SRI VENKATESWARA UNIVERSITY::TIRUPATI
S.V.U.COLLEGE OF SCIENCES
DEPARTMENT OF BIO-CHEMISTRY
(Revised syllabus for regular students those who study in S.V.U. College (Campus), Tirupati)
(with effect from the batch of students who admitted during the academic year 2015-16)

M.PHARMACY

(CHOICE BASED CREDIT SYSTEM)
SCHEME OF INSTRUCTION AND EXAMINATION

Semester	Course Code	Title of the Course	Core /Elective	No.of credits	Internal Marks	Semester end marks	Total Marks
First Semester							
Paper-1	MPH 101	Modern Analytical Techniques	Core	4	30	70	100
Paper -2	MPH 102	Bio Statistics	Core	4	30	70	100
Paper-3 (Pharmacology)	MPH 103 A	General & Systemic Pharmacology	Elective	4	30	70	100
(Pharmaceutics)	MPH 103 B	Advanced Pharmaceutical Technology	Elective	4	30	70	100
Paper-4 (Pharmacology)	MPH 104 A	Clinical Pharmacology & Toxicology	Elective	4	30	70	100
(Pharmaceutics)	MPH 104 B	Advanced Pharmaceutics	Elective	4	30	70	100
Paper-5	MPH 105	PRACTICAL-I	Core	2			100
Paper-6	MPH 106	PRACTICAL-II	Core	2			100
Second Semester							
Paper-1	MPH 201	Bio-Pharmaceutics& Pharmacokinetics	Core	4	30	70	100
Paper-2	MPH 202	Drug Regulatory affairs	Core	4	30	70	100
Paper-3 (Pharmacology)	MPH 203 A	Molecular Pharmacology	Elective	4	30	70	100
(Pharmaceutics)	MPH 203 B	Industrial Pharmacy	Elective	4	30	70	100
Paper-4 (Pharmacology)	MPH 204 A	Methods in Drug Evaluation	Elective	4	30	70	100
(Pharmaceutics)	MPH 204 B	Process Validation & CGMP	Elective	4	30	70	100
Paper-5	MPH 205	PRACTICAL-I	Core	2			100
Paper-6	MPH 206	PRACTICAL-II	Core	2			100
Third Semester							
Paper-1	MPH 301	Mid-Term Evaluation of Research paper.	Core	4			100
Fourth Semester							
Paper-1	MPH 401	Project thesis submission	Core	12			200

IA: Internal Assessment for Non-CBCS Students 20 80 100

FIRST SEMESTER

Paper-1(MPH 101): Modern analytical techniques

UNIT- I

Thermal methods: Principle,Instrumentation involved in DSC. Glass transition temperature. Sample preparation. Gases used in this method. Plotting graphs of DSC.Interpretation of Graphs of DSC. Applications of DSC. X-ray crystallography: Generation of X-rays. Introduction.Elementary crystallography, miller indices,X-ray diffraction,Bragg's law,X-ray powder diffractometer, sample preparation.UV-Visible spectroscopy: Electromagnetic spectrum. Chromophores and their interaction with electromagnetic radiation.Absorption spectra of organic compounds and its utilization in quantitaive and qualitative analysis of drugs. Instrumentation and working of various types of UV-Vis spectroscopes. Derivatisation spectrophotometry. Shifts and their effects. Solvent effects.

UNIT- II

Chromatographic techniques: Liquid Chromatography: Principle involved in HPLC.Instrumentation in HPLC, analytical, preparative and micropore columns,normal and reverse phase packing materials,reverse phase HPLC. Column selection,mobile phase selection,efficiency parameters,resolution, detectors in HPLC.Comparision of sensitivity,selectivity and field of applications of these detectors. HPTLC:Principle,Instrumentation and applications.

Gas chromatography: Principle involved in GC. Instrumentation GC. Columns in GC.Sensitivity.Applications of GC. GC coupled with Mass spectroscopy.

