MANAV BHARTI UNIVERSITY

SYLLABUS OF
M. PHARMA
(PHARMACEUTICS)
COURSE STRUCTURE
2009

SUBMITTED BY:
SHALINI SHARMA

MANAV BHARTI UNIVERSITY
SYLLABUS OF M.PHARMA (PHARMACEUTICS)

Semester I

No.	Subjects
1	Advanced Pharmaceutical Analysis
2	Industrial Pharmacy
3.	Biopharmaceutics and Pharmacokinetics
4	Advances in Drug Delivery System
5	Cosmetic Technology

Semester II

No.	Subjects
1	Advanced Pharmaceutical Analysis
2	Industrial Pharmacy
3.	Biopharmaceutics and Pharmacokinetics
4	Advances in Drug Delivery System
5	Cosmetic Technology
6.	Pharmaceutics Practicals

Semester III & IV

Project and Dissertation work
Every student for the degree of Master of Pharmacy shall be required to undertake a project involing methodical research under the supervision of an guide and submit copies of thesis.

SEMESTER – I

PCS 101 : ADVANCED PHARMACEUTICAL ANALYSIS

1. ULTRAVIOLET AND VISIBLE SPECTROSCOPY :

Brief review of electromagnetic spectrum, UV-Visible range, Interaction of electro-magnetic radiation (UV-Vis) and matter and its effects, Chromophore and their interaction with EMR, Woodward-Fieser rule. Beer-Lambert's Law, Multicomponent analysis, derivative spectroscopy, spectral correlation with structure.

2. SPECTROFLUORIMETRY:

Fluorescence, Phosphorescence - Theory, instrumentation and applications.

3. INFRA-RED SPECTROSCOPY:

Nature of Infra-red radiation, Interaction of IR radiation with organic molecule and effects on bonds. Brief outline of IR instrument

tation and interpretation of spectra, including sample preparation for spectroscopy, Influence of substituents, ring size, hydrogen bonding, vibrational coupling and field effect on frequency, Quantitative methods, FT-NIR and applications, spectral interpretation with example.

4. RAMAN SPECTROSCOPY

Principle, instrumentation and applications.

5. LASER SPECTROSCOPY

Introduction, principle, instrumentation and applications.

6. RADIO IMMUNO ASSAY AND ELISA

Introduction, principle, instrumentation and applications

7. ELECTROPHORESIS

Principle, techniques, instrumentation including detection strategies and applications.

8. HYPHENATED TECHNIQUES

Introduction and applications.

Recommended books:

1. Principles of Instrumental Analysis, Skoog, Saunders Publishers, Philadelphia.
2. Instrumental Methods of Analysis, Willard, Merritt, Dean, CBS, Delhi.
3. Instrumental Methods of Chemical Analysis, Ewing, McGraw Hill Book Co, NY.
4. Instrumental Methods of Chemical Analysis, BK Sharma, Goel Publ, India.
5. Drug & Pharma Sciences Series, Marcel Dekker Inc.

6. Remington’s Pharmaceutical Sciences.
7. Aldrich FT-IR Spectral Library.
8. Modern Methods of Pharmaceutical Analysis, Vol 1,2,RE Schirmer,Franklin Book Co.

PCS 102 : INDUSTRIAL PHARMACY

1. PREFORMULATION

Introduction, essential information useful in preformulation study such as organoleptic properties, purity, particle size, shape, and surface area. Solubilisation.

2. PRODUCTION PLANNING AND SCHEDULING

Introduction, product rate change, product life cycle, product mix

3. OPTIMIZATION TECHNIQUES IN PHARMACEUTICAL FORMULATION AND PROCESSING

Concept of optimization, optimization parameters, classical optimization, stastical design and applied optimization methods.

4. INDUSTRIAL SAFETY

Industrial hazards due to fire, accidents, mechanical and electric equipments, chemical and pharmaceuticals. Monitoring and prevention system

5. EFFLUENT TESTING AND TREATMENT

Introduction, BOD, COD, Effluent treatment techniques.

Recommended books:

1. The theory & Practice of Industrial Pharmacy, L. Lachman, Varghese Publ, Bombay.
2. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
3. Dispersed System Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
4. Physical Pharmacy by Martin, Lea and Febiger, Philadelphia.
5. Pharmaceutical Preformulation by Wells, J.I., Ellis Hordwood Ltd., NY, 1988.

