IV/IV B.PHARMACY (7th Semester)

701 PHARMACEUTICS-III (Theory) (75 hrs.)

(BIOPHARMACEUTICS, PHARMACOKINETICS & NEW DRUG DELIVERY SYSTEMS)

Unit : 01

Biopharmaceutics :

Introduction , Definitions, Fate of drug after administration , Blood level curves, Routes of drug administration, Drug absorption and disposition . Significance in product, formulation and development. Drug absorption –Structure of biological membrane, drug transport mechanisms, factors and kinetics involved – Physico- chemical and biological factors involved in drug absorption. Formulation and dosage form considerations in drug absorption .

Drug Dissolution : Mechanisms , factors and kinetics of dissolution dissolution rate significance and evaluation – Official methods

Unit : 02

Bioavailability : Concept and definitions, Factors involved on Assessment and significance of Drug Distribution. Plasma protein binding and its implications- Enterohepatic cycling.

Drug Elimination : Drug metabolism, path ways of drug metabolism Excretion- Excretion through urine, faeces, lungs and skin –Mechanism of renal excretion- renal clearance.

Unit : 03

Pharmacokinetics : Introduction – Compartment models –study of the methods of estimation, significance of the following parameters, biological half- life, apparent volume of distribution, renal clearance, total body Clearance, absorption rate, AUC - Mathematical expressions describing the variation in blood concentrations following I.V. and oral routes . Introduction to dosage regimen.

Unit : 04

Non-linear Pharmacokinetics : Non-linear Pharmacokinetics with special reference to one compartment model after IV drug administration, Michaeles-Menten equation. Detection of non linearity (Saturation Mechanism)

Unit : 05

Sustained release dosage forms : Principles and concepts involved, dosage calculations, methods adopted in release controlling, Design, manufacture and evaluation of various types of sustained release products. parenteral long acting products, implants.

Microencapsulation : Purpose and applications – Techniques of microencapsulation

Unit : 06

Novel Drug Delivery Systems : Introduction to Novel Drug Delivery systems – concept of controlled drug delivery, oral and Transdermal delivery systems - Liposomes, Concept on niosomes and resealed erythrocytes

702 PHARMACEUTICS-III (BIOPHARMACEUTICS, PHARMACOKINETICS & NEW DRUG DELIVERY SYSTEMS)

(Practicals) (75 hrs.)

01*. Dissolution rate testing and analysis of data
02*. Effect of surfactant on the solubility and dissolution rate of salicylic acid
03*. Effect of diluents on dissolution rate of salicylic acid
04*. Effect of concentration of magnesium stearate on dissolution rate of salicylic acid.
05. Evaluation of drug release from semi solid dosage form
06. Relation ship between pH, solubility, partition coefficient and percent ionization of salicylic acid .
07*. Enhancement of dissolution rate by solid dispersion technique
08*. Evaluation of diltiazem hydrochloride conventional and sustained release marketed tablets.
09*. Evaluation of nifedipine conventional tablet & capsule
10. Evaluation of disintegration and dissolution rate of commercial tablets
11. Basic pharmacokinetic calculations
12. Determination of bioavailability of four brands of given drug
13. Determination of absorption rate constant by Wagner-Nelson method
14. Determination of K_E & biological half life from plasma concentration and urinary excretion data
15. Determination of absorption rate constant by method of residuals
16. Preparation of microcapsules of naproxen
17. Calculation of pharmacokinetic parameter as per one compartment model
18. Estimation of renal clearance of creatinine and glomerular filtration rate
19. Determination of construction of standard graph for the estimation of sulphamethoxazole in blood.
20. Determination of biological half-life of rifampicin by urinary excretion data

TEXT BOOKS :

01. Pharmacokinetics by Gibaldi
02. Biopharmaceuticals and Pharmacokinetics by R.E.Notari.
03. Pharmacokinetics by Ritschal
04. Modern Pharmaceutics by G.S.Banker
05. Applied Biopharmaceutics and Pharmacokinetics, Leon Shargel
06. Clinical Pharmacokinetics; Concepts and applications by T.Rowland and Tozer
07. Bioavailability and bioequivalence by Ganesan & Pal.
08. Dissolution , bioavailability and bioequivalence by Hamed M.Abdou.