UNIT- III

Nuclear Magnetic resonance spectroscopy: Fundamental principles of NMR(magnetic properties of nuclei, applied field, precissional frequency, absorption and transition frequency). Chemical shift,isotopic nuclei,reference standards.

Proton magnetic resonsnce spectroscopy: Continous wave NMR, Relaxation,Pulsed Fourier transform spectroscopy,Rotating frame of reference. Instrumentation and sampling. Chemical shift, simple spin coupling.Protons in oxygen,nitrogen,sulfur,chlorine,bromine or iodine nuclei. Chemical shift equivalance.Magnetic equivalance.Nuclear Overhauser effect difference spectrometry.Decoupling.

^{13}C NMR: chemical shift equivalance. Chemical shift and chemical classes. ^{13}C-^{1}H coupling. DEPT. Quantitaive analysis.Correlation spectrometry(COSY): Theory.^{1}H-^{1}H COSY. ^{1}H-^{13}C COSY:HECTOR. Proton detected HECTOR:HQMC. Proton detected long range ^{1}H-^{13}C heteronuclear correlation:HBMC and short range ^{13}C-^{13}C Correlations:INADEQUATE. Gradient field NMR.Relayed coherence transfer:TOCSY. 2D and 3D NMR.

UNIT- IV

Infrared spectroscopy: FT-IR spectrometer(interferometer). Influence of substituents,ring size, hydrogen bonding, coupled interactions, vibrational coupling and field effects on frequency. Instrumentation, Sample handling. Interpretation of spectra.Characteristic group absorptions.Transparent regions of solvent and mulling oils. Applications. Qualitative interpretaion of I.R.Spectra. Mass spectrometry: Basic principle and brief outline of instrumentation and working. Recognition of molecular ion peak: Useful ionisation techniques,metastable ions,fragmentation process,basic fragmentation types and rules, factors influencing fragmentation,fragmentation associated with various functional groups.Chemical ionisation mass spectrometry: FAB mass spectroscopy.

Books recommended:

1. Instrumental methods of chemical analysis by H.Kaur(Pragati prakashan, meerut)
2. Instrumental methods of chemical analysis by G.Chatwal and S.Anand(Himalaya Publishing Home, Delhi)
3. Instrumental methods of chemical analysis by B.K.Sharma (Goel Publishing Home, Meerut.) Basic Concepts in Statistics by L Tatto W.Kemp, "Organic spectroscopy". 4. Production and operation management by P Ramamurthy 5. Probability and Statistics by R Murray
6. Hand book of modern pharmaceutical analysis by Satinder Ahuja, Stephen scypinski
7. Robert M.Silverstein, "Spectrometric Identification of Organic compounds".Wiley

PAPER-II (MPH102) : BIO-STATISTICS

UNIT- I

A study of the following with reference to Pharmaceutical Sciences Definition of Statistics: Concepts, relevance and general applications of statistics in pharmaceutical sciences. Collection, Classification, presentation, analysis and interpretation of data. Definition and concept of Degrees of freedom, precision, accuracy, mean error, relative error, significant numbers Scales of measurement (nominal, ordinal, interval, ratio)Types of variables- Continous, discrete, dependent and independent variables. Types of series-Simple, continuous and Discrete.Definitions, Concept, Applications of merits and demerits of mean, median, modeVariability: Types of measures of variability- Range, Quatrile deviation, Percentile deviation, Mean deviation, standard deviation, relative standard deviation, variance, coefficient of variation, skewness, kurtosis.

UNIT- II

Normal distribution: Concept and properties, Sampling distribution, Standard error, Confidence interval and its applications in interpretation of results. Normal probability curve. Concept, applications, properties, calculations involved in correlation (**Pearson's correlation coefficient, Spearman's rank correlation coefficient**) and regression (linear regression, least square method).

Probability: Definitions (Random event, Elementary event, Exhaustive event, mutually exclusive events, complementary events, independent events, classical and modern definitions of probability, random variable.)

