GOA UNIVERSITY

P.O TALEIGAO PLATEAU

GOA – 403 206

SYLLABUS FOR M. PHARM (PHARMACOLOGY)

APPROVED BY THE BOARD OF STUDIES

FOR THE ACADEMIC YEAR **2014-2015**

PURPOSE

To train a Pharmacist who shall:

- Display talent and competence, backed by reasoning ability to achieve standards in manufacture of quality products in pharmaceutical industry and to lead a company towards achieving global standards through proper inprocess standards.
- Exercise a sense of power and confidence to focus attention on irregularities, errors, exceptions and deviations from standards.
- Articulate a compelling vision to the future by encouraging and implementing ideas, procedures and techniques by thinking out of the box.

PRE-REQUISITES

A candidate who has passed the B. Pharm. Examination of Goa University or an examination of any other Indian University recognized as equivalent thereto with at least **50%** marks in aggregate in one and the same sitting and with **GPAT (Or any other qualifying examination specified by AICTE/PCI/Govt. of Goa)** be admitted to the M. Pharm. Course (partly by papers and partly by thesis) in one of the specialization of Pharmacy mentioned below in which he registers as a post-graduate student. However, if the **GPAT** candidates are not available then the vacant seats shall be filled by admitting the candidates without **GPAT** but who have passed the **B. Pharm**. Examination with at least **50%** marks in aggregate in one and the same sitting

GOA UNIVERSITY

Syllabus of M.PHARM (PHARMACOLOGY)

(2 years course)

SEMESTER I

Sr. No	Code	Subject	Hr/Semester 3hr/Week	Marks	
				Internal Examination	Final Examination
1	MP001T	Modern Pharmaceutical Analysis (Theory)	54	30	70
2	MPPO101T	Drug Screening-I (Preclinical Studies) (Theory)	54	30	70
3	MPPO102T	Molecular Pharmacology (Theory)	54	30	70
4	MPPO103T	Advanced Pharmacology I (Theory)	54	30	70
5	MP001P	Modern Pharmaceutical Analysis (Practical)	72 (6 hr)	30	70 (6hr)
6	MPPO101P	Drug Screening-I (Preclinical Studies) (Practical)	72 (6 hr)	30	70 (6hr)
7	MP002	Seminar Evaluation including Journal Club	1 hr/week	50	Nil
8	MP003	Entrepreneurship Management	2 hr/week	50	Nil
		TOTAL – 700		**280**	**420**

SEMESTER II

Sr. No	Code	Subject	Hrs/Semester 3 hr/Week	Marks	
				Internal Examination	Final Examination
1	MPPO201T	Drug Screening II (Clinical Studies) (Theory)	54	30	70
2	MPPO202T	Clinical & Hospital Pharmacy (Theory)	54	30	70
3	MP004T	Research Methodology (including Biostatistics & Computer Applications) (Theory)	54	30	70
4	MPPO203T	Advanced Pharmacology II (Theory)	54	30	70
5	MPPO202P	Clinical & Hospital Pharmacy (Practical)	72 (6 hr)	30	70 (6hr)
6	MPPO203P	Advanced Pharmacology II (Practical)	72 (6 hr)	30	70 (6hr)
7	MP006	Seminar Evaluation including Journal Club	1 hr /week	50	Nil
8	MP007	Field Activity and Soft Skills	2 hr/week	50	Nil
		TOTAL – 700		**280**	**420**

Scheme of Examination

Sr. No.	Synopsis	Major Expt.	*Minor Expt.	Viva-voce	Total
1.	10	30	20	10	70

SEMESTER –III & IV

Dissertation	Evaluation
The examiners will jointly assign the mark for The allotment of marks shall be as under: 1. Methodology 2. Scientific Contents 3. Presentation / Communication 4 .Results & Discussion 5. References/Grammar 6. Viva -voce. **Total**	 25 50 50 50 25 50 **250**
Professional Training*	50

******A candidate shall be required to undergo professional training of four weeks in any industry/research centre/hospital /community pharmacy and submit a completion certificate along with a report for evaluation.*

SEMESTER -I

MODERN PHARMACEUTICAL ANALYSIS

(Theory: 54 Hr – 18 weeks)

Semester - I

Subject Code: MP001T | Sessional exam: 30

Period/Week : 3 hr | Uni. Examination: 70

Examination : Theory | Exam Duration : 3 hr

Importance of the following analytical techniques to be elaborated along with their applications in Pharmaceutical Sciences

Sr. No	TOPICS	NUMBER OF HOURS
1	**UV-Visible Spectroscopy**: a) Theory of Interaction of Electromagnetic Radiation with matter and effects, Spectra of isolated Chromophores, Absorption spectrum and its application in qualitative and quantitative studies of drugs, Types of Shifts and their interpretation, Solvent and Substituent effects, b) Woodward-Fischer Rules in predicting absorption maxima in conjugated systems. c) Multicomponent analysis, Derivative spectroscopy,	**3** **1** **2**
2	**Infra-Red Spectroscopy**: a) Theory, Application of Hookes Law in predicting IR absorption frequencies, Force constant, Effect of Mechanical Coupling/ Interaction, Fermi Resonance on absorption frequency, b) Sample preparation and handling, FT-IR and ATR, c) Rules for IR spectra Interpretion, Interpreting spectra of organic compounds and study of spectra in pharmacopoeia, use of IR in polymorph studies.	**3** **2** **3**
3	**Nuclear Magnetic Resonance Spectroscopy:** a) ^{1}H NMR, Chemical Shift, Inductive effect, Anisotropic effect, δ scale, Spin-spin coupling, Use of Coupling Constant. b) Instrumentation – NMR spectrometer c) Principles of ^{13}C spectroscopy, Decoupling Techniques, Nuclear Overhauser Effect, Shift reagents, d) Introduction to 2-D NMR techniques Applications of NMR technique in Pharmaceutical and Chemical sciences – Fundamental rules for interpreting NMR spectra (Low resolution and High Resolution) with suitable examples	**3** **1** **2** **1** **3**

