# ORDINANCES
# &
# SYLLABUS

**(w.e.f. Session 2009-10)**

for

**MASTER OF PHARMACY (M. Pharm.)**
**in**
## PHARMACEUTICS

## DEPARTMENT OF PHARMACY
**BHIMTAL CAMPUS**
**KUMAUN UNIVERSITY**
**NAINITAL (UTTARAKHAND)**

# INTRODUCTION

The Pharmaceutical sector is one of the leading industries in India. The Growth in this sector has been phenomenal due to globalisation, which has created innumerous opportunities for pharmacy professionals to become world leaders.

Pharmacy education has made rapid strides in the past two decades. Kumaun University realized the employment potential of the sector and started the graduate program, Bachelor of Pharmacy, in the then Department of Pharmacy at Post Graduate Chemistry Building at Durham (Nainital) in the year 1998.

Since its very inception the department has been instrumental in generating high quality professionals, holding key positions in the country's top Pharmaceutical Industries, Pharmacy Education Institution, Universities, Research Institutions, Drug Administration and Regulatory bodies.

Feeling the Pulse of the sector, the Department realized that Post Graduate & Doctoral Programmes be started, as there was dearth of such programs in the state. This lead to the commencement of M. Pharm Program in four disciplines in the year 2008 with the reincarnation of the department as Department of Pharmaceutical Sciences, Bhimtal under the Faculty of Technology.

# CONTENTS

## I. PREAMBLE

Whereas, it is expedient to provide ordinance leading to the degree of Master of Pharmacy, for the purpose hereinafter appearing, it is enacted as follows:-

1. This Ordinance may be called Master of Pharmacy (M. Pharm) Ordinance, 2008".
2. This Ordinance shall come into force with effect from the Academic session 2008-09.
3. In this Ordinance unless the context otherwise requires the expression "University" shall mean Kumaun University, "Department" shall mean the Department of Pharmacy, Bhimtal.
4. The courses leading to the Degree of (Master of Pharmacy) shall be as follows, namely:
   - I) Pharmaceutics
   - II) Pharmaceutical Chemistry
   - III) Pharmacology
   - IV) Pharmacognosy

## II. ELIGIBILITY:

The eligibility, of the candidate who has passed the examination for the degree of B. Pharm of this University or any other statutory University/ institute in India or abroad, recognized as equivalent thereto by the University, for admission to first semester of Master of pharmacy two years (four semesters) course shall be:-

(i) 50% of B.Pharm marks with GATE Score for GATE qualified students.

(ii) 50% of B.Pharm marks for Non-GATE students.

(iii) 50% of B.Pharm marks for Candidates sponsored by the Industry/ Academic Institutions.

(iv) 50% of B.Pharm marks for NRI/NRI Sponsored candidates.

(v) Any other qualification as laid down by the University.

**Note: 5% relaxation in B. Pharm Marks for eligibility of SC/ST candidate.**

**III. INTAKE:**

| | | | |
|---|---|---|---|
| I) | Pharmaceutics | - | 10 seats |
| II) | Pharmaceutical Chemistry | - | 10 seats |
| III) | Pharmacology | - | 10 seats |
| IV) | Pharmacognosy | - | 10 seats |

**Note: 02 seats are reserved for sponsored candidate in each discipline.**

**Incase of nonavailability of sponsored candidates seats will be filled by university norms.**

**IV. ADMISSION TO M. PHARM. COURSE**

**IV.1.** The admission to the 1st year of M. Pharm shall be on the basis of merit of GATE score and/or B. Pharm merit or as may be decided by the University from time to time.

**IV.2.** Reservation as per State Government / University norms.

**V. DURATION:**

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

**VI. FEES:**

**VI.1 Tuition and other fees:** The Tuition fees, other fees and deposits like Library and Laboratory deposit will be as prescribed by the University from time to time.

**VI.2 Refund of fees:** If a candidate wishes to withdraw from the course, request for refund of fee should be made to the Vice Chancellor, Kumaun University within two weeks of commencement of classes.