Addition theorem, Multiplication theorem, Baye's theorem.

UNIT- III

Probability distributions such as normal, binomial and poisson distributions. Sampling distribution, standard error, confidence limits.

Elements of sampling theory: Definitions and concepts of population, sample, discrete variable, continuous variable, different sampling methods.

Fundamentals of Testing of hypothesis: Definition and concept of null hypothesis, alternate hypothesis types of error(Type I, Type II), level of significance, criterion value, Parametric and non Parametric tests, P value and its interpretation, T-test, , Statistical significance and clinical significance.

UNIT- IV

Design of experiments: Factorial design of experiments. Significance of statistical methods:

Parametric tests: Z-test, students T test: paired and unpaired. F-Test, ANOVA, Multiple ANOVA.

Non-Parametric tests: χ2-test, Fishers Exact test, McNemars Test, Wilcoxon Test, Mann-Whitney U test.

Optimisation, Response Surface Methodology, Artifitial Neural Networks.

Applications of statistical methods in pharmacy.

Recommended Books:

1.Comprehensive Statistical Methods, by P.N.Arora, Sumeet Arora, and S. Arora (S. Chand & company)
2. Miller & Freund's Probability and statistics for engineers by Richard A. Johnson, (Pearson Education Publishers)
3.Statistics – Theory, Methods and Application by DC Sancheti and VK Kapoor()(Sulthan and chand&sonsPublishers)
4. Pharmaceutical Statistics by S. Bolton
5. Biostastics and computer applications by G.N.Rao and N.K Tiwari published by pharma book syndicate.

PAPER-III (MPH 103A): ADVANCED PHARMACEUTICAL TECHNOLOGY (Pharmacology)

UNIT – I

Drug Absorption, Drug distribution, Drug metabolism, Drug Elimination, Bioavailability and bioequivalence.

UNIT – II

Neuotransmission in CNS and ANS,.Drug acting on CNS: Sedatives & Hypnotics, General anesthetics, Non steroidal anti inflammatory drugs, Opiod analgesics, Antipsychotic drugs, anti anxiety drugs, antidepressant drugs, CNS Stimulants, Antiepileptics drugs, Antiparkinsonism drugs. Drug acting on ANS: Cholinergic drugs, Anticholinergic drugs, Adrenergic drugs, antiadrenergic drugs, Neuromuscular blocking agents.

UNIT – III

Drugs acting on CVS: Antiarrythmic drugs, Antianginal drugs, Antihypersensitive drugs, Drug therapy in congestive cardiac failure.

Drugs acting on GIT: Anti ulcer drugs, Emetics, Anti emetics.

Drugs acting on Respiratory System: Anti asthmatic drugs.

Drugs acting on uterus: Uterine stimulants, Uterine relaxants.

UNIT – IV

Drugs acting on Kidney: Diuretics, Antidiuretics.

Chemotherapy of : Tuberculosis, Leprosy, Malaria, Amoebiasis, Cancer.

Antidiabetic drugs, Anti thyroid drugs.

References:

1.The Pharmacological basis of therapeutics by Joel G. Hardman, Lee E. Limbird and Alfred Goodman Gilman
2. Principles of Medicinal Chemistry by William O. Foye, Tomas L. Lemke and David A. Williams
3. Pharmacology by H.P. Rang, M.M. Dale, J.M. Ritter & P.K. Moore 4. Essentials of Pharmacotherapeutics by F.S.K. Barar

Paper-3(MPH 103 B): Advanced Pharmaceutical Technology

Unit :I

Drug Targeting Principles: Targeting , Principles and its importance in therapeutics. Methods in drug targeting. Advantages and disadvantages of targeting. Protein and peptide based drug delivery systems.

Carrier based drug delivery: Principles, formulation and evaluation of micro particulate drug carriers such as niosomes, resealed erythrocytes, monoclonal antibodies ,Cell ghost and cell ghosts. **Genetic vaccines:** A role of liposomes. Preparation and evaluation of liposomes.

