Osmania University Syllabus for
M. Pharmacy
(Pharmacology)
(w.e.f. academic year 2009-10)

FACULTY OF TECHNOLOGY
HYDERABAD
### Scheme of Instruction and Evaluation for M. Pharmacy (Pharmacology)
#### I – Semester – Revised-2009

<table>
<thead>
<tr>
<th>Subject Code</th>
<th>Subject / Paper</th>
<th>Theory / Practical</th>
<th>Instruction Hours per week</th>
<th>Evaluation</th>
<th>Duration of External Examination</th>
</tr>
</thead>
<tbody>
<tr>
<td>M.PCOL.T.1.101</td>
<td>Pharmaceutical Analytical Techniques</td>
<td>Theory</td>
<td>4</td>
<td>30</td>
<td>70</td>
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<tr>
<td>M.PCOL.T.1.102</td>
<td>Drug Design and Molecular Pharmacology</td>
<td>Theory</td>
<td>4</td>
<td>30</td>
<td>70</td>
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<tr>
<td>M.PCOL.T.1.103</td>
<td>Bioassays and Screening Methods</td>
<td>Theory</td>
<td>4</td>
<td>30</td>
<td>70</td>
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<tr>
<td>M.PCOL.T.1.104</td>
<td>Principles of Toxicology</td>
<td>Theory</td>
<td>4</td>
<td>30</td>
<td>70</td>
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<tr>
<td>M.PCOL.P.1.105</td>
<td>Pharmaceutical Analytical Techniques</td>
<td>Practical</td>
<td>-</td>
<td>6</td>
<td>30</td>
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<tr>
<td>M.PCOL.P.1.106</td>
<td>Bioassays and Screening Methods</td>
<td>Practical</td>
<td>--</td>
<td>6</td>
<td>30</td>
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<tr>
<td>M.PCOL.T.1.107</td>
<td>Scientific and Technical Writing (SAIL)</td>
<td>Tutorial</td>
<td>2</td>
<td>A/B/C/D</td>
<td>-</td>
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<tr>
<td>M.PCOL.1.108</td>
<td>Seminar</td>
<td>Theory</td>
<td>8</td>
<td>50</td>
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### Scheme of Instruction and Evaluation for M. Pharmacy (Pharmacology)
#### II– Semester – Revised-2009

<table>
<thead>
<tr>
<th>Subject Code</th>
<th>Subject / Paper</th>
<th>Theory / Practical</th>
<th>Instruction Hours per week</th>
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<th>Duration of External Examination</th>
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<tr>
<td>M.PCOL.T.1.201</td>
<td>Intellectual property rights &amp; Regulatory affairs</td>
<td>Theory</td>
<td>4</td>
<td>30</td>
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<tr>
<td>M.PCOL.T.1.202</td>
<td>Advances in Pharmacology</td>
<td>Theory</td>
<td>4</td>
<td>30</td>
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<tr>
<td>M.PCOL.T.1.203</td>
<td>Biopharmaceutics and Pharmacokinetics</td>
<td>Theory</td>
<td>4</td>
<td>30</td>
<td>70</td>
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<tr>
<td>M.PCOL.T.1.204</td>
<td>Pharmacology &amp; Pharmacotherapeutics</td>
<td>Theory</td>
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<tr>
<td>M.PCOL.P.1.205</td>
<td>Advances in Pharmacology Practicals.</td>
<td>Practical</td>
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<tr>
<td>M.PCOL.P.1.206</td>
<td>Biopharmaceutics and Pharmacokinetics</td>
<td>Practical</td>
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<tr>
<td>M.PCOL.T.1.207</td>
<td>Entrepreneurship Management (SAIL)</td>
<td>Tutorial</td>
<td>2</td>
<td>A/B/C/D</td>
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<tr>
<td>M.PCOL.1.208</td>
<td>Seminar</td>
<td>Theory</td>
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SAIL: Self assess Instrumentation Learning
Scheme of Instruction and Evaluation for M. Pharmacy
(Pharmacology)

Semester III and IV

**DISSERTATION** – Original research work carried out by the candidate under the guidance of regular teaching faculty/visiting faculty of the department should be submitted in a bound form.

