DR. BABASAHEB AMBEDKAR MARATHWADA UNIVERSITY, AURANGABAD
SYLLABUS FOR THE FINAL YEAR B. PHARM. COURSE

Sr. No.	Subject	Theory hours per week	Practical hours per week
4.1.	Dosage form Design	3	3
4.2.	Pharmacognosy and Phytochemistry	3	3
4.3.	Medicinal Chemistry - II	3	3
4.4.	Pharmacology and Bioassay	3	3
4.5.	Pharmaceutical Management	3	--
4.6.	Quality Assurance Techniques	3	3
4.7.	Pharmaceutical Jurisprudence and Intellectual Property Rights	3	--
	Total	21	15

4.1 : Dosage Form Design – Theory (Final B. Pharm.) - 3 HRS. / WEEK

Sr. No.	Topics and contents	Hours
	SECTION - A	
1.	**Preformulation: -** Concept of preformulation, Organization of preformulation activity, Essential information of new drug for preformulation, Principle areas of preformulation: - Analytical preformulation, Bulk Characterization, Solubility, Stability Analysis.	08
2.	**Solubility and Dissolution: -** Methods of expressing solubility, Prediction of solubility Physicochemical prediction of solubility Solubility Parameters Factors affecting on solubility Dissolution mechanisms Factors affecting dissolution Intrinsic dissolution Measurement of dissolution rates	10
3	**Stability: -** Definition: - Expiry date, Shelf life, Order of reaction. Environmental factors influencing stability: - pH, Solvent, Solubility, Additives, Light, Temperature, Acid Base Catalysis, Ionic Strength Modes of drug instability and methods to prevent them: - Chemical and Physical Technique of stability prediction, Tentative expiry dating Introduction to cGMP guidelines in stability testing and expiry dating(No details) Effect of packaging material on stability of drug.	10
4	**Package Development: -** Structure and composition Glass- types, manufacture of glass, glass container, evaluation Plastic- definition, material properties (mechanical, electrical and optical), physicochemical properties (mass transfer, chemical attack), types-thermoplastic, thermoset with example and applications. Drug plastic interactions, evaluation of plastics Collapsible tubes- metal, plastic, lamination Closure: closure types (rubber, plastic), closure liners, tamper resistant packaging, film wrappers, blister packing material, strip package, bubble pack, shrink banding, pouches, bottle seal, taper seals, breakable caps, tape seals, seal cartons.	10

SECTION B

5	**Oral Sustained Release and Introduction to NDDS: -** Introduction, Terminology Biopharmaceutical aspects: - Steady state concepts, Calculation of loading and maintenance dose. Design of oral SRDF systems: - Biological factors, Physicochemical factors Diffusional systems: - Reservoir system, Lag time, Burst effect Matrix system, Effect of porosity and tortuosity Dissolution controlled system, Cube route dissolution equation, Diffusion layer controlled dissolution. Bioerodible and Combination of diffusion and dissolution systems Evaluation: - Official and unofficial methods of evaluation of SRDF/CRDF system Polymers used in SRDF system *Introduction to NDDS(Novel Drug Delivery System): -* Osmotically controlled system, osmotic pumps Ion exchange system Transdermal system Occular system Intravaginal and intrauterine system Injection and implant Biomucoadhesive system Iontophhoretic system Sonophoretic system Targeted drug delivery system: - Liposome, Nanoparticles, Prodrugs, Resealed erythrocytes, Antibody targeted systems	15
6	**Scale Up Techniques: -** Introduction Steps involved in scale up General consideration Scale up examples of: Solid dosage form Liquid dosage forms- Solution, Suspension, Emulsion. Semi solid dosage forms- Suppository	06
7	**Optimization and Experimental Design: -** Introduction Concepts of optimized drug product Various optimization parameters like problem types and variables Optimization techniques: - Classical optimization, Statistical design Optimization methods : Evolutionary, Simplex, Langarian, Search (Introduction only). *Experimental design (Introduction to)* Designing strategy and purpose of experimental design along with pharmaceutical examples. Stages in experimental design Starting of experimental design- Definition, Important concepts of experimental design, Software for designing.	07
8	**Design of Dosage Form:-**	06

Principles of dosage form design (DFD)
Biopharmaceutical aspects of DFD
Drug related factors in DFD
Therapeutic considerations in DFD.

References:

- Leon Lachmann, H. Liebermann, "Principles and Practice of Industrial Pharmacy
- Banker's Modern Pharmaceutics
- Pharmaceutical Experimental Design, , M and D series by Lewis Vol-92
- Kim, Advanced Pharmaceutics
- Aulton, Pharmaceutics.
- Rawland, Pharmaceutics.
- "Remington's Science and Practice of Pharmacy", 20th edition, Vol-I and II
- ICH guidelines for stability study
- Indian Pharmacopoeia – Current Editions
- British Pharmacopoeia – Current Editions
- United State Pharmacopoeia – Current Editions
- S.P.Vyas, R.K.Khar, Targeted and controlled drug delivery system, CBS Publication
- Chein, Controlled Drug Delivery Systems, Marcel Dekkers Publication.

4.1 : Dosage Form Design – Practical (Final B. Pharm.) - 3 HRS. / Batch / Week

1 Compare oxidative degradation of ascorbic acid at pH 2.0 and 8.0.

2 Compare the degradation rate constant of ascorbic acid in presence of cuppric ions.

3 Construction and analysis of Plaquette Burman design to a hypothetical system.

4 Demonstration of fluidised bed processing technique.

5 Demonstration of mixing performance evaluation of mixer (Sigma/ Planetary/ ribbon/ RMG)

6 Demonstration of Preparation of microcapsules of given sample of drug by extrusion & sperodization technique.

7 Determination of compressibility of given material

8 Determination of effect of solvent on aspirin solution stability

9 Determination of F value of given dosage form

10 Determination of micromeritic properties of given material (MCC/ Starch etc.)

11 Determination of Phase solubility analysis of drug β-CD complex

12 Determination of solubility of given drug at different pH

13 Determine the energy of activation of hydrolysis of aspirin/ ascorbic acid solution

14 Determine the optimum dielectric constant for maximum solubility of drug.

15 Evaluate antimicrobial adsorption property of given sample of rubber closure.

16 Fitting of data to linear, log and polynomial system to determine best fit.

17 Perform pharmacopeia test for given sample of glass vial / ampoule.

18 Perform physicochemical test as per pharmacopoeia on given sample of plastic.

19 Preparation of ion exchange complex of given drug sample and evaluation of its release

20 Prepare & evaluate beads of given sample of drug using melt dispersion

21 Prepare & evaluate beads of given sample of drug using polymer coacervation

22 Study of effect of homogenizing time on emulsion globule distribution of liquid paraffin emulsion

References:

- Leon Lachmann, H. Liebermann, "Principles and Practice of Industrial Pharmacy
- Banker's Modern Pharmaceutics
- Pharmaceutical Experimental Design, , M and D series by Lewis Vol-92
- Kim, Advanced Pharmaceutics
- Aulton, Pharmaceutics.
- Rawland, Pharmaceutics.
- "Remington's Science and Practice of Pharmacy", 20th edition, Vol-I and II
- ICH guidelines for stability study

- Indian Pharmacopoeia – Current Editions
- British Pharmacopoeia – Current Editions
- United State Pharmacopoeia – Current Editions
- S.P.Vyas, R.K.Khar, Targeted and controlled drug delivery system, CBS Publication
- Chein, Controlled Drug Delivery Systems, Marcel Dekkers Publication.

4.2 : Pharmacognosy and Phytochemistry – Theory (Final B. Pharm.) - 3 HRS. / Week

Section A

1. Phytochemical investigation of crude drugs and it's importance

   (1)

   Detail study of each category of drugs under phytochemical scheme including biosynthesis

2. VOLATILE OIL AND TERPENOIDS:

   (12)

   Definition composition Chemistry and extraction of volatile oils, biosynthesis, terpeneless volatile oils

   Study of drugs containing volatile oils

   a) Monoterpenoids: Rosemary, Anise, Cummin, Celery, Lavender, Gaultheria, Palmarosa, Citronella, Thyme, Camphor, Chenopodium, Eucalyptous, Lemongrass, Turpentine, Pepprmint oil, Caraway, Cardamom, Coriander, Ajowan, Dill, Fennel, Lemon peel, Orange peel, Nutmg, Cassia, Cinnamon, jatamansi, garlic, Sweet basil, Sacred basil, Musk, Civet
   b) Sesquiteerpenoids: Artemisia, Davana, Arnica, Sandalwood, Clove, Hops, Saussurea, Cubeb, Valerian, Ferverfew
   c) Diterpenoids: Taxus, Coleus
   d) Triterpenoids: Ambergris
   e) Tetraterpenoids and polyterpenoids: Annatto, Saffron
      Structure determination and elucidation of, Citral, Geraniol, Menthol, Santonin, Beta carotene

3. ALKALOIDS**:**

   (12)

Definition, distribution, classification, methods of isolation, properties, chemistry and biosynthesis of following group of alkaloids

Study of alkaloid containing drugs,

1) Tropane: Belladonna, Datura, Hyoscamus, Stramonium, Coca, Duboisa
2) Indole: Ergot, Nuxvomica, Physostigma, Rauwolfia, Vinca,
3) Isoquinoline: Opium, Ipecac, berberis, Hydrastis, Curare,
4) Quinoline; Cichona, and Camptotheca
5) Pyridine: Lobelia, Areca
6) Quinazoline: Vasaka
7) Purine; Coffee, Tea, and Coca
8) Imidazole; Pilocarpus
9) Steroidal: Veratrum, Kurchi, Ashwagandha,
10) Protoalkaloids: Ephedra, Colchicum, Aconite, Gloriosa

Structure determination and elucidation of, Reserpine, Morphine, Atropine, Caffeine, Ephedrine

4. MARINE DRUGS**:** **(04)**

Indroduction, importance, classification of drug molecules from marine organisms

a) Cytotoxic and antineoplastic agents
b) Cardiovascular drugs
c) Marine toxins

d) Antimicribial drugs
e) Antibiotic substances
f) Antiinflammatory and antispasmodics
g) Miscelleneous pharmacologically active substances

Section B

1. Extraction isolation and analysis of phytopharmaceuticals
   (06)
   - A detailed study of various methods of extraction and isolation of phytopharmaceuticals namely infusion, decoction, digestion, maceration, percolation, successive solvent extraction, supercritical fluid extraction, steam distillation, had space techniques, sepbox, selection of suitable extraction process
   - Application of chromatography and spectroscopy to plant drug analysis
2. Industrial importance and status of herbal drugs
   (02)
   Role of medicinal and aromatic plants in national economy
   Importance and status of herbal medicines, aromatics and cosmetics
3. Worldwide trade in medicinal and aromatic plants and their derived products. A brief account of plant based industries and institutions involved in work of medicinal and aromatic plants and their products in India
   (02)
4. Details of methods of isolation including industrial identification, chemistry and estimation of, a) Quinine b) Ephedrine c) Cardiac glycosides d) Ca sennosides e) Diosgenin f) Glycyrrhizin g) Citrus bioflavonoids h) Rutin i) Andrographolides j) Phyllanthin k) Guggulosterol l) Gymnrmic acid m) Asiaticoside/ madecassoside n) Withanolides **(10)**
5. Standardization of herbal drugs:
   (05)
   i) Importance of standardization of raw materials, extracts and formulation
   ii) problems involved in standardization of herbs
   iii) Standardization of single drug and compound formulation
   iv) Estimation of parameter limits used for standardization
   v) Herbal extracts
   vi) WHO guidelines or quality standardization of herbal formulation
6. HERBS AND HEALTH FOODS**:** **(10)**
   - Introduction
   - Nutraceuticals, Antioxidants, Prebiotics and probiotics, Poluunsaturated fatty acids, (PUFA), Dietry fibres
   - Definition Introduction status, safety quality control and efficacy and brief study of herbs such as, Alfalfa, Angelica, Arnica, Apricot, Borage, Bran, Chamomile, Chicory, Colcellana, Cucumber, Damiana, Devil's claw, Fenugreek, Garlic, Onion, Gentian, Ginseng, Ginkgo biloba, Hydrocotyl, Golden sal, Hibiscus, Hops, Honey, Kelp, Marigold, Mormontea, Parsley, Passiflora, pennyroyal, Soyabeen, Ganoderma fruits, evening primrose, corn oil, Tejpat oil, Blessed thistle, Balm lemon foliage and flower
   a. Herbal formulations: **(05)**

A comparative study of traditional and modern dosage forms. Classification general considerations and different stages of herbal formulations and dosage forms

b. Herbal cosmetics:

(05)

Definition, classification and role and importance of herbs in cosmetics
Study of following herbal cosmetics

i. Shampoo- soapnut
ii. Conditioner- Amla, Henna, Hibiscus and Tea
iii. Hair darkners; Amla and Henna
iv. Skin care: Aloe vera, Turmeric, Sandalwood, Glycyrrhizin
v. Herbal soap
vi. Herbal mouthwash
vii. Herbal hair tonic
viii. Liquid cream
ix. Lotion

c. Patenting of natural products

(02)

Different aspects of obtaining patents in natural products (rules and regulations therein)

4.2 : Pharmacognosy and Phytochemistry– Practical (Final B. Pharm.)-3 Hrs/batch/ Week

1. Pharmacognostic study excluding histology of following plants:
   Nutmeg, Orange peel, Lemon peel, Jatamansii, Sandalwood, Tulsi, Aconite, Ergot, Colchicum, Swertia, Picrorrhiza, Andrographis

2. Pharmagcognostic study including morphological, histological, powdered drug characteristics of following drugs
   Leaves: Vasaka, Vinca, Neem, Eucalyptus, Datura, Tulsi, Sweet basil,
   Fruits: Fennel, coriander, Anise, Cardamom, Dill,
   Bark: Cinnamon, Kurchi, Ashoka, Arjuna
   Root: Rauwolfia, Ashwagandha, Ipecac, Colchicum
   Stem: Ephedra
   Bud: Clove
   Seed: Nux-vomica
   Entire plant: Picrorrhiza, Andrographis
3. Extraction of active constituents followed by separation by TLC identification by suitable method (At least 10 from the following list)
   i. Extraction of caffeine from tea
   ii. Extraction of hesperidin from orange peel
   iii. Extraction of pectin from any suitable source
   iv. Extraction of alkaloids from vinca
   v. Extraction of vasicine from vasaka
   vi. Extraction of piperine from piper nigrum
   vii. Extraction of strychnine and brucine from nux vomica
   viii. Extraction of curccumine from Curcumma longa
   ix. Extraction of oleoresin from ginger
   x. Extraction of tannic acid from myrobalan
   xi. Extraction of hecogenin from agave
   xii. Extraction of solasodine from suitable source
   xiii. Extraction of berberine from berberis root
   xiv. Extraction of nicotine from tobacco leaves
   xv. Extraction of ammonium glycyrrhizinate from liquorice
   xvi. Extraction of eucalyptus oil, lemongrass oil, cumin oil, coriander oil and dill oil
4. Preparation and evaluation of at least two from each category of the following herbal cosmetics categories
   i. Shampoo
   ii. Conditioner
   iii. Hair darkners
   iv. Skin care
   v. Herbal soap
   vi. Herbal mouthwash
   vii. Herbal hair tonic

viii. Liquid cream
ix. Lotion

References:

- Dr. Pulok Mukherjee, Quality control of Herbal Drugs, Business Horizon G59, Masjid Moth, Gk-2, New Delhi
- Dr. S S Agrawal, Herbal Drug Technology, Orient Longman Pvt. Ltd.3-6-752 Himayat Nagar Hyderabad -29
- Ciddi Veeresham Medicinal Plant Biotechnology CBS Publishers & Distributor , New Delhi
- Amritpal Singh Saroyi, Glossary of Medicinal Plant used in Ayurved, Scientific Publishers (India) P.O. Box 91 Jodhpur
- The Wealth of India Raw Materials (All Volumes) Council of Scientific & Industrial Research, New Delhi
- Peach K and Tracey M V, Modern Methods of Plant Analysis Vol 1 - 4 , Narosa Publishing House, New Delhi
- Swain T, Chemical Plant Taxonomy, Academic Press, London
- Swain T, Comparative Phytochemstry , Academic Press, London
- Wallis T E, Analytical Microscopy ,J A Churchill Ltd. London
- Industrial Gums, Polysaccharides and their derivatives.Second Edition Academic Press, New Delhi
- Iyengar M A, Pharmacognosy Lab Manual, Manipal Power Press, Manipal
- Youngken H W Natural Drugs : Morphologic & Taxonomic consideration
- Chakrabarty Pharmaconomic An Approach to new drug development
- A K Gupta, Neeraj Tandon & Madhu Sharma Quality standards of Indian Medicinal plants Vol -2 1999
- Indian Council for Medical Reasearch, Ansari Nagar, New Delhi
- Kokate C.K Purohit A.P and Gokhale S.B, Pharmacognosy, Nirali Prakashan.
- Kokate C.K Practical Pharmacognosy, Vallabh Prashan, Delhi.
- Atal C.K and Kanpur B.M Cultivation and Utilization of Medicinal Plants, RRL, Jammu.
- Brain K.R and Turner T.T, The Practical Evaluation of Phytopharmaceuticals, Wright-Scientechnica, Bristil.
- Official Methods of Analysis, Association of Official Analytical Chemists Publications, Washington.
- Swain.T, Comparative Phytochemistry, Academic Press London.
- Wallis, T.E Analytical Microscopy, J.A Churchill limited, London.
- Wallis, T.E Textbook of Pharmacognosy, J.A Churchill limited, London.
- Whistler R.L, Industrial Gums, Polysaccharides and their Derivatives, 2nd edition Academic press, New Delhi.
- Tyler, V.E, Brady,R.,Pharmacognosy.
- Wagner, S.B., Zgainsky, Plant Drug Analysis.
- Poluk Mukherjee, Quality Control Of Herbal Drugs, Business Horizons, Pharmaceutical Press, 1st Edition, 2001.
- www.ars.grin.gov/hpgs/tax/index/html
- www.botanical.com

- National and International Journals- phytochemistry, fitoterapia, journal of natural products, Indian journal of natural remedies, journal of ethnopharmacology, phytotherapy research.
- J.S Quadri, Textbook of Pharmacognosy, B.S Shah Prakashan, Ahemdabad,
- Manske R.H.F, The Alkaloids- Academic Press, New York.
- Iyengar M.A., Study of Crude Drugs, Manipal power press, Manipal, 14th edition,2001.
- Herbal Pharmacopiea of India, Govt. of India. Ministry of Health, vol 1 & 2, (1998 and 2001)
- Ashutosh Khar, Pharmacognosy and Pharmacobiotechnology, New Age International Publishers.
- S.H Ansari, Essentials Of Pharmacognosy, CBS Publishers, New Delhi.
- Kaliya, Textbook of Industrial Pharmacognosy, CBS Publisher, New Delhi.
- S.V Bhatt ,Chemistry of Natural Products, Narosa Publishing House, New Delhi.
- Indian Herbal Pharmacopiea, Indian Drug Manufacturers Association, Mumbai.(New Editon, 2002)
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- V.D. Rangari, Pharmacognosy and Phytochemistry, Vol.1 & 2.
- O.P Agrawal, Chemistry Of Organic Natural Products, Vol 1 & 2
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- Quality Standards Of Indian Medicinal Plants, Vol 1 – 8, Indian Council Of Medical Research, New Delhi.
- Trease, G.E and Evans W.C Pharmacognosy, 12th edition, Bailliere tindal, Eastbourne, UK.

4.3 : Medicinal Chemistry – II – Theory (Final B. Pharm.) - 3 Hrs /Week

Section A

1) Introduction- Drug Design, QSAR
(04)

2) Relationship of drug metabolism to drug design
(02)

3) Introduction to prodrug, softdrugs, hard, drugs, orphan drugs.
(02)

4) Combinatorial chemistry-
(03)

Basic concept of combinatorial chemistry, compound libraries, combinatorial synthesis, general techniques used in combinatorial synthesis, screening and identification of lead compounds.

5) Receptors:
(03)

Types of receptors, Drug receptor interactions, receptor site theories, intracellular cyclic nucleotides and other mediators of biological response.

Development of following classes of drugs including introduction, classification, nomenclature(chemical and generic), chemistry, Structure activity relationship(SAR), mechanism of action and Therapeutic uses.

6) Cholinergic agents:
(06)

Neurotransmitters, impulse generation, propagation and release of neurotransmitter in the synapse. Biosynthesis of acetylcholine, its release and metabolism. Cholinergic agonist and antagonist.

7) Adrenergic agents
(05)

Biosynthesis, release and metabolism of Noradrenalin, receptor subtypes and their structural features. Adrenergic agonist and antagonist.

8) Cardiovascular drugs: (10)

Cardiotonic drugs, antianginal agents, antiarrthymic agents, antihypertensive agents, Antihyperlidemic agents

9) Local anesthetic agents: (02)

10) Synthesis of Carbachol, Bethnechol, Dicyclomine, noradrenaline, methyl dopa, propranolol, salbutamol, terbutaline, captopril, verapmil. Atenolol, clondine, lignocaine, procaine, benzocaine, clofibrate,

Section B

11) CNS stimulant drugs: (02)

Analeptics, respiratory stimulants, Hallucinogens

12) CNS depressants:
(06)

General anesthetics, Sedative-Hypnotic agents and Anticonvulsants.

13) Psychotherapeutic agents:
(04)

Antipsychotic agents, antidepressant and anxiolytics.

14) Narcotic agents:
(06)

Receptor subtypes, opoid agonist and opoid antagonist, skeletal and peripheral modification of morphine

15) Non narcotic analgesic anti-inflammatory and antipyretic agents
(04)

16) Antihistaminic and antiulcer agents: (04)

Structural features of histamine, histamine receptors and their structural features, H_1 blockers, H_2 blocker and Proton pump blockers.

17) Steroids: (08)

Steroidal anti-inflammatory agents, Sex hormones and their synthetic analogues, anti-fertility agents.

18) Prosatglandins: (02)

Introduction, Classification, SAR, Uses.

19) Drugs used for Parkinsonism. (01)

20) Drugs used for Alzheimer's disease
(01)

21) Synthesis of Nikethamide, Phenametrazine, Phenobarbitone, Hydantoin, diazepam, valproic acid, meperidine, methadone, ibuprofen, indomethacin, naproxen, rofecoxib, omeprazole, prolidine, chlorpheniramine, diethyl stilbesterol. imipramine, doxepine, diazepam. Meprobamate, fluperazine, Chlorpromazine.

References:

- Burgers Medicinal chemistry-The Basis of Medicinal chemistry by Manfred E. Wolff I (John Wiley & Sons).
- Foye: Principles of Medicinal Chemistry (Varghese & Co.)
- Ariens: Medicinal Chemistry Series
- Ellis and West: Progress in Medicinal Series
- Butterworther: Progress in Medicinal Chemistry Series
- Wilson and Gisvold's Text book of Medicinal Chemistry (J. B. Lippincoff cam)
- Comprehensive Medicinal Chemistry – Series – I-VI (Academic Press) 1. Ariens-Drug Design, Vol. VII.
- Smith-William-Introduction to the Principle of Drug Design.
- Introduction to the Principles of Drug Design by John Smith & Hywel Williams (Wright PSG)
- Guide to Chemical Basis of Drug Design by Alfred Burger (John Wiley & Sons)

4.3 : Medicinal Chemistry – II – Practical (Final B. Pharm.) - 3 Hrs /Batch/Week

Synthesis and characterization of

1) Sulphonamides
2) Benzocaine
3) Paracetamol
4) Benzoyl glycine
5) Hippuric acid
6) Acetoacetanilide
7) Benzalacetone
8) 7-Hydroxy-4-methyl Coumarine
9) Phenytoin
10) 1-Phenyl-2,3-dimethyl pyrazole-5-one
11) Reactions involving following operation- oxidation, reduction, FCA, Perkin etc.
12) Few one or two step synthesis.

References:

- Organic Synthesis: Fieser and William Son (CBS Publisher)
- Mann and Saunders, practical Organic Chemistry (Orient Longman)
- Al Vogel, Practical Qualitative and Quantitative Organic Chemistry (Orient Longman)
- Introduction to organic laboratory techniques – A microscale approach by Vavia.
- Advanced Practical Organic Chemistry by N.K. Vishnoi.

4.4 : Pharmacology and Bioassay – Theory (Final B. Pharm.) - 3 Hrs / Week

S.N.	TOPIC	HRS
	SECTION A	
1.	**Drugs acting on Central Nervous system:** CNS synaptic transmission including neurotransmitters, neuromodulators, transduction system in central nervous system. Receptors present in CNS and their interrelation with each other.	2 1
	Aliphatic alcohols: Pharmacology of alcohol, drug and food interaction of alcohol and pharmacotherapy of alcoholism.	2
	General anesthetics: Classification, theory of anesthesia, stages of anesthesia, Pharmacology of diethyl ether, halothane, enflurane, thiopental sodium and ketamine. Anesthetic medication, Neuroleptanalgesia.	3
	Sedatives and Hypnotics: Physiology of sleep, insomnia. Pharmacological account of barbiturates, benzodiazepins and non-barbiturates.	3
	Antiepileptic agents: Neuropharmacology of epilepsy, Classification epilepsy. Classification and Pharmacological account of drugs from each class of antiepileptic drugs.	5
	Drugs used in mental illness: Discuss the socio-economical implication of mental illness. Neuropharmacology of mental illness. Antipsychotic agents, Antianxiety, Antidepressants, Antimanic drugs and Hallucinogens.	4 1
	Drugs used in Pain and Inflammations: Opioids, analgesics, Non-opioid analgesics, Non-steroidal Anti-inflammatory agents and Local anesthetics. Pharmacology of Gout, Rheumatoid arthritis, Osteoarthritis.	2 3
	Pharmacological accounts of central nervous system stimulats.	
	Drugs used in Parkinson's and Alzimer's disease: Neuropharmacology of Parkinson's and Alzimer's disease. Drugs used from Parkinson's and Alzimer's disease.	
	Screening of drugs belongs to CNS category: Organization and general method of screening for CNS depressants and antidepressants, Ataractics, Analgesics, Anti-inflammatory agents, Anticonvulsants, CNS stimulants, local and general anesthetics. Drugs used in parkinsonism	
2.	**Bioassay:** Principles, Requirements, Design. Methods, Advantages and Limitations of bioassay. Bioassay of Acetylcholine, Histamine, d-tubercurarine, Digitalis, Adrenaline, Heparin, Insulin, Oxytocin.	8
3.	**Drugs acting on Respiratory System: A**nti-tussives and Expectorants. Pharmacotherapy of cough, bronchial asthma and pneumonia.	3
	SECTION B	
4.	**Drugs acting on Gastro-Intestinal Tract:** Purgatives, Laxative, Antidiarrhoeals, Antiemetics, Antacids and Antiulcer drugs.	2
5.	**Drugs acting on cardiovascular system:** A general account of treatment of cardiovascular complications. Diuretics and antidiuretic agents, antihypertensive agents. Drugs used from Angina pectoris, cardiac arrhythmias, Congestive cardiac failure, Myocardial infarction, shock	10
	Screening of drugs belong to CVS category: Organization and general method of screening for cardio tonic, Bronchodilators, Vasopressives,	4

S.N.	TOPIC	HRS
	diuretics, netriuretic agents.	
	Pharmacology of drug action on blood and blood forming organs: Coagulants, Anticoagulatns, Hemopoietics, Thrombolytic and antiplatlet agents, antihyperlipidemias, plasma expanders.	2
6.	**Clinical Pharmacology:** General Principles, preparation, maintenance, analysis of observational records in clinical pharmacology. Clinical trials, types and phases of clinical trials, placebo, ethical and regulatory issues including GCP in clinical trials. Therapeutic drug monitoring. Adverse drug reactions (ADR), Type of ADR, mechanism of ADR, Drug interaction, Monitoring and reporting ADR and its significance, Drug information services. Drug Interactions. Drug treatment in pediatric and geriatric patients, Drug treatment during pregnancy, lactation and menstruation	20

References:

- Katzung B.G. Basic and Clinical Pharmacology, Lange Medical Publication, California
- Barar F.S.K., Essentials of Pharmacotherapeutics, S.Chand and Co. New Delhi
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- Melon K.L., Morelli, Clinical Pharmacology, Basic Principles in Therapeutics, McMillan, New York
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- Laurence D.R., Bennett P.N., Clinical Pharmacology, Churchill Livingstone Edinburg
- Das M.M., Dutta S.K.R., Ghosh's Modern Concept on Pharmacology and Therapeutics, Hilton and Co., Calcultta
- Satoskar R.S. Bhandarkar S.D., Pharmacology and Pharmacotherapeutics, Popular Prakashan
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- Rang H.P. and dale M.M., Pharmacology, Churchill Livingstone, U.K.
- Tripathi K.D., Medical Pharmacology, Jaypee Publications, New Delhi
- Avery G.S. Drug Treatment, Adiss Press, Sydney
- Bevan J.A., Thompson J.H., Essential of Pharmacology, Harper and Row Publishers, Philadelphia
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- Drill V.A., Pharmacology in Medicine, Mc Graw Hill co, New York
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- Krantz and Carr: Pharmacology Principles of Medical Practice, Williams and Wilkins Co, Baltimore
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- Pharmacopoeia of India (1985), Controller of Publication, Delhi
- Prashan S.N., Maickel R.P. and Dutta S.N., Pharmacology in Medicine-Principles and Practice, S.P.Press International Inc., Maryland
- Turner R.A., Screening Methods in Pharmacology, Academic Press, London
- Balaraman R., Gulati O.D, Patil P.N., Goyal R.K., Topics in History of Pharmacology, BS Shah Publications, Ahmedabad
- Bauer L.A., Applied Clinical Pharmacokinetics, McGraw-Hill Professional Singaapore
- DiPiro J.T., Encyclopedia of Clinical Pharmacology, Marcel Dekker, New York
- DiPiro J.T., Pharmacotherapeutics: A Pathophysiological Approach, Elsevier Publications, London
- Hansten P.D.: Drug Interactions, Lea and Febiger, Philadelphia
- Harisons: Principles of Internal Medicines, McGraw Hill Publications, Singpore
- Herfindal E: Clinical Pharmacy and therapeutics, Willimas and Wilkons Publications, New York
- Parthasarathy G:, A textbook of Clinical Pharmacy Practice-Essential Concept and Skills, Orient Longman Hongking.
- Pradhan S.N., Maicjel R.P. and Dutta S.N.: Pharmacology in Medicine-Principles and Practice, S.P. Press Internaltional Inc, Maryland
- Rodrignes A.D.: Drug-drug interaction, Vol 116, Marcel Dekkar, New York
- Speight T.M. and Holford N.H.G., Avery's Drug treatment, Blackwell Publishing, New York
- Stcokely L.H., Drug Interactions, Pharmaceutical Press London
- Tripathi K.D., Essentials of Medical Pharmacology, Jaypee Brothers, Medical Publishers, New Delhi

- Walker R. and Edwards C: Clinical Pharmacy and Therapeutics, Churchill Livingstons, London
- Dart Medical Toxicology, Third edition, Lippincott William and Wilkins
- Herfindal Gaureley, Text Book of Therapeutics: Drug and diseases management, Seventh edition, Lippincott William and Wilkins.

4.4 : Pharmacology and Bioassay – Practical (Final B. Pharm.) - 3 Hrs /Batch/Week

1. Screening of drugs - Various principles of screening of drug. Rational of each method, importance and use of method in screening of drug for various categories of drugs, Irwin's schedule and Smith's schedule of drug screening.
2. To study various instruments used in experimental pharmacology like Eddi's hot plate analgesiometer, Tail flick analgesiometer, Rota rod apparatus, Pole climbing apparatus, actophotometer, Telethermometer, Activity cage, Elevated maze pluse, metabolic cage, Physiograph, polygraph, Respiratory pump, Operation table, Plethysmometer etc.
3. To study the effect of ions (Potassium, Calcium and Sodium) on suitable animal tissue.
4. To study the effect of agonists and antagonists (adrenergic and cholinergic) on tissue response using suitable animal tissue.
5. To find out the given unknown (amongst ion, agonist, antagonist) using suitable animal tissue.
6. To study analgesic activity of drug using Eddi's hot plate analgesiometer OR tail flick radiant heat analgesiometer
7. To study analgesic activity of drug using tail immersion / tail clip method
8. To study locomotor activity of drug using actophotometer
9. To study anticonvulsant activity of drug using maximal electroshock method
10. To study anticonvulsant activity of drug using chemical (Pentylenetetrzole, picrotoxin, strychnine) induces convulsion
11. To study the muscle relaxant property of drug using rota-rod
12. To study haloperidol / beclofen / pentazocine induced catalepsy (Demonstration)
13. To study local anesthetic effect of drug using suitable animal model
14. Bioassay of Acetyl Choline by interpolation method using suitable animal isolated tissue
15. Bioassay of Acetyl Choline by matching method using suitable animal isolated tissue
16. Bioassay of Acetyl Choline by bracketing method using suitable animal isolated tissue
17. Bioassay of Acetyl Choline by 4 point method using suitable animal isolated tissue

18. Bioassay of histamine by interpolation / matching method on suitable animal isolated tissue
19. Bioassay of histamine by bracketing / 4 point method on suitable animal isolated tissue
20. Bioassay of adrenaline by interpolation / matching method on suitable animal isolated tissue
21. Bioassay of adrenaline by bracketing / 4 point method on suitable animal isolated tissue
22. Bioassay of oxytosine by interpolation / matching method on suitable animal isolated tissue
23. Bioassay of oxytosine by bracketing / 4 point method on suitable animal isolated tissue
24. Bioassay of d-tubocurarine using suitable method and suitable animal isolated tissue
25. Comment of special instructions, drug interactions and Adverse drug reactions in prescriptions.

NOTE: The Principal, Head of Department and the subject in charge should look in the matter of utilization of animals for experimental Pharmacology Practical. The Institute should seek permission from CPCSEA (Registration) as per *The Prevention of Cruelty to Animals act of 1960, The Experiments on Animals (Control and Supervision) Amendment Rules (1998) and the Breeding of and Experiments on Animals (Control and Supervision) Rules (1998)*. The protocols used for above experiments must be approved in IAEC (Institutional Animal Ethical Committee) meeting.

References:

- Burn J.H., Practifcal Pharmacology, Blackwell Scientific Co Oxford
- Ghosh M.N., Fundamental of Experimental Pharmacology, Scientific Book Agency, Bombay
- Jaju B.P., Pharmacological Practical Exercise Book, Jaypee Brothers, New Delhi
- Kulkarni S.K., Hand Book of Experimental Pharmacology, Vallabh Prakashan, New Delhi
- Laurence D.R. and Bacharach A.L., Evaluation of Drug activity: Pharmacometritics, Academic Press, London
- Perry W.L.M., Pharmacological Experiments on Isolated Preparations E and SP Livingston, London
- Sheth U.K., Dadkar N.K. and Kamat U.G., Selected topics in Experimental Pharmacology, Kothari Book Depot, Bombay
- Turner R.A., Screnning methods in Pharmacology, Academic Press, London
- Bolton, Sanford and Bon, Charles Pharmaceutical Statistics (Drug amnd the Pharmaceutical sciences: a series of Textbooks and Monographs), Dekkers, New Delhi
- Daniel Wayne W., Biostatistics: A fundamental for analysis in the health science, Wiley series in probability ans statistics, Wiley interscience, USA
- Goyal R.K., Practical Experimental Pharmacology., BS Shah Prakashan, Ahmedabad
- Patil C.R. X-Cology (Software), Pragati book Co. Pvt. Ltd.
- Ravindran R: X-Pharm (Software), Indian Journal of Pharmacology, JIPMER, Pondichery
- Tozer R., Clinical Pharmacokinetics, Wiliams and Wiljins Publications, New York
- Koppanyi T and karczmar A.G., Experimental Pharmacodynamics
- Vogel's Drug discovery and evluation, Second edition, Springer

- V.G.Ranade, Shalini Pradhan, P.N.Joshi, A Text book of Practical Physiology, Fourth edition, Pune Vidyarthi Griha Prakashan, Pune

4.4 : Pharmaceutical Management – Theory (Final B. Pharm.) - 3 Hrs /Week

SECTION - A

1) Concept of management: Definition, management as science and art, Nature of management. Management by objective, management by result.
(03)
2) Development of management thought: Contribution of F.W. Taylor as scientific management, Contribution of Henry Fayol to management.
(03)
3) Functions of management: Planning, organizing, Controlling, Staffing, directing, coordinating, Motivating, commanding, leading, decision making. Function of Top level, middle level and supervisory level management.
(03)
4) Management skills: Technical, conceptual, Human Skills.
(01)
5) Principles and theories of organizations
(02)
6) Authority, Responsibilities, Delegation and Steps in delegation process.
(02)
7) Performance: Definition, need and objective of performance appraisal, types/ approaches of performance appraisal.
(02)
8) Communication**:** Importance, nature of communication, types of communication- oral vs. written, media of communication. Barriers to communication, Communication failure, achieving effective communication.
(02)
9) Forms of Business organizations: Sole Proprietorship, Partnership, Company(Public and private limited)
(03)

<u>Pharmaceutical Marketing:</u>

1) Concept of Marketing and selling, Difference between consumer marketing and pharmaceutical marketing.
(02)

2) Organization of Marketing and sells department ,Role of medical representative, Ideal characteristics of MR,

(02)

3) Evolution/ development of marketing management concept: Product concept, Production concept, selling concept and marketing concept.

(02)

4) Marketing research: Definition, objectives, need, steps in marketing research, reasons for failure of market research.

(02)

5) Customers in Pharmaceutical marketing: Types of customers, behavior and types of doctors, role of retailer and wholesaler in pharmaceutical marketing.

(02)

6) Role of Advertisement in Pharmaceutical Marketing, legal aspects, steps in development of advertisement, medias for advertisement, role of publicity.

(02)

7) Sales management: Functions of sales management, steps and advantages of Personal selling, Effective pharmaceutical detailing, Hospital/ Institutional sell.

(03)

SECTION - B

8) Pricing: Methods for pricing a product, Role of DPCO, NPPA (National Pharmaceutical pricing authority).

(02)

9) Product Management: Types of Pharmaceutical products, Steps in development of new product, reasons for failure of new product, Functions and role of product management department, Product life cycle, Various stages and strategies in various stages of product life cycle.

(04)

10) Sales promotion: Objective and steps in development of Sales promotion Schemes, Methods for sales promotion of pharmaceutical product.

(03)

11) Sales Budgets: Objective and various methods for calculation of sales budgets.

(02)

12) Sales Forecasting: Objective and various methods for Sales Forecasting.

(02)

13) Distribution of product: Channels of distributions, Functions and role of channel members, Function of distribution department, various Medias/ ways for transportation of pharmaceutical products.

(03)

Production and material management:

1) Concept of production management, definitions of production, organization of production Department.

(02)

2) Functions and activities of production management (line and staff).

(01)

3) Production planning and control department.

(02)

4) Maintenance Management: objective and role in production department, preventive maintenance and its benefits.

(01)

5) Material management systems: Inventory control procedures/ methods, various levels of inventory in the stores, Safety stocks, Inventory carrying costs and fixed cost, Lead time, EOQ model, Value analysis, ABC and VED analysis. Perpetual inventory control, various equipments for material handling, scrap and surplus management. (04)

6) Store keeping: Functions of store keeping, methods for releasing the materials from the stores to production department (LIFO, FIFO, NIFO etc), Purchasing procedure, tender/ quotation systems.

(02)

7) Project management: Definition and concept of project, Activities/steps in project management, Project management cycle, Controlling the project activities, PERT and CPM techniques.

(03)

8) Quality management system: Concept of quality, Statistical quality control and total quality management system. Concept of ISO.

(02)

Personnel Management:

Function of Personnel management department, Manpower planning, sources of recruitment, selection and training of staff, job evaluation, merit rating, wage administration and system of wage payment, incentive, trade unions and industrial relations, reasons for industrial dispute and various ways to resolve the industrial disputes. (04)

Establishment of a pharmaceutical factory

Choice of site/ location for a plant, plant facilities, various types of plant layout, need for good plant layout.

(02)

References:

- Principles and practice of Management by L.M.Prasad, M/s Sultan Chand and sons Publisher, New Delhi.
- Principles of Marketing by Kotler and Armstrong, Prentice Hall of India Pvt. Ltd, New Delhi.
- Personnel management and Industrial Relations, by R.S. Davar.
- Essentials of Management, by Koontz and Weihrich, Tata Mc-Graw Hills Pub. Ltd, New Delhi.
- Pharmaceutical Marketing in 21st Century, by Smith Mickey Viva Books Pvt. Ltd.
- Managing for Total Quality, by Logothetis N. Prentice Hall of India Pvt. Ltd, New Delhi.

4.6 : Quality Assurance Techniques - Theory (Final B. Pharm.) - 3 Hrs /Week

SECTION - A

1. Introduction to Quality Standards 01 hr

Definitions of Quality, Quality Standards, Advantages and Disadvantages

2. Introduction to Quality Assurance
10 hrs

Historical development of QC & QA, Concept of Quality control and Quality Assurance, Quality Assurance and Quality Management in the Pharma industry, Functions & advantages of QC & QA, Organizational structure of QA, Customer requirement of Quality

3. Statistical quality control 02 hrs

4. Regulatory aspects of QA
04 hrs

Introduction- History of GLP, QA in GLP. , Good Manufacturing Practices - Introduction- Good Manufacturing Practices, WHO guidelines on GMP for Pharmaceutical Products

5. Advances in concept of QA
04hrs

Total Quality Management (TQM) , ICH guidelines

6. Pharmaceutical Validation
05 hrs

Introduction, Types of Validation, Scope of Validation, Importance of Validation, Limitations of Validation, Organization of Validation, Validation Master Plan, Elements of Validation (IQ, OQ, PQ, and DQ), Cleaning validation

7. Validation of analytical methods as per ICH guidelines, Calibration, Difference in Validation and Calibration
02 hrs

8. Quality Assurance and Stability Testing of Herbal Drugs.
05 hrs

Introduction, Indicative substances for Quality Assurance, GMP in Traditional systems of Medicine, Physical Quality Assurance, Quality Assurance by cultivation and Breeding, Stabilization and Stability Methods of Stabilization

9. Validation of Analytical Procedures as per ICH guidelines.
02hrs

SECTION -B

10. Chromatography

12 hrs

Introduction, Chromatographic separation methods, Concepts of Mobile Phase, Stationary Phase, Retention time, Retention volume, resolution. Chemical equilibrium and the properties of the equilibrium constant, Thermodynamics and kinetics in Chromatographic separations, Band Broadening and its mechanism, Multiple Path Processes, Broadening by diffusion, Resistance to mass transfer (RTMT), Development of Chromatogram, Capacity Factor, Column resolution, optimization of column performance, Classification of Chromatography, Qualitative and quantitative analysis by chromatography.

11. Paper Chromatography
3 hrs

Introduction, Principle, Migration Parameters, Types of paper Chromatography, Steps involved in Paper Chromatography, Applications.

12. Thin Layer Chromatography
3 hrs

Introduction, Principle, Coating Materials, Preparation of TLC Plates, Experimental details for TLC. Advantages & Applications

13. Gas Chromatography 5 hrs

Introduction, Theory and Principle,. Instrumentation, Advantages and Disadvantages. Applications.

13. High Performance (Pressure) Liquid Chromatography (HPLC) 4 hrs

Introduction, Theory and Principle., Instrumentation, Ion Pair Chromatography

Ion Exchange Chromatography, Normal and Reverse Phase Chromatography.

Advantages, Disadvantages and Applications.

14. High Performance Thin Layer Chromatography (HPTLC)
4 hrs

Introduction, Theory and Principle., Instrumentation, Advantages and Disadvantages, Applications.

15. Advances in Chromatography
4 hrs

Introduction of supercritical fluid chromatography (SFC), capillary electrophoresis (CE), GC-MS & LC-MS

References:

- 1. Quality Control of Herbal Drugs- Dr. Pulok A Mukherjee (Business Horizons Pharmaceutical Publishers)
- cGMP for Pharmaceuticals – Manohar A Potdar (Pharma Med Press)
- Validation of Active Pharmaceutical Ingredients-Ira R Berry (CRC Press)
- 4. Guidelines on c GMP and Quality of Pharmaceutical Products- S.Iyer (DK Publication)
- Quality Assurance and Quality Management in Pharmaceutical Industry- Y.Anjaneyulu (Pharma Book Syndicate)
- Quality assurance in Analytical Chemistry, B. W. Wenclawiak., M. Koch. E. Hadjicostas,Springer
- Handbook of Thin Layer Chromatography, John H. Kennedy
- Gas Chromatography- Ian A Fowlis (John Wiley and Sons)
- High Performance Liquid Chromatography (HPLC)- Sandy Lindsay (John Wiley and Sons)

- Pharmaceutical Analysis- David G Watson (Elsevier)
- Handbook of Pharmaceutical Analysis- Lena Ohannesian (Marcell Dekker)
- Instrumental Methods of Analysis – Ewing
- Good manufacturing practices for pharmaceuticals, Sidney H. Willig, Pg No. 273-300
- Good manufacturing practice, Rational & compliance, John Sharp, CRC Press
- Pharmaceutical Analysis – Higuchi & Brochmann (Wiley Inter science)
- Quality Control Handbook – Juran (Mc Graw Hill) .
- Chemical separations, principles ,techniques & expetiments, Clifton E. MEloan, Wiley interscience
- Basic statistics & pharmaceutical statistical applications , James E. De Muth

4.6 : Quality Assurance Techniques – Practical (Final B. Pharm.) - 3 Hrs /Batch/Week

1. Introduction to development of mobile phase.
2. Determination of Rf Value of Amino acids by Paper Chromatography.
3. Determination of Rf Value of Amino acids by Circular Paper Chromatography.
4. Preparation and activation of TLC Plates.
5. Determination of Rf Value of Amino acids by TLC.
6. IPQC of Tablets – Paracetamol, Propranolol Hydrochlothiazide
7. IPQC of Capsules – Rifampicin.
8. IPQC of liquid dosage forms
9. IPQC of semisolid dosage forms
10. Evaluation of Dibasic Calcium phosphate
11. Physical and Chemical Examination of plastic containers
12. Physical and Chemical Examination of glass containers
13. Physical and Chemical Examination of Rubber containers
14. Evaluation of labels, cartons and other printed materials.
15. Spectrophotometric analysis of Raw materials.
16. Demonstration of HPLC.
17. Demonstration of GC.
18. Demonstration of GC-MS (Optional)
19. Demonstration of method development of any one marketed preparations
20. Demonstration of validation parameters of HPLC

References:

- IP, USP,BP, European Pharmacopoeia, International pharmacopoeia
- Pharmaceutical analysis-Higuchi and Brochmann
- The quantitative analysis of drugs- Garrat
- Analytical chemistry- MEITES H.B.
- Analytical chemistry- Garry Chrisian
- Principles of instrumental analysis- Skoog
- Vogel textbook of quantitative chemical analysis

- Instrumental methods of analysis- Willard, Dean
- Instrumental methods of analysis-Ewing
- Instrumental methods of analysis- Chatwal and Aanand
- Practical pharmaceutical chemistry, Vol II by Beckett and Stenlake

4.7 : Pharmaceutical Jurisprudence and Intellectual Property Rights – Theory (Final B. Pharm.) –

3 Hrs /Batch/Week

Section A

1. Historical background:

Drug legislation in India, Code of Ethics for Pharmacists
5hr

2. A detailed study (inclusive of recent amendments) of the following:

a) Pharmacy Act 1948 3hr
b) Drugs and Cosmetics Act 1940, Rules 1945 12 hr
c) Narcotic Drugs and Psychotropic Substances Act, and Rules there under 3 hr
d) Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 2 hr
e) Medicinal and Toilet Preparations (Excise Duties) Act 1955, Rules 1976 3 hr
f) Poisons Act 2 hr
g) Medicinal Termination of Pregnancy Act 1970 and Rules 1975 2 hr
h) Prevention of Cruelty to Animals Act 1960 3 hr
i) Drug (Price Control) Order 3 hr

Section B

j) Bombay Shops and Establishment Act 1948 with the Maharashtra Shops and Establishments Rules 1961 3 hr
k) Factory Act 3 hr
l) The Insecticide Act 2 hr
m) Consumer Protection Act 4 hr
n) Indian Pharmaceutical Industry- An Overview 2 hr
o) Industrial Development and Regulation act 1951 3 hr
p) Introduction to Intellectual Property Rights and Indian Patent Act 1970 6 hr
q) An Introduction to Standard Institutions and Regulatory Authorities such as BIS, ASTM, ISO, TGA, USFDA, MHRA, ICH, WHO 4 hr
r) Minimum Wages Act 1948 2 hr
s) Prevention of Food Adulteration Act 1954 and Rules 1955 3 hr
t) Bibligraphy

References:

- Kuchekar B.S., Khandatare A.M., Itkar S., Forensic Pharmacy, Nirali Prakashan, Pune. Latest edition.
- Mittal B.M., Textbook of Forensic Pharmacy, National Book Centre, Dr. Sundari Mohan Avenue, Kolkata, Latest edition.
- Relevant Acts (Bare acts) and Rules Published by the Govt. of India. Latest edition.

- Jain N.K., A Textbook of Forensic Pharmacy, Vallabh Prakashan, New Delhi, Latest edition.
- Singh Harkrishan, ''History of Pharmacy in India, vol-I, II, & III'' Vallabh Prakashan, Delhi, Latest edition.
- S.G.Deshpande, Gandhi, Drugs and cosmetic Act 1940 and Rules their under. Sushmit Publication.