Unit :II

Transdermal drug delivery: Theory, formulation and product evaluation.

Implants: Types of implants,Osmotic pumps,design and evaluation methods.

Inserts: Types of inserts,Design and evaluation methods.

Nano particles: Nanocapsules preparation , characterisation and therapeutic applications.

Polymeric nanoparticles as drug carriers. Dendrimers as nanoparticulate carriers.

Magnetic nanoparticles and its applications.Solid Lipid nanoparticles.

Unit :III

Theory of Controlled release: Fundamental Concepts in controlled release. Factors influencing the kinetics of solute release. Zero Order Kinetics. Theory of diffusion,release and diffusion of drugs from polymers, Mechanism and Kinetics. Evaluation of controlled drug delivery systems.

Unit :IV

Microencapsulation. Biodegradable polymers, non-degradable polymers, natural polymers and hydrogels.
Bio-adhesive drug delivery systems,Mucosal drug delivery systems like Nasal, ocular etc.,
Diffusion controlled Matrix systems, Erodible systems,Osmotic drug delivery,Oral controlled release drug delivery.

References:

1. The theory and practice of Industrial Pharmacy by L Lachman 2. Modern pharmaceutics by Banker
3. Dispersed system vol 1,2,3 by Lachman 4. Mathowiz,Encyclopedia of Controlled Drug delivery.
5. Agis Kydonieus, Treatise on controlled drug delivery. 6. Alfred Martin, Essential of Physical Pharmacy.

Paper-4(MPH 104A): Clinical Pharmacology

UNIT – I

Pathophysiology and treatment of following disorders like schizophrenia, Depression, Anxiety, Epilepsy,, Alzerimer's and Parkinsonism.

UNIT – II

Pathophysiology and treatment of CVS disorders like congestive cardiac failure, hyperlipidemia, angina & myocardial infraction, Atherosclerosis, Arrhythmias, Hypertension.

UNIT – III

a) Pathophysiology and treatment of immunological disorders like Hypertensive reaction, Asthma, Inflammation, Rheumatoid arthritis, gout.

b) Pahtophysiology and treatment of adrenal gland disorders, Thyroid and pancreas disorders, & menstrual disorders.

c) Drug Therapy in infectious diseases and urinary tract infections, Tuberculosis, Leprosy and Pathophysiology and treatment of cancer.

UNIT – IV

a) Toxicology & clinical Pharmacokinetics, ADR, Drug interactions, TDM, theory metal poisoning etc.

b) Drug therapy in Geriatrics, Pediatrics and Pregnancy and lactation.

References:

1. Clinical Pharmacy and Therapeutics by Roger Walker and Clive Edwards
2. Clinical Pharmacy by D.R. Laurence, P.N. Bennett and M.J. Brown 3. Clinical Pharmacology by Herphendol

Paper-4(MPH 104B): Advanced pharmaceutics.

Unit I

Diffusion and dissolution.

a) Diffusion: Measurement of diffusion coefficients. Ficks Laws of Diffusion. Hixon-Crowells Cube root Law. Higuchi Model of Drug Release.

b) Dissolution: Basic theories of dissolution. Physiological parameters relevant to dissolution testing. Development of dissolution tests based on GIT physiology. Dissolution method development. Invitro dissolution testing models and compendial dissolution testing requirements. Fitment of dissolution data into various mathematical equations,f1 and f2 test's. Sink conditions and its importance.Invitro-invivo corelation and its interpretation.

Unit II

Equilibrium Phenomenon.

a)Solutions of electrolytes and Ionic equilibrium: Strong acids and bases,Monoprotic weak acids and bases,Polyprotic weak acids and bases,Sparingly soluble salts.

b)Solubility and solubilization technology: Importance of solubility,Phase solubility analysis..Factors affecting solubility. Applications of solubilization.

c) Solutions and distribution: Solutions of solids and non-volatile liquids in liquids.
Solutions of volatile liquids in liquids.Solutions of gases in liquids(Henry's law). Colligative properties.Distribution law(partition coefficient).