Sr. No	TOPICS	NUMBER OF HOURS
4	**Mass spectrometry**: a) Theory and Principles, b) Instrumentation – Ionization sources – Hard and Soft techniques – their relative applications, Analyzers – Single and Double Focus, TOF, Quadrupole, FT-ICR, Ion Trap; Tandem Mass spectrometry, Detectors, c) Applications – Rules for interpreting Mass spectra with relevant examples.	**2** **4** **4**
5	**Optical Rotatory Dispersion**: Principle, plain curves, Cotton effect, Circular dichroism. Measurement of rotation angle in ORD and applications.	**2**
6	**X- Ray Crystallography**: Production of X-rays, X-Ray Diffractometer, Bragg's law, Rotating crystal technique, X ray powder technique, Types of crystals, Interpretation of Diffraction patterns and applications of X-ray diffraction.	**3**
7	**Separation Science – Techniques of Chromatography and Electrophoresis:** **a) HPLC** - Liquid chromatography, Principles of separation in HPLC, Partition, Adsorption, Ion –pair, Ion exchange, Size exclusion, Supercritical, gel-permeation, flash chromatography; Bonded phase supports, Chiral columns, Criteria for Column and Mobile phase selection, Application of PDA detectors, System suitability, Peak resolution Derivatization techniques, , Applications- Techniques of Quantitative analysis by HPLC. FDA & ICH Guidelines, etc for System suitability & validation. a) **HPTLC** - Stationary phases and their selection, Detection methods – Densitometry, Applications of HPTLC. b) **Gas Chromatography**: Types, Plate theory and Rate theory, Van-Deemter equation, Column types and parameters, Resolution, Pharmacopoeial Stationary Phases, Carrier gases and their properties, Derivatization techniques, Programmed Temperature Gas Chromatography and Applications in solvent and volatile component analysis. c) **Capillary electrophoresis**: Introduction, methods and Applications.	**2** **1** **2** **1** **3** **1**
8	**Hyphenated Techniques:** LC-MS and GC-MS, Instrumentation, Importance of Interface, ESI, APCI, APPI, Applications – Molecular weight determination, Structural Determination, Metabolite and herbicide detection techniques, Impurity profiling.	**2**

Sr. No	TOPICS	NUMBER OF HOURS
9	**Thermal Methods of Analysis:** Theory, instrumentation and applications of Thermo Gravimetric Analysis (TGA), Differential Thermal Analysis (DTA), Differential Scanning Calorimetry (DSC) and Thermo Mechanical Analysis (TMA).	3

References:

1. Willard, H.H., Merrit, L.L., Dean, J.A., Settle P.A., Instrumental Methods of Analysis, Van Nostrand.
2. Skoog, D.A., Heller, F.J., Nieman, T.A., Principles of Instrumental Analysis, WB Saunders.
3. Spectrometric identification of Organic Compounds, Robert. M. Silverstein et al, 7th Edition.
4. Fundamentals of Mathematical Statistics, S.C. Gupta and V.K. Kapoor.
5. Pharmaceutical Analysis – Modern Methods – Part A, Part B, James W. Munson.
6. Vogel's Text Book of Quantitative Chemical Analysis, 6th Edition.
7. Chromatographic Analysis of Pharmaceuticals, John A. Adamovics, 2nd Edition.
8. Practical Pharmaceutical Chemistry, Part two, A. H. Beckett & J. B. Stenlake – 4th Edition.
9. Instrumental Methods of Chemical Analysis – B. K. Sharma - 9th Edition.
10. Organic Spectroscopy – William Kemp, 3rd Edition.
11. Techniques and Practice of Chromatography – Raymond P. W. Scott, Vol. 70.
12. Liquid Chromatography – Mass Spectrometry, W. M. A. Niessen, J. Van Der Greef, Vol. 58.
13. Spectroscopy of Organic Compounds by P. S. Kalsi.

Journals:

1. Journal of Pharmaceutical Analysis (Elsevier)
2. Journal of Pharmaceutical and Biomedical Analysis (Elsevier)
3. Current Pharmaceutical Analysis (Bentham Science)
4. Journal of Chromatography A and B (Elsevier)
5. International Pharmaceutical Abstracts
6. Journal of Liquid Chromatography (Taylor and Francis)
7. Journal of Chromatography and Separation Techniques (OMICS)
8. Chromatographia (Springer)
9. Analytical Chemistry (ACS Journal)
10. Analytical and Bioanalytical Chemistry (Springer)
11. Journal of Analytical Chemistry (Springer)
12. Journal of Applied Spectroscopy (Springer)

Modern Pharmaceutical Analysis

(Practical)

Semester – I

Subject Code: MP001P

Periods/Week:-1 of 6 hr duration

Internal Assessment:-30 (6 hr duration), Univ. Practical Examination:-70 marks (6 hr duration)

Examination:-Practical Examination Duration:-6 hr

List of Experiments

*A minimum of 18 Practical's (Exercises on both Quantitative, Qualitative analyses to be elaborated) shall be conducted from the topics covering **Spectroscopy** (UV, IR, NMR, Mass) and **Separations Science**.

Practical-1 to 2

Calibration of Analytical weighing Balance, UV-Visible spectrophotometer, FT-IR spectrometer, HPLC & HPTLC.

Calibration of Volumetric glassware.

Practical- 3

Plotting of UV/Visible spectrum - Scanning of a simple organic compounds for UV- absorption and correlation with structures

Isosbestic point detection in case of mixtures.