MODEL QUESTION PAPER

701 PHARMACEUTICS - III

(BIOPHARMACEUTICS, PHARMACOKINETICS AND NOVEL DRUG DELIVERY SYSTEMS) (Theory)

Time : 3 hours Max.Marks : 80

SECTION - A

Answer any FOUR questions (4 x 10 = 40 marks)

1. Define Drug absorption ? Enumerate salient features of various drug transport mechanisms ? Explain about fick's first law of diffusion.
2. Define Bioavailability and Bioequivalence ? Explain about experimental protocol in determination of bioavailability ?
3. Elucidate any one method to calculate absorption rate constant for an extra vascular administration following one compartment model. Mention merits and demerits and derive expressions for C_{max} and t_{max}
4. Explain about Michaelis - Menten's equation ? How do you estimate K_m and V_{max} after i.v. bolus administration of drug following non-linear kinetics.
5. Explain the Principle and factors involved in design of sustained release formulations ? How will you calculate the loading and maintenance doses for SR products.
6. Define liposomes ? Enumerate various methods to produce liposomes ? Add a note on applications.

SECTION - B

Answer any TEN questions (10 x 4 = 40 marks)

7. Write about gastric emptying time ?
8. Explain pH partition theory and mention its limitation ?
9. Explain enterohepatic cycling ?
10. Explain mechanisms of Renal excretion ?
11. Explain significance and application of A.U.C., volume of distribution (Vd) and clearance.
12. Define dosage regimen ? Explain the significance of two parameters in designing dosage regimen ?
13. Define Non linearity and causes for non-linearity
14. Write about michael-Menten's equation ?
15. Explain about coaceration - phase separation mechanism
16. Write short notes on implants ?
17. Write short notes on niosomes ?
18. Write short notes on transdermal drug delivery system ?

MODEL QUESTION PAPER (Practicals)

702 PHARMACEUTICS-III

(BIOPHARMACEUTICS, PHARMACOKINETICS AND NOVEL DRUG DELIVERY SYSTEMS)

Time : 6 hours Max.Marks : 80

1.	Synopsis	:	10 Marks
2*.	Major Experiment	:	35 Marks
3.	Minor Experiment	:	20 Marks
4.	Viva-Voce	:	15 Marks

		Total:	80 Marks

IV/IV B.PHARMACY (7th Semester)

703 PHARMACOLOGY-II (Theory) (75 hrs.)

Unit : 01

Pharmacology of drugs acting on cardiovascular system : Cardiac glycosides, antihypertensive drugs, coronary dilators, antihyper-lipidemic drugs, antiarrhythmic drugs. Drugs acting on the blood and blood forming agents, coagulants, anticoagulants, haematinics : Iron, Vitamin-B_{12} and folic acid.

Unit : 02

Pharmacology of drugs acting on Respiratory system : Bronchodilators, antitussives and expectorants.

Autocoids: Histamine–antihistaminics, serotonin, serotoninantagonists, prostaglandins.

Unit : 03

Chemotherapy : General principles – Sulphonamides, antibiotics, antiprotozoal drugs, antimalarials, antiamoebic, antifungal and antiviral drugs, chemotherapy of tuberculosis, leprosy and cancer.

Unit : 04

Pharmacology of drugs acting on endocrine system : Thyroid, anti-thyroid drugs, insulin and oral hypoglycemics, glucagon, adrenocortical steroids, pituitary hormones, sex hormones and oral contraceptives.

Unit : 05

Bioassays : General principles of bioassays, Estimation of errors in bioassays. Study of the official biological assay methods of adrenaline, posterior pituitary hormones, insulin, gonadotrophic hormones, test for pyrogens.