Unit III

Polymer Science.

Classification of polymers. Molecular weight determination and molecular weight distribution of polymers. Characterization of polymers by viscosity method, Osmometry,light scattering,Size exclusion chromatography etc,. Drug-polymer compatibility studies by DSC, IR, XRD and Biological evaluation.

Unit IV

Stability studies.

Principles and methods,ICH guidelines,Protocols and testing programs for solid, liquid and semisolid dosage forms. Methods of stabilization.Methods of accelerated stability testing in dosage forms.Stability testing of light sensitive and water sensitive drugs. working principle of drug stability chambers.

Books recommended:

1) Cherng-Ju Kim , Advanced Pharmaceutics,Physicochemical principles. CRC press.
2) Alfred Martin, Essentials Of Physical Pharmacy,Walter and Kluwers.
3) ICH guidelines.
4) J.T.Cartensen, Drug Stability:Principles and practices.

Paper 5(MPH 105): Practical I

Paper 6(MPH 106): Practical II

Second Semester

Paper 1(MPH 201): Bio-Pharmaceutics& Pharmacokinetics

Unit I

Foundations of pharmacokinetics: The Birth of compartments: The Rutherford equations, The Benke Equations, The Toerell Equations and Tracer kinetics.Compartmental modelling. Basics of Model building. One Compartmental Model. Two Compartmetal Model. Multi Compartmental Model.

Unit II

Physiological Pharmacokinetic modelling: Blood flow rate limited models, blood clearance, lung clearance, apparent volume of distribution, non-linear disposition. Membrane limited models. Relationship between Physiologically based models and usual compartment models. Non-compartmental analysis: Non compartmental analysis based on statistical moment theory. Bioavailability, clearance, half-life, absorption kinetics, apparent volume of distribution etc., Steady state.

Unit III

Non-Linear Pharmacokinetics: Michaelis Menten Kinetics, Estimation of Km and Vm, Clearance, Half Life, Volume of distribution, steady state, bioavailability etc., Urinary excretion process and other non-linear elimination process. Problems in quantifying non-linear pharmacokinetics.

Multiple Dosing: IV, IV infusion, First order absorption and determination of PK parameters from multiple dosing data

Unit IV

Kinetics of Pharmacologic response:

a) Kinetics of directly reversible pharmacologic response.

b) Kinetics of indirect pharmacologic response.

c) Kinetics of irreversible pharmacologic response.

Applications of PK principles: Multiple dosing, Dose adjustments in Renal failure, Hemo dialysis, Methods for determination of Individual Patient parameters. Assessing Bio Availability of Drug Delivery systems.

Modelling in Pharmacodynamics: Classical Pharmacodynamics,Non-Classical Pharmacodynamics.

Books recommended:

1) Hedaya, Basic pharmacokinetics. 2) Milo Gibaldi, Pharmacokinetics.
3) J.C.Wagner, Fundamentals of Clinical Pharmacokinetics. 4) Bert.N.Ladu, Fundamentals of drug metabolism and disposition.

Paper 2(MPH 202): Drug Regulatory affairs

Unit I

Regulatory requirements involved in the preformulation studies, solid, liquid and semi-solid dosage forms, controlled release preparations, ocular preparations as per the European community, United States and Indian regulatory authorities. Regulatory requirements for manufacturing process, equipment and document. Validation of manufacturing process, equipment, documentation, inspection requirement of regulatory guidelines for active ingredients, data requirement for new drug, international aspects of excipients, approval as per guidelines of all the territories.

Unit II

Stability testing: ICH guidelines and WHO guidelines and stability protocols for dosage forms. Regulatory affairs in respect of residual solvents as per the ICH guidelines. Analytical method validation, pharmacokinetic and toxico kinetic validation.