Practical-4 to 6

Effect of solvents and pH on UV spectrum of drugs

Study of Bathochromic and Hypsochromic Shifts, Calculation of Extinction coefficient/ Absorptivity (Qualitative Applications for characterization)

Practical-7 to 9

Estimation of multi component formulation by UV- Spectrophotometry in formulations and Drug mixtures

(Simultaneous equation Method, Absorbance Ratio Method)

Experiments based on the application of derivative spectroscopy.

Practical- 10 to 12

Experiments based on HPLC (Isocratic and Gradient elution) techniques.

- Single and multiple component analysis
- Separation analysis of degradation components
- Calculation of System Suitability Parameters

Practical- 13 to 14

Pharmacopoeial spectra interpretation (atleast 10) for correlation of structural features with absorption frequencies.

Practical- 15 to 17

Problems Solving: (UV, IR, NMR, Mass) structural elucidation of atleast three simple compounds with UV, IR, NMR and Mass spectral data.

Practical-18

Separation of amino acids by Paper chromatography

Practical-19

Separation of alkaloids by TLC/ HPTLC

Practical -20

Impurity profiling – Characterization and determination techniques – use of TLC,HPLC, IR spectroscopy, UV spectrometry to demonstrate presence of impurity and quantification.

Practical -21

Use of IR spectra and DSC curves to study Drug-Excipient interaction in Formulations.

Practical -22

Demonstration – Interpretation of XRD diffractograms.

REFERENCES:

1. Practical Pharmaceutical Chemistry, Part One and Two, A. H. Beckett & J. B. Stenlake – 4th Edition
2. Spectrometric identification of Organic Compounds, Robert. M. Silverstein et al, 7th Edition.
3. Identification of Drugs and Pharmaceutical Formulations by Thin Layer Chromatography – P. D. Sethi, DilipCharegaonkar, 2nd Edition.
4. HPTLC – Quantitative Analysis of Pharmaceutical Formulations – P. D. Sethi.
5. The Controller of Publications; New Delhi, Govt. of India, Indian Pharmacopoeia.
6. P.D. Sethi; Quantitative Analysis of Drugs in Pharmaceutical Formulations, 3rd Edition.
7. Practical HPLC method development by Lloyd R. Snyder, Joseph J. Kirkland, Joseph I. Glajch, John Wiley and Sons 2nd Edition.

DRUG SCREENING –I (PRECLINICAL STUDIES)

(Theory: 54 Hr – 18 weeks)

Semester – I

Subject Code: MPPO101T
Period/Week : 3 hr
Examination : Theory

Sessional exam: 30
Uni. Examination: 70
Exam Duration : 3 hr

Sr. No	TOPICS	NUMBER OF HOURS
1	**Introduction to various Indian Systems of Medicines (** Ayurveda, Siddha, Unani and Homeopathy) in relation to research.	**6**
2	**History and development of Modern Drugs**	**3**
3	**Drug Discovery Approaches** Drug developmental program – in general, Methods, advantages and disadvantages of different conventional drug designs, Modern methods of drug discovery, High through put (HTP) screening.	**4**
4	**CPCSEA guidelines** to conduct experiments on animals- Study in detail. Brief introduction to prevention of Cruelty to Animal's Act. ICMR Guidelines on Research – Animal. Animal house: Design and facilities to maintain the animals, Common lab animals: description, handling and applications. Transgenic animals: Production, maintenance and applications Anesthetics for animals.	**2** **2** **2** **2**
5	**Pre-clinical studies (Animal studies)** **Preclinical screenin**g: General screening, and the specific screening procedures for : a) CVS – Anti-stroke, Angiogenesis, antihypertensive, Anti-anginals; Anti-arrhythmic; Anti-atherosclerotic, cardiotonic, antiplatelet. b) CNS –Antipsychotic, antidepressant, Antiepileptic, anti-Alzheimer's, Parkinson's, anti-migraine, analgesic, anti-anxiety. c) GIT –Anti ulcer, Motility, antiemetic. d) Hormone –Sexual dysfunction, anti-fertility, Anti-obesity, antidiabetic. e) Anticancer drugs f) Eye: anti-cataract, anti-glaucoma. g) Local anesthetics: Neuromuscular blocking agents, h) Anti-inflammatory, anti-asthmatic agents i) Receptor binding and estimation of neurotransmitters, micro-dialysis.	**3** **5** **1** **3** **2** **1** **1** **1** **1**
Sr.	**TOPICS**	**NUMBER**

No		OF HOURS
6	**Toxicity Studies**: a) Acute, sub-acute and chronic studies: Protocols, objectives, methods of execution and regulatory requirements. b) Reproductive toxicology assessment: Male reproductive toxicity, spermatogenesis, risk assessment in male reproductive toxicity, c) Female reproductive toxicology, oocyte toxicity, alterations in reproductive endocrinology, relationship between maternal and developmental toxicity, with emphasis on Teratogenicity. d) Mutagenicity: Ototoxicity, Photo toxicity.	**6** **2** **4** **3**

DRUG SCREENING –I (PRECLINICAL STUDIES)

(Practical)
Semester - I
Subject Code: MPPO101P
Periods/Week:- 1 of 6 hr duration
Internal Assessment:-30 (6 hr duration), Univ. Practical Examination:-70 marks (6 hr duration)
Examination:-Practical Examination Duration:-6 hr

*Minimum of 18 experiments should be performed.

1. Study of common laboratory animals, breeding, care, maintenance, handling as per CPCSEA regulations or other statutory regulations in force.