Unit : 06

Principles of Toxicology : Poisons, general treatment of poison, systemic antidotes, treatment of insecticide poisoning, heavy metal poisoning, narcotic drug, barbiturate and organophosphorous poisoning. Drug dependence, drug abuse, addictive drugs and their treatment.

IV/IV B.PHARMACY (7th Semester)

704 PHARMACOLOGY-II (Practicals) (75 hrs.)

01. Introduction to basic equipment used in experimental pharmacology
02. Study of mydriatic & miotic effects on rabbit eye
03. Evaluation of local anaesthetic activity by surface anaesthesia method
04. Concentration response curve of acetylcholine
05. Bioassay of acetylcholine by interpolation method

06*. Effect of neostigmine on dose response curve of acetylcholine
07*. Effect of pancuronium on dose response curve of acetylcholine
08*. Three point bioassay method.
09*. Effect of adrenaline and acetylcholine on isolated frog's heart
10*. Effect of calcium chloride and potassium chloride on isolated frog's heart
11*. Effect of adrenaline in presence of a β-blocker on isolated frog's heart
12*. Effect of acetylcholine in presence of atropine on isolated frog's heart

TEXT BOOKS :

01. Goodman and Gilman- "The Pharmacological Basis of Therapeutics"
02. Textbook of Phramacology by Rang and Dale.
03. Quientessence of Medical Pharmacology by C.Chowdary.
04. Lippincott's illustrated reviews : Pharmacology by Richard, D.Howland and MeryJ.Mylek.
05. Basic and clinical pharmacology by Bertran G.Katzung.
06. Review of medical pharmacology by F.H.Meyers, E.Jawetz and A.Goldfien.
07. Essentials of Medical Pharmacology by K.D.Tripathi.
08. Essential of Pharmacotherepeutics by F.S.K.Barar.

IV/IV B.PHARMACY (7th Semester)

MODEL QUESTION PAPER

703 PHARMACOLOGY - II (Theory)

Time : 3 hours Max.Marks : 80

SECTION - A

Answer any four questions (4 X 10 = 40 marks)

1. Classify antihypertensives with examples and describe the mechanism of action and clinical uses of any three different groups of antihypertensives.
2. Explain the pathogenesis of asthma. Classify antiasthmatic drugs and discuss the pharmacology of β-selective drugs.
3. Discuss in detail about various mechanisms of actions of different antibiotics with suitable examples.
4. What is diabetes ? Classify antidiabetic drugs and discuss the pharmacology of Insulin.
5. Define bioassay. What are its advantages and disadvantages ? How is posterior pituitary extract standardised for "oxytocic" activity.
6. Outline the principles of treatment of acute poisoning in general. Discuss about the management of organophosphorous poisoning.

SECTION - B

Answer any TEN questions (10 x 4 - 40 marks)

7. Describe the mechanism of action, therapeutic uses and unwanted effects of digitalis.
8. Write notes on HMG-CoA reductase inhibitors.
9. Write short notes on expectorants.
10. Write short notes on pharmacology of prostaglandins.
11. Write about antimetabolites.
12. Write briefly on bacterial resistance.
13. Write about corticosteroids.
14. Write short notes on antithyroid drugs.
15. Write short notes on errors in bioassays.
16. Write short notes on test for pyrogens.
17. Give an account on drug addiction.
18. Write short notes on heavy metal poisoning and its treatment.

IV/IV B.PHARMACY (7th Semester)

MODEL QUESTION PAPER (Practicals)

704 PHARMACOLOGY-II

Time : 6 hours Max.Marks : 80

1.	Synopsis	:	10 Marks
2*.	Major Experiment	:	35 Marks
3.	Minor Experiment	:	20 Marks
4.	Viva-Voce	:	15 Marks

		Total:	80 Marks

IV. B.PHARMACY (7th Semester)

705 PHARMACEUTICAL ANALYSIS –II

(Theory) (75 hrs.)

General treatment of the theory, instrumentation and applications of the following analytical methods.

