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<th>Sr. No.</th>
<th>Subject</th>
<th>Theory hours per week</th>
<th>Practical hours per week</th>
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<tr>
<td>4.1.</td>
<td>Dosage form Design</td>
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<td>4.2.</td>
<td>Pharmacognosy and Phytochemistry</td>
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<td>4.3.</td>
<td>Medicinal Chemistry - II</td>
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<td>4.4.</td>
<td>Pharmacology and Bioassay</td>
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<td>4.5.</td>
<td>Pharmaceutical Management</td>
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<td>4.6.</td>
<td>Quality Assurance Techniques</td>
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<td>4.7.</td>
<td>Pharmaceutical Jurisprudence and Intellectual Property Rights</td>
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<td>Sr. No.</td>
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<td><strong>SECTION - A</strong></td>
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<tr>
<td>1.</td>
<td><strong>Preformulation:</strong> -</td>
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<td>Concept of preformulation,</td>
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<td>Organization of preformulation activity,</td>
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<td>2.</td>
<td><strong>Solubility and Dissolution:</strong> -</td>
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<td>Methods of expressing solubility,</td>
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<td>Prediction of solubility</td>
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<td>Physicochemical prediction of solubility</td>
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<td>Solubility Parameters</td>
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<td>Factors affecting on solubility</td>
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<td>Dissolution mechanisms</td>
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<td>Factors affecting dissolution</td>
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<td>Intrinsic dissolution</td>
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<td>Measurement of dissolution rates</td>
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<td><strong>Stability:</strong> -</td>
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<td>Definition: - Expiry date, Shelf life, Order of reaction.</td>
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<td>Environmental factors influencing stability: - pH, Solvent, Solubility, Additives, Light, Temperature, Acid Base Catalysis, Ionic Strength</td>
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<td>Modes of drug instability and methods to prevent them: - Chemical and Physical</td>
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<td>Technique of stability prediction, Tentative expiry dating</td>
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<td>Introduction to cGMP guidelines in stability testing and expiry dating (No details)</td>
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<td>Effect of packaging material on stability of drug.</td>
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<td><strong>Package Development:</strong> -</td>
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<td>Structure and composition</td>
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<td>Glass- types, manufacture of glass, glass container, evaluation</td>
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<td>Plastic- definition, material properties (mechanical, electrical and optical), physicochemical properties (mass transfer, chemical attack), types-thermoplastic, thermoset with example and applications.</td>
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<td>Drug plastic interactions, evaluation of plastics</td>
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<td>Collapsible tubes- metal, plastic, lamination</td>
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<td>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.</td>
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</tbody>
</table>
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.
Biodegradable 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
Ocular system
Intravaginal and intrauterine system
Injection and implant
Biomucoadhesive system
Iontophoretic system
Sonophoretic system
Targeted drug delivery system: - Liposome, Nanoparticles, Prodrugs, Resealed erythrocytes, Antibody targeted systems

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

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, Lagarian, 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.

8 Design of Dosage Form:-
Principles of dosage form design (DFD)
Biopharmaceutical aspects of DFD
Drug related factors in DFD
Therapeutic considerations in DFD.

References:
• Leon Lachmann, H. Lieberman, “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 cupric 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).
7. Determination of compressibility of given material.
10. Determination of micromeritic properties of given material (MCC/Starch etc.).
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.
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.
- 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.
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, Peppermint oil, Caraway, Cardamom, Coriander, Ajowan, Dill, Fennel, Lemon peel, Orange peel, Nutmeg, Cassia, Cinnamon, jatamansi, garlic, Sweet basil, Sacred basil, Musk, Civet
   b) Sesquiterpenoids: Artemisia, Davana, Arnica, Sandalwood, Clove, Hops, Saussurea, Cubeb, Valerian, Feverfew
   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, Duboisia
   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)
   Introduction, importance, classification of drug molecules from marine organisms
   a) Cytotoxic and antineoplastic agents
   b) Cardiovascular drugs
   c) Marine toxins
d) Antimicrobial drugs

e) Antibiotic substances

f) Antiinflammatory and antispasmodics

g) Miscellaneous 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, sepbok, 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)

   (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), Dietary 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, Picrorhiza, 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 curcumine 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, Comparative Phytochemistry, Academic Press, London
- Youngken H W, Natural Drugs : Morphologic & Taxonomic consideration
- Chakrabarty, Pharmacoeconomics: 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 Research, Ansari Nagar, New Delhi
- Kokate C.K, Practical Pharmacognosy, Vallabh Prashan, Delhi.
- Tyler, V.E, Brady,R., Pharmacognosy.
- 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, Ahmedabad,
• Herbal Pharmacopoeia of India, Govt. of India. Ministry of Health, vol 1 & 2, (1998 and 2001)
• Ashutosh Khar, Pharmacognosy and Pharmacobiotechnology, New Age International Publishers.
• Kaliya, Textbook of Industrial Pharmacognosy, CBS Publisher, New Delhi.
• S.V Bhatt, Chemistry of Natural Products, Narosa Publishing House, New Delhi.
• Peach K, And Tracey M.V, Modern Methods of Plant Analysis, 1-4 Narosa Publishing House, New Delhi.
• Miller L.P Phytochemistry Vol 1-3 Van Nostrand Co.
• Miller L.P Phytochemistry, 1-3 Van Nostrand Reinhold Co.
• O.P Agrawal, Chemistry Of Organic Natural Products, Vol 1 & 2
• Ghosh, Plant Physiology, Zew Central Book Agency Pvt. Ltd., 8/1 Chintamoni Das Lane, Kolkata.
• 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.
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, antiarrhythmic agents, antihypertensive 
agents, Antihyperlidemic agents

9) Local anesthetic agents:  
   (02)
10) Synthesis of  Carbachol, Bethnechol, Dicyclomine, noradrenaline, methyl dopa, propranolol, salbutamol, terbutaline, captopril, verapamil. Atenolol, clonidine, 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, opioid agonist and opioid antagonist, skeletal and peripheral modification of morphine

15) Non narcotic analgesic anti-inflammatoary 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) Prostaglandins: (02)
Introduction, Classification, SAR, Uses.

19) Drugs used for Parkinsonism. (01)

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

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
- Butterworth: Progress in Medicinal Chemistry Series
- Wilson and Gisvold's Text book of Medicinal Chemistry (J. B. Lippincott cam)
- 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)
Synthesis and characterization of

1) Sulphonamides
2) Benzocaine
3) Paracetamol
4) Benzoyl glycine
5) Hippuric acid
6) Acetoaceta-nilide
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.
## 4.4 : Pharmacology and Bioassay – Theory (Final B. Pharm.) - 3 Hrs / Week

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


**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
- Koda Kimble M.A., Katches B.S., Young L.Y., Applied Therapeutics for Clinical Pharmacists, Applied Therapeutics
- 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., Calcutta
- Satoskar R.S. Bhandarkar S.D., Pharmacology and Pharmacotherapeutics, Popular Prakashan
- Tripathi K.D., Medical Pharmacology, Jaypee Publications, New Delhi
- Avery G.S. Drug Treatment, Adiss Press, Sydney
• Drill V.A., Pharmacology in Medicine, Mc Graw Hill co, New York
• Krantz and Carr: Pharmacology Principles of Medical Practice, Williams and Wilkins Co, Baltimore
• Pharmacopoeia of India (1985), Controller of Publication, Delhi
• Balaraman R., Gulati O.D, Patil P.N., Goyal R.K., Topics in History of Pharmacology, BS Shah Publications, Ahmedabad
• DiPiro J.T., Encyclopedia of Clinical Pharmacology, Marcel Dekker, New York
• Hansten P.D.: Drug Interactions, Lea and Febiger, Philadelphia
• Harisons: Principles of Internal Medicines, McGraw Hill Publications, Singapore
• Herfindal E: Clinical Pharmacy and therapeutics, Willimas and Wilkons Publications, New York
• Stockely 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


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., Practical 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
- 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
- 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
- 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
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)


(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)

Pharmaceutical Marketing:

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

(02)
2) Organization of Marketing and sales 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)
   (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.
- Personnel management and Industrial Relations, by R.S. Davar.
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

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

   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

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

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

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)
- 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)
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.
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
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 Christian
- 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
1. Historical background:
   Drug legislation in India, Code of Ethics for Pharmacists
   5 hr

2. A detailed study (inclusive of recent amendments) of the following:
   a) Pharmacy Act 1948          3 hr
   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
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
f) Bibliography

References:

- 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.
• S.G.Deshpande, Gandhi, Drugs and cosmetic Act 1940 and Rules their under. Sushmit Publication.