2. Calculation of area requirement, cages, feed and water.

3. Study of various strains, species & Sex of animals (Gross observations, weighing and recording).

4. Dose calculation and adjustment of strength of drug, vehicle etc.

5. Study the withdrawal of blood (Rat tail vein, rabbit ear vein).

6. Study of various routes of administration and effect of drug:

a) i.v. administration: 100, 200, 400 mg/kg

b) i.p. administration: 300, 600, 1200 mg/kg

c) oral administration: 500, 1000, 2000 mg/kg

7. Study of use of anaesthetics: induction and maintenance of anaesthesia.

8. Study the spontaneous behaviour of rat with regards to motor activity (Observational assessment**).**

9. Study the spontaneous behaviour of rat with regards to motor activity (Observational assessment**).**

10. Study of Motor activity & Grip strength (Rota-rod).

11. Study of unconditioned reflex: Conflict Test (Vogel) Anxiometer.

12. Study of antianxiety drugs (Elevated Plus Maze).

13. Study of analgesic activity (Hot plate).

14. Effect of drug on learning and memory (Water maze).

15. Effect of drug on learning and memory (Radial maze).

16. Study of Conditioned reflex using Cook's pole climbing apparatus.

17. Behavioral study using Autotrack activity meter.

18. Measurement of BP using NIBP, (MP 100).

REFERENCES:

1. Drug Discovery and Evaluation, Gerhard Vogel, Springer
2. Drug Screening Methods, SK Gupta Second Edition JAYPEE publication
3. Dose finding in Drug Development, Naitee Ting Spinger InternationalS
4. A Practical Approach to PG Disseratation; Dr. R Ravindran, JAYPEE publication
5. Handbook of Experimental Pharmacology, Dr. SK Kulkarni, vallabh Prakashan
6. Evaluation of drug activities Pharmacometrics by D R Laurence and A L Bacharach
7. General and applied toxicology B.B allantyne, T. Man-s, P. Turner (Eds) The Macmillan Press Ltd.London.

Journals, Websites & Data base

1) Indian Journal of Pharmacology.
2) Journal of Ethnopharmacology
3) Ind. Journal of Pharm. Science
4) Ind. J. Pharmacy Education & Res.
5) Indian Journal of Expt. Biology
6) International Journal of Pharmaceutics
7) Journal of Pharmacy and Pharmacology
8) http://www.iuphar-db.org/
9) http://www.fda.gov/
10) http://www.cdc.gov/
11) http://www.who.int
12) www.cdsco.nic.in/
13) www. mohfw.nic.in/ (CPCSEA)
14) **www.oecd.org/chemicalsafety/testing/oecdguidelinesforthetestingofchemicals.htm**
15) **http://www.ich.org/**
16) Micromedix

MOLECULAR PHARMACOLOGY

(Theory: 54 Hr – 18 weeks)

Semester - I

Subject Code: MPPO102T | Sessional exam: 30

Period/Week : 3 hr | Uni. Examination: 70

Examination : Theory | Exam Duration : 3 hr

Sr. No	TOPICS	NUMBER OF HOURS
1	General concepts in Molecular Pharmacology, Study of mechanism of drug in relation to receptors and other proteins. Receptors, Classification as per IUPHAAR.	**1**
2	Synaptic Transmission (Inhibitory and Excitatory)	**4**
3	**Synaptic Plasticity** a) Cortical circuits and their flexibility b) Long term modifications at inhibitory synapses c) Molecular mechanism of long term plasticity d) Inhibitory plasticity in auditory function, addiction, pain & injury, learning and memory.	 **1** **2** **3** **2**
4	**Targets For Drug Action** **Type 1: Ligand-gated ion channels /ionotropic receptors** Molecular structure the gating mechanism. **Type 2: G-Protein-coupled receptors /GPCR's** Targets for G-proteins, The adenylyl cyclase/cAMP system, The Phospholipase C/Inositol Phosphate system, Ion channels as targets for G-proteins, Agonist specificity, RAMPs and RGS proteins. **Type 3: Kinase-linked and related receptors** Epidermal growth factor and nerve growth, transforming growth factor (TGF), Interferons and colony-stimulating factors, Protein phosphorylation and Kinase cascade mechanisms. **Type 4: Nuclear receptors** NR family as *ligand-activated transcription factors,* classification of nuclear receptors, control of gene transcription. G-protein-independent signaling, receptor phosphorylation, receptor internalization (endocytosis).	 **2** **3** **2** **3**
Sr. No	**TOPICS**	**NUMBER OF**

		HOURS
5	Isolation And Cloning of Receptors, Desensitization and Tachyphylaxis, Quantitative aspects of Drug-Receptor Interactions. Change in receptors, translocation of receptors, exhaustion of mediators, increased metabolic degradation of the drug, physiological adaptation, active extrusion of drug from cells.	**2**
6	Recent developments in receptor expression and regulation with specific emphasis on peripheral adrenergic, cholinergic (ANS), dopaminergic, serotoninergic, histaminergic, Purinoceptors, Nitric Oxide Orphan and other 7TM receptors.	**4**
7	**Autacoids and drugs involved with it**: a) Introduction to Histamine, Bradykinins, PAF, Eicosanoids: prostaglandins, thromboxanes, leukotrienes and related compounds. b) Cytokines and their actions, Cox- l, Cox-2 inhibitors and their role in inflammatory process, anti-inflammatory agents, asthma and COPD. c) Neuropeptide FF/ neuropeptide AF W/ B Y receptors Opioid receptors.	**2** **3** **3**
8	**Pharmacogenomics**: Historical perspectives and current status, Human Genome and Genomic Applications, Genetic Polymorphism of Metabolic Reactions, SNPs, Association Studies in in-vivo Assay. Genotyping Method Selection.	**3**
9	**Pharmacogenomics in Personalized Medicine:** a) Pharmacogenomics of Cardiovascular Diseases, Screening of high risk individuals. b) Alignment of chemotherapy. c) Detection of circulating endothelia cells, post remission surveillance.	**2** **1** **2**
10	**Bio-tech products:** Current medicinal products: a) Insulin, GH, Vaccines, b) Monoclonal antibodies, FSH, Tissue plasminogen activator (t-PA).	**2** **3**
11	Transgenic animals, Nude and knock out mouse/animals.	**4**

REFERENCES:

1. Rang and Dale's Pharmacology ;H P Rang and M M Dale, Sixth Edition, Churchill Living Stone
2. Essentials of Human Genetics, Manu L Kothari, Lopa Mehta; University Press
3. Pharmacogenomics: Methods and Protocols (Methods in Molecular Biology) First Edition (2005) Federico Innocenti, Humana Press Inc, New Jersey, USA.
4. Pharmacological Basis of therapeutics; Goodman & Gillman Press Ltd. London.

