laboratory Technology by Godkar
14. Fundamentals of Experimental Pharmacology by M.N. Ghosh.

**Systemic Pharmacology-II (M.PL125T)**

1. Principles of Pharmacology by Paul L. Munson, Rober A Mucller, George R Breese
2. Pharmacological Basis of Therapeutics by Goodman & Gilman
3. Pharmacology by Rang & Dale
4. Principles of Drug Action:Basis of Pharmacology by Goldstein, Arnow L, Kalman S M
5. Modern Pharmacology by Charles R, Craing P, Rober E, Stitzel (editor)
6. Essentials of Pharmacotherapeutics by F.S.K. Barar
7. Pharmacological and Pharmacotherapeutics by Satoshkar and Bhandarkar
8. Clinical Pharmacology by Laurance and Bennett.
9. Essentials of Medical Pharmacology by Tripathi.
10. Basic & Clinical Pharmacology by Bertram G. Katzung
11. Lewis Pharmacology by Crossland
12. Internal Medicine by Harrison
13. Textbook of Pharmacology by V.N. Sharma

**Pharmaceutical Management-I (M.PMRA113T)**


1. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.0
2. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo..
3. Corporate Strategy by Ansoff, H.T.; McGraw Hill, New York.
4. Modern Management by Hempran David R.; McGraw Hill, New York.
5. Management by Stoner and Freeman; Prentice Hall, New Delhi.
6. Motivation and Personality by Maslow, Abraham, Harper & Row, New York.
7. Management of Organizational Behavior, Utilizing the Human Resources by Harcey, Paul and Blanchard Kenneth; Prentice Hall of India, New Delhi
8. Organization Structure, Process and out comes V $^{th}$ Edition Richard. H. Hall
9. Principles and Methods of Pharmacy Management III rd Edition Harry A. Smith.
10. Management "Global Perspective Heinz Weihrich, Harold Koontz by Tata Mcgraw Hill".
11. Personnel Management and Industrial Relations by P. C. Tripathi.


**Total Quality Management (M.PMRA114T)**


1. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
2. Quality Assurance of Pharmaceuticals–A Compendium of Guidelines and Related Materials, Vol.–1; WHO Publications.
3. A Guide to Total Quality Management by Kaushik Maitra and Sedhan K. Ghosh.
4. GMP by Mehra.
5. How to Practice GMP by P.P. Sharma.
6. ISO 9000 and Total Quality Management by Sadhan K.Ghosh.
7. Good Manufacturing Practices for Pharmaceuticals-A Plan for Total Quality Control by Sidney H. Willing & James R Stoker. (Drugs & Pharm. Sciences) Vol. 78; Marcel Dekker Inc.
8. OPPI-Quality Assurance.
9. USP.


**Drug Regulatory affairs-I (M.PMRA115T)**


1. Original laws published by Govt. of India.
2. Text Book of Forensic Pharmacy by Mithal B. M.; Vallabh Prakashan, New Delhi.
3. Laws of Drugs in India by Hussain.
4. Text Book of Forensic Pharmacy by Jain N. K.; Vallabh Prakashan, New Delhi.


**Advances in Pharmaceutical Sciences including Biostatistics (M.121T & M.122P)**


1. Pharmaceutical Statistics by Sanford Bolton; Marcel Dekker.
2. Pharmaceutical Statistics of Industrial Pharmacy by Lachman.
3. Text Book of Biopharmaceutic Analysis by Smithe, Stewart.
4. Methods in Biostatistics by Mahajan.
5. Fundamental of Applied Statistics by S. C. Gupta and C. K. Kapoor.
6. Mathematical Statistics by Kapoor and Saxena.
7. Statistics by Gofeti Radhakrishna.
8. Web Resources in Pharmacy, In Pharma Publication, Bangalore.
9. Basic Statistics and Pharmaceutical Statistics Application by James E.De Muth; Marcel Dekker Inc.
10. Pharmaceutical Experimental Design by G.A. Lewis, D. Matheia, Roger Phan-Tan-Luu; Marcel Dekker Inc.
11. Pharmaceutical Experimental Design and Interpretation by N.A. Armstrong, L.K.C. James; Taylor & Francis.
12. Current Patent Acts of various countries.
13. Web Resources in Pharmacy by Mueen Ahmed K.K.


**Pharmaceutical Management-II (M.PMRA123T)**


1. Management by Tripathi P. C. and Reddy P. N.; Tata Mc Graw Hill.
2. Business Organization and Management by Shukla M. C.; S. Chand and Company.
3. Business Organization and Management by Sherlakar S. A.; Himalaya.
4. Personnel Management by Filippo E. B.; McGraw Hill.
5. Marketing Management by Kotler Philip.; Prentice Hall of India.
6. Organizational Behavior by Rao and Narayan; Konark Publishers.
7. Personnel Management by Tripathi P. C.; S. Chand and Company.
8. Principle and Practice of Marketing in India by Memoria C. B.
9. Principles of Pharmaceutical Marketing By Mickey Smith C.B.S. Publications.
10. Marketing Hand Book Vol. II , Marketing Management by Edwin – E Bobrow, Mark – D. Bobrow.
11. Production and Operations Management by S.N.Chary

**Pharmaceutical Management-III (M.PMRA124T)**

1. Financial Management by Johnson, R.W.; The Ronald Press.
2. Fundamental of Financial Management by Van Horne, J.C.; Prentice Hall of India (P) Limited.
3. Stock Exchange and Investment Analysis by Briston, R. J.
4. Indian Financial System by Khan, M. Y.; Tata McGraw Hill.
5. Tax Planning for Industrial Projects by Agarwal R. K.; Hind Law Publishers, New Delhi.
6. Project Management by Chaudhary, S.; Tata McGraw Hill.
7. Project Management: A System Approach to Planning Scheduling and Controlling by Harold Kerzner; CRS Publishers and Distributors, Delhi.
8. Financial Management by Gupta And Sharma I st Edition 1996.
9. Accounting for Management Planning and Control III rd Edition Richard M. Lynch

**Drug Regulatory Affairs-II (M.PMRA 125T)**

1. Original Laws of the Respective Country.
2. Original Laws published by Govt. of India.
3. Guidelines for Developing National Drug Policies; WHO Publications, 1998.
4. Export Marketing by Cherian and Parab; Himalaya Publishing House, Delhi
5. Handbook of Procedures, Import and Export Promotion; Government of India, New Delhi
6. International Financial Management–An Indian Perspective by Varshney, R.L. and Bhashyam, S.; Sultan Chand & Co., New Delhi.
7. International Financial Management by Weston, J. Fred and Brat W. Sorge.; New York, McGraw Hill.