

**Punyashlok Ahilyadevi Holkar Solapur University, Solapur**



**Name of the Faculty: Science & Technology**

**CHOICE BASED CREDIT SYSTEM**

**Syllabus: Bachelor of Pharmacy**

**Name of the Course: B. Pharmacy IV (Sem.–VII & VIII)  
(Syllabus to be implemented from w.e.f. June 2019)**

## Punyashlok Ahilyadevi Holkar Solapur University, Solapur

Faculty of Science & Technology

### Bachelor of Pharmacy

Choice Based Credit System Structure of Teaching & Examination w.e.f. 2016-17

Final Year B. Pharmacy (Semester-VII)

| Code  | Course                       | Hrs./Week |          |           | Credits   | Examination Scheme |            |            |             |
|---|------------------------------|-----------|----------|-----------|-----------|--------------------|------------|------------|-------------|
|   |                              | L         | T        | P         |           | ISE                | ESE        | ICA        | Total       |
| 4.7.1   | Sterile Dosage Forms         | 3         | -        | -         | 3         | 30                 | 70         | -          | 100         |
| 4.7.2   | Pharmaceutical Jurisprudence | 3         | -        | -         | 3         | 30                 | 70         | -          | 100         |
| 4.7.3   | Medicinal Chemistry-III      | 3         | -        | -         | 3         | 30                 | 70         | -          | 100         |
| 4.7.4   | Pharmaceutical Analysis-V    | 3         | -        | -         | 3         | 30                 | 70         | -          | 100         |
| 4.7.5   | Pharmacology-III             | 3         | -        | -         | 3         | 30                 | 70         | -          | 100         |
| 4.7.6   | Pharmacognosy-III            | 3         | -        | -         | 3         | 30                 | 70         | -          | 100         |
|   | <b>Total</b>                 | <b>18</b> | <b>-</b> | <b>-</b>  | <b>18</b> | <b>180</b>         | <b>420</b> | <b>-</b>   | <b>600</b>  |
| <b>Practical</b>  |                              |           |          |           |           |                    |            |            |             |
| 4.7.7   | Sterile Dosage Forms         | -         | -        | 3         | 1.5       | -                  | 70         | 30         | 100         |
| 4.7.8   | Pharmaceutical Analysis-V    | -         | -        | 3         | 1.5       | -                  | 70         | 30         | 100         |
| 4.7.9   | Pharmacology-III             | -         | -        | 3         | 1.5       | -                  | 70         | 30         | 100         |
| 4.7.10  | Pharmacognosy-III            | -         | -        | 3         | 1.5       | -                  | 70         | 30         | 100         |
|   | <b>Total</b>                 | <b>-</b>  | <b>-</b> | <b>12</b> | <b>6</b>  | <b>-</b>           | <b>280</b> | <b>120</b> | <b>400</b>  |
|   | <b>Grand Total</b>           | <b>18</b> | <b>-</b> | <b>12</b> | <b>24</b> | <b>180</b>         | <b>700</b> | <b>120</b> | <b>1000</b> |
| <p><b>Abbreviations:</b> L- Lectures, T- Tutorials, P-Practicals,<br/> <b>ISE</b> - In Semester Exam., <b>ESE</b> - End Semester exam, <b>ICA</b>- Internal Continuous Assessment<br/> <b>Note :</b> <b>ISE</b> -Three Tests , <b>ESE</b> - University Theory paper shall be of 70 marks of 3 hrs. duration</p> |                              |           |          |           |           |                    |            |            |             |

## Punyashlok Ahilyadevi Holkar Solapur University, Solapur

Faculty of Science & Technology

### Bachelor of Pharmacy

Choice Based Credit System Structure of Teaching & Examination w.e.f. 2016-17

Final Year B. Pharmacy (Semester-VIII)

| Code  | Course   | Hrs./Week |          |          | Credits   | Examination Scheme |            |           |             |
|---|--|-----------|----------|----------|-----------|--------------------|------------|-----------|-------------|
|   |  | L         | T        | P        |           | ISE                | ESE        | ICA       | Total       |
| 4.8.1   | Novel Drug Delivery Systems                            | 3         | -        | -        | 3         | 30                 | 70         | -         | 100         |
| 4.8.2   | Pharmaceutical Business Management                     | 3         | -        | -        | 3         | 30                 | 70         | -         | 100         |
| 4.8.3   | Medicinal Chemistry-IV                                 | 3         | -        | -        | 3         | 30                 | 70         | -         | 100         |
| 4.8.4   | Pharmaceutical Analysis-VI                             | 3         | -        | -        | 3         | 30                 | 70         | -         | 100         |
| 4.8.5   | Pharmacology-IV  | 3         | -        | -        | 3         | 30                 | 70         | -         | 100         |
| 4.8.6   | Herbal Technology                                      | 3         | -        | -        | 3         | 30                 | 70         | -         | 100         |
| 4.8.7   | Structural Elucidation of Organic Molecules            | -         | 3        | -        | 3         | 100                | -          | -         | 100         |
| 4.8.8   | Clinical Research, Pharmacovigilance & Data Management |           |          |          |           |                    |            |           |             |
| 4.8.9   | Introduction to Pharmacological Screening              |           |          |          |           |                    |            |           |             |
|   | <b>Total</b>   | <b>18</b> | <b>3</b> | <b>-</b> | <b>21</b> | <b>280</b>         | <b>420</b> | <b>-</b>  | <b>700</b>  |
| <b>Practical</b>  |  |           |          |          |           |                    |            |           |             |
| 4.8.10  | Novel Drug Delivery Systems                            | -         | -        | 3        | 1.5       | -                  | 70         | 30        | 100         |
| 4.8.11  | Medicinal Chemistry-IV                                 | -         | -        | 3        | 1.5       | -                  | 70         | 30        | 100         |
| 4.8.12  | Herbal Technology                                      | -         | -        | 2        | 1         | -                  | 70         | 30        | 100         |
|   | <b>Total</b>   | <b>-</b>  | <b>-</b> | <b>8</b> | <b>4</b>  | <b>-</b>           | <b>210</b> | <b>90</b> | <b>300</b>  |
|   | <b>Grand Total</b>                                     | <b>18</b> | <b>3</b> | <b>8</b> | <b>25</b> | <b>280</b>         | <b>630</b> | <b>90</b> | <b>1000</b> |
| <p><b>Abbreviations:</b> L- Lectures, T- Tutorials, P-Practicals<br/> <b>ISE</b> - In Semester Exam., <b>ESE</b> - End Semester exam, <b>ICA</b> - Internal Continuous Assessment<br/> <b>Note :</b> ISE -Three Tests , ESE - University Theory paper shall be of 70 marks of 3 hrs. duration</p> |  |           |          |          |           |                    |            |           |             |