ADVANCED PHARMACOLOGY- I

(Theory: 54 Hr – 18 weeks)

Semester - I

Subject Code: MPPO103T — Sessional exam: 30

Period/Week : 3 hr — Uni. Examination: 70

Examination : Theory — Exam Duration : 3 hr

Sr. No	TOPICS	NUMBER OF HOURS
1	**Recent Developments in Pharmacotherapy of CVS:** a. Hypertension, Ischaemic heart disease, CCF, Cardiac arrhythmias, Thrombosis, and Hyperlipidaemia. b. Nitric oxide / EDRF, Endothelin receptors: and vascular substances, oxygen free radicals and their scavengers, Adenosine, Angiotensin receptors, Platelet-activating factor receptor.	**6** **4**
2	**Recent Developments in Pharmacotherapy of Respiratory System:** Asthma and COPD.	**3**
3	**Recent Developments in Pharmacotherapy of Musculoskeletal System:** Rheumatoid & Osteoarthritis, Gout and hyperuricaemia, Myasthenia gravis.	**3**
4	**Recent Developments in Pharmacotherapy of Renal System:** Acute and chronic renal failure.	**2**
5	**Recent Developments in GIT Therapy:** Peptic ulcer, inflammatory bowel diseases, constipation & diarrhoea.	**3**
6	**Recent Developments in Hepatobiliary drugs:** Drug induced hepatotoxicity and hepatic diseases.	**4**
7	**Recent Developments in Ocular Therapy:** Glaucoma.	**1**
8	Recent Pharmacotherapeutic Developments in special groups like in pregnancy and lactation, Pediatrics and Geriatrics.	**2**
9	**Recent Developments in Blood and Blood forming agents:** Haemopoietic Growth Factors.	**2**
10	**Obesity**: The role of gut and other hormones in body weight regulation, neurological circuits that control body weight and eating behavior. The pathophysiology of human obesity genetic factors and obesity. Pharmacological approaches to the problem of obesity with special reference to new approaches.	**4**
Sr. No	**TOPICS**	**NUMBER**

		OF HOURS
11	**Immunomodulators & Hormonal Drugs** a. The molecular and cellular mechanisms of immunomodulators, autoimmune disorders and Immunosuppressants. b. Genetics of Fertility, Reproduction, neonates: Preconception –prenatal screening, Non invasive prenatal screening, Down syndrome- triosome, screening for inherited genetic disorders. c. Menopause and Alignment of HRT, Osteoporosis. d. Recent Developments in Oncogenetics : Screening of high risk individuals, alignment of chemotherapy, detection of circulating tumor cells, post remission surveillance e. Pharmacogenetics of critical drugs like anti-Diabetics, Anti hyperuricemia, osteoporosis, antibiotic, High end Analgesic, Anti-inflammatory drugs.	**2** **2** **2** **3** **2**
12	Recent Advances in Chemotherapy of a) Tuberculosis with emphasis on MDR, XDR b) Viral infections like AIDS, H1N1, c) Parasitic infections like Malaria, Dengue, Chickengunia	**3** **2** **2**
13	Recent advances in Sports Medicine	**2**

REFERENCES:

1. Rang and Dale's Pharmacology ;H P Rang and M M Dale, Sixth Edition, Churchill Living Stone
2. Essentials of Human Genetics, Manu L Kothari, Lopa Mehta; University Press
3. Pharmacogenomics: Methods and Protocols (Methods in Molecular Biology) First Edition (2005) Federico Innocenti, Humana Press Inc, New Jersey, USA.
4. Pharmacological Basis of therapeutics; Goodman & Gillman Press Ltd. London.

ENTREPRENEURSHIP MANAGEMENT

(Theory: 36 Hr – 18 weeks)

Semester - I

Subject Code: MP003 Sessional exam: 50

Period/Week : 2 hr

Examination : Theory (Internal) Exam Duration : 1hr

Course Objectives:

- To provide conceptual inputs regarding entrepreneurship management.
- To sensitize and motivate the students towards entrepreneurship management.
- To orient and impart knowledge towards identifying and implementing entrepreneurship opportunities.
- To develop management skills for entrepreneurship management.

Sr. No	TOPICS	NUMBER OF HOURS
1	**CONCEPTUAL FRAME WORK** Concept need and process in entrepreneurship development. Role of enterprise in national and global economy Types of enterprise – Merits and Demerits An introduction to laws governing establishments like Factories Act, Shops and Establishment Act, Labour Act, etc; Government policies and schemes for enterprise development Institutional support in enterprise development and management	**5**
2	**THE ENTREPRENEUR** Entrepreneurial motivation – dynamics of motivation. Entrepreneurial competency – Concepts. Developing Entrepreneurial competencies - requirements and understanding the process of entrepreneurship development, self awareness, interpersonal skills, creativity, assertiveness, achievement, factors affecting entrepreneur role	**5**
3	**LAUNCHING AND ORGANISING AN ENTERPRISE** Environment scanning – Information, sources, schemes of assistance, problems. Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis. Resource mobilisation - finance, technology, raw material, site and manpower. Costing and marketing management and quality control. Feedback, monitoring and evaluation.	**6**

