### M.PHARMACY

**SCHEME OF INSTRUCTION AND EXAMINATION**

<table>
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<tr>
<th>Semester</th>
<th>Course Code</th>
<th>Title of the Course</th>
<th>Core /Elective</th>
<th>No.of credits</th>
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<td>General &amp; Systemic Pharmacology</td>
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**IA: Internal Assessment for Non-CBCS Students**

| 20 | 80 | 100 |
FIRST SEMESTER

Paper-I (MPH 101): Modern analytical techniques

UNIT-I

UNIT-II

UNIT-III

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)
5. Probability and Statistics by R. Murray
6. Hand book of modern pharmaceutical analysis by Satinder Ahuja, Stephen scypinski

PAPER-II (MPH 102) : BIO-STATISTICS

UNIT-I

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, Artificial 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)
4. Pharmaceutical Statistics by S. Bolton

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

UNIT – I
Drug Absorption, Drug distribution, Drug metabolism, Drug Elimination, Bioavailability and bioequivalence.

UNIT – II
Neurotransmission 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: Antidysmotics 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
4. Essentials of Pharmacotherapeutics by F.S.K. Barar

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

Unit :I


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.

Unit :III

Unit :IV

References:
1. The theory and practice of Industrial Pharmacy by L Lachman
2. Modern pharmaceuticals by Banker
3. Dispersed system vol 1,2,3 by Lachman
5. Agis Kydonieus, Treatise on controlled drug delivery
6. Alfred Martin, Essential of Physical Pharmacy

UNIT – I
Pathophysiology and treatment of following disorders like schizophrenia, Depression, Anxiety, Epilepsy, Alzerner’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) Pathophysiology 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 104A): Clinical Pharmacology

UNIT – I
Pathophysiology and treatment of following disorders like schizophrenia, Depression, Anxiety, Epilepsy, Alzerner’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) Pathophysiology and treatment of adrenal gland disorders, Thyroid and pancreas disorders, & menstrual disorders.
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a) Toxicology & clinical Pharmacokinetics, ADR, Drug interactions, TDM, theory metal poisoning etc.
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2. Clinical Pharmacy by D.R. Laurence, P.N. Bennett and M.J. Brown
3. Clinical Pharmacology by Herphendol


Unit I
Diffusion and dissolution.
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 correlation 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**


Books recommended:
3. ICH guidelines.

**Paper 5(MPH 105): Practical I**

**Paper 6(MPH 106): Practical II**

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**Second Semester**

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

**Unit I**


**Unit II**


**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.


Books recommended:
1. Hedaya, Basic pharmacokinetics.
2. Milo Gibaldi, Pharmacokinetics.

**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**


**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.
3. Pharmaceutical dosage forms and drug delivery systems by Howard Ansel et al.
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 antagonist and their importance in various cardio vascular diseases.
b) GPCR- Structure & function, signal transduction and termination of receptor activity.
c) Adrenergic receptor classifications, agonists and antagonist.
d) Cholinergic receptors classifications, agonists and antagonist.
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
Immunopharmacology
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
6. Essentials of pharmacotherapeutics by F.S.K. Barar
7. Clinical Pharmacology by Molmon and Morelli.
8. Principles of drug action by Golstein, Aranow and Kalman

Paper-3(MPH 203B): Industrial Pharmacy

Unit I

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

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. Lyophilization 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. Encyclopedia of pharmaceutical technology set 2nd end 2002 by Swarbrick
5. The theory and Practices of Industrial Pharmacy by Lachman and Lieberman.
6. Remington’s Pharmaceutical Sciences, L.Wiliams & Wilkins, 21st Ed. (Vol. 1 & II)
7. Theory & Practice of Industrial Pharmacy by Lachman.
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 atheroslerotic, aphrodiasiac,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

Unit II

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 pharmaceuticals. 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-I(MPH 301): Mid-Term Evaluation of Research paper.

Fourth Semester:
Paper-I(MPH 401): Project thesis submission