Unit III

New Drug Application: Steps involved in the development of new drug. New drug applications as per WHO guidelines and abbreviated NDA. Requirement and guidelines on clinical trials.

Clinical trials: Definition, phase I, phase II phase III, phase IV studies, design documentation, presentation and interpretation, statistical analysis of clinical data.

Unit IV

Intellectual Property Rights: Introduction, purpose, international scenario and Indian scenario ,guidelines as per European community, United states and Indian regulatory authorities ,documentation, presentation and application.

References:

1.Drug stability by J.CARSTENSEN 2.Quality Assurance of Pharmaceutics Vol I & II of WHO publications, 1999.
3.Pharmaceutical dosage forms and drug delivery systems by Howard Ansel et al, 4.Drug Regulatory affairs by M ArthurHorowitz

5.Guide book of Regulatory submissions by Sandy Weinberg

Paper-3(MPH 203A): Molecular Pharmacology

UNIT – I

Drug Receptor theory, concept of Receptor, Theories of drug receptor interaction, Receptor polymorphism, Dimerization and importance in Drug design.

UNIT – II

a) Endothelin receptors, agonist and antiagonist and their importance in various cardio vascular diseases.
b) GPCR- Structure & function, signal transduction and terimimination of receptor activity.
c) Adrenergic receptor classifications, agonists and antiagonist.
d) cholinergic receptors classifications, agonists and antiagonist.
e) Pharmacology of NMDA receptors.
f) Pharmacology of 5HT receptors, classification & role of 5HT agonist and antagonist in various disorders.
g) Pharmacology GABA receptors.
h) Mol. Mechanism of PPAR g agonist.
i) Pharmacology of voltage-gated ion channels.

UNIT – III

a) Role of Nitric oxide in various physiological functions and its importance in Hypertension, Angina and Erectile dysfunction.
b) Lipid peroxidation, free radicals & role of antioxidants in various diseases
c) Leptin in the pathogenesis & treatment of obesity.

UNIT – IV

Immunopharmocology

a) Role of cytokines, Prostaglandins, bradykinins in various immunological & inflammatory disorders.
b) Molecular mechanisms of immune disorders with references to AIDS
c) Molecular mechanism of action of immunomodulation and immune suppressive.

References:

1. Drug discovery and evaluation by Vogel 2. Screening Methods in Pharmacology by Robert A.Turner
3. I.P. 4. Goodman and Gillman's The Pharmacological basis of therapeutics 10th edition.
5. Pharmacology 5th edition by H.P. Rang M.M. Dale, J.M. Ritter, P.K.Moore 6. Basic and clinical pharmacology 8th edition edited by Bertram G. Katzung.7. Essentials of pharmacotherapeutics by F.S.K. Barar 8. Clinical Pharmacology by Molmon and Morelli.
9. Principles of drug action by Golstein, Aranow and Kalman. 10. Reviews of Physiology, Biochemistry and Pharmacology.

Paper-3(MPH 203B): Industrial Pharmacy

Unit I

Preformulation studies in Pharmaceutical product development-Factors involved in Formulation. Physical characteristics- Particle size, polymorphism, crystal form, solubility, Interfacial tension, Salt formation, pKa and solubility partition coefficient, crystal morphology, polymorphism, wetting of solids, flow characteristics, compressibility and Partition coefficient. Chemical Characteristics- Degradation: Hydrolytic, oxidative, reductive and photolytic, Drug – Excipient compatibility studies. Biopharmaceutical Characteristics- Lipid solubility, dissociation constant, dissolution rate, drug stability in G.I.tract, complexation.

Unit II

Compaction and compaction: Compaction of powders with particular reference to distribution and measurement of forces within the powder mass undergoing compression. Effect of particle size,moisture content,lubrication etc., on the strength of the tablets.