**VII. SCHEME OF COURSES OF STUDY:**

**VII.1. Registration :**

**VII.1.1** Every student admitted to the I[st] semester, II[nd] semester, III[rd] semester or IV[th] semester of the course must get registered at the beginning of the each semester in the department by completing the necessary formalities, as specified by the University.

**VII.1.2** In each semester, a last date shall be fixed and notified in the beginning of the

session after which admissions / re-admissions / promotions / registrations shall not be entertained.

**VII.2. Regularity and Attendance:**

**VII.2.1** No Candidate shall be permitted to appear in semester examination, unless he/she has regularly attended not less than 75% classes in aggregate of all subjects. The university may however, condone not more than 10% shortage in attendance in each subject for any of the following reasons.

Participation in NCC/ NSS Camps.

Participation in University/ Inter-university/ State-level Games.

Participation in other extra-curricular activities at University/ Inter-university/ State level.

Prolonged Illness.

A student can avail of this relaxation only on any one of the above grounds. Further, such relaxation can be granted only on submission of certificate/evidence from appropriate authority.

**VII.3. Cancellation of Admission :**

The admission of a student at any stage of study shall be cancelled if:-

**(i)** He / she is not found qualified as per norms / guidelines or the eligibility criteria fixed by the University.

**(ii)** He / she is found involved in creating indiscipline in the Institution/ Campus or in the University.

**(iii)** He / she is unable to complete the course within four years from the date of admission.

**VIII. SCHEME OF TEACHING AND EXAMINATION:**

**VIII.1 Scheme of Teaching:**

The syllabi of the subjects for M. Pharm. First, Second, Third and Fourth Semester are given as under. **(Annexure I)**

**VIII.2 Scheme of Examination:**

There shall be a University examination at the end of each semester. The examination shall be as per the scheme mentioned.

**VIII.2.1 SESSIONALS**

**VIII.2.1.1** Twenty five percent of the marks for each theory subject/paper shall be allotted for sessionals, while the allotment of Practical marks shall be Thirty percent.

**VIII.2.1.1.1 Theory:** Two sessional examinations shall be held during each semester for each theory paper/subject from which one best answered by the candidate shall be considered for the award of sessional marks.

**VIII.2.1.1.2 Practical:** Marks shall be awarded on the basis of the experiments performed by the students, prior preparation for the experiment, conduct in the laboratory, results of the experiments, day to day completion of the records and viva-voce.

**VIII.2.1.1.3** Improvement will be allowed in sessional of theory and practical marks by reappearing in the regular sessional examinations for failed candidates.

**VIII.2.2 EXAMINATIONS:**

**VIII.2.2.1** There shall be one university examination at the end of each semester. These examinations will be designated as follows:

**(a) During first year:**

M.Pharm. I semester

M.Pharm. II semester

**(b) During second year:**

M.Pharm III semester

M.Pharm IV semester

**VIII.2.2.2** The examination at the end of each semester will consist of the theory papers, practicals and or viva-voce.

**VIII.2.2.3** A candidate who fails to secure the minimum marks in any subject may improve the same at the next semester.

**VIII.2.2.4** The examination for progress in project will be conducted in III semester and Viva-voce of Research shall be conducted in the fourth semester.

**VIII.2.2.5** There will be no supplementary examination.

**VIII.2.4 DISSERTATION:**

The topics for the dissertation shall be assigned by the Guide, a recognized Post-graduate

Teacher, within one month of the beginning of second semester. Every candidate presenting himself/herself for the M. Pharm. fourth semester examination is required to submit four typewritten copies of the dissertation duly certified by the Guide. Out of five/ six copies of dissertation, one copy is to be submitted in the college Library. The dissertation also needs to be certified by the Head of the Department. The dissertation is to be submitted not before 23 months from the date of commencement of first term of M. Pharm Course. If candidate fails to submit his/her dissertation within 24 months, he/she will have to submit dissertation in subsequent semester.