Unit : 01

Spectrophotometry (UV, Visible, IR), Nephalometry and Turbidimetry, Fluorimetry and Flame Photometry

Unit : 02

Potentiometry and pH metry, conductometry and high frequency titrations, polarography and amperometry.

Unit : 03

Chromatography-introduction, paper chromatography , Thin layer chromatography, Column chromatography, Gas Chromatography and Ion-exchange chromatography.

Unit : 04

High performance liquid chromatography, High performance thin layer chromatography, Electrophoresis and counter current distribution.

Unit : 05

Differential thermal Analysis, Basic Principles of Radio immuno assay and its applications in Pharmaceutical Analysis. Basic theory, instrumentation and applications of Nuclear magnetic resonance spectroscopy.

Unit : 06

Basic Theory, instrumentation and applications of mass spectroscopy, Electron spin resonance spectroscopy and X-ray diffraction.

IV/IV. B.PHARMACY (7th Semester)

706 PHARMACEUTICAL ANALYSIS – II (Practicals) (75 hrs.)

I. Visible Spectrophotometry

01. Determination of absorption maximum for potassium permanganate
02. Estimation of dapsone in tablets by colorimetry
03*. Estimation of sulfamethoxazole in oral suspension by colorimetry
04. Estimation of riboflavine in tablets by colorimetry
05. Estimation of terbutaline in Tablets by colorimetry
06*. Estimation of salbutamol sulphate in tablets by colorimetry
07. Estimation of isoxsuprine HCl in tablets.
08*. Estimation of salbutamol sulphate with Diazo Dapsone reagent
09*. Estimation of terbutaline sulphate with Diazo Dapsone reagent
10. Estimation of isoxsuprine HCl in tablets by colorimetry
11. Estimation of analgine in tablets by colorimetry
12. Estimation of ampicillin in capsules by colorimetry
13. Estimation of metoclopramide HCl in injections by colorimetry.

II. U.V.Spectrophotometry

14. Estimation of paracetamol in tablets by U.V.method.
15. Estimation of ciproflaxacin HCl in tablets by U.V.method

III. Nephelometry

16*. Estimation of sulphates by nephelometry

IV. Potentiometry

17*. Titration of strong acid with a strong base
18. Determination of dissociation constant of weak acid

V. Complexometry

19. Determination of hardness of tap water

VI. Chromatography

20. Identification of aminoacids by paper chromatography
21. Identification of aminoacids by TLC

VII. Karl Fisher Titration

22*. Determination of moisture content by KFR

TEXT BOOKS :

01. Quantitative Pharmaceutical Chemistry by Jenkins
02. A Text Book of Pharmaceutical Analysis by K.A.Connors.
03. Instrumental Methods of Analysis by H.H.Willard.
04. Modern methods of Pharmaceutical Analysis by R.E.Schirmer
05. Instrumental methods of chemical analysis by B.K.Sharma
06. Instrumental methods of chemical analysis by G.R.Chatwal.
07. Practical Pharmaceutical Chemistry by Becket and Stenlake
08. Organic spectroscopy by William Kemp
09. Pharmaceutical Drug Analysis by Ashuthosh Kar.

IV/IV. B.PHARMACY (7th Semester)

MODEL QUESTION PAPER

PHARMACEUTICAL ANALYSIS - II (Theory)

Time : 3 hours Max.Marks : 80

SECTION - A

Answer any FOUR questions (4 x 10 = 40 marks)

1. Explain Beer-Lambert's law and discuss about the deviations from Beer's law
2. Explain the principles of polarography ? Write the construction and working of a instrument used in polarography.
3. Explain detectors used in gas chromatography with a neat diagram.
4. Write the instrumentation of HPLC with a neat diagram.
5. What is differential thermal analysis ? Discuss the factors affecting DTA curve.
6. Explain the instrumentation of mass spectrometer with a neat diagram.