Unit III

Improved tablet production: Tablet production process, unit operation improvements, granulation and pelletization equipments, granulators, spheronizers and drying equipments, Coating technology: Process, equipments, particle coating, fluidized bed coating, and application techniques. Capsule production: Production process, improved capsule manufacturing and filling machines for hard and soft gelatin capsules. Layout and problems encountered.

Unit IV

Parenteral production: Area planning and environmental control, wall and floor treatment, and machineries, change rooms, personnel flow, utilities and equipment location, engineering and maintenance. Lyophillization technology: Principles, process and freeze drying equipments.

References:

1. Pharmaceutical production facilities by Cole 2. Pharmaceutical dosage forms (tablets) vol-1, 2, and 3 by Haliberman
3. Encyclopaedia of pharmaceutical technology set 2nd end 2002 by Swarbrick 4. Pharmaceutical Engineering by K Sambamurthy.
5. The theory and Practices of Industrial Pharmacy by Lachman and Lieberman. Pharmaceutical Product development by NK Jain.
6.Remington's Pharmaceutical Sciences, L.Wiliams & Wilkins, 21st Ed. (Vol. I & II)
7. Theory & Practice of Industrial Pharmacy by Lachman. 8. Pharmaceutics of Solids and Solid dosage forms by J. Cartensen.
9. Advances in Pharm. Sciences by Beckett. 10.Pharmaceutical Technology by Parrot.

Paper-4(MPH 204 A): Methods in Drug Evaluation

UNIT –I

a) New drug discovery process, preclinical studies

b) Guidelines and regulatory agencies – CPCSEA, OECD

C) Acute, sub acute and chronic toxicity studies, carcinogenesis and mutagenesis, Teratogenicity.

UNIT – II

a) Commonly used laboratory animals, transgenic animals, Techniques of blood collection, anesthesia, euthanasia, various routes of drug administration & maintenances & breeding of laboratory animals.

b) Evaluation of drugs cvs, respiratory, psychotropic, neurotropics, analgesic, anti inflammatory, antipyretic, immunomodulatory, anti diabetic, anti obesity, anti atheroselrerotic, aphrodisiac,antiulcer and antineoplastic agents.

UNIT – III

a) Bioassays – Methods, general principles, types and procedures involved in bioassays of ACH, histamine, insulin, oxytoxin, digoxin, d-tubocurarine.

b) General Principles of Immunoassay, ELISA.

UNIT – IV

Clinical Trails – Definition, Types, guidelines for Investigational New drug Application (IND).

References:

1. Clinical Pharmacy and Therapeutics by Roger Walker and Clive Edwards
2. Clinical Pharmacy by D.R. Laurence, P.N. Bennett and M.J. Brown
3. Clinical Pharmacology by Herfindel

Paper-4(MPH 204 B): Process Validation & CGMP

Unit I

Basic concepts of quality assurance: Requirements of cGMP/GLP. ISO 9000 series. Quality audits. Concept of Validation: Validation of manufacturing equipment and analytical equipments. Process validation in production of pharmaceuticals. Preparation of documents for NDA and export registration.

Unit II

Statistical concepts in process validation and cGMP: Precision, Accuracy and Biases. Sampling operation. Sampling plans. Operating characteristic curves. Statistical inference in estimation of hypothesis testing. Statistical procedures in assay development.

Unit III

Development of new analytical methods like, dissolution tests,assays using HPLC,GC and other chromatographic techniques and other similar tests.

Unit IV

In-Process Quality control tests for various dosage forms.

In-Process Quality control tests for packaging and labelling operations.

Books recommended:

1) S.H.Willig, GMP for phamaceuticals. 2) B.T.Loftus, Pharmaceutical process validation.
3) S.Bolton, Pharmaceutical statistics: Practical and statistical applications.
4) G.S.Banker, Modern Pharmaceutics.

Paper 5(MPH 205): Practical I

Paper 6(MPH 206): Practical II

Third Semester:

Paper-1(MPH 301): Mid-Term Evaluation of Research paper.

Fourth Semester:

Paper-1(MPH 401): Project thesis submission