Evaluation of the dissertation shall be done by external and internal examiners appointed by the university.

Dissertation viva-voce

Dissertation report

Grade A/B/C/D/F

<table>
<thead>
<tr>
<th>A. Excellent</th>
<th>B. Very good</th>
<th>C. Good</th>
<th>D. Fair</th>
<th>F. Fail</th>
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UNIT – I


UNIT – II
**Nuclear Magnetic Resonance Spectroscopy**: Fundamental principles of NMR, instrumentation (components and their significance). Chemical shifts concept, spin- spin coupling, spin-spin decoupling, shielding and deshielding, solvents. signal multiplicity phenomena in high resolution PMR. Interpretation of PMR spectra.
Brief introduction about Carbon-13 NMR and 2D NMR Spectroscopy.

UNIT – III
**Mass Spectrometry**: Basic principles and instrumentation (components and their significance). Ionization techniques, mass spectrum and its characteristics, molecular ion, metastable ions, fragment ions; fragmentation processes, fragmentation patterns and fragment characteristics in relation to parent structure and functional groups. Relative abundances of isotopes and their contribution to characteristic peaks.

UNIT – IV
**Chromatographic Techniques**: Classification of chromatographic methods based on mechanism of separation and their basic principles. **Gas chromatography**: Instrumentation, column efficiency parameters, derivatisation methods, applications in pharmaceutical analysis. **Liquid chromatography**: Comparison of GC and HPLC, instrumentation in HPLC, normal and reversed phase packing materials, column selection, mobile phase selection, efficiency parameters, applications in pharmaceutical analysis. Instrumentation and applications of HPTLC, ion exchange chromatography, gel permeation chromatography, chiral chromatography, flash chromatography, and supercritical fluid chromatography (SFC).

UNIT – V
**Electrophoresis**: Principles, instrumentation and applications of moving boundary electrophoresis, zone electrophoresis (ZE), isotachphoresis, isoelectric focusing (IEF), continuous electrophoresis (preparative) and capillary electrophoresis. SDS gel electrophoresis and blotting techniques.
**Radio immunoassay and ELISA**: Principle, instrumentation, applications and limitations.
Recommended books

UNIT –I

Pharmacokinetics approach to New Drug Discovery
Basic concepts and Definition, importance of ADME parameters in disposition, therapeutics and development their implication on drug discovery.

UNIT-II

Overview on computer aided Drug design (CADD) including QSAR, Combinational Chemistry, High Throughout screening (RTS)

UNIT-III

Molecular Basis of Drugs Action: Cell signaling, communication between cells and their environment, ion-channels, organizations of signal transduction pathways, third messengers, biosensors.
Drug Latentiation :Basic concept, Prodrugs of functional groups, Bio-precurssor prodrugs, chemical delivery system.

UNIT – IV


UNIT – V

Herbal Neutraceuticals as new source for medicines.
Study of Advanced drugs from natural sources of following groups:
Anticancer, Anti AIDS, Hepatoprotectives, Antidiabetics, Brain Tonics, Anti urolithiates, Antifilarial, Antihyperlipidimics.
Modern phytochemical screening techniques and evaluation of herbal drugs and their extracts and formulations, Concept of Reverse Pharmacognosy.

Books recommended

5. Chakravarty T.K. “ Herbal Options”.
UNIT – I


Bioassays : Basic principles of bioassays officia bioassays, experimental models and statistical designs employed in biological standardization. Biological standardization of vaccines and sera with certain examples with reference to IP. Development of new bio assay methods.

UNIT – II

Preclinical models employed in the screening of new drugs belonging to following categories.

Antifertility agents, sympathomimetics, parasympathomimetics, muscle relaxants (both central and peripheral). Sedatives, hypnotics, antiarrhythmic agents, cardiac stimulants, cardiotonic agents bronchodilators, antihistaminics, eicosanoids.