PCS 103 : BIOPHARMACEUTICS AND PHARMACOKINETICS

1. ABSORPTION OF DRUGS:

Definition, gastrointestinal absorption – Mechanism, Factors affecting drug absorption. Absorption of drugs from non-oral route.

2. DISTRIBUTION OF DRUGS:

Definition, Factors affecting drug distribution, Volume of distribution, Protein binding-factor affecting, significance and kinetics.

3. BIOTRANSFORMATION OF DRUGS:

Definition, Phase I and Phase II reactions and Factors affecting biotransformation.

4. EXCRETION OF DRUGS:

Definition, Renal and non- renal excretion, Concept of clearance- Organ clearance, Total clearance, Hepatic clearance and Renal clearance

5. NON LINEAR PHARMACOKINETICS

Cause of non-linearity, Michalis-Menten equation, Estimation of Km and Vmax.

Recommended books:

1. Biopharmaceutics and Clinical Pharmacokinetics, Mile Gibaldi, Lea and Febriger, Philadelphia.
2. Current concepts in Pharmaceutical Sciences, Swarbrick, Lea and Febriger, Philadelphia.
3. Theory & Practice of Industrial Pharmacy, L.Lachman, Varghese Publ, Bombay.
4. Clinical Pharmacokinetics, Rowland and Tozer, Lea and Febriger, Philadelphia.
5. Biopharmaceutics and Clinical Pharmacokinetics, Niazi, Prentice Hall, London.
6. Remingtons Pharmaceutical Sciences, Mack & Co.
7. Biopharmaceutics & Clinical Pharmacokinetics, DM Brahmankar, Vallabh, Delhi.

PCS 104 : ADVANCES IN DRUG DELIVERY SYSTEM

1. SUSTAINED RELEASE DRUG DELIVERY SYSTEMS. (SRDDS):

Introduction; Rationale of SRDDS; Advantages and Disadvantages of SRDDS; Factors influencing the design and performances of SRDDS; Physicochemical properties of a drug influencing design and performance: a)Aqueous solubility, b)Partition coefficient and Molecular size, c)Drug Stability, d)Protein binding; Biological factors influencing design and performance of SRDDS: a)Absorption, b)Distribution, c)Metabolism, d)Duration of Action, e)Side effects, f)Margin of safety, g)Role of disease state. Microencapsulation techniques.

2. CONCEPT AND SYSTEM DESIGN FOR RATE CONTROLLED DELIVERY

Rate programmed release, modulated activation and feed back regulated drug delivery system, effect of system parameters on controlled release drug delivery.

3. POLYMERS USED IN CONTROLLED DRUG DELIVERY SYSTEMS:

Introduction, Polymer-classification, Applications for Polymers in formulation of controlled drug delivery systems, Biodegradable and Natural polymers.

4. TRANSDERMAL DRUG DELIVERY SYSTEMS (TDDS):

Permeation through skin, Factors affecting permeation, Basic components of TDDS, Formulation approaches used in development of TDDS and their evaluation, Permeation enhancers

Recommended books:

1. Novel Drug Delivery System, Y.W. Chein, Vol 50, Marcel Dekker, NY.
2. Controlled Drug Delivery Systems, Robinson, Vol 29, Marcel Dekker, NY.
3. Transdermal Controlled Systemic Medications, YW Chein, Vol 31, Marcel Dekker, NY.
4. Bioadhesive DDS, E. Mathiowitz, Vol 98, Marcel Dekker, NY.

PCS 105 : COSMETIC TECHNOLOGY

1. RAW MATERIALS USED FOR COSMETIC PREPARATION
Detailed knowledge of various raw materials used in cosmetic industry like surfactants, humectants, water, polymers and thickeners , perfumes and colours.

2. COSMECUTICALS
Cosmeceuticals actives and applications of cosmeceuticals

3. SKIN CARE PRODUCTS
Introduction, anatomy and physiology of skin, formulation of skin cleaner, moisturizers, sunscreen products and acne products.

