## SYLLABI OF BACHELOR OF PHARMACEUTICAL SCIENCES

### FINAL YEAR B. PHARMACY

### 4.1 (T) PHARMACEUTICS-III

(Theory) 90 Hrs. (3 hrs per week)

<table>
<thead>
<tr>
<th>Topic No</th>
<th>SECTION-I</th>
<th>Hrs.</th>
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<tbody>
<tr>
<td>Sterile formulations</td>
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<tr>
<td>i) <strong>Preformulation Methodology for Parenteral Products</strong>: Physicochemical properties of drug substances, accelerated stability study, preformulation studies for proteins, peptides</td>
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<tr>
<td>ii) <strong>General Requirements</strong>: Routes of administration, significance of tonicity adjustment and sterility, freedom from pyrogens and particulate matter, stability aspects and quality control tests, sterility tests for ointment, antibiotic preparations, powders</td>
<td>10</td>
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<tr>
<td>iii) <strong>Small Volume Parenterals (SVPs)</strong>: Classification, formulation of solutions and suspensions, types of vehicles, selection of vehicles and added substance, processing and manufacturing of SVPs, Pilot plant scale up for SVPs. Special types of SVPs: Formulation of peptides and proteins, freeze dried products, parenteral suspensions, emulsions and Reconstituted products.</td>
<td>7</td>
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<tr>
<td>iv) <strong>Large Volume Parenterals (LVPs)</strong>: Types of LVPs, concept of formulation, influence of physiological, formulation and packaging parameters, stabilization of LVPs, processing of LVPs, Total Parenteral Nutrition (TPN) and Peritoneal dialysis fluid. Pilot plant scale up for LVPs.</td>
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<td>v) <strong>Ophthalmic Products</strong>: General requirements, formulation, types of dosage forms. Contact lens and lens care products.</td>
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<td>vi) <strong>Packaging of Parenterals</strong>: Various materials used, official quality control tests, packaging components and types, specifications and methods of evaluation, stability, factors influencing choice of containers, prefilled syringes, blow-fill-seal technique.</td>
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<tr>
<td>vii) <strong>GMP-Design of Parenteral Production Facility</strong>: Product characteristics, water treatment plant, operational assessment and area planning, batch Vs continuous operation, environmental control zones, filling area design, utility distribution systems, heating ventilation air conditioning (HVAC), HEPA filter testing and rating, laminar flow area working, development of facility layout, automation in parenteral industry.</td>
<td>5</td>
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<tr>
<td>2. <strong>Validation of Sterilization Techniques</strong>: Introduction: Basic concepts, types and stages of validation, Validation Master Plan (VMP), equipment and process validation for steam sterilization and membrane filtration techniques.</td>
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## SECTION- II

<table>
<thead>
<tr>
<th>3.</th>
<th>Modified Drug Release Systems</th>
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<td>ii) Novel Drug Delivery Systems:</td>
<td>Introduction, merits, demerits, and application of following: (Formulation aspect is excluded) Mucosal drug delivery system, Transdermal drug delivery system (TDDS), Parenteral implants, Ophthalmic insets, Intrauterine drug delivery system (IUDs), Liposomes, Targeted drug delivery systems; micro encapsulation of living cells and tissues, hemoglobin, multienzyme systems artificial cells as drug carriers, Probiotics and Prebiotics. Externally modulated devices and delivery; iontophoresis and sonophoresis.</td>
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<td>4.</td>
<td>Microencapsulation:</td>
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<td>5.</td>
<td>Formulation And Processing of Therapeutic Aerosols:</td>
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<td>Aerosol component and factors affecting its selection. Recent advances, objectives of therapeutic aerosols, fundamentals and principle of design, drug substances, important physicochemical properties of aerosol system solutions, suspensions and emulsions, formulation design and stability, typical formulations from, metered dose, intranasal and topical applications, factors influencing drug deposition, manufacturing techniques, product evaluation including safety considerations.</td>
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<td>6.</td>
<td>Optimization Techniques in Pharmaceuticals:</td>
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<td>Basic concept of optimization, factors variable and design of experiment, introduction to two level factorial design with suitable pharmaceutical samples.</td>
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### 4.1 Pharmaceutics-III (practical 3Hrs/week)