If the subject of dissertation entails collaboration with other departments, pharmaceutical industries, hospitals and research institutes, the collaborative portion of the work will be supervised by Co-Guide, designated by the Head of the Department in consultation with the Guide. Where a Co-Guide is involved, the dissertation will be certified jointly by the Guide & Co-guide.

The Guide or any other Recognized Post-graduate teacher in the subject (Internal Examiner) and an External Examiner appointed by the University will examine the dissertation. The Examiners will jointly assign the marks for dissertation out of 300 (including viva-voce of 200 marks). The allotment of marks of the dissertation shall be as under.

| | |
|---|---|
| Disserattion | 100 marks |
| Viva- voce | 200 marks |

The allotment of marks for Viva-voce shall be as under:

| | | |
|---|---|---|
| 1. | Scientific contents | 80 marks |
| 2. | Presentation/Communication | 60 marks |
| 3. | Discussion & Defense | 60 marks |
| | ---------- | 200 marks |

**VIII.3.0 STANDARD OF PASSING:**

**VIII.3.1** In each subject (theory and practical) of every semester criteria of passing shall be as under:

**VIII.3.1.1** Minimum 50% marks should be obtained in aggregate of sessional and semester examination.

**VIII.3.1.2** Each theory paper and practical will be treated as separate subject for passing.

**VIII.3.1.3 (a)** An examinee who fails to obtain minimum marks in not more than two papers (theory and practical should be treated as separate paper) at any of the semester examinations shall be declared to have obtained A.T.K.T. (allowed to keep term). Such candidates may be admitted provisionally to the class for next higher semester. In case he fails to clear the backlog in the A.T.K.T. examination he shall be treated as having failed.

**(b)** A candidate failing in more than two papers (theory and practical should be treated as separate paper) at any of the semester examinations shall be treated to have failed.

**(c)** A candidate failing in two papers at any semester examination may be readmitted to a subsequent main examination of that semester without necessary prosecuting a further course of study. He shall, however be required to appear and clear only those subjects in which he had failed to secure the minimum pass marks. The marks in the subjects already cleared by him shall be carried over.

**(d)** The failed candidate as per para- VIII.3.1.3 (b) above shall not be permitted to continue in the course. He shall, however be eligible to take admission to the next higher semester class after he has passed the examination at which he had failed as provided at para (c) above.

**(e)** The candidate failing in third/fourth semester examination may seek readmission however he/she shall submit his/her dissertation after necessary improvement and/or modification or re-written dissertation on a same or different topic approved by the Head of the department in the college.

## VIII.4.0 DIVISION AND MERIT LIST

**VIII.4.1** The division shall be awarded only after IV semester examination and shall be based on the aggregate marks obtained at his/her successful attempts at the I, II, III and IV semester examinations i.e. full examination of M.Pharm. There will be only four divisions as follows:

| S.No. | Marks | Grade |
|---|---|---|
| 1. | Above 75% | A(First class with Distinction) |
| 2. | Above 60% & below 75% | B (First class) |
| 3. | Above 50% & below 60% | C(Second class) |
| 4. | Below 50% | D(Fail) |

**VIII.4.2** The University shall declare the merit after the main examination of the fourth semester of M.Pharm on the basis of the integrated performance of all the 2 Years. The merit list shall include the first three candidates securing at least first class and passing all semester examinations in single attempt in each discipline.

**IX. MEDIUM OF INSTRUCTION AND EXAMINATION:**

The medium of instruction and examination shall be English throughout the course of study.

**X. AMENDMENT**

Any ordinance, fee structure and eligibility etc are subject to amendment from time to time as may be decided by an appropriate body of the University.

# Annexure I

**Course Structure :** The course work shall be divided into four semesters. The course contents are given as under. Modern Analytical Techniques theory and Practical mentioned under section A shall be common for the M. Pharm Course in the following branches

I) Pharmaceutics

II) Pharmaceutical Chemistry

III) Pharmacology

IV) Pharmacognosy

**Section A**

| Sem | Name of the Subject | Paper No. | Paper Code | Duration Of Exam | Marks | | Total Marks |
|---|---|---|---|---|---|---|---|
| | | | | | Main Exam | Sessional Exam | |
| I | Modern Pharmaceutical Analytical Techniques | I Theory | M.P.1.1 | 3 | 75 | 25 | 100 |
| I | Modern Analytical Techniques | I Practical | M.P.1.2 | 6 | 70 | 30 | 100 |

## Section B

| Branch I. Pharmaceutics | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Sem** | **Name of the Subject** | **Paper No.** | **Paper Code** | **Duration Of Exam** | **Marks** | | **Total Marks** |
| | | | | | **Main Exam** | **Sessional Exam** | |
| I | Pharmaceutics – I (Product Development and Quality Assurance) | II Theory | M.P.S.1.3 | 3 | 75 | 25 | 100 |
| I | Pharmaceutics - I | II Practical | M.P.S.1.4 | 6 | 70 | 30 | 100 |
| II | Pharmaceutics – II (Industrial Pharmacy and Packaging Technology) | III Theory | M.P.S.2.1 | 3 | 75 | 25 | 100 |
| II | Pharmaceutics – III (Advances in Drug Delivery Systems& Biopharmaceutics) | IV Theory | M.P.S.2.2 | 3 | 75 | 25 | 100 |
| II | Pharmaceutics II | III Practical | M.P.S.2.3 | 6 | 70 | 30 | 100 |
| II | Pharmaceutics III | IV Practical | M.P.S.2.4 | 6 | 70 | 30 | 100 |
| III | Progress Report | | M.P.S.3.1 | 6 | | | 100 |
| IV | | | | | | Dissertation | 100 |
| | | | | | | Viva Voce | 200 |
| | | | | | | | **Total 1200** |

| Branch II. Pharmaceutical Chemistry | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Sem** | **Name of the Subject** | **Paper No.** | **Paper Code** | **Duration Of Exam** | **Marks** | | **Total Marks** |
| | | | | | **Main Exam** | **Sessional Exam** | |
| I | Pharmaceutical Chem. – I (Drug Design including Organic name reactions) | II Theory | M.P.C.1.3 | 3 | 75 | 25 | 100 |
| I | Pharmaceutical Chemistry-I | II Practical | M.P.C.1.4 | 6 | 70 | 30 | 100 |
| II | Pharmaceutical Chemistry-II (Chemistry of Natural Products) | III Theory | M.P.C.2.1 | 3 | 75 | 25 | 100 |
| II | Pharmaceutical Chemistry-III (Medicinal chemistry) | IV Theory | M.P.C.2.2 | 3 | 75 | 25 | 100 |
| II | Pharmaceutical Chemistry II | III Practical | M.P.C.2.3 | 6 | 70 | 30 | 100 |
| II | Pharmaceutical Chemistry III | IV Practical | M.P.C.2.4 | 6 | 70 | 30 | 100 |
| III | Progress Report | | M.P.C.3.1 | 6 | | | 100 |
| IV | | | | | | Dissertation | 100 |
| | | | | | | Viva Voce | 200 |
| | | | | | | | **Total 1200** |