Antipsychotic agents, antianxiety agents nootropic drugs antidepressant drugs; antiparkinsonism agents, antiepileptics; analgesics and anti-inflammatory agents; antilucer agents; infarction; antiatherosclerotic drugs; antidiabetics; models for status epilepticus drugs. cerebroventricular and other newer techniques of drug administration and development; transgenic animals and other genetically prone animal models.

UNIT – III

Alternatives to animal screening procedures, cell-line handling and maintenance and propagation of cell lines, patch-clamp technique, in-vitro cell line based assays diabetics and arthraitis models, molecular biology techniques.

UNIT – IV

Principles of toxicity evaluations, ED50, LD50 and TD values, International guidelines (ICH Ethics and animal experimentation recommendations).Guidelines and regulatory agencies – CPCSEA,OECD,FDA, FHSA,EPA,EEC,WHO etc,

UNIT – V

Books recommended

1. Pre – Clinical Drug Development, Rogge
2. Basic and clinical Pharmacology, Katzung
3. Pharmacological screening methods, N.S. Parmer and Shivkumar
4. Pharmacological screening methods, N.S. Parmer and Shivkumar
5. Calculations for Pharmaceutical Practice, Winfield
6. Pharmacoepidemiology, Storm
7. CPCSEA, OECD, FDA, WHO, ICH guidelines from respective website downloads.
BASIC PRINCIPLES OF TOXICOLOGY

Subject Code     : M.PCOL T.1.104                  Sessional     : 30
Periods/Week    : 4                                 Examination  : 70
Nature of Exam  : Theory                               Exam Duration : 3 Hrs

Unit – I

Unit – II
Single dose and repeat dose toxicity studies; Factors influencing such studies such as species, sex, size, route, dose level; Data evaluation and regulatory requirements. Determination of Maximum Tolerated Dose (MTD) and LD 50 as per revised OECD guidelines. Allergenicity testing, dermal toxicity, immunotoxicology and in vitro methods of toxicology.

Unit – III
Reproductive toxicology assessment of male reproductive toxicity, spermatogenesis; Risk assessment in male reproductive toxicity; Female reproductive toxicology; Oocyte toxicity; alterations in reproductive endocrinology; Relationship between maternal and developmental toxicity.

Unit – IV
Mutagenicity; Mechanisms of mutagenesis, point mutations,; Individual chromosomes and complete genome mutations, germ cell mutations, somatic cell mutation; Tests systems in vitro, chromosome damage and chromosomal aberration test, gene mutation, in vivo micronucleus tests in rodents, metaphase analysis.

Unit – V
Preclinical toxicological requirements for biologicals and biotechnological products; safety analysis; problems specific to recombinant products, toxicokinetics, principles of GLP as per OECD guidelines for conducting preclinical toxicity studies.

Books recommended

1. Drug safety Evaluation, Shayne C Gad, Wiley Interscience
2. The toxicologist’s pocket handbook, Michael J derelanko 2nd Ed,2008,CRC press
3. Relevant OECD guidelines (Internet resources)
   http://www.ingentaconnect.com/content/oecd/16073/2001/00000001/00000004
List of Experiments

1. UV/Visible spectrum scanning of a few organic compounds for UV- absorption and correlations of structures (5 compounds) and isosbestic point in case of mixtures.
2. Effect of solvents and pH on UV spectrum of drugs (2 experiments).
3. Estimation of multicomponent formulation by UV- Spectrophotometer in formulations. (2 experiments).
4. Experiments based on the application of derivative spectroscopy. (2 experiments).
5. Experiments based on HPLC (Isocratic and Gradient elution) techniques. (2 experiments).
6. Interpretation of drugs by IR spectra.
7. Workshop of spectroscopy: (UV, IR, NMR, MASS) structural elucidation of at least 5 compounds (4 experiments).
9. Any other relevant experiments based on theory.
List of Experiments