1) Validation of aseptic area.
2) Pharmacopoeial evaluation of glass and plastic containers and rubber closures used for injectables.
3) Formulation, isotonicity, packaging and quality control of the following SVPs as per Indian pharmacopoeia. Also explain industrial scale manufacturing processes.
a) Sterile water for injection  
b) Ascorbic acid injection  
c) Calcium gluconate injection  
d) Atropine sulphate injection  
e) Chloramphenicol injection  
f) Sodium chloride injection

4) Formulation, isotonicity, packaging and quality control of the following LVPs as per Indian pharmacopoeia. Also explain industrial scale manufacturing processes.
   a) Intraperitoneal dialysis fluid  
   b) Contact lens solution  
   c) Sodium chloride and Dextrose infusion

5) Formulation, isotonicity, packaging and quality control of following parameters:
   a) Sulphacetamide eye drops BPC  
   b) Tetracycline eye ointment IP  
   c) Xylomethazoline nasal drops IP

6) Optimization of formulations using 2 level factorial design: (of any one following dosage form)
   a) Suspension  
   b) Microsphere  
   c) Emulsion

7) Formulation and evaluation of marketed lyophilized products as reconstitutable solution for injection.


9) Micro encapsulation (using one solid and one liquid drug) by coacervation and polymer incompatibility, evaluation of microcapsules.

10) Formulation of sustained release formulations (any one of following dosage forms)
    a) Tablet  
    b) Capsule

11) Accelerated stability testing of a SVP and LVP

**Recommended books:**

13. Howard C. Ansel; Pharmaceutical calculations, 13th Ed, Lippincott Williams & Wilkins Publication, 2010
14. Cooper and Gunn; Dispensing for Pharmaceutical Students, 12th Ed, CBS Publication
25. Ray & May; Freeze Drying / Lyophilization of pharmaceutical & Biological Products, Marcel Dekker.

4.2 (T) BIOPHARMACEUTICS AND PHARMACOKINETICS
(Theory) 60 Hrs. (2 hrs per week)

<table>
<thead>
<tr>
<th>Topic No</th>
<th>SECTION-I</th>
<th>Hrs.</th>
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<tbody>
<tr>
<td>1.</td>
<td>Concept, definition and introduction to Biopharmaceutics, Pharmacokinetics, Pharmacodynamics and clinical Pharmacokinetics with respect to design of dosage regimens. Plasma drug conc. Profile.</td>
<td>3</td>
</tr>
</tbody>
</table>
| 2. | Absorption of Drug  
Cell membrane, Mechanisms of drug absorption, Factors affecting drug absorption-  
i) Physicochemical ii) Physiological iii) Pharmaceutical. pH partition hypothesis. | 6 |
| 3. | Drug distribution  
4. **Drug metabolism.**  
Study of factors affecting metabolism. Bioactivation and first pass effect.

5. **Excretion**  
Introduction, types of drug excretion, Renal excretion, Mechanism, concept of clearance, factors affecting renal clearance, Non renal routes of elimination. Extraction ratio, hepatic clearance, biliary excretion, extra hepatic circulation.

6. **Prodrug:** Biopharmaceutical aspect of prodrug.

7. **Bioavailability and Bioequivalence:**  
Definition and concept of absolute & relative bioavailability. Methods of assessing bioavailability. Measures of bioavailability ($C_{max}$, $t_{max}$, AUC etc.) Bioequivalence study and introduction to various study designs. Single dose bioequivalence study and relevant statistics. Review of regulatory requirements for conducting bioequivalence study. Clinical significance of bioavailability and bioequivalence. Introduction to orange book.

### SECTION- II

8. **Dissolution studies.**  
Introduction to Biopharmaceutical classification system, Mechanism of dissolution, *In-vitro* studies, and all latest models: Zero order, Matrix, First order, Higuchi. *In-vitro in-vivo* correlation: Definition, objectives & methods.

9. **Compartment models** –  
Concepts and their importance in the study of pharmacokinetics. One compartment open model. Assessment of pharmacokinetic parameters from plasma and urine data after i. v. bolus, i.v. infusion, i. v. injection with loading dose and oral administration. Percent absorbed time plot and determination of absorption rates based on one compartment model.  
Introduction to ‘Two compartment model.’