| Branch IV. Pharmacognosy | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Sem** | **Name of the Subject** | **Paper No.** | **Paper Code** | **Duration Of Exam** | **Marks** | | **Total Marks** |
| | | | | | **Main Exam** | **Sessional Exam** | |
| I | Pharmacognosy– I (Advances in Pharmacognosy) | II Theory | M.P.G.1.3 | 3 | 75 | 25 | 100 |
| | Pharmacognosy -I | II Practical | M.P.G.1.4 | 6 | 70 | 30 | 100 |
| II | Pharmacognosy – II (Phytochemistry and Biogenesis) | III Theory | M.P.G.2.1 | 3 | 75 | 25 | 100 |
| II | Pharmacognosy – III (Cultivation & Standardi-sation of Medicinal Plants) | IV Theory | M.P.G.2.2 | 3 | 75 | 25 | 100 |
| II | Pharmacognosy - II | III Practical | M.P.G.2.3 | 6 | 70 | 30 | 100 |
| | Pharmacognosy - III | IV Practical | M.P.G.2.4 | 6 | 70 | 30 | 100 |
| III | Progress Report | | M.P.G.3.1 | 6 | | | 100 |
| IV | | | | | | Dissertation | 100 |
| | | | | | | Viva Voce | 200 |
| | | | | | | | **Total 1200** |

**Semester – I**

**Modern Analytical Technique**

(This paper is Common in first Semester of all Branches)

**Paper – I Modern Analytical Technique**

| | | |
|---|---|---|
| Modern Analytical Technique | Theory | 4 Hours / Week |
| Modern Analytical Technique | Practical | 6 Hours / Week |

**Branch- I Pharmaceutics**

| | | |
|---|---|---|
| Paper – II | | |
| Pharmaceutics – I | Theory | 4 Hours / Week |
| Pharmaceutics – I | Practical | 6 Hours / Week |

**Branch – II Pharm. Chemistry**

| | | |
|---|---|---|
| Paper – II | | |
| Pharm Chemistry – I | Theory | 4 Hours / Week |
| Pharm Chemistry – I | Practical | 6 Hours / Week |

**Branch III (Pharmacology)**

| | | |
|---|---|---|
| Paper – II | | |
| Pharmacology – I(Basic Principles of Drug Therapy & Clinical Pharmacology) | Theory | 4 Hours / Week |
| Pharmacology – I | Practical | 6 Hours / Week |

**Branch IV Pharmacognosy**

| | | |
|---|---|---|
| Paper – II | | |
| Pharmacognosy –I (Advances in Pharmacognosy) | Theory | 4 Hours / Week |
| Pharmacognosy –I | Practical | 6 Hours / Week |

## Semester – II

**Branch – I Pharmaceutics**

| | | | |
|---|---|---|---|
| Pharmaceutics | II (Paper III) | Theory | 4 Hours/Week |
| Pharmaceutics | III (Paper IV) | Theory | 4 Hours/Week |
| Pharmaceutics Pract. III & IV | | Practical | Each 6Hours/Week |

**Branch – II Pharm. Chemistry**

| | | | |
|---|---|---|---|
| Pharm. Chem. | II (Paper III) | Theory | 4 Hours/Week |
| Pharm. Chem. | III (Paper IV) | Theory | 4 Hours/Week |
| Pharmaceutical Chem Pract. III & IV | | Practical | Each 6Hours/Week |

**Branch III (Pharmacology)**

| | | | |
|---|---|---|---|
| Pharmacology | II (Paper III) | Theory | 4 Hours/Week |
| Pharmacology | III (Paper IV) | Theory | 4 Hours / Week |
| Pharmacology Pract. III & IV | | Practical | Each 6Hours/Week |

**Branch IV Pharmacognosy**

| | | | |
|---|---|---|---|
| Pharmacognosy | II (Paper III) | Theory | 4 Hours/Week |
| Pharmacognosy | III (Paper IV) | Theory | 4 Hours / Week |
| Pharmacognosy Pract. III & IV | | Practical | Each 6Hours/Week |

## Semester III & IV

Third and Fourth Semester will be entirely devoted to the research project.
The examinations shall consist of a Progress report , disseratation and Viva- Voce. The Weightage of marks for the Progress report ,Dissertation and Viva Voce shall be as under

- Progress report 100 marks
- Dissertation - 100 marks
- Viva Voce - 200 marks

# Syllabus For M. Pharm
# in
# Pharmaceutics

(Including the Syllabus of Modern Analytical Techniques
{Theory & Practical} common in the Ist Semester of all Branches of M. Pharm)
Effective from Session 2008-2009

## Semester – I
## MODERN PHARMACEUTICAL ANALYTICAL TECHNIQUES

Principles of separation and applications of TLC. Column chromatography. Paper chromatography, Ion exchange chromatography, Counter current chromatography, G.C., DCCC, HPTLC & HPLC and electrophoresis.