Sr. No	TOPICS	NUMBER OF HOURS
4	**GROWTH STRATEGIES AND NETWORKING** Performance appraisal and assessment Profitability and control measures, demands and challenges Need for diversification Future Growth – Techniques of expansion and diversification, vision strategies Concept and dynamics Methods, Joint venture, co-ordination and feasibility study	**7**
5	**PREPARING PROJECT PROPOSAL TO START ON NEW ENTERPRISE** Project work – Feasibility report; Planning, resource mobilisation and implementation.	**6**
6	State owned industrial zones, SEZ, EOU, Bond Sale, High Sea Sales, Custom, Excise	**4**
7	Business Ethics	**3**

REFERENCES

1. Akhauri, M.M.P.(1990): Entrepreneurship for Women in India, NIESBUD, New Delhi.
2. Hisrich, R.D & Brush, C.G.(1996) The Women Entrepreneurs, D.C. Health & Co., Toranto.
3. Hisrich, R.D. and Peters, M.P. (1995): Entrepreneurship – Starting, Developing and Managing a New Enterprise, Richard D., Inwin, INC, USA.
4. Meredith, G.G. etal (1982): Practice of Entrepreneurship, ILO, Geneva.
5. Patel, V.C.(1987): Women Entrepreneurship – Developing New Entrepreneurs, Ahmedabad EDII.

SEMESTER – II

DRUG SCREENING-II (CLINICAL STUDIES)

(Theory: 54 Hr – 18 weeks)

Semester -II

Subject Code: MPPO201T | Sessional exam: 30

Period/Week : 3 hr | Uni. Examination: 70

Examination : Theory | Exam Duration : 1hr

Sr. No	TOPICS	NUMBER OF HOURS
1	**Clinical Trial Regulation** Schedule Y for new drugs. International guidelines (ICH recommendations) GCP. ICMR guidelines	 **3** **2** **1**
2	**Clinical Trials** Different Phases, CROs, Protocol Development, Feasibility Studies, Case Report form, Review and designing, Report writing, monitoring, QA and data management. Bioavailability studies, Role and responsibilities of clinical trial personnel of a. Sponsor, b. Investigators, c. Clinical research associate, d. Auditors, e. Contract research coordinators Role of Regulatory authority Composition, responsibilities, procedures of IRB / IEC	 **3** **2** **2** **2** **1** **1**
3	**Fundamentals of Clinical Trials** a) Volunteers, informed consent with regards to rules and procedures. design of clinical trials (single blind, double blind, cross over, randomization, placeboes, controlled studies) b) Clinical trials of Orphan drugs and emergency medicines.	 **3** **1**
4	Guidelines for Human Equivalent dose calculations	**3**
5	**NDA/ANDA (Product Registration)** a) New Drug Application (NDA) and Abbreviated New Drug Application (ANDA) Guideline, Contents and format for filling NDA & ANDA. b) Biological products and biotechnology. c) Exclusivities, Orange Book. d) BA/BE Studies e) DMFs and their importance	 **2** **2** **2** **2** **2**
6	a) Human Rights b) IPR, TRIPS, GATT c) Patent (types & Procedure)	**1** **2** **4**
7	Historical perspective of Indian patent acts, important court judgments	**2**
8	Advertising of drugs. Labeling requirements and design , PIL, Inserts, Magic remedies acts, telemedicine. Advertisement norms for medicines (ASCI)	**4** **1** **2**
9	Biomedical waste : Handling and regulations Environment Laws protecting Environment	**4**

REFERENCES:

1. Text Book of Clinical Trials: David Machin, Wiley
2. ICMR guidelines
3. http://ctri.nic.in/Clinicaltrials/
4. http://www.fda.gov/
5. http://www.who.int
6. www.cdsco.nic.in/
7. **http://www.ich.org/**

CLINICAL & HOSPITAL PHARMACY

(Theory: 54 Hr – 18 weeks)

Semester -II

Subject Code: MPPA202T | Sessional exam: 30

Period/Week : 3 hr | Uni. Examination: 70

Examination : Theory | Exam Duration : 3hr

Sr. No	TOPICS	NUMBER OF HOURS
1	**Hospital Pharmacy**	
	a) Ward round participation (Basic Types)	**1**
	b) Rational use of the drug and ESSENTIAL drug concepts	**1**
	c) Medication adherence and compliance	**1**
	d) Drug therapy review and enveloping therapeutic guidelines	**2**
	e) Medication errors	**2**
	f) Patient counseling	**2**
	g) Management of Hospital pharmacy, PTC Functioning	**1**
2	**Clinical Pharmacy**	
	a) Interpreting laboratory data. Biochemical parameters	**4**
	b) Hematological data and their implications in therapeutics	**3**
	c) Pharmacoeconomics & Pharmacoepidemiology	**2**
	d) OTC medicines	**1**
	e) Medical Insurance concept & Type	**2**
3	**Pharmacokinetic & Drug Interaction**	
	a) Physiological concepts and kinetics, Movement of the drugs through biological membranes - Absorption, Distribution, Metabolism / Biotransformation, Elimination.	**2**
	b) Integration with kinetics Variability, genetics, age and weight, disease, interacting drugs, and monitoring of the same.	**2**
	c) Compartmental models, non-compartmental and physiological models. Nonlinear pharmacokinetics, multiple dosing and dosage regimen.	**2**
	Clinical Pharmacokinetics: Clinical Pharmacokinetic parameters and their implications in therapeutics (Details on bio-availability, volume of distribution, clearance, half life, zero and first order kinetics, steady states, loading and maintenance doses).	**6**
4	**Therapeutic Drug Monitoring**: Objectives, Strategies for target concentration interventions and applications of TDM.	**2**
	Simulation in silico models using softwares like Gastroplus	**6**