1. Biological standardization of drugs like acetylcholine/Histamine
2. Experiments on CNS. General screening methods of drugs on CNS
   CNS stimulants and depressants, anxiogenics and anxiolytics, amnestic
   and nootropics, anti convulsants, analgesics, safety pharmacology.
3. Drugs acting on Gastrointestinal tract
   General screening methods for the anti ulcer activity, intestinal motility, and anti-diarrhoeals.
4. Experiments on CVS
   General screening procedure of anti-arrhythmic agents, anti-hypertensives, anti-ischemics.
5. Experiments on Local anesthetics
   General methods for evaluating local anesthetic activity
6. Experiments on General Pharmacology
   Enzyme induction activity, drug dependence and withdrawal effects.
7. Experiments on Diuretics
   General screening methods for evaluating the diuretic activity.
8. Screening procedure for antidiabetic drugs.
9. Experiments on analgesic and anti-inflammatory agents
   General methods of screening for the evaluation of analgesics and
   anti inflammatory agents, [both acute and chronic models]
10. General methods for evaluating the antimicrobial activities of chemotherapeutic agents.
11. Estimation of biochemical and free radical scavengers.

Recommended books

3. Hand book of Laboratory Animal Science: Selection and Handling of Animals in Biomedical
   research: v 1, Per Svendsen, Jann Hau, 1994
Course Objectives
To be able to appreciate and understand importance of writing scientifically.
• To develop competence in writing and abstracting skills.
• To write either a draft research proposal or a chapter of dissertation.

UNIT – I
COLLECTION AND EVALUATION OF INFORMATION
Identification sources, searching information, classifying information under fact/opinion, tabulating information, summarizing a text and presenting sequence of topics in different forms.

UNIT – II
WRITING AS A MEANS OF COMMUNICATION
- Different forms of scientific and technical writing.
- Articles in journals, Research notes and reports, Review articles, Monographs, Dissertations, Bibliographies.
How to formulate outlines: The reasons for preparing outlines
   (i) as a guide for plan of writing      (ii) as skeleton for the manuscript
Kinds of outline: topic outlines, conceptual outline, sentence outlines and combination of topic and sentence outlines

UNIT – III
DRAFTING TITLES, SUB TITLES, TABLES, ILLUSTRATIONS
- Tables as systematic means of presenting data in rows and columns and lucid way of indicating relationships and results.
- Formatting Tables: Title, Body stab, Stab Column, Column Head, Spanner Head, Box Head
- Appendices: use and guidelines
The Writing process: Getting started, Use outline as a starting device, Drafting, Reflecting and Re-reading
Checking: Organization, Headings, Content, Clarity and Grammar
Brevity and Precision in writing - Drafting and Re-drafting based on critical evaluation

UNIT – IV
PARTS OF DISSERTATION/RESEARCH REPORT/ARTICLE
Introduction, Review of Literature, Methodology, Results and Discussion
Ask questions related to: content, continuity, clarify, validity internal consistency and objectivity during writing each of the above parts.

UNIT – V
WRITING FOR GRANTS
Clearly state the question to be addressed; Rationale and importance of the question being address; Empirical and theoretical conceptualization; Presenting pilot study/data; Research proposal of method; Clarity, specificity of method; Clear organization; Outcome of study and its implications; Budgeting; Available infra-structure and resources and Executive summary
References

UNIT – I
Concepts of total quality management, good laboratory practices and ISO.
Quality assurance & Quality control for active pharmaceutical ingredients (APIs) and other intermediates in process and finished products. GMP for bulk drugs and formulations.

UNIT – II
Validation of process, equipment, procedures, validation master plans.
Regulatory compliance records, Distribution records, Drug recall registers, management review records etc.

UNIT – III

UNIT – IV

UNIT – V
Indian Patent Act as amended up to date with reference to drugs and Intellectual property rights, world trade Organization, filing a patent under Indian patent Act, Filing International patent, Infringement of patent; Doha Declaration, Trade Related Intellectual Property rights. (TRIPS).Patent search, patent challenging and para IV filing

Recommended Books

1. Drugs & Cosmetics Act 1940 by Vijay Malik.
2. Drugs Laws by Hussain.
3. Indian patent Act.
5. Quality control & Application by Bentrand L. Hanser.
UNIT – I
Receptor Pharmacology
General aspects of receptor pharmacology, structural and functional aspects of receptors, regulation of receptors, isolation, classification and characterization of receptors.