**Infrared spectroscopy**

**Introduction:** The IR absorption process; the modes of vibration bond properties and absorption trends. The Hook's Law & calculations of frequencies for different types of bonds; coupled interactions; hydrogen bonding; radiation source, sample handling, qualitative and quantitative applications and introduction about FT-IR

**Ultraviolet spectroscopy :**

**Introduction:** The nature of electronic excitation, the origin of UV band structure; principle of absorption spectroscopy; Beer and Lambert's Law, Chromophores, transitions; shifts reagents effects of substituents; effect of conjugation' confirmations and geometry; calculation of Lamda maxima, effect of solvents, qualitative and quantitative applications

**Nuclear Magnetic Resonance spectroscopy :**

**A. 1H NMR Spectroscopy:** Principle, Instrumentation techniques. Chemical equivalence, spin-spin coupling, The origin of spin-spin splitting, Pascal triangle, the coupling constant chemical shift reagents Pharm. application including interpretation of Proton-NMR spectra.

**B. 13C NMR Spectroscopy:** Peak assignments, off resonance decoupling, selective proton decoupling, chemical shift equivalence, chemical shifts and spin coupling.

**Mass Spectrometry:**

Basic principle and theory involved, Instrumentation, types of ions, fragmentation, rearrangements; mass spectra of representative compounds, recognition of molecular ion peak, chemical ionization mass spectrometry, field desorption mass spectrometry, mass spectrometry, fast atom bombardment mass spectrometry.

**Thermal analysis:**

Introduction to various thermal methods of analysis, basic principle and theory;

differential thermal analysis and differential scanning calorimetry and micro calorimetry. Different types of calorimeters and micro calorimeters.

- Pharmacological evaluation of drugs in biological fluids: Bioassay.
- Microbiological assays.
- Radioimmunoassays.
- Research Methodologies.

## BIOSTATISTICS AND COMPUTER APPLICATION

1. Methods of collection of data, classification of data, graphical representation of data, frequency, polygon, histogram, measure of central tendency, mean mode and median dispersion and standard deviation.
2. Confidence level, Null hypothesis, calculation of statistical significance between two means, analysis of variance.
3. Association of attributes centigency, classification of attributes, coefficient of association, chi square test.
4. Theory of probability, simple probability, law of probability, Permutation and combinations, ratios percentages and proportions and statistical difference between proportions. Analysis of variance two way ANOVA and multiple comparison procedures.
5. Correlation and regression, least square method and its application, significance of coefficient of correlation, non linear regression.
6. Calculation of ED50, LD50, probit analysis.

II COMPUTER APPLICATIONS

## BOOK RECOMMENDED

1. R.M. Silverstein, F.X. Webster, Spectrometric Identification of organic compounds, 6th ed. John Wiley & sons, New-York, 1998.

2. Remington, The science and practice of pharmacy, Mack publishing company. Easton Pennsylvania.
3. Organic spectroscopy by Willam Kemp
4. E. Heftmann, A laboratory handbook of chromatography, New - York.
5. H.H.Willard, L.L.Merritt and J.A.Dean, Instrumental methods of analysis, Van Nostrend Reinhold, New York.
6. WWM. Wenland, Thermal analysis, John Willy and sons, New-York.
7. Principle of instrumental analysis,V ed. By Skoog, Holler-Niemen.
8. Modern analytical chemistry by David Harvey. (MC Graw-Hill international edition).

**PRACTICALS**

Practicals based on instrumental methods of analysis. A sufficient training will be given through exercises using different kinds of spectral analysis.