Sr. No	TOPICS	NUMBER OF HOURS
5	**Pharmacovigilance:** Definition and classification. ADR: mechanism detections and monitoring. **Drug interactions:** Definition and mechanisms (Pharmacokinetic and dynamic) of drug interactions.	**4** **4**
6	**Poisoning :** General principles of management of acute poisoning cases. Drug and Poison information centers, Databases etc.	**4**

REFERENCES:

1. Clinical Pharmacy and Therapeutics, Roger Walker Fourth Edition, Churchill Living Stone
2. Basic Pharmaokinetics, Sunil Jambhekar & Philip Breen; Pharmaceutical press.
3. Text Book of Clinical Pharmacy , G Parthsarthi University Press
4. Basic Skills in Interpreting laboratory Data; Mary Lee ASHSP

CLINICAL & HOSPITAL PHARMACY

(Practical)

Semester - II

Subject Code: : MPPO202P

Periods/Week:- 1 of 6 hr duration

Internal Assessment:-30 (6 hr duration), Univ. Practical Examination:-70 marks (6 hr duration)

Examination:-Practical Examination Duration:-6 hr

***Minimum of 18 experiments should be conducted:**

Practical 1: Study of ideal prescription – its analysis.

Practical 2: Patient counselling & preparation of bills.

Practical 3: Study of medical insert literature, label- its components & various aspects of Labeling (global & Indian). Identifying flaws in labels

Practical 4: Determination of routine parameters e.g. blood glucose, BP, BMI.

Practical 5-6: Analysis of patient's laboratory data.

Practical 7-8: Case studies & reporting of adverse drug reactions.

Practical 9-11: Problem solving—calculation of doses (maintenance, loading), clearance value, etc., in various cases.

Practical 12-14: Simulated experiments based on silico models using softwares like Gastroplus

Practical 15-16: Therapeutic Drug monitoring of at least one drug using suitable analytical technique studied in Sem I (Modern Pharm Analysis).

Practical 17-18: Identification of poisons/drugs/substances of abuse. Handling of poisoning cases; study of various poisons, their antidotes & drug information center.

RESEARCH METHODOLOGY
(including Biostatistics and Computer Applications)

(Theory: 54 Hr – 18 weeks)

Semester - II

Subject Code: MPP004T — Sessional exam: 30

Period/Week : 3 hr — Uni. Examination: 70

Examination : Theory — Exam Duration : 3 hr

Sr. No	TOPICS	NUMBER OF HOURS
I	**Research Methodology**	
1	Introduction: Meaning of research, purpose of research and types of research (clinical experimental, basic, applied and patent and oriented research), Approaches to research, Criteria for good research, qualitative & quantitative research methods.	3
2	Literature survey: Using library, book and journals, online data bases like MEDLINE, Science direct, use of internet for procuring patents and reprints of articles as sources for literature survey	4
3	Methods and tools used in research: Selection of research problem, research design; meaning, concept & features of research design, experimental design, plan of research work. Qualitative studies, quantitative studies. Simple data organization, descriptive data organization. Limitations and sources of errors. Enquiries in forms of questionnaire, opinionaire and interviews	6
4	Research report/paper writing/thesis writing / poster presentation: Different parts of research report or paper Title-title of project with authors name Abstract-statement of the problem, background list in brief, purpose and scope, Key words , Methodology-subject, apparatus/instrumentation and procedure. Results-tables, graphs, figures and statistical presentation Discussion-support or non-support to hypothesis. Practical and theoretical implications. Acknowledgements, References , Errata , Importance of spell check, Use of foot notes, Bibliography, referencing styles.	8

Sr. No	**TOPICS**	**NUMBER OF HOURS**
5	Principles of validity and reliability of research work, Ethical aspects of research methodology, special emphasis on plagiarism.	4
7	Cost analysis of the project Cost incurred on raw materials, Procedure, instrumentations	2
8	Industrial-institution interaction- Industrial projects, their, feasibility reports.	2
9	Writing projects for various funding agencies	2
II	**Biostatistics& Computer Applications**	
1	Introduction, Concept of Statistics in Quality Control (SQC), its role and uses. Collection, organization, measurement of central tendencies & dispersion; degree of freedom, standard deviation, standard error, Coefficient of variation, Probability, Sample and Sampling method. Process capability study. Statistical process control Charts.	4
2	Estimation and Hypothesis testing: Null Hypothesis, confidence level, Point & interval estimation, concept of hypothesis testing & types of error, Student 't' test, Chi-Square test	4
3	Linear regression and Correlation: Analysis of variance (one way & two way), Factorial design	3
4	Brief review of non parametric tests, experimental design in clinical trials, statistical test for bioequivalence, Dose-Response study, statistical quality control; validation, optimization techniques & screening design, significance of coefficient of correlation, non-linear regression, Application of software for statistical calculations.	6
5	Designing and development of databases , information storage and retrieval, report Generation.	2
6	Statistical data Analysis using statistical software /Data Analysis Tool pack-MS Excel Descriptive statistics, Hypothesis Testing Regression and Correlation Formation of linear regression equation.	4

REFERENCES:

1. Research in education – John W. Best Jems V. Kahn
2. Research methodology – C. R. Kothari
3. Methodology and techniques of social research – Willkinson and Bhandarkar
4. Presentation skills – Michel Halton – Indian society for institute education
5. Practical introduction to copyrights – Gavin Mofariane
6. Thesis projects in sciences and engineering – Richard M. Devis
7. Scientist in legal system – Ann Labor Science
8. Thesis and assessment writing – Janolthon Anderson
9. Writing a technical paper – Donald Manzel
10. Effective business report writing – Lel and Brown
11. Protection of industrial property rights – Purshottam Das and Gokul Das
12. Spelling for millions – Edna Furmess
13. Preparation for publications – King Edwards hospital foundation for London
14. How to write and publish a scientific paper – Robert A. Day Cambridge University Press 4^{th}Edition, 1994
15. Introduction to Statistical Methods- C. B. Gupta
16. A first course in Mathematical Statistics- C. E. Weatherborn
17. Introduction to Biostatistics-Mahajan
18. Experimental Pharmacology by S K Kulkarni.
19. Fundamentals of Science & Technology Communication – N R Rajagopal, NISCAIR (CSIR)