UNIT – II
Neurotransmission Pharmacology
General aspects and steps involved in neurotransmission
Neurohumoral transmission in autonomic nervous system.
Neurohumoral transmission in central nervous system
Non-adrenergic non-cholinergic transmission [NANC].

UNIT – III
A detailed study of the mechanism of action, pharmacology of drugs used in
ANS-Parasympathomimetics and lytics, sympathomimetics and lytics, agents acting at neuromuscular junction and ganglia.
CNS- General anaesthetics, sedatives, hypnotics. Drugs used to treat anxiety, depression, psychosis, mania, epilepsy, neurodegenerative diseases, drug dependence and addiction.
CVS- diuretics, anti isemics, antihypertensives, antiarrythmics, drugs for heart failure and dyslipidemia.

UNIT – IV
A detailed study of the mechanism of action, pharmacology of drugs used in
Autocoid pharmacology- a study of the mechanisms involved in the formation, release, pharmacological actions and possible physiological role of histamine, serotonin, kinins, prostaglandins, opioidautocoids and cyclic 3’ – 5’ AMP. Systemic pharmacology of drugs acting as agonists and antagonists to the autocoids.
GIT Pharmacology – anti ulcer, prokinetics, antiemetics, antidiarrhoal and drugs for constipation and irritable bowel syndrome.
Hormone and hormone antagonists. Anti biotics and chemotherapeutic agents.
Analgesics and anti-inflammatory agents.

UNIT – V
FREE RADICAL AND IMMUNO PHARMACOLOGY
Generation of free radicals, role of free radicals in etiopathology of various diseases, protective activity of certain important antioxidants. Cell and biochemical mediators involved in allergy, immunomodulation and inflammation. Classification of hypersensitivity reactions and diseases involved. Therapeutic agents for allergy, asthma, COPD and other immunological diseases with emphasis on immunomodulators.
Recommended books

1. Clinical Pharmacology by D.R.Lawrence and P.N.Bennette
3. The Pharmacology basis of therapeutics. 10th edition by Louis S.Goodman and Altred Gillman
4. Pharmacology by H.P. Rang and M.A. Dale
5. Biopharmaceutics and Pharmacokinetics and introduction by E. Notary
6. Drug Metabolism by Berhard Tests and Peter Jenner.
10. Pharmaceutical Practice , Win field
BIOPHARMACEUTICS AND PHARMACOKINETICS

Subject Code : M.PCOL.T.1.203
Sessional : 30
Period / Week: 4
Examinations : 70
Nature of Exam: Theory
Duration of Exam: 3 hrs

UNIT -1
Bioavailability and Bioequivalence: Objectives, bioavailability & variations, measurements of bioavailability, enhancing bioavailability, concepts of equivalents, official bioequivalence protocols & therapeutic equivalence.

UNIT -2
Drug Distribution: Factors affecting, protein & tissue binding, kinetics, determination of rate constants & different plots (direct, Scatchard, & reciprocal).

UNIT -3
Pharmacokinetics: Parameters & determination, pharmacokinetic models – one compartment, multi compartment in IV bolus, IV infusion & extra vascular, drug & metabolites levels in blood, urine and other biological fluids. Integration of kinetics.
Application of pharmacokinetics in new drug development, design of dosage forms and novel drug delivery systems.

UNIT -4
Drug Disposition and Excretion: Biotransformation, factors affecting biotransformation, Phase I & Phase-II reactions.
Clearance: Concept, renal, non-renal clearance, mechanism, determination, % drug metabolized, different volume of distribution.

UNIT – 5
Pharmacokinetics of Multiple Dosing: Various terminology, determination, adjustment of dosage in renal & hepatic impairment, individualization of therapy, therapeutic drug monitoring.
Non-linear kinetics: Cause of non-linearity, estimation of various parameters, bioavailability of drugs that follow non-linear kinetics. Chronopharmacokinetics & pharmacokinetics of elderly and infants.

Recommended books

3. Theory & Practice of Industrial Pharmacy, L.Lachman, Varghese Publ, Bombay.
UNIT –I

Principles of Pharmacokinetics.