Modern Pharmaceutical Analytical Techniques (Theory & Practical) is a common subject in the first semester of the different branches of Master of Pharmacy

## PHARMACEUTICS - I

## (PRODUCT DEVELOPMENT AND QUALITY ASSURANCE)

**1. Preformulation Studies :**

Timings and goals of Preformulation, Pre-formulation methodology, solid state properties, partition coefficient, solubility, dissolution, crystal form and stability, compatibility tests, dissolution of drug substances and dosage.

**2. Kinetic principles and stability testing :**

Order of reaction, influence of pH, temperature, Acid - base catalysis. Effect of Ionic strength on degradation, Complex reactions, amide hydrolysis, Ring alteration, Oxidation - reduction, Chemical &Physical stability of dosage forms, Influence of packaging components on dosage form stability.

3 . A. introduction to Pharmaceutical dosage form: oral, parentral, topical, aerosol.

B. Optimization Techniques in Pharmaceutics, Formulation and Processing . Optimization parameters, statistical design, and other application.

**4. A. Documentation**

Relevance and importance of documentation, statuary requirements and procedure for documentation, critical examination of documents.

B. Pharmaceutical Process Validation :

Regulatory basis, Validation of sterile products, Solid dosage forms, Process Validation and non-sterile Analytical method Validation.

**5. Quality Control : Process of dosage forms :**

Process control ; Control of quality Validation, Control of manufacturing Process, Statistical quality control, control charts, sampling plans, Automated & process control, Dosage form control, Testing programme & method, Product identification systems, Adulteration, Misbranding, maintenance of records, Bioavailability, Bioequivalence, manufacturer's reliability, Manufacturer/drug information profile. Ecvaluation of Pharmaceutical formulation in vitro and in vivo methods.

**Books Recommended :**

1. Lachman, Leon and H. A. Lieberman, The theory and Practice of Industrial

pharmacy, 3rd edition, Varghese Publishing Co.

2. Gilbert S. Banker and C.T Rhodes, Modern Pharmaceutics, Marcel Decker.
3. Bernard T. L. and Robert A. Narth, Pharmaceutical process validation, volumes 23, Marcel Decker.
4. Norman A., Hodges and Stephen P. Denyer, haul book of Microbiological Quality control, Tayler and Francis, London.
5. Horth Tonneson, Photostability of Drugs and Drug Formulations, Taylor and Francis, London.

**Practical II:** To illustrate the topics included under theory. (min. 15 practicals) – 100 marks

# Semester – II
# PHARMACEUTICS - II

**INDUSTRIAL PHARMACY AND PACKAGING TECHNOLOGY**

1. General Consideration, Preparation of Master Manufacturing Procedure

Material Handling, Blending, Granulation, Drying, Slugging Compression, Coating liquid Dosage Forms Contract Manufacturing

2 . A. Production and Planning Management

Space Allocation, environmental factors, Manufacturing, Materials, Master formula generation and SOP.Management, Sales forecasting, Cost Control.

B. Good Manufacturing Practices : GMP in manufacturing, Processing, Packaging and holding of Drugs ; Control of Components, Containers and closures, Production and process controls : Packaging & labeling controls ; Inspection for compliance with GMP Potable water standards ; Premises : Design, Construction, maintenance, equipment ; maintenance, warehousing, . ISO 9000 certification.

3. Drug Regulatory Methods

Definitions ; Federal food, Drug and Cosmetic Act ; Kafaurver Harre's Amendments, New Drug Application, Drug efficacy study, Implementation Review, OTC Drug review, Drug Listing. Drug amendments, Patents, Copy right, Trade Marks, Drug recalls,

product liability, Clinical Trials.

4 . A. Polymers, biopolymers and their application

B. Nutraceuticals introduction and scope.

6 . Packaging materials science :Packaging design and specifications, packaging validation trials, material of construction, component product validation, Regulatory requirements, Quality control Testing and Standards, GMP requirements & its deficiencies ; In process control during component manufacture Documentation ; Sterilization of packaging components ; Packaging and filling equipment ; Pharmaceutical Packaging including sterile filling area ; customer complaints.