4. COLOUR COSMETICS
Introduction, lip colour, nail polish, facial make-up and eye make-up.

5. DENTAL PRODUCTS
Dentifrices, oral rinses, tooth powder and tooth paste.

6. PERSONAL HYGIENE PRODUCTS
Toilet soaps, shaving soaps, antiperspirant and deodorants.

Recommended books

1. Harry's Textbook of Cosmeticology.
2. Cosmeceuticals, Marcel Dekker Inc., NY.

SEMESTER – II

PCS 101 : ADVANCED PHARMACEUTICAL ANALYSIS

1. NUCLEAR MAGNETIC RESONANCE SPECTROSCOPY

Introduction of NMR, magnetic nuclear, chemical shift, shielding, relaxation process, chemical & magnetic non equivalence, local diamagnetic shielding and magnetic anisotropy, spin splitting, Pascal triangle, coupling constant, mechanism of coupling. Effect of stereochemistry on the spectrum, shift reagent, application of H^1NMR with some examples. C^{13} NMR introductions and its structural applications.

2. MASS SPECTROSCOPY

Introduction of mass, Essential components of a mass spectrometer, types of ions, molecular ion, fragment ion, rearrangement ion, metastable ion, Isotopic ions and their corresponding peaks, rules of fragmentation, Mc Lafferty rearrangement, Retro Diels Alder and other fragmentation patterns. Chemicals ionization mass spectroscopy (CIMS) , field ionization mass spectroscopy (FIMS) , Fast atom bombardment mass spectroscopy (MFABMS). Introduction to LC-MS, GC-MS.

3. CHROMATOGRAPHIC TECHNIQUES

a) Classification of chromatographic methods based on mechanism of separation: paper chromatography, thin layer chromatography, ion exchange chromatography, column chromatography and affinity chromatography – techniques and applications.

b) Theory, Principal and applications of following chromatographic techniques – Gas Chromatography (GC), high performance liquid chromatography (HPLC), RP – HPLC, high performance thin layer chromatography (HPTLC)

Recommended books

1. “Contemporary practices of chromatography” by Poole, Colin F. and Siela A. Schueete.
2. “Pratical HPLC method development” by L.R. Snyder Willey Interscience, Second Ed.
3. Drug & Pharma Sciences Series, Marcel Dekker Inc.
4. Remington’s Pharmaceutical Sciences.

PCS 102 : INDUSTRIAL PHARMACY

1. PILOT PLANT SCALE UP TECHNIQUES

Pilot study of some important dosage forms such as tablets, capsules and liquid orals and discussion on important parameters such as formula and equipment, product uniformity and stability. Raw materials and process, physical layouts and personnel requirements.

2. PRODUCTION MANAGEMENT AND DOCUMENTATION

ISO 9000 series, Intellectual Property Rights, Total Quality Management, Inventory control, GMP consideration, ICH guidelines, process and equipment validation for tablets and parenterals

3. PRODUCTION TECHNOLOGY

a) Tablet production

A brief study on the formulation aspects of tablets such as effervescent, sublingual, buccal, chewable tablets and medicated lozenges. Compaction of powder with special reference to distribution and measurement of forces within the powder mass undergoing compression.

b) Parenteral production

Product development, production processing, Quality control, Packaging and Lyophillization or Freeze drying technique.

4. PACKAGING OF PHARMACEUTICALS:

Desirable features and a detailed study of different types of Pharmaceutical containers and closures (Glass, Plastics and Rubber), including their merits and demerits; selection and evaluation of Pharmaceutical packaging materials.

Recommended Books:

1. Modern Pharmaceutics by Banker, Vol 72, Marcel Dekker, NY.
2. Pharmaceutical Dosage Forms, Tablets, Vol 1, 2, 3 by Lachman, Lieberman, Marcel Dekker, NY.
3. Pharmaceutical Dosage Forms, Parentral medications, Vol 1, 2 by K.E. Avis, Marcel Dekker, NY.
4. Pharmaceutical Production Facilities, design and applications, by G.C. Cole, Taylor and Francis.
5. Packaging Pharmaceutical and Health Care, H.Lockhard.

6. Quality Control of Packaging Materials in Pharmaceutical Industy, .Kharburn, Marcel Dekker, NY.
7. Freeze drying / Lyophilization of Pharmaceuticals & Biological Products, L. Ray, Vol 96, Marcel Dekker, NY.
8. Tablet Machine Instrumentation in Pharmaceuticals, P.R. Watt, Ellis Horwood, UK.