A. Revision of Basic concepts.
B. Clinical Pharmacokinetics.
   1. Dose – response in man
   2. Influence of renal and hepatic disease on Pharmacokinetics
   3. Therapeutics drug monitoring

UNIT – II

Basics in clinical pharmacology
Clinical trials of drugs, design of clinical trials
Therapeutic drug monitoring and criteria for TDM.
Adverse Drug Reactions, Drug Interactions and ADR monitoring.

UNIT – III

Pathophysiology and drug therapy of the following disorders.

   Schizophrenia, anxiety, depression, epilepsy, Parkinson’s Alzheimer’s diseases Migraine hypertension, angina pectoris, arrhythmias, atherosclerosis, myocardial infraction, TB, leprosy, leukemia, solid tumors, lymphomas, psoriasis, respiratory, urinary, g.i. tract infections, endocarditic, fungal and HIV infection, rheumatoid arthritis, glaucoma, menstrual disorders, menopause.

UNIT – IV

Drug therapy and Pharmacokinetics in
a. Geriatrics
b. Pediatrics
c. Pregnancy & Lactation.

UNIT - V

Recommended Books

1. Biopharmaceutics and Pharmacokinetics, Venkateshwarlu
2. Clinical Pharmacy and therapeutics, Herfindal
3. Drug Disposition and Pharmacokinetics, H.Curry
4. Pharmacokinetics, Milo Gibaldi
5. Managing clinical Drug development, Cocchetto
6. Pharmacogenomics, Kalow
7. Drug discovery and development, Rang
8. Basic Statistics and Pharmaceutical Statistical applications, Muth
9. Pharmacokinetics for the Pharmaceutical Scientist, Wagner
11. Clinical Pharmacology by D.R.Lawrence and P.N.Bennette
List of Experiments.

Minimum 8 experiments shall be conducted.

1. Experiments for studying the effects of the more important biogenic agents like histamine, acetylcholine, 5HT, oxytocin and their effect in the presence of antagonist on suitable isolated tissue preparations.
2. Estimation of PA2 values of various antagonists under suitable isolated tissue preparations.
3. Experiments on CVS- effect of various drugs on isolated heart preparations on various animal models under normal arrhythmic and hypo dynamic conditions.
4. Drugs acting on Gastro intestinal tract. To study the drug activity on oesophagal motility.
6. Action of CNS stimulants and depressants using suitable experimental model.
7. Evaluation of antidepressant and anti anxiety drugs.
8. Drug absorption and elimination studies.
9. Any other experiment based on the topics mentioned in theory,
10. Virtual and stimulated experiments are permitted.
Suggested experiments

1. Comparative dissolution studies on different dosage forms for drugs.
2. Effect of pH / particle size on dissolution studies.
3. Plasma protein binding studies on different drugs.
5. Estimation of creatinine clearance.
6. Estimation of pharmacokinetic parameters for the given urinary excretion data.
7. Estimation of pharmacokinetic parameters for the given oral absorption data.
ENTREPRENEURSHIP MANAGEMENT

Subject Code: M.PCOL T 1.207
Sessional: 50
Periods/week: 2
Examination: --
Nature of Exam: Tutorials
Exam Duration: --

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.

UNIT – I: CONCEPTUAL FRAME WORK
- Concept need and process in entrepreneurship development.
- Role of enterprise in national and global economy
- Types of enterprise – Merits and Demerits
- Government policies and schemes for enterprise development
- Institutional support in enterprise development and management

UNIT – II: 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.

UNIT – III: LAUNCHING AND ORGANISING AN ENTERPRISE
- Environment scanning – Information, sources, schemes of assistance, problems.
- Enterprise selection, market assessment, enterprise feasibility study, SWOT Analysis.
- Resource mobilization - finance, technology, raw material, site and manpower.
- Costing and marketing management and quality control.
- Feedback, monitoring and evaluation.

UNIT – IV: 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

UNIT – V: PREPARING PROJECT PROPOSAL TO START ON NEW ENTERPRISE
- Project work – Feasibility report; Planning, resource mobilization and implementation.

Reference