**Books Recommended :**

1. Lachman Leon & H. A. Liberman, The theory and practice of Industrial Pharmacy, Varghese Publishing Co.
2. Gilber S. Banker and C. T. Rhodes, Modern Pharmaceutics Marcel Dekker Inc.
3. Kenneth Harburn, Quality Control of Packaging materials in the pharmaceutical

Industry.

4. Sidney H. Willing, Good Manufacturing Practice for pharmaceuticals, Mercel Decker Inc.

5. Kinam Park, Shalaby. S. W, and Haesun park, Biodegradable Hydrogel for Drug Delivery, Technomic Basel.

6. Armstrong, N. A. and James K. C. , Pharmaceutical Experimental Design and Interpretation, Taylor and Francis, London.

7. Brody, A. L. and Marsh , K.S. , Encyclopedia of Packaging Technology, John wiley and sons, New York.

## PHARMACEUTICS –III

## (ADVANCES IN DRUG DELIVERY SYSTEMS & BIOPHARMACEUTICS )

### 1. Fundamentals of Controlled release drug delivery systems :

Fundamentals and Rationale of Sustained / controlled drug delivery, factors influencing the design & performance of sustained/ Controlled release products, Drug Targeting, Use of polymers in controlled release of active agents, Pharmacokinetic / Pharmacodynamic basis of controlled drug delivery systems, regulatory requirements.

### 2 . Design & Fabrication of Controlled Drug Delivery Systems :

Novel chemical approaches for sustained drug delivery, Design & fabrication of oral controlled release drug delivery systems. Parenteral products, Implantable systems. Transdermal systems, ocular , Intra - Vaginal, intra - uterine systems.

### 3 . Biochemical and Molecular Biology approaches Controlled Drug Delivery :

Microparticulate drug Carriers ; Liposomes, Microspheres and cells, selective endocytosis of macromolecular drug carriers, Antibodies for drug delivery, Resealed erythrocytes, Niosomes. Nanoparticals and other advance drug delivery systems.

4 . Advances in the monitoring of pharmacotherapeutics and in drug delivery system design. Basic principals of Biopharmaceutivs and pharmacokinetics including compartment model, bioavailabilty and bioequivalence

5. Clinical Practices , Principles of clinical trials.

**Books Recommended :**


1. Robinson & Lee, Controlled Drug Delivery Fundamentals & Applications, Volume 29, 2nd edition, Marcel Dekker Inc.
2. James Swarbrick, Novel Drug Delivery Systems.
3. Gilbert S. Banker and C. T. Rhodes, Modern Pharmaceutics 2nd Edition.
4. Robinson J. R. and Vincet H. L Lee, Controlled Drug Delivery, Fundamentals And Applications, Volume 29, 2nd edition, Mercel Dekker Inc.
5. Avis, K. E, Leon Lachman, And H. Lieberman, Pharmaceutical Dosage Forms : Parenteral Medications Volume - 2.
6. Lierberman H. A. and Leon Lachman , Pharmaceutical Dosage Forms : tablets Volume 3, Marcel Dekker.
7. Scher, H. B., Controlled release Delivery Systems of Pesticides, Marcel Dekker.
8. Kim. C., Controlled Release Dosage form Design, Technomic Publishing Co, Basel.


**Pharmaceutics Practical III:** To illustrate the topics included under theory.

Practical orientation towards nutraceutical formulation, biopolymers and packaging materials. (15 practicals)

**Pharmaceutics Practical-IV :** Practical based on some topics covered in the theory part will be carried out.

1. Formulation and evaluation of various novel drug delivery systems

2. Practicals based of biopharmaceutis and pharmacokinetics

**Semester III**

Progress report on the allotted project - 100 marks

Presentation – 50 marks

Progress report – 50 marks

**Semester-IV**

Thesis of Research Work - 100

Viva Voce – 200 marks