SECTION - B

Answer any TEN questions (10 x 4 = 40 marks)

7. Mention the different types of electronic transitions observed in organic molecules.
8. Write the principle involved in fluorimetry
9. Give the principle involved in potentiometry
10. Mention the applications of conductometry
11. Write the adsorbants and spray reagents used in TLC.
12. Write the methodology for paper chromatography.
13. Write advantages of HPTLC over TLC
14. Mention briefly process involved in electrophoresis.
15. List out the applications of radioimmuno assay in pharmaceutical analysis
16. Write the theory involved in nuclear magnetic resonance spectroscopy
17. What is the principle involved in ESR
18. Write the theory involved in XRD analysis

IV/IV. B.PHARMACY (VIIth Semester)

MODEL QUESTION PAPER (Practicals)

706 PHARMACEUTICAL ANALYSIS-II

Time : 6 hours Max.Marks : 80

1.	Synopsis	:	10 Marks
2*.	Major Experiment	:	35 Marks
3.	Minor Experiment	:	20 Marks
4.	Viva-Voce	:	15 Marks

		Total :	80 Marks

IV/IV. B.PHARMACY (7th Semester)

707 INDUSTRIAL MANAGEMENT AND PHARMACEUTICAL MARKETING (50 hrs.)

Unit : 01

Elements of Organization and Management : Functions of management

Unit : 02

Plant location and lay-out of an industry : various factors affecting locational aspect, layout of building and equipment product lay-out v/s process layout, drug store location and selection of premises, drug store management.

Unit : 03

Production planning and Control : Scientific purchasing, quality control, problems of productivity, stores organization, location of stores, receiving, inspection of materials, issue from the store, control of stores and stocks, Store Accounting and Records.

Personnel management : Selection, Appointment, training, transfer, Promotion, demotion policies, remuneration, job evaluation , human relations.

Unit : 04

Sales organisation : Market, definition–Determent approaches to the study of marketing, institutional approach, Market planning – Product planning, method of marketing, wholesale retailers, functional approach, cost and efficiency in marketing commodity approach.

Distribution polices : pharmaceutical product marketing, sales promotion policies-Detailing to physician, professional persons, sampling, window and interior display, product advertising , sales promotion, publicity.

Unit : 05

Elementary Industrial Accountancy : Elements of Double entry book Keeping, Books of Accounts-Journal and ledger, cash book. Balance sheet, Profit and Loss Account, Principles of Costing and Estimating.

Unit : 06

Regulatory affairs :

(a) Schedule M of Drugs and Cosmetics act
(b) Drug Development Stages - NDA and NADA filing
(c) ICH guidelines - Introduction.

TEXT BOOKS :

01. Production Management by K.Aswathappa.
02. Marketing Management by Sherlekar.
03. Drug Store Management by Mahesh
04. Pharmaceutical Production and Management by C.V.S.Subrahmanyam
05. Advanced accounts by M.C.Shukla

IV/IV. B.PHARMACY (7th Semester)

MODEL QUESTION PAPER **(Theory)**

INDUSTRIAL MANAGEMENT

Time : 3 hours Max.Marks : 80

SECTION-A

Answer any FOUR questions (4 X 10 = 40 marks)

1. Explain the elements of organization.
2. What are the factors that affect the plant layout ?
3. Discuss various methods of selection. Explain the job evaluation methods suitable for pharmaceutical industry.
4. Explain about sales promotion policies
5. Write the importance and method of preparation of Balance sheet.
6. Discuss about ICH guidelines in detail.

SECTION - B

Answer any TEN questions (10 X 4 = 40 marks)

1. Explain about any two functions of management
2. Write about personal management
3. Draw layout for parenterals manufacturing.
4. Write a note on drug store management.
5. How materials are issued from the store ?
6. How the records are maintained in the store ?
7. Write a short notes on method of marketing .
8. Write the differences between wholesale marketing and retail marketing
9. Write a note on journal
10. What is cash book and what are the diffrerent forms of it ?
11. Write a short notes on schedule “M”
12. How the NDA filling was carried for a drug ?