## Final Year B.Pharmacy

### Semester-VII

#### 4.7.1 Sterile Dosage Forms

**1. Parenteral Products**

History of parenterals, conceptual origin, advantages and disadvantages, various parenteral routes of administration, essential characteristics like sterility, freedom from particulate matter and apyrogenicity

**2. Preformulation Study**

Detailed study of formulation parameters like volume, solvents, official monograph of solvents used for parenterals, osmotic pressure and adjustment of isotonicity, pH, maintenance of sterility, solubility, stability and other parameters

**3. Design of Production Facilities for Parenterals**

Design of facilities in sterile area, examples of plant layout, change room design, windows, doors and services, laminar flow benches and their efficiency tests, sources of contamination, personnel, environmental control, cleanliness classes, air handling (HVAC) system, HEPA filters, regulatory guidelines for the manufacture of parenterals

**4. Processing of Formulations Parenterals**

Classification, manner of labeling, solutions, suspensions, emulsions and sterile solids, total parenteral nutrition (TPN).

Different documents used in processing; aseptic and non-aseptic approaches of manufacturing, cleaning, filling and sealing of parenterals, applications of different methods of sterilization, validation of sterilization and environment

**5. Packaging of Parenterals**

Packaging components and types, specifications, quality control tests for packaging materials, factors influencing choice of containers, prefilled syringes, form-fill-seal technique, labeling requirements

**6. Quality Control Tests for Parenterals**

Test for sterility, pyrogen/endotoxin test, test for particulate matter, leaker test and other tests, quality assurance aspects of parenterals

**7. Ophthalmic Products**

Anatomy of eye, ocular bioavailability, formulation of ophthalmics such as solutions, suspension, ointments, packaging, quality control tests, labeling requirements, contact lens care solutions

**8. Pilot Plant Scale-up Techniques**

Introduction, process considerations, scientific principle of scale-up, general considerations including personnel, space requirements, raw materials, pilot plant scale up considerations for solid, liquid oral, semi solid formulations, relevant documentation, SUPAC guidelines, overview of Technology Transfer

**Reference Books:**

1. Avis K.A., Lachman L. and Liberman H.A., Pharmaceutical Dosage Forms: Parenteral Medications, Vol. I, II & III, Latest Edition, Marcel Dekker Inc., New York.
2. Swarbrick J. and Boylan J., Encyclopedia of Pharmaceutical technology, 2<sup>nd</sup> Ed., Marcel Dekker, 2002.
3. Turco S. and King R.E., Sterile Dosage Forms, 3<sup>rd</sup> Ed., Lea & Febiger, Philadelphia, 1985.

4. Banker G.S. and Rhodes C.T., Modern Pharmaceutics, 4<sup>th</sup> Ed., Marcel Dekker Inc., 2002.
5. Pelczar M.J., Reid R.D. and Chan E.C.S., Microbiology, 5<sup>th</sup> Ed., Tata McGraw Hill Publishing Co., New Delhi.
6. Carter S.J., Cooper and Gunn's Dispensing for Pharmaceutical Students, Latest Edition, Pitman Medical Publishing Co., New Delhi.
7. Gennaro A.R., Remington: The Science and Practice of Pharmacy, Vol-I & II, Lippincott Williams & Wilkins, New York.
8. Hugo W.B. and Russel A.D., Pharmaceutical Microbiology, Latest Edition, Blackwell Scientific Publications, London.
9. Aulton M. E., Pharmaceutics: The Science of Dosage Form Design, 2<sup>nd</sup> Ed., Churchill Livingstone, 2002.
10. Lachman L., Liberman H.A. and Kanig J.I., The Theory and Practice of Industrial Pharmacy, 3<sup>rd</sup> Ed., Verghese Publishing House, 1987.
11. Mitra A.K., Ophthalmic Drug Delivery, Latest Edition, Marcel Dekker INC., New York.
12. Akers M.J., Quality Control of Parenterals, Latest Edition, Marcel Dekker Inc., New York.
13. Alen L.V., Popovich N.G. and Ansel H.C., Pharmaceutical Dosage Forms and Drug Delivery Systems, 7<sup>th</sup> Ed., Lippincott Williams and Wilkins, London.
14. Carleton F.J. and Agalloco J.P., Validation of Pharmaceutical Sterile Products, 2<sup>nd</sup> Ed., Merce Dekker, New York, 1999.
15. Levin M., Pharmaceutical Process Scale-Up, 2<sup>nd</sup> Ed., Vol.157, CRS Press, New Delhi, 2006.
16. Mitra A.K., Ophthalmic Drug Delivery System, 1<sup>st</sup> Ed., Vol-58, Marcel Dekker, 1993.
17. Rey L. and May J.C., Freeze Drying / Lyophilization of Pharmaceutical & Biological Products, Marcel Dekker, New York.
18. Ansari A.M., Naik S.R., Advances in Formulation and Technology of Sterile Products, Latest Edition, Nirali Prakashan, Pune.

#### **4.7.7 Sterile Dosage Forms**

1. Perform the microbiological validation of aseptic area.
2. Perform validation of aseptic filling.
3. Preparation, filling, sealing, sterilization and evaluation of the following injections:
  - a. Sodium chloride Injection I.P.
  - b. Dextrose Injection I.P.
  - c. Calcium gluconate Injection I.P.
  - d. Ascorbic acid Injection I.P.
  - e. One injection in suspension form
  - f. One injection with the use of co-solvents
  - g. Intravenous fat emulsion for TPN
4. Preparation, filling, sealing, sterilization and evaluation of the eye drops and eye ointment (one each).
5. Evaluation of marketed parenteral suspension and emulsion for parameters like particle size, sterility and rheological parameters.

## 4.7.2 Pharmaceutical Jurisprudence

### 1. **Pharmaceutical Legislations in India:**

A brief review

### 2. **Pharmacy Act 1948:**

Objective, Definitions

Constitution and Functions of Central and State Pharmacy Councils,

Education Regulations and Approval of Courses and Institutions

Registration of Pharmacists, Preparation of Registers and qualifications for entry into register

Offences and Penalties

### 3. **Drugs and Cosmetic Act 1940 & Rules 1945:**

Definitions

Administrative Bodies:

Advisory: Constitution and function of Drugs Technical Advisory Board (DTAB) and Drug Consultative Committee (DCC),

Analytical: Central Drug Laboratory (CDL), Drug Control Laboratories, Government Analyst

Executive: Drug inspectors, Licensing Authorities, Controlling Authorities and Customs Collectors

Provisions Governing Import, Manufacture and Sale of Drugs

Labeling and Packaging of Drugs

Provisions applicable to manufacture and Sale of Ayurvedic Drugs

Provisions governing Import, Manufacture and Sale of Homeopathic Drugs

Various offences and corresponding Penalties

Broad content of various Schedules of the Drugs and Cosmetic Act and Rules

### 4. **Drugs and Magic Remedies (Objectionable Advertisements) Act 1954 & Rules 1955:**

Objectives, Definitions, Official's duties, Classes of Prohibited Advertisement, Classes of Exempted Advertisement, Offences & Penalties

### 5. **Narcotic Drugs and Psychotropic Substances Act 1985:**

Definitions

Narcotics Commissioner and other officers

Illicit Traffic and measures to prevent illicit traffic of opium

Offences and Penalties

### 6. **Prevention of food adulteration act 1954:**

Definitions, central committee for food standards, central food laboratory; composition & functions, public analyst; qualification & duties, food inspectors; qualification, powers duties & sampling procedures, offences & penalties.

### 7. **Drug (Price Control) Order 1995:**

Object, Definitions, Retail price of formulation, Drugs Prices Display Rule 1961 and other relevant orders

**Reference Books:**

1. "Forensic Pharmacy", Kuchekar and Kadtare and Itkar, Nirali Prakashan, 5 th edition, 2005.
2. "Textbook of Forensic Pharmacy" N. K. Jain, Vallabh prakashan, 4 th edition, 1999.
3. D & C Acts, 1940 and Rules, 1945, S. W. Deshpande and Nilesh Gandhi, Sumit Publishers, 2006, Mumbai.
4. Govt. of India Publication of above Acts and Rules.
5. 'Text Book of Forensic Pharmacy', Mithal B.M. 7th ed, National Book Centre, Calcutta, 1985.
6. Jain N.K., 'A Text Book of Forensic Pharmacy (Pharmaceutical Jurisprudence)', Vallabh Prakashan, Pune, 1989.
7. Kuchekar B.S. & Khandatare A.M., Forensic Pharmacy including Industrial and Labour Laws. Nirali Publication, Pune, 1989.
8. 'Code of Pharmaceutical Ethics', Pharmacy Council of India (P. B. No. 337), New Delhi Year.
9. Current Government of India Publications of all Drugs Acts and Rules.

### 4.7.3 Medicinal Chemistry-III

The following classes of drugs should be discussed in relation to:

- A) Introduction to the rational development (if any)
- B) Detailed Classification of each class
- C) Chemical nomenclature
- D) Structure-activity relationship
- E) Mechanism of action
- F) Synthesis of compounds with asterisk

#### 1. Drugs acting on central nervous system:

##### a. Anxiolytics, Hypnotics and Sedatives:

**Benzodiazepines:** Diazepam\*, Oxazepam, Nitrazepam, Midazolam, Alprazolam.

**Barbiturates:** Phenobarbital, Amobarbital, Pentobarbital\*;

**Miscellaneous :** Glutethimide, Meprobamate

##### b. Anticonvulsants:

**Hydantoins:** Phenytoin\*, Mephenytoin.

**Oxazolinediones:** Trimethadione, Paramethadione;

**Succinimides:** Phensuximide, Ethosuximide;

**Barbiturates:** Mephobarbital;

**Benzodiazepines:** Clonazepam;

**Ureas:** Carbamazepine, Oxcarbazepine;

**Miscellaneous:** Primidone, Phenacemide, Sodium Valproate.

##### c. Psychotherapeutic Agents:

**Phenothiazines:** Chlorpromazine\*, Triflupromazine, Fluphenazine, Thioridazine  
Thiothixene;

**Fluorobutyrophenones:** Haloperidol .

**Benzodiazepines:** chlorodiazepoxide, Flurazepam, diazepam, Lorazepam,  
Clonazepam.

**Tricyclic Antidepressants:** Imipramine, Desipramine, Amitriptyline, Nortriptyline,  
Doxepin, Maprotiline;

**MAO inhibitors:** Phenelzine, Tranylcypromine;

**Selective Serotonin reuptake inhibitors:** Fluoxetine, paroxetine,

**$\beta$ -aminoketones:** Molindone.

##### d. CNS Stimulants:

**Analeptics:** Pentylenetetrazole;

**Central Sympathomimetic agents:** Amphetamine, Methamphetamine,  
Fenfluramine, Phenmetrazine;

**Methylxanthines:** Caffeine, Theophylline

#### 2. Narcotic Analgesic Agents:

**Morphine and related compounds:** Morphine, Codeine, thebaine, ethylmorphine,  
dihydrocodeine, Heroin\*, Levorphanol, Dextromethorphan, Meperidine\*, Bemidone,  
anilaridine, Methadone\*, Fentanyl, dextropropoxyphene and pentazocine;

**Morphine antagonist:** Nalorphine, Naloxone, Naltrexone



**3. Analgesics, Antipyretics and Anti-inflammatory agents (NSAIDs) :**

**Salicylic acid derivatives:** Aspirin\*;

**Aryl acetic acid derivatives:** Indomethacin, Naproxen, Ketoprofen, Ibuprofen\*, Diclofenac, Sulindac, Ketorolac, Nimesulide, piroxicam;

**p-aminophenol derivatives:** Acetaminophen\*;

**Pyrazolidinedione derivatives:** Phenylbutazone, Oxyphenbutazone;

**N-arylanthranilic acid:** Mefenamic acid,

**Selective COX-2 inhibitors:** Rofecoxib, Valdecoxib;

**Antigout-Allopurinol, Probenecid**

**4. Antihistaminics, Antiemetics and antiulcer drugs:**

**H<sub>1</sub> antagonist drugs:** Diphenhydramine\*, Doxylamine, Triprolidine, Pheniramine, chlorpheniramine\*, Promethazine, Tripelenamine\*, Cyclizine, Meclizine, Cyproheptadine, Terferadine, Cetirizine;

**H<sub>2</sub> antagonist drugs:** Cimetidine; Famotidine,

**Proton pump inhibitors:** Omeprazole, Lansoprazole, Ranitidine, Rabeprazole, Pentaprazole;

**Antiemetic drugs:** Ondansetron, Domperidone.

**5. Steroids:**

**Adrenocorticoids:** Cortisol, Hydrocortisol acetate, Fludrocortisone acetate, Dexamethasone, Betamethasone, Flucinolone acetonide, Triamcinolone, Prednisone, Prednisolone, Aldosterone.

**Androgens and Anabolic Steroids:** Testosterone, Fluoxymesterone, Oxymesterone.

**Estrogens:** Estrone, Ethinyl estradiol, Estriol, Menstranol, chlorotrianisene, Dienesterol, Diethylstilbesterol.

**Progestational agents:** Progesterone, Norethinodrel, Norgestrel, Medroxyprogesterone acetate, Dimethisterone,

**Oral contraceptives-Mestranol, Lynestrenol**

**Reference Books:**

1. Chemistry by Ashutosh Kar, 1st edition, New Age International Publications.
2. Vogel's Elementary M.E. Wolf: Burger's Medicinal Chemistry, John Wiley and Sons, New York.
3. R.F. Doerge, Wilson & Gisvold's: Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott.
4. W.O.Foye: Principles of Medicinal Chemistry, Lea & Febiger, Philadelphia.
5. D.Lednicer and L.A. Mitschier: Ale Organic Chemistry of Drug synthesis Vol. 1, II & III John Wiley and Sons, New York.
6. S.N.Pandeya: A Textbook of Medicinal chemistry, Vol-I, S.G.Publishers, Varanasi.
7. Ashutosh Kar: Medicinal Chemistry, Wiley Eastern, Ltd., New Delhi
8. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry by Wilson and Gisvold, J. Lippincot Co. Philadelphia.
9. Medicinal Chemistry-A Biochemical Approach by Nogrady T, Oxford University Press New York, Oxford.

10. Antibacterial Chemotherapeutic Agents by SL Dax, Blackie Academic and Professional Publications, Chapman and Hall, 1997.
11. Principles of Medicinal Chemistry by Kadam SS, Mahadik KR, Bothara KG, Vol. I & II, 10 th Edition, Nirali Prakashan.
12. Introduction to Medicinal Chemistry' – How Drugs Act and Why by Alex Gringauz,
13. Willey-VCH Publication 1997.
14. Practical Organic Chemistry by Mann FC & Saunders BC, The English Language
15. Book Society and Longman Group Limited, London.
16. Vogel's A Text book of Practical Organic Chemistry by Vogel, 3rd edition, The English language book society and Longman group limited, London.
17. Advanced practical Medicinal Practical Organic Chemistry Small Scale Preparation by Arthur I., 2nd Edition, Part-I, CBS Publication.

## 4.7.4 Pharmaceutical Analysis-V

### **Chromatography:**

Definition & classification of chromatography, Terminology- Retention time, Retention volume, Adjusted retention time & volume, height equivalent to theoretical plate (HETP), temperature programming, resolution, column performance, derivatization, detection.

#### **1. Paper Chromatography:**

Introduction, papers used, development techniques & applications.

#### **2. Thin Layer Chromatography :**

Introduction, selection of adsorbent, preparation of the chromatoplate, sample spotting, development of chromatogram, detection of compound, qualitative & quantitative measurements and applications.

**HPTLC**-introduction, theory & applications.

#### **3. Column Chromatography:**

Introduction & classification

- a. Adsorption chromatography- theory, adsorbents used and applications.
- b. Partition chromatography- theory & applications.
- c. Ion-exchange chromatography – introduction, principle, types of ion exchange resins, applications.
- d. Gel chromatography – theory & principle, gels used, applications.

#### **4. Gas Chromatography :**

Introduction(GLC & GSC), carrier gas, columns, sample injection system, Detectors- Flame ionization detector (FID), Thermal conductivity detector,(TCD), Electron Capture detector (ECD), Atomic emission Detector (AED),Thermionic detector (TID), Nitrogen Phosphorous detector (NPD), Photoionisation detector (PID), Flame photometric detector(FPD) & Applications.

#### **5. High Performance Liquid Chromatography :**

Introduction, scope, principle & Instrumentation-

**Mobile phase reservoirs**- solvent treatment systems, Isocratic Elution, Gradient Elution.

**Pumps**-Reciprocating pump, Displacement pump & Pneumatic pump.

**Injection system**- sample loop system, stop flow etc.

**Columns**-Analytical columns, Guard columns, column thermostats, Types of column packing, Column packing material.

**Detectors**-solute property detector & solvent property detector (Absorbance detectors, IR detector, Fluorescence detectors, Refractive index detectors, Evaporative light scattering detector, electrochemical detectors)

**Reference Books:**

1. H. Beckett, J. B. Stenlake, practical pharmaceutical chemistry, 4<sup>th</sup> edition, CBS publications.
2. Vogel's textbook of quantitative chemical analysis, J Mendham, R.C. Denney, D. Barnes, M. Thomas, B, Sivasankar, VI th edition, pearson.
3. Principles of instrumental analysis, 4<sup>th</sup> edition, Skoogh, Holler, Nieman, Thomson
4. Gurdeep R. Chatwal, Sham K. Anand, Instrumental methods of chemical analysis, Himalay Publishing House.
5. Indian pharmacopoeia.
6. Handbook of Modern Pharmaceutical Analysis. Edited by Satinder Ahuja, Stephen Scypinski
7. Handbook of Pharmaceutical Analysis by HPLC. Edited by Satinder Ahuja, Michael Dong
8. Connors K A, A Textbook of Pharmaceutical Analysis, Wiley Interscience, New York.
9. Willard H. H., L. L. Merritt & John Dean Instrumental Method of Analysis, 6<sup>th</sup> edition,
10. Dr. B. K. Sharma Instrumental Methods of Chemical Analysis

**4.7.8 Pharmaceutical Analysis-V**

1. Separation of mixture using Thin-layer chromatography (Four).
2. Separation of mixture using paper chromatography (Two)
3. Separation of mixture using column chromatography
4. Demonstration of HPLC
5. Estimation of drugs in multicomponent formulation by simultaneous equation method.
6. Estimation of drugs in multicomponent formulation by absorption ratio method.

## 4.7.5 Pharmacology-III

Classification, pharmacokinetics, mechanism of action, pharmacological actions, adverse effects, contraindications, therapeutic uses, drug interaction, dosage, symptoms and treatment of poisoning of drugs acting on following categories:

**I. Central Nervous System:** General considerations- study of neurotransmitters and their mechanisms

1. Alcohols: Ethyl alcohol, aldehyde dehydrogenase inhibitors and methyl alcohol poisoning and treatment
2. General anaesthetics: comparison between local and general anaesthetics, stages of anaesthesia, properties of an ideal anaesthetic, complications of general anaesthesia and preanaesthetic medications
3. Antiepileptics: definition of epilepsy, seizures and convulsions and types of epilepsy
4. Sedatives, hypnotics and anxiolytics
5. Antipsychotic and antimanic drugs
6. Antidepressant and antianxiety drugs
7. CNS stimulants and cognition enhancers
8. Neurodegenerative disorders: antiparkinsonian drugs

**II. Drugs used for Pain Management:**

1. Opioid analgesics: opioid receptors, opioid antagonists, endogenous opioid peptides
2. Antipyretic-analgesics
3. Nonsteroidal anti-inflammatory drugs

**III. Immunopharmacology**

1. Immunostimulants
2. Immunosuppressant  
Protein drugs, monoclonal antibodies, target drugs to antigen, biosimilars

**IV. Hormone and related drugs**

1. Diabetes mellitus and antidiabetic drugs: definition, types and symptoms of diabetes mellitus, comparison between type-I and type-II diabetes mellitus, insulin and oral hypoglycaemic agents
2. Thyroid and antithyroid drugs,
3. Androgens and drugs for erectile dysfunction
4. Estrogens, progestins and contraceptives
5. Oxytocin and other drugs acting on uterus

**Reference Books:**

1. Satoskar R.S. and Bhandarkar S.D.: Pharmacology & Pharmacotherapeutics, Popular Prakashan, Bombay.
2. Tripathi K.D.: Essentials of Medical Pharmacology, Jaypee Brothers, Medical Publishers, New Delhi.
3. Goodman and Gillman: Pharmacological Basis of Therapeutics, McGraw-Hill, Medical Publishing Division, New York.
4. Rang H.P. and Dale M.M.: Pharmacology, Churchill Livingstone, Edinburgh.
5. Katzung B.G.: Basic and Clinical Pharmacology, Lange Medical Publications, California.
6. Craig C.R. and Stitzel R.E.: Modern Pharmacology, Little Brown and Co., Boston.

7. Bowman W.C. and Rand M.J.: Textbook of Pharmacology, Blackwell Scientific Publications, Oxford.
8. P.N Bennett & M J Brown: Clinical Pharmacology, Churchill Livingstone, Edinburgh.

### 4.7.9 Pharmacology-III

#### Discussion of the following aspects

1. Introduction to experimental pharmacology.
2. Commonly used instruments in experimental pharmacology.
3. Study of common laboratory animals.
4. Study of different routes of drugs administration in mice/rats.
5. Introduction to *in-vitro* pharmacology and physiological salt solutions.

#### Experiments

6. Record and interpret the concentration response of acetylcholine/histamine using suitable isolated tissues.
7. Introduction to general principles, types and applications of bioassays.
8. Bioassay of acetylcholine/histamine using chick ileum preparation.

#### Simulated Experiments

9. Effect of drugs on rabbit eye (miotic, mydriatic and local anaesthetic).
10. Effects of skeletal muscle relaxants using rota-rod apparatus.
11. Effect of drugs on locomotor activity using actophotometer (CNS stimulant/depressant).
12. Study of analgesic activity of drugs using Eddy's hot plate and tail-flick method analgesiometer.

*Note: All laboratory techniques and animal experiments are demonstrated by simulated experiments by softwares and videos*

#### Reference Books/Softwares:

1. Ghosh M.N., Fundamentals of Experimental Pharmacology, Scientific Book agency, Calcutta.
2. S.K. Kulkarni., Hand book of Experimental Pharmacology, 2<sup>nd</sup> Ed., Vallabh Prakashan, Delhi.
3. Shivsharan B. Dhadde., Handbook of Experimental Pharmacology, 1<sup>st</sup> Ed., Studium Press (INDIA), Pvt. Ltd.
4. Software: X-Pharma, X-cology, Animal simulator

## 4.7.6 Pharmacognosy-III

### 1. Alkaloids:

Definition, occurrence, properties, General methods of Extraction, classification, chemistry & uses of Alkaloids. Source, constituents, uses, adulterants & substitutes of following drugs:

- a. Indole – Ergot\*, Rauwolfia, Nux-vomica, Vinca
- b. Tropane – Datura\*, Coca
- c. Quinoline – Cinchona
- d. Isoquinoline – Opium\*, Ipecac
- e. Pyridine/ Piperidine – Lobelia
- f. Quinazoline – Vasaka
- g. Amino alkaloids – Ephedra\*
- h. Steroidal – Ashwagandha

\*Biosynthetic pathway to be studied

### 2. Glycosides:

Introduction, definition, occurrence, properties, classification, chemistry, uses along with their hydrolysis product. General methods of extraction

- a. Anthraquinones – Senna, Aloe
- b. Cardioactive - Digitalis, Squill
- c. Saponins – Liquorice
- d. Bitters - Kalmegh, Chirata
- e. Cynogenetic – Bitter almond
- f. Isothiocyanate – Mustard

### 3. Marine Drugs:

Sources and Pharmacological activities of newer medicinal agents of Marine source with special reference to Anti-inflammatory, Cardiovascular and anticancer agents.

### 4. Proteins and Enzymes:

Papain, Bromelin, Streptokinase, Serratiopeptidase and Urokinase.

### 5. Bioflavonoids:

Introduction and their medicinal importance, Green tea, Citrus peel, Gingko leaves and Soyabean.

### Reference Books:

1. Trease and Evans, Pharmacognosy, Saunders company, London.
2. Tyler, Brady, and Robbers, Pharmacognosy, Lea Febiger, USA.
3. Wallis T. E., Text Book of Pharmacognosy, CBS publishers & distribution, Delhi.
4. Kokate, Purohit, Gokhale, Pharmacognosy, Nirali Prakashan, pune.
5. Rangari V.D., Pharmacognosy & Phytochemistry, Vol I, II, Career Publication,
6. E. Ramstad, Modern Pharmacognosy, Mc-graw hill Book Company.

7. Pridham J B, Swain T, Biosynthetic pathway in higher plants, Academic Press, New York.
8. Scheuer P G, Marine natural products, Academic Press, London.
9. Shah and Quadri Text Book of Pharmacognosy.
10. Ayurvedic Pharmacopoeia.
11. Ayurvedic Formulary.
12. Indian Pharmacopoeia.
13. British Pharmacopoeia.
14. Martindale Extra Pharmacopoeia.
15. Indian Herbal Pharmacopoeia.
16. Wagner, Plant drug analysis.
17. M. A. Iyengar, S. G. K Nayak "Pharmacognosy Lab Manual", Manipal Press.
18. M. A. Iyengar, "Anatomy of Crude Drugs", Manipal Press.
19. M. A. Iyengar, "Pharmacognosy of powdered crude drugs", Manipal Press.
20. Dr. Pulok K. Mukharjee, Quality control on Herbal Drugs, Business Horizon.
21. Kalia A. N., Industrial Pharmacognosy.
22. Mohd. Ali, "Pharmacognosy" CBS Publication. New Delhi.
23. Aushotosh Kar "Pharmacognosy & Pharmacobiotechnology" New Age International Publisher.

#### **4.7.10 Pharmacognosy-III**

1. Study of morphological, Histological(TS) characters, chemical microchemical tests for following crude drugs:
  - Leaf – Vinca
  - Root- Rauwolfia & Liquorice
  - Bark – Cinchona
  - Stem- Ephedra
  - Seed – *Nux-Vomica*
2. Powder Analysis of following drugs:
  - a) Vinca
  - b) Rauwolfia
  - c) Liquorice
  - d) Cinchona
  - e) Ephedra
  - f) Nux vomica
3. Identification of crude drugs mentioned in theory syllabus by their Morphological and physical characteristic.
  - a) Alkaloids- Vasaka, Aswagandha
  - b) Glycosides- Kalmegh, Mustard, Chirata
  - c) Bioflavonoids- Soybean, Citrus peel
4. General methods of extraction along with their identification test.
  - Alkaloids and Glycosides



## **Semester-VIII**

### **4.8.1 Novel Drug Delivery Systems**

**1. Fundamentals of Novel Drug Delivery Systems:**

Basic concepts, different terms used, classification, advantages and disadvantages, comparative study with conventional release monographs, commercial importance

**2. Polymer Science:**

Introduction, classification, examples, properties, advantages and applications of polymers in formulation of controlled release drug delivery systems.

**3. Oral Modified Release Systems:**

Introduction, historical development, pre-requisites of drug candidates, pertinent physiological parameters, biopharmaceutical considerations, dose calculation, various approaches to design sustained and controlled release, dissolution, diffusion controlled systems, matrix formulations, mechanisms of drug release from matrix, reservoir systems, ion exchange systems, osmotically controlled systems, gastroretentive systems, delayed release approaches like bioadhesive systems, colon targeting, different drug release kinetics and model fitting, official and unofficial methods of evaluation

**4. Recent Advances in Drug Delivery Systems:**

Introduction, classification, principle involved, merits, demerits and applications of following systems excluding formulation aspects: targeted drug delivery systems, nanoparticles, liposomes, resealed erythrocytes transdermal drug delivery system, iontophoresis, sonophoresis, implants, intrauterine drug delivery system, naso-pulmonary systems, ocular delivery systems

**Reference Books:**

1. Chien Y.W., Controlled Drug Delivery: Fundamentals and Applications, 2<sup>nd</sup> Ed. Marcel Dekker Inc., New York.
2. Robinson J.R., Sustained and Controlled Drug and Delivery, Marcel Dekker Inc., New York.
3. Kydonieus A, Treatise on Controlled Drug Delivery: Fundamentals, Optimization and Applications. Latest edition, Marcel Dekker Inc., New York.
4. Jain N.K., Advances in Controlled and Novel Drug Delivery, 1<sup>st</sup> Ed., CBS Publication, New Delhi, 2001.
5. Rowe R.C., Handbook of Pharmaceutical Excipients, 5<sup>th</sup> Ed., Pharmaceutical Press, New York, 1991.
6. Tarcha P.J., Polymers for Controlled Drug Delivery, 1<sup>st</sup> Ed., CRC Press, New Delhi, 2006.
7. Benita S., Microencapsulation: Methods and Industrial Applications, 2<sup>nd</sup> Ed., Vol. 158, CRC Press, New Delhi, 2006.
8. Hadgraft J. and Guy R.H., Transdermal Drug Delivery, 1<sup>st</sup> Ed., Vol. 35, Marcel Dekker, New York, 1989.
9. Hillery A.M., Lloyd A.W. and Swarbrick J., Drug Delivery and Targeting for Pharmacists and Pharmaceutical Scientists, Latest Edition, Taylor & Francis, London.
10. Williams A.C., Transdermal and Topical Drug Delivery: From Theory to Clinical Practice, Latest Edition, Williams Pharmaceutical Press, New York.

11. Hillery A.M. and Lloyd A.W., Drug Delivery and Targeting, 1<sup>st</sup> Ed., Tylor and Franicis, London.
12. Banker G.S. and Rhodes C.T., Modern Pharmaceutics: Revised and Expanded, 4<sup>th</sup> Ed., Marcel Dekker Inc., New York, 2002.
13. Gennaro A.R., Remington: The Science and Practice of Pharmacy, Vol. I & II, Lippincott Williams & Wilkins, New York.
14. Aulton M. E., Pharmaceutics: The Science of Dosage Form Design, 2<sup>nd</sup> Ed., Churchill Livingstone, 2002.
15. Lachman L., Liberman H.A. and Kanig J.I., The Theory and Practice of Industrial Pharmacy, 3<sup>rd</sup> Ed., Verghese Publishing House, 1987.
16. Alen L.V., Popovich N.G. and Ansel H.C., Pharmaceutical Dosage Forms and Drug Delivery Systems, 7<sup>th</sup> Ed., Lippincott Williams and Wilkins, London.

#### **4.8.10 Novel Drug Delivery Systems**

1. Study of drug release requirements in different pharmacopoeias.
2. Formulation and evaluation of any one fast dissolving tablets.
3. Formulation and pre-compressional study of any one matrix tablets.
4. Evaluation of matrix tablets.
5. Formulation of any one multiparticulate oral sustained release formulation.
6. *In-vitro* drug release study of multiparticulate system.
7. Dissolution study of any one marketed products.
8. Formulation of a multiple emulsion.
9. Study on diffusion of drug through membranes.
10. Applications of software in modeling of drug release.

## 4.8.2 Pharmaceutical Business Management

### 1. Introduction to the Concepts of Management:

Managerial work, functions of management-primary functions like planning, organizing, Staffing, directing & controlling. Secondary functions like decision making, leadership, Delegation of authority/responsibility.

### 2. Introduction to Forms of Business Organization:

Forms of business Organization (in brief), Hindu Undivided family, Sole proprietorship, Partnership, Company and Cooperative Society.

### 3. Channels of Distribution:

Need of distribution channels, various channels of distribution like carrying & forwarding agents, super stockist, Wholesale & retail sellers.

### 4. The Pharmaceutical Product:

Market consideration in product development, marketing mix, product life cycle, modification of existing product, Marketing Generic drug, Branding- concept of brand, different types of brand, importance & reasons of branding.

### 5. Pharmaceutical Marketing:

Meaning & scope of marketing, quantitative & qualitative aspect, size & composition of market, market segmentation, marketing research. Uniqueness of medical products marketing. Professional Sales Representative-qualities of PSR, duties of PSR, purpose of detailing, selection & training of PSR.

### 6. Marketing Management:

Identifying and classifying market, understanding market behavior/consumer behavior, Pharmaceutical market in India, Pharmaceutical Industry Scenario.

### Reference Books:

1. Koontz and O'Donnell., 'Principles of Management' by International Student edition of McGraw Hill.
2. Reddin. W. J., 'Effective Management', New Delhi, Tata M. C. Graw Hill, Publishing Co. Ltd.,
3. Peter Drucker, 'Practice of Management' Allied Publishers, New Delhi.
4. Principles and Practice of Drug store administration - Dr. Mahesh Burande [Nirali Prakashan
5. R. M. Mehta - Drug Store and Management [Vallabh prakashan]
6. Smith - Principles and methods of Pharmacy management
7. The practice of Management by Peter Drocket [Allied Publication, New Delhi.
8. Pharmaceutical Marketing Management – Mukhopadhyaya
9. Marketing Management by Philip Kotlar; Prentice-Hall of India Ltd., New Delhi.
10. Management and Organization by Louis A. Allen; McGraw Hill, Tokyo.
11. Marketing Management 2nd edition by Dr. Rajan Saxena.

### 4.8.3 Medicinal Chemistry-IV

The following classes of drugs should be discussed in relation to:

- A) Introduction to the rational development (if any)
- B) Detailed Classification of each class
- C) Chemical nomenclature
- D) Structure-activity relationship
- E) Mechanism of action
- F) Synthesis of compounds with asterisk

#### 1. Drugs Acting on Cholinergic Nervous System:

**Biosynthesis and metabolism of Acetylcholine.**

**Cholinergic receptor agonist:** Acetylcholine, Bethanechol, Carbachol, Pilocarpine;

**Cholinesterases Reversible Inhibitors:** Neostigmine, Physostigmine;

**Cholinesterases Irreversible Inhibitors:** Echothiophate iodide, Isoflurophate, Parathione, Malathion;

**Anticholinergics:** Atropine, Scopolamine, Hyoscyamine, Dicyclomine\*, Cyclopentolate\*, benztropine, procyclidine, Isopropamide, Papaverine;

**Ganglionic blocking agents:** Mecamylamine;

**Neuromuscular blocking agents:** d-Tubocurarine chloride, Succinyl choline chloride

#### 2. Drugs Acting on Adrenergic Nervous System:

**Biosynthesis and metabolism of Epinephrine/norepinephrine.**

**Drugs affecting catecholamine biosynthesis:** Metyrosine;

**Drugs affecting catecholamine storage and release:** