SRI VENKATESWARA UNIVERSITY::TIRUPATI

S.V.U.COLLEGE OF SCIENCES

DEPARTMENT OF BIO-CHEMISTRY

(Common Syllabus for SV University College and affiliated colleges under SVU Area)

(Revised Scheme of Instruction and Examination, Syllabus etc., with effect from the Academic Years 2016-17 for I and II Semesters and 2017-18 for III and IV Semesters)

M.Pharmacy (Pharmaceutics/Pharmacology)

Choice Based Credit System (CBCS)-Syllabus: w.e.f. 2016-17.

SCHEME OF INSTRUCTION AND EXAMINATION

I SEMESTER

Semester	Course code	Title of the course	Instruction Hours/per week	No.of Credits	Internal Marks	Semester end marks	Total marks
Core Paper-1	**MPH 101A (Pharmacology)**	General &Systematic Pharmacology	6	4	20	**80**	**100**
	MPH 101B (Pharmaceutics)	Advanced Pharmaceutical Technology					
Core Paper-2	**MPH 102A (Pharmacology)**	**Clinical Pharmacology & Toxicology**	6	4	20	**80**	**100**
	MPH 102B (Pharmaceutics)	Advanced Pharmaceutics					
Core Paper-3	**MPH 103**	**Practical 1**	6	4	--	**100**	**100**
Core Paper-4	**MPH 104**	**Practical 1**	6	4	--	**100**	**100**
Compulsory Foundation Paper-5	**MPH 105**	**Modern Analytical Techniques and biostatics**	6	4	20	**80**	**20**
Elective Foundation Paper-6	**MPH 106**	**Human Values and Professional Ethics-I**	6	4	20	**80**	**20**
	MPH 107	**Comprehensive Viva**	-	**2**	-	**50**	**50**

II SEMESTER

Semester	Course code	Title of the course	Instruction Hours/per week	No.of Credits	Internal Marks	Semester end marks	Total marks
Core Paper-1	**MPH 201A (Pharmacology)**	Molecular Pharmacology	6	4	20	80	100
	MPH 201B (Pharmaceutics)	Industrial Pharmacy					
Core Paper-2	**MPH 202A (Pharmacology)**	Methods in Drug Evaluation	6	4	20	80	100
	MPH 202B (Pharmaceutics)	**Process Validation & CGMP**					
Core Paper-3	**MPH 203**	**Practical 1**	6	4	--	**100**	**100**
Core Paper-4	**MPH 204**	**Practical 1**	6	4	--	**100**	**100**
Compulsory Foundation Paper-5	**MPH 205**	**Bio-Pharmaceutics & Pharmacokinetics**	6	4	20	**80**	**20**
Elective Foundation Paper-6	**MPH 206**	**Human Values and Professional Ethics-II**	6	4	20	**80**	**20**
	MPH 207	**Comprehensive Viva**	**-**	**2**	**-**	**50**	**50**

III SEMESTER

Semester	Course code	Title of the course	Instruction Hours/per week	No.of Credits	Internal Marks	Semester end marks	Total marks
Core Paper-1	**MPH 301**	Mid-Term Evaluation of Research project	--	4	--	**200**	**200**
Open Elective to others (For other department students)	A General Pharmacology		6	4	20	**80**	
	B Industrial Pharmacy						

IV SEMESTER

Semester	Course code	Title of the course	Instruction Hours/per week	No.of Credits	Internal Marks	Semester end marks	Total marks
Core Paper-1	**MPH 401**	Project thesis submission & presentation	--	10	--	**250**	**250**
		Project Viva voce	--	2	--	**50**	**50**
Open Elective to others (For other department students)	A Molecular Pharmacology B Drug Regulatory Affairs		6	4	20	**80**	

I SEMESTER

CORE PAPER-1

MPH 101 A : GENERAL & SYSTEMIC PHARMACOLOGY

UNIT – I

Drug Absorption, Drug distribution, Drug metabolism, Drug Elimination,

Bioavailability and bioequivalence studies.

UNIT – II

Neuotransmission in CNS and ANS,

Drug acting on CNS: General anaesthetics, sedatives and hypnotoics, Opiod analgesics, NSAIDS, CNS Stimulants and depressants, Antipsychotic drugs, Antiepileptic drugs

Drug acting on ANS: Adrenergic and adrenergic blockers, cholinergic and cholinergic blockers. Autocoid pharmacology: study of mechanisms involved in the formation, release & Pharmacological actions & role of histamine, serotonin, prostaglandins and kinins.

UNIT – III

Drugs acting on CVS disorders like Cardiav arrythmias, Angina pectoris, congestive cardiac failure and Hypertension

Drugs acting on GIT: Emetics, antiemetics, Constipation, Antiulcer

drugs Antiasthmatic drugs, diuretic and antidiuretic drugs,

Antidiabetic drugs.

UNIT – IV

Antibiotics and chemotherapeutic agents used in parasitic infections like malaria tuberculosis, amoebiasis and leprosy

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
5. Principles of drug action by Golsteins, Aranow and Kalman

MPH 101 B : ADVNCED 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 microparticulate 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.

CORE PAPER-2

MPH 102 A : CLINICAL PHARMACOLOGY & TOXICOLOGY

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

MPH 102 B : 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.

CORE PAPER-3

MPH 103

Practicals related to the *two* core papers (*Two Pharmaceutics / Two Pharmacology papers*)

CORE PAPER-4

MPH 104

Practicals related to the compulsory foundation paper

COMPULSORY FOUNDATION PAPER-5

MPH 105 : MODERN ANALYTICAL TECHNIQUES AND BIOSTATISTICS

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. Gas chromatography: Principle involved in GC. Instrumentation GC.

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.

Infra red spectroscopy, Mass spectrometry: Basic principle and brief outline of instrumentation and working.

Unit IV

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

Normal distribution: Concept and properties, Sampling distribution, Standard error

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

Books recommended:

1. Instrumental Methods of Chemical analysis by Willard, Merrit and Dean (CBS Publishers)
2. Instrumental methods of chemical analysis by H.Kaur(Pragati prakashan, meerut)
3. Instrumental methods of chemical analysis by G.Chatwal and S.Anand(Himalaya Publishing Home, Delhi)
4. Instrumental methods of chemical analysis by B.K.Sharma (Goel Publishing Home, Meerut.)
5. Basic Concepts in Statistics by L Tatto
6. W.Kemp, "Organic spectroscopy".
7. Production and operation management by P Ramamurthy
8. Probability and Statistics by R Murray
9. Hand book of modern pharmaceutical analysis by Satinder Ahuja, Stephen scypinski

Robert M.Silverstein, "Spectrometric Identification of Organic compounds".Wiley

ELECTIVE FOUNDATION PAPER-6

MPH 106 : HUMAN VALUES AND PROFESSIONAL ETHICS-I

Unit I

Definition and Nature of Ethics- Its relation to Religion, Politics, Business, Law, Medicine and Environment. Need and Importance of Professional Ethics- Goals- Ethical Values in various Professions.

Unit II

Nature of Values – Good and Bad, Ends and Means , Actual and potential Values, Objective and Subjective Values, Analysis of basic moral concepts- right , ought, duty, obligation, justice, responsibity and freedom , Good behavior and respect for elders, Character and Conduct.

Unit III

Individual and Society:

Ahimsa (Non- Violence), Satya (Truth), Brahmacharya (Celibacy), Asteya (Non possession) and Aparigraha (Non- stealing). Purusharthas (Cardinal virtues) – Dharma (Righteousness), Artha (Wealth), Kama (Fulfillment Bodily Desires), Moksha (Liberation).

Unit IV

Bhagavad Gita- (a) Niskama Karma (b) Buddhism- The Four Noble Truths- Arya astanga marga, (c) Jainism- mahavratas and anuvratas. Values Embeded in various Religions, Religious Tolerance, Gandhian Ethics.

Unit V

Crime and Theories of punishment (a) Reformative , Retributive and Deterrent. (b) Views on manu and Yajnavalkya.

BOOKS FOR STUDY

1. John S Mackenjie: A manual of ethics.
2. The Ethics of Management" by Larue Tone Hosmer, Richard .D. Irwin Inc.
3. Management Ethics-integrity at work" by Joseph A. Petrick and John F. Quinn, Response Books: New Delhi.
4. Ethics in management" by S.A.Sherlekar, Himalaya Publishing House.
5. Harold H. Titus:Ethics for Today.
6. Maitra,S.K: Hindu Ethics.
7. William Lilly : Introduction to Ethics

II SEMESTER

CORE PAPER-1

MPH 201 A : 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.

MPH 201 B : 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.

CORE PAPER-2

MPH 202 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

MPH 202 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.

CORE PAPER-3

MPH 203

Practicals related to the *two* core papers (*Two Pharmaceutics / Two Pharmacology papers*)

CORE PAPER-4
MPH 204

Practicals related to the compulsory foundation paper

COMPULSORY FOUNDATION PAPER-5

MPH 205 : 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.

ELECTIVE FOUNDATION PAPER-6

MPH 206 : HUMAN VALUES AND PROFESSIONAL ETHICS-I I

Unit I

Value Educattion- Defination- relevance to present day- Concept of Human Values- self introspection-Self esteem- Family Values – Components, Structure and responsibilities of family- Neutralization of anger- Adjustability- Treats of famiy life – Status Of women in family and society- Caring for needy and elderly – Time allotment for sharing ideas and concerns.

Unit II

Medical ethics- Views of Charaka, Sushruta and Hippocratus on moral responsibility of medical practitioners. Code of ethics for medical and Health care professionals. Euthanasia, Ethical obligation to animals, Ethics issues in relation to health care professionals and patients. Social justice in health care, Human cloning, Problems of abortion. Ethical issues in genetic engineering and Ethical issues raised by new biological technology or knowledge.

Unit III

Business ethics- Ethical standards of business- Immoral and illegal practices and their solutions. Characteristics of ethical problems in management, ethical theories, causes of unethical behavior, ethical abuses and work ethics.

Unit IV

Environment ethics- Ethical theory, man and nature- Ecological crisis, Pest control, Pollution and waste, Climate change, Energy and population, Justie and Environmental health.

Unit V

Social ethics- Organ trade, Human trafficking, Human rights violation and social disparities, Feminist ethics, Surrogacy/ pregnancy. Ethics of media- Impact of Newspaper, Television, Movies and Internet.

Recommended Books

1. John S Mackenjie: A manual of ethics.
2. The Ethics of Management" by Larue Tone Hosmer, Richard .D. Irwin Inc.
3. Management Ethics-integrity at work" by Joseph A. Petrick and John F. Quinn, Response Books: New Delhi.
4. Ethics in management" by S.A.Sherlekar, Himalaya Publishing House.
5. Harold H. Titus: Ethics for Today.
6. Maitra, S.K: Hindu Ethics.
7. William Lilly: Introduction to Ethics
8. Sinha: A Manual of Ethics
9. Manu: Manu Dharma Sastra or the Institute of Manu : Comprising the Indian System of Duties: Religious and Civil (ed.) G.C. Haughton.
10. Susruta Samhita: Tr. Kaviraj Kunjalal ,Kunjalal Brishagratha, Chowkamba Sanskrit series, Vol I,II and III, Varanasi, Vol 1 OO, 16-20, 21-32 and 74- 77 only.
11. Caraka Samhita: Tr. Dr. Ram Karan Sarma and Vaidya Bhagavan Dash, Chowkambha Sanskrit Series Office , Varanasi Vol 100, 16-20,21-32 and 74-77 only.
12. Ethics: Theory and Contemporary Issues., Barbara Mackinnon Wadsworth/ Thomson Learning , 2001.
13. Analysing Moral Issues, Judith A. Boss, Mayfield Publishing Company ,1999.
14. An Introduction to Applied ethics (Ed.) John H.Piet and Ayodhya Prasad, Cosmo Publications.
15. Text Book for Intermediate logic, Ethics and Human Values , board of intermediate Education & Telugu Academic Hyderabad.

III SEMESTER

PAPER-1

MPH 301

Mid-Term Evaluation of Research Project.

OPEN ELECTIVE A: GENERAL PHARMACOLOGY

UNIT – I

Defnition of drug , pharmacology,

Different routes of drug administration, Advantages and disadvantages of routes of drug administration Neuotransmission in CNS and ANS,

UNIT – II

Factors and mechanisms of Drug Absorption , Drug distribution, Drug metabolism, Drug Elimination, Bioavailability and bioequivalence studies.

UNIT – III

Drug therapy in Geriatrics, Pediatrics and Pregnancy and lactation,

Drug acting on pancreas, adrenal gland and thyroid gland.

UNIT – IV

Toxicology & clinical Pharmacokinetics, ADR, Drug interactions, TDM,

theory metal poisoning etc

Mechanisms of different Antibiotics.

References:

1. The Pharmacological basis of therapeutics by Joel G. Hardman, Lee E. Limbird and Alfred Goodman Gilman
2. Aranow and Kalman 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 Principles of drug action by Golsteins

OPEN ELECTIVE B : 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.

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.

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.

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.

IV SEMESTER

PAPER-1

MPH 401

Project thesis submission & presentation.

Project viva voce.

OPEN ELECTIVE A: MOLECULAR PHARMACOLOGY

UNIT – I

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

UNIT – II

GPCR- Structure & function, signal transduction and terimimination of receptor activity.
Adrenergic receptor classifications, agonists and antiagonist.
cholinergic receptors classifications, agonists and antiagonist. Mol. Mechanism of PPAR g agonist. Pharmacology of voltage-gated ion channels.

UNIT – III

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

UNIT – IV

Role of cytokines, Prostaglandins, bradykinins in various immunological & inflammatory disorders.
Molecular mechanisms of immune disorders with references to AIDS

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.

OPEN ELECTIVE B: DRUG REGULATORY AFFAIRS

Unit I

Regulatory requirements involved in the preformulation studies, solid, liquid and semi-solid dosage forms, ocular preparations as per the Indian regulatory authorities.
Regulatory requirements for manufacturing process, equipment and document.
Validation of manufacturing process, equipment, 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. Analytical method validation, pharmacokinetic and toxico kinetic validation.

Unit III

New Drug Application: Steps involved in the development of new drug.
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 and Indian regulatory authorities.

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. www.fda.gov
5. Drug Regulatory affairs by M ArthurHorowitz
6. Guide book of Regulatory submissions by Sandy Weinberg

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Model Question paper

M.Pharmacy:(Pharmacology/Pharmaceutics):

Semester I/II
Title of the Paper

Time 3 Hrs **Max marks 80M**

Attempt any five from part A (5 x 4 = 20 marks) and all from Part B (4 x 15 = 60 marks)

PART A (4 x 15= 60 Marks)

1. Unit 1
2. Unit 1
3. Unit 2
4. Unit 2
5. Unit 3
6. Unit 3
7. Unit 4
8. Unit 4

PART B (4 x 15= 60 Marks)

9. Unit 1 a or b
10. Unit 2 a or b
11. Unit 3 a or b
12. Unit 4 a or b