PCS 103 : BIOPHARMACEUTICS AND PHARMACOKINETICS

1. PHARMACOKINETICS:

Basic considerations, Compartment modeling - one compartment open model, I.V. Bolus, I.V. Infusion, extra vascular administration, urinary excretion data. Two compartment model: I.V. bolus, I.V. infusion, extra vascular administration.

2. BIOAVAILABILITY AND BIOEQUIVALENCE STUDIES:

Definition, Objectives, measurement of bioavailabilty, Plasma level-time study, urinary excretion studies, in-vitro dissolution testing models, in-vitro in vivo correlation, Bio equivalence study and methods of enhancing bioavailablity of drug.

Recommended books

1. Textbook of applied Biopharmaceutics and Pharmacokinetics by Shargel.
2. The pharmaceutical Codex.
3.Encyclopedia of Pharmaceutical Technology

PCS 104: ADVANCES IN DRUG DELIVERY SYSTEM

1. ORAL CONTROLLED DRUG DELIVERY SYSTEM

Using osmotic pressure control, membrane permeation control, pH control, ion exchange, controlled gel diffusion, controlled and hydrodynamically balanced systems, modulation of gastrointestinal transit time.

2. OCULAR DRUG DELIVERY SYSTEM:

Development of ocular controlled release therapeutic system.

3. PARENTERAL DRUG DELIVERY SYSTEMS

Injectable controlled release formulations and subdermal implants.

4. INTRAUTERINE DRUG DELIVERY SYSTEMS

Medicated IUDS, Copper IUD, Hormone releasing IUD.

5. TARGETED DRUG DELIVERY SYSTEMS

Concept, advantages and disadvantages, targeting of drugs by using nanoparticle, liposomes, resealed erythrocytes, monoclonal antibodies and magnetic microsphere

Recommended Books

1. Nasal System Drug Delivery, K.S.E. Su, Vol 39, Marcel Dekker, NY.
2. Drug Delivery Devices, Vol 32, P Tyle Marcel Dekker, NY.
3. Polymers for Controlled Drug Delivery, P.J. Tarcha, CRC Press.
4. Protein Formulation & Delivery, E.J. McNally, Vol 99, Marcel Dekker, NY.
5. Drug Targeting, M.H. Rubinstein, John Wiley, NY.

PCS 105 : COSMETIC TECHNOLOGY

1. HAIR CARE PRODUCTS

Introduction, hair structure, shampoos, conditioners, styling aids, settling lotion, hair creams, hair dyes.

2. SAFETY TESTING OF COSMETIC PRODUCTS

- Microbiology in cosmetics.
- Knowledge of various microbial contaminants in cosmetic products.
- Knowledge of various preservative system for cosmetic product.
- Selection criteria for preservatives.
- Efficacy and safety testing of preservatives in cosmetic products.

3. PACKAGING IN COSMETICS

- Knowledge of various packaging materials used in cosmetic product
- Knowledge of various machines used in cosmetic product
- Contemporary trends in cosmetic packaging

Recommended books

1. Harry's Textbook of Cosmeticology.

EXPERIMENTS IN PHARMACEUTICS

1. Preparation and evaluation of diclofenac sodium gel.
2. Study of the effects of various binding agents on the properties of tablets
3. Formulation and evaluation of coated tablet and compare with marketed preparations
4. Study on In-vitro dissolution of various sustained release formulations of marketed products
5. Effect of surfactant on dissolution of tablet.
6. To study the dissolution kinetics of IR & ER dosage from.
7. Effect of hardness of the tablets on disintegration time.
8. Study on diffusion of drugs through various polymer membranes
9. Calculations of Ka, Ke, t and Tmax from given data
10. Calculation of AUC from given data
11. Calculation of bioavailability from urinary excretion data
12. Comparative dissolution studies on different dosage forms for drugs.
13. Preformulation study of tablets
14. Evaluation of packaging material
15. Improvement of dissolution method of drug by different methods.
16. Validation of sterilization.
17. Effluent testing treatment.
18. Calibration of UV.
19. Study of drug- drug / experiment interaction using DSC.
20. Preparation of albumin microsphere by heat stabilization technique and their particle size characterization.
21. Preparation of resealed erythrocytes from blood, loading of various drugs and study on release pattern.
22. Preparation of wax embedded microsphere of diclofenac sodium and theophylline.