10. **Non-Linear Pharmacokinetics**  
Detection of non-linearity (saturation mechanism).Michaelis Menten equation. Definition of $V_{max}$ and $K_m$. Determination of $V_{max}$ and $K_m$. Significance of Non-Linear Pharmacokinetics: Case studies.

11. **Applications of Pharmacokinetics**  
i) Therapeutic drug monitoring. Case study of Digoxin and theophyline.  

13. **Numerical:**  
Based on AUC, Elimination half life ($t_{1/2}$), Volume of distribution (Vd), Clearance (Cl), elimination rate constant (ke) and amount of drug (X).

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**References:**
1. Brahmankar and Jaiswal; Biopharmaceutics and Pharmacokinetics: A treatise; 2nd Edition; CBS Publication;2009
4.3 (T) MEDICINAL CHEMISTRY – II
(Theory) 90 Hrs. (3 Hrs/week)

<table>
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<tr>
<th>Topic No</th>
<th>SECTION-I</th>
<th>Hrs.</th>
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<tbody>
<tr>
<td>1</td>
<td>Introduction to drug design and discovery, phases involved, different methods in brief, some case studies e.g. development of ciprofloxacin, antidiabetics, and recent cephalosporins. Introduction to QSAR, Lead discovery &amp; optimization Introduction to different target sites of bacteria, fungi, viruses, parasites with respect chemical composition, comparison with mammalian targets, enzymes, receptors etc. Principles of Drug Design including some case studies from following categories- antihistaminic, antihypertensive, psychotherapeutics. QSAR, Hansch &amp; Free Wilson Analysis, Mechanism based Drug Design including Quantum Mechanics, Molecular Mechanics and Molecular Modeling.</td>
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<td>2</td>
<td>Drug Metabolism: Study of drug metabolising enzymes, phase I &amp; phase II reactions with selected examples of following drugs, Diazepam, Tolbutamide, Cyclobarbital, Paracetamol, Imipramine, Amphetamine, Mesoridazine and Sulindac. Applications of drug metabolism studies in new drug discovery. History and general aspects of the design &amp; development of drugs including, classification, structure activity relationship (SAR), mechanism of action, adverse effects, therapeutic uses and recent developments of following categories</td>
<td>06</td>
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</tbody>
</table>

Chemotherapeutic Agents
3 a. Synthetic antibacterial agents eg. Sulfonamides, Quinolones, Nitrofurans etc.
b. Antitubercular & Antileprotic agents
c. Antifungal agents
d. Antimalarials
e. Antiamebic agents
f. Trypanosomicidal drugs, drugs acting against leishmaniasis.
g. Anthelmintics
h. Antiviral agents including antiretroviral
i. Antineoplastic agents including recent drugs and monoclonal antibodies

SECTION II

4 Antibiotics:

β-lactam antibiotics: (Penicillins and Cephalosporins, oxopenams
carbepenams, monobactams)
The aminoglycosides
The tetracycline
The macrolides
The Lincomycins
The Polypeptides
Unclassified antibiotics

5 Hormones: Thyroid and antithyroidal agents

6 Steroids
a. Steroidal anti-inflammatory agents
b. Sex hormones and their synthetic analogs
c. Antifertility agents

7 Opioid analgesic agents: Receptor subtypes and opioid antagonists

8 NSAIDs & Antipyretics

9 Prostaglandin analogs

10 Antihistaminic agents: Structural features of Histamine receptor and its Subtypes and their structural features, H1 blockers and H2 blockers, Proton Pump Inhibitors

11 Scheme of synthesis of following drugs from various therapeutic categories: Carbachol, dantrolene sodium, methyldopa, propranolol, atenelol, salbutamol, fenfluramine, thiopental sodium, lignocaine, benzocaine, propoxyphene, loperamide, methadone, chlorpheniramine, pirodine, prazocin, guanethidine, terbutaline, captopril, 17 β-estradiol, prednisolone, amitryptiline, hydralazine, imipramine, doxepin, diazepam, chlorpromazine, haloperidol, trifluperazine, ibuprofen, diclofenac, phenytoin, sodium valproic acid, lamotrigene, losartan, alprazolam, respiridone, metazepine, fluoxetine, clofibrate, zolpidem, sumatriptan, ondansetron, omeprazole
4.3 (P) MEDICINAL CHEMISTRY - II
(Practical) 90 Hrs. (3 hrs. per week)

1. Synthesis of following medicinally important compounds or drug intermediates.
   a. Hydroquinone to 2,5-dihydroxyacetophenone
   b. Anthranilic acid
   c. Anthranilic acid to o-iodobenzoic acid
   d. 2-phenyl indole
   e. Benzene to propyl benzene
   f. 4-fluroacetophenone
   g. 2-methyl benzimidazole
   h. 2-mercapto benzimidazole
   i. Hantzch Synthesis
   j. Ethylnicotinate
   k. Caprolactam
   l. Canizarro reaction (benzyl alcohol)
   m. O-nitro aniline to p-nitro aniline

2. Column chromatographic separation
3. Preparative TLC
4. Separation of o/p-nitro phenols by steam distillation
5. Establishing Pharmacopoeial standards & spectral studies of drugs synthesized
6. Demonstration experiments
   6.1. High vacuum distillation
   6.2. Recrystalisation
   6.3. Steam distillation
   6.4. Dean stark azeotropic water separation
   6.5. pH based amino acid separation
   6.6. Catalytic hydrogenation

Recommended Books for Theory and Practical
9 Exploring QSAR Vol; I Fundamentals and Applications in Chemistry and Biology by C Hansh and A Leo Vol. II: hydrophobic, Electronic and Steric Constants by C Hansh, A Leo and D Hockman ACS Book Catalog.
25 Steric Constants by C Hansch, A Leo and D Hockman, ACS Book Catalog.

4.4 (T) PHARMACEUTICAL ANALYSIS-III
(Theory) 90 Hrs. (3 Hrs/week)

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<tr>
<th>Topic No</th>
<th>SECTION-1</th>
<th>Hrs.</th>
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82
The following analytical techniques to be discussed with special reference to quality control and assurance of the pharmaceuticals, its scope and importance in the pharmaceutical industry along with suitable examples.

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<tr>
<th></th>
<th>Technique</th>
<th>Scope</th>
<th>Hrs.</th>
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<tbody>
<tr>
<td>1</td>
<td>Infrared Spectroscopy: Origin of IR spectra, Molecular vibrations, fundamental bands, Vibrational frequency, Fermi resonance, Instrumentation, Applications, Important spectral regions, FTIR and Raman spectroscopy – Theory, Instrumentation, sample handling, structural analysis.</td>
<td></td>
<td>07</td>
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<td>2</td>
<td>X-ray diffraction techniques: Introduction, Instrumentation, Pharmaceutical applications and simple calculations based on 2θ, calculation of Redia, different crystal faces. Polymorphism</td>
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<td>3</td>
<td>Atomic Emission Spectroscopy Instrumentation, Principle and Application</td>
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<td>4</td>
<td>Nuclear Magnetic Resonance (NMR) Spectroscopy: Theory, Chemical shift, shielding-deshielding, Spin-Spin Coupling (Splitting), Coupling Constant, Chemical and Magnetic Equivalence, Double resonance, NOE, Shift reagents, Solvents, Factors affecting chemical shift, Anisotropy, Instrumentation, application and simple structure determination, HID calculation, C¹³ NMR-Introduction.</td>
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<td>14</td>
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<td>5</td>
<td>Mass spectrometry: Introduction, Theory, Instrumentation, Resolution and application. Brief discussion on GC-MS, LC-MS and MS-MS</td>
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<td>6</td>
<td>ESR: Introduction, principle &amp; instrumentation</td>
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<td>7</td>
<td>Validation, Quality Audit: Quality of equipment, validation of equipment and Validation of Analytical Methods as per ICH or USP guidelines.</td>
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**SECTION-II**

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<tr>
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<th>Technique</th>
<th>Scope</th>
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<tr>
<td>8</td>
<td>Gas chromatography: Theory, Instrumentation and applications. Van Deemter equation, Band broadening, HETP, and various parameters, Sample handling, Columns, Detectors, Derivatisation quantitation (area normalization, percent area, Internal standard, External standard method), Application.</td>
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<td>9</td>
<td>High performance Liquid Chromatography (HPLC): Theory, Instrumentation and applications, Adsorption, partition, Isocratic, Gradient, Pumps, Columns phases, Detectors, Tubing, Degassing techniques, Quantitation technique, Trouble shooting in brief. Ion Exchange and ion pair and ion chromatography. Capillary Zone electrophoresis, System Suitability Testing, UPLC- theory columns, advantages over HPLC.</td>
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<td>Flash Chromatography</td>
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<td>11</td>
<td>Super Critical Fluid Extraction, Simulated moving bed technology Instrumentation, Principle and Application.</td>
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<td>12</td>
<td>Radio Chemical Methods – Nuclear reactions and radiations, Neutron sources, Measurement of radioactivity, tagging of compounds, Pharmaceutical Applications.</td>
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<td>13</td>
<td>Scanning Electron Microscopy, Scanning Probe Microscopy, TEM ESCA, brief introduction, principle and application of all these techniques</td>
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**4.4 (P) PHARMACEUTICAL ANALYSIS-III**

(Practical) 90Hrs. (3 hrs. per week)
Calibration of Spectrophotometer as per official procedure.

1. Spectrophotometric estimation of two-component formulations by simultaneous analysis. (Minimum two experiments)

2. Validation of Analytical methods (Spectrophotometry & HPLC) as per official USP/ICH Guidelines (minimum four experiments)

3. Spectrophotometric Analysis of two components by Q-Method. (Minimum four experiments)

4. Separation of amino acid on Ion Exchange Resins. (Minimum three experiments)

5. Separation on anion exchange of Cations/Anions/ Pharmaceuticals (minimum three experiments)

6. Recording of IR spectra of compounds with different functional groups (-COOH, -COOR, -CONHR, -NH₂, -NHR, -OH, -CHO, -CO etc.) (Minimum two experiments)

7. Demonstration Practicals/Calculations/Interpretations

9.1 Study of Quantitation Techniques in HPLC or GC (% Area / Area Normalization, Internal Standard addition)

9.2 Study of system suitability parameters as per BP/USP protocol for HPLC or GC methods.

9.3 Workshop to interpret the structure of simple organic compounds using UV, IR, NMR, MS

9.4 Interpretation of X-ray powder diffraction pattern and to identify crystal types.

**Recommended Books for Theory and Practical**


4. Pharmaceutical Analysis by Higuchi.

5. Pharmaceutical Analysis: Modern Methods, James W. Munson (Marcel Decker, New York)


10. Introduction to Chromatography (Theory and Practice) by VK Srivastav and KK Shrivastav.


17. Indian Pharmacopoeia.


24. Introduction to Spectroscopy- Donald L. Pavia, Gary M. Lampman, George S. Kriz, Thomson/ Brooks Cole
25. Pharmaceutical Analysis- David G. Watson

4.5 (T) PHARMACOLOGY
(Theory) 90 Hrs. (3 Hrs/week)

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<tr>
<th>Topic No</th>
<th>SECTION-I</th>
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<tbody>
<tr>
<td>Basic pharmacology (classification, mechanism of action, pharmacokinetics, pharmacological actions, adverse effects, contraindications, therapeutic uses, drug interaction, dosage, symptoms and treatment of poisoning) and Clinical Management of diseases and drugs acting on following categories:</td>
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<tr>
<td><strong>Chemotherapy</strong></td>
<td>a) Introduction to Chemotherapy including Drug resistance</td>
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<td>b) Sulfonamides and trimethoprim</td>
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<td>c) Penicillins and Cephalosporins</td>
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<td>d) Tetracyclines and Chloramphenicol</td>
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<td>e) Macrolide, Aminoglycoside, Polypepe and Polypeptide antiboitics</td>
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<td>f) Quinolones and Fluoroquinolones</td>
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<td>g) Antifungal agents</td>
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<td>h) Antiviral agents including anti-HIV agents</td>
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<tr>
<td></td>
<td>i) Chemotherapy of Tuberculosis, Leprosy, and Malaria</td>
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<td>j) Chemotherapy of Protozoal infections (amoebiasis, Giardiasis)</td>
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<td></td>
<td>k) Pharmacology of antihelminthic drugs</td>
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<td>l) Chemotherapy of neoplastic diseases (Anticancer drugs)</td>
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<td><strong>Cardio-vascular system diseases</strong></td>
<td>a) Drugs used for Congestive Cardiac Failure (CCF)</td>
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<td>b) Anti-arrhythmic drugs</td>
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<td></td>
<td>c) Antianginal and other anti-ischemic drugs</td>
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<td>d) Anti-hypertensive drugs</td>
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<td><strong>Drugs acting on kidney</strong></td>
<td>a) Diuretics</td>
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<td></td>
<td>b) anti-diuretics</td>
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<td><strong>Immunopharmacology</strong></td>
<td>a) Pharmacology of immunosuppressants and stimulants</td>
<td>04</td>
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<td>b) Vaccines and Sera.</td>
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<td><strong>Principles of Toxicology</strong></td>
<td>a) General principle of treatment of poisoning</td>
<td>08</td>
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<td>b) Signs, Symptoms and treatment of acute and chronic poisoning due to: Heavy metals (Lead, Mercury, Arsenic), snake venom</td>
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Sections II: Hospital Pharmacy and Clinical Pharmacology
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<tr>
<th>6</th>
<th>Hospital Pharmacy: To discuss in detail of various aspects of hospital pharmacy.</th>
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<tbody>
<tr>
<td>8</td>
<td>Hospital drug Policy. Hospital and therapeutic committee, hospital formulary, role of hospital pharmacist in hospital committees and practice of rational drug therapy</td>
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<td>8</td>
<td>Hospital Documentation Introduction to prescription recording, drug profile, patient medication profile.</td>
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<td>9</td>
<td>Drug distribution in Hospitals Outpatient and in patient services, unit dose, drug distribution system, floor ward stock system, satellite pharmacy services, bed side pharmacy, distribution of control drugs</td>
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<td>10</td>
<td>Patient compliance and counseling Methods of assessment of compliance, Reason for patient non-compliance, strategies to improve compliance, precaution and directions for medication, administration instructions</td>
<td>05</td>
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<td>11</td>
<td>Adverse Drug reactions (ADR): Epidemiology, Classification, Risk factors, Monitoring, Detecting and reporting of ADR</td>
<td>04</td>
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<td>12</td>
<td>Drug interactions: Types, General Considerations and Mechanisms</td>
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<td>13</td>
<td>Introduction to Clinical Trials History, terminologies, types of clinical research, phases of clinical research, role of clinical trial in new drug developments 1. Ethical issues in clinical trials- Principle of regulatory requirements, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing), The Nuremberg Code, The Declaration of Helsinki, The Belmont Report 2. Good Clinical Practice-Concept, importance, and GCP guidelines including ICH guidelines</td>
<td>12</td>
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<tr>
<td>14</td>
<td>Bioavailability, bioequivalence and Therapeutic Drug Monitoring-Concept, organization, advantages, special issues, applications.</td>
<td>04</td>
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**Recommend Books**

16. Indian Pharmacopoeia, Govt. of India, *Controller of publication, New Delhi.*

### 4.5 Pharmacology- III
*(Practical) (90 hrs: 3 hrs/week)*

**Hospital Pharmacy**

Critical appraisal of fixed dose drug combinations of marketed preparations with respect to comments on prescriptions of some proprietary preparations and multiple drug therapy (rational /irrational) mentioning possible indications, dose, route of drug administration, justification of inclusion of each ingredient, and adverse reactions, contraindications, precautions and special instructions for patients. (Minimum 10 combinations to be discussed).
Clinical Pharmacology

Prescription auditing and standard treatment protocols: Comment on given prescriptions with reference to case reports mentioning possible indications and contraindications with dose, route of administration and justification of each ingredient. Comment on special instructions, drug interactions and ADRs (if any), discharge medication (on the basis of available evidences from literature) (Minimum 10 prescriptions to be discussed).

Biostatistics

To carry out the statistical analysis of given experimental data using appropriate method(s) based on parametric or non-parametric methods (Minimum 5 exercises).

Recommend Books

1. Bolton, Sanford and Bon: Charles Pharmaceutical Statistics, (Drugs and the Pharmaceutical Sciences: a Series of Textbooks and Monographs), Dekker, New York, USA.
### Section I

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<td><strong>Note:</strong> Drugs mentioned in Bold must be studied in detail for their cultivation, collection and extraction.</td>
</tr>
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</table>

1. **Alkaloids:** Introduction, definition, occurrence, properties, classification, chemistry. General Biosynthetic pathways for Indole, Tropane Quinoline and Isoquinoline alkaloids Systematic pharmcognostic study of following crude drugs containing Alkaloids.
   - Indole - **Ergot, Rauwolfia, Nux-vomica, Vinca.**
   - Tropane - **Datura, Coca, Belladona.**
   - Purines - **Tea, Theobroma.**
   - Quinoline - **Cinchona.**
   - Isoquinoline - **Opium, Ipecac.**
   - Pyridine/ Piperidine - **Lobelia.**
   - Imidazole - **Pilocarpus.**
   - Quinazoline - **Vasaka**
   - Amino alkaloids - **Colchicum, Ephedra.**
   - Steroidal - **Ahwagandha, kurchi, solanum, khasianum.**


3. **Flavonoids** - Introduction, properties, classification, chemistry, extraction and general biosynthetic pathway.
   2. Isoflavones: Derris Roots, Soyabean,
   3. Flavonol: Buch Wheat, Green Tea
   4. Flavonones: Liquorice, Citrus Peels
   5. Chalcones: Safflower
   6. Bioflavones- Gingko
   7. Anthocynidine- Blueberry, Blackcurrent, Vine
   8. Flavonolignans: *Sylibum marianum*

4. **Plant Allergens** – Classification (inhalants, injectants, contactants, infectants and infestants), plants causing Hay fever, allergy. Preparation of allergenic extracts.

5. **Drugs of Traditional systems of medicine** – Vernacular names, Biological source, chemical constituents and uses of Gulwel, Bhuiamla, Bramhi, Shankhpushpi, Madhunashini, Nagarmotha, Bhilwa, Rasna, Gokhru, Punarnava, Neem, Safed musli and Pipali.

### Section II

**Herbal Drug Technology**

6. A] Phytochemical investigation – Preliminary Phytochemical Screening, applications of chromatographic technique in evaluation of herbal drugs.
   B] A study of analytical profiles for Structural elucidation of following
<table>
<thead>
<tr>
<th>7. Phytochemical screening of crude drugs: Extraction, isolation, purification chromatographic profiles of following phytoconstituents. Phytoconstituents Reserpine, Atropine, Quinine, Morphine, Digoxin</th>
<th>7</th>
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<tbody>
<tr>
<td>8. A Brief account of plant based industries involved in work on medicinal and aromatic Plants in India</td>
<td>3</td>
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<td>9. Regulatory requirements of herbal medicines.  - Infrastructure  - Quality control and evaluation parameters. Regulatory control for Import and Export of herbal products.</td>
<td>6</td>
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<tr>
<td>11. Toxicity in Herbals and their interaction.  ( Liquorice, Cinchona, Cannabis, Garlic, Digitalis, St John’s wort)</td>
<td>6</td>
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<tr>
<td>12. 12] Herbal cosmetic.  - Introduction and brief history. Skin and hair care products, production and quality control thereof</td>
<td>6</td>
</tr>
</tbody>
</table>

**Reference Books:**

1. Trease and Evans, Pharmacognosy, Saunders company, London.
2. Tyler, Brady, and Robbers, Pharmacognosy, Lea Febiger, USA.
4. Kokate, Purohit, Gokhale, Pharmacognosy, Nirali Prakashan, pune.
8. Shah and Quadri Text Book of Pharmacognosy.
11. Wealth of India.
16. Dr. Pulok K. Mukharjee, “Quality control Herbal Drugs” Business Horizons,
17. Ayurvedic Pharmacopoeia.
20. Wagner, Plant drug analysis.
4.6 PHARMACOGNOSY III
(Practical) (90 hrs: 3 Hrs./week)

1] Study of morphological, microscopical characters, chemical / microchemical Tests for following crude drugs in entire and in powdered form (including Surface preparation wherever required).

Leaf – Datura, Vinca, Vasaka Root- Rauwolfia, Ashwagandha
Bark – Cinchona, Kurchi, Stem- Ephedra.
Seed – Nux-Vomica

2] Identification of crude drugs mentioned in theory syllabus by their Morphological and physical characteristic.

3] Determination of volatile oil content and its evaluation(atleast two herbs).

4] Determination of lipid content by solvent extraction method.

5] Extraction, Isolation, evaluation by UV and chromatography of following phytopharmaceuticals.
   - Caffeine from tea
   - Eugenol from clove oil
   - Curcuminoids from curcuma longa
   - Hesperidine from orange peel
   - Quinine from cinchona bark
   - Aloe from Aloe vera


7] Preparation and evaluation of herbal cosmetics, (Minimum 4 each)
   - Hairs cosmetics
   - Skin cosmetics

8] Evaluation of Marketed Herbal Formulations (Minimum 3)
9) Column Chromatography for separation of Phytoconstituents (Demonstration)

Reference Books:
7. Wagner, Plant drug analysis.
10. Ayurvedic Pharmacopoeia of India.
11. Indian Pharmacopoeia.

4.7 Pharmaceutical Jurisprudence
(Theory) (60 Hrs:2 hrs/week)

<table>
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<tr>
<th>Sr. No</th>
<th>SECTION- I</th>
<th>Hrs.</th>
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<tr>
<td></td>
<td>Study of following in detail</td>
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<tr>
<td>1.</td>
<td>Legislation to regulate import, manufacture, distribution &amp; sales of drugs &amp; cosmetics. The Drugs and Cosmetics Act 1940 &amp; rules 1945 &amp; amendments.</td>
<td>9</td>
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<tr>
<td>2.</td>
<td>Legislation to regulate then profession of Pharmacy. The Pharmacy act 1948</td>
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<td>Brief study of following legislations</td>
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<td>3.</td>
<td>The Drugs and Magic Remedies Act &amp; Rules 1976.</td>
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<td>4.</td>
<td>The Drugs Price Control Order 1998 with latest amendments.</td>
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<td>5.</td>
<td>Narcotic Drugs &amp; Psychotropic substances act 1985.</td>
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<td></td>
<td>Aim, Objectives and Salient features only of following legislations</td>
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<td>6.</td>
<td>Prevention of Food Adulteration Act 1954.</td>
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<td>7.</td>
<td>Consumer Protection Act.</td>
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<td>8.</td>
<td>Industrial Development &amp; Regulation Act 1951.</td>
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<td>9.</td>
<td>Industrial Safety &amp; Health.</td>
<td>1</td>
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<tr>
<td>10.</td>
<td>Cyber Law.</td>
<td>1</td>
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SECTION II

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<th>Sr. No</th>
<th>IPR</th>
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<tbody>
<tr>
<td>11.</td>
<td>a) Introduction of IPR (Patents, Design, Trademarks, Copyrights, Geographical Indications etc)</td>
</tr>
</tbody>
</table>
### Patent System
- Definition of Patent
- Criteria for obtaining patent (Novel, Non-obvious Applications)

### Filing and Processing of Patents
- General procedure for securing patents in India: Case studies
- Opposition to Grant of Patent
- Patent infringement: Case studies

### Silent features of Indian Patents Act 1970 with latest amendments with special reference to-
- Product & Process Patents
- Provision of compulsory license
- Exclusive Marketing Right
- The Term of Patent
- Patent offices in India

### Pharmaceutical patents in U. S. and the Hatch Waxman Act with reference to generic Drugs
- The Orange book
- The difference between New Drug Application (NDA) and Abbreviated New Drug Application (ANDA)
- The contents of ANDA and bioequivalence
- Patent Certification (Para-I, Para-II, Para-III and Para-IV)

### Drug Regulatory Affairs

#### a) Brief Information of agencies of Drug Regulatory affairs in different countries
- U.S. - Food & Drug Administration (FDA)
- Australia- Therapeutic Goods Administration (TGA)
- Europe- European Agency for the Evaluation of Medicinal Products (EMEA)
- Japan-Ministry of Health and Welfare (MHW)
- U.K. (MHRA)

#### b) Preparation of the Investigation New Drug Application (IND) and New Drug Application (NDA) or Biologics & Licensing Application (BLA), Electronic Submission, Drug Master File (DMF)

#### c) World Wide Harmonization of Regulatory Affairs (ICH) & World Health Organization (WHO) guidelines

### Recommended Books