ADVANCED PHARMACOLOGY II

Theory: 54 Hr – 18 weeks (3hrs/week)

Semester – II

Subject Code: MPPO203T
Period/Week : 3 hr
Examination : Theory

Sessional exam: 30 marks
Uni. Examination: 70 marks
Uni. Exam Duration:3 hr

Sr. No	TOPICS	NUMBER OF HOURS
1	**Advances in Neurotransmitter & Receptors, (IUPHAAR Classification)** Classification (subtypes), neurotransmission , function and drugs (agonists and antagonists) involved in following receptors: Adrenergic, dopaminergic, cholinergic and serotonin, GABA/BZ (Inhibitory Amino acids), Glutamate (excitatory amino acid), purine receptors, cannabinoid receptors. Opioid, vannilloid, Adenosine receptors. Aging and neurodegenerative disease.	**5** **4** **4** **4** **1**
2	**Drug dependence and substance of abuse** Study of various substance of abuse. Mechanism /pathology underlying drug dependence and drug addiction. Test kits for substance of abuse and other products available in market and their application	**6**
3	**Endocrine Pharmacology:** Molecular and cellular basis of mechanisms of actions of hormones (growth hormone, prolactin, thyroid, Glycoprotein hormone receptors, insulin, Glucagon receptor family and oral hypoglycaemic agents, sex hormones and oral contraceptives, corticosteroids, Corticotropin-releasing factor receptors, and drugs affecting calcium regulation) and their antagonists. Ghrelin receptor, Calcitonin receptors, Adrenomedullins receptor, Melanocortin receptors, Melatonin receptors, Neurotensin receptors, Relaxin family peptide receptors, Urotensin receptor, VIP and PACAP receptor. Hormone Calcitonin receptors Calcium-sensing receptors, Bile acid receptor Estrogen (G protein-coupled) receptor, Glycoprotein hormone receptors, Gonadotrophin-releasing hormone, Melanin-concentrating hormone receptors, Melanocortin receptors, Melatonin receptors. Parathyroid hormone receptors Prolactin-releasing peptide receptor, Vasopressin and oxytocin receptors, Cholecystokinin receptors.	**8** **3** **2**

Sr. No	TOPICS	NUMBER OF HOURS
4	**Nuclear hormone receptors** Retinoic acid receptors 1C. Peroxisome proliferator-activated receptors 1-Retinoic acid-related orphans receptors, Vitamin D receptor-like receptors, Retinoid X receptors Nerve growth factor IB-like receptors, Germ cell nuclear factor receptors.	**4** **2** **2** **2**
5	**Biological assays:** Types of Bioassays & their applications Bioassay of standard drugs like Heparin.	**7**

REFERENCES:

1. Rang and Dale's Pharmacology ;H P Rang and M M Dale, Sixth Edition, Churchill Living Stone
2. Medical Pharmacology. KD Tripathi JAYPEE publication
3. Pharmacological Basis of therapeutics; Goodman & Gillman
4. Basic and Clinical Pharmacology . B Katzung
5. http://www.iuphar-db.org/

ADVANCED PHARMACOLOGY

(Practical)

Semester – II

Subject Code:- MPPO203P

Periods/Week:- 1 of 6 hr duration

Internal Assessment:-30 (6 hr duration), Univ. Practical Examination:-70 marks (6 hr duration)

Examination:-Practical Examination Duration:-6 hr

List of Experiments:

1. Study of various equipments, assemblies used in isolated tissue experiments.
2. Dissection and of Isolation of various animal tissues and their preservation.
3. Study of Bioassay equipments (MP 100) and its set up & study of ECG.
4. Preparation of physiological solutions and monitoring their parameters
5. Bioassay of acetylcholine using suitable ileum preparation by interpolation method.
6. Bioassay of acetylcholine using suitable ileum preparation by 3-point method.
7. Bioassay of Histamine using suitable mammalian ileum preparation.
8. Bioassay of epinephrine using suitable mammalian colon.
9. Bioassay of epinephrine using suitable mammalian fundus strip

10- 11 Bioassay of 5-HT/ Oxytocin using mammalian uterus.

12-14 Antimicrobial screening of some antibacterial drugs/herbal extracts.

15 Screening of Anti-inflammatory drugs.

16-17 PA2 values of various antagonists using suitable isolated tissue preparations.

18 Simulated experiments on isolated and intact animals

Field Activity & Soft Skills

Semester – II

Subject Code: MP007 Sessional exam: 50

Period/Week : 2 hr

Examination: Internal

A) Field Activity

Involvement in celebration of days of importance, Participation in CEP/Seminar/Conference, Health camps, Blood donation camps and such community centric activities.
Field surveys on drug, disease and social and health management.
Fund raising /Application for grants/ Project submission Indian funding agencies
Application to foreign Universities.
Visit to research centres, NGO's, effluent treatment plants, forest department, etc;

B) Soft Skills

1. ETIQUETTE & ETHICS ON THE JOB
   Understanding Body Language, Social & Business Etiquette, Netiquette Communication Ethics.
   Telephone/Mobile Etiquette

2. GROUP DISCUSSION SKILLS & SPOKEN ENGLISH
   Interacting and working in a group.
   Analyzing a case study working in a Group & presenting a Case Study.

3. PRESENTATION SKILLS
   Essentials of Effective Presentation Oral skills in Presentation, Putting together PowerPoint Presentations use of Laptops, LCD, Multimedia.
   Writing resume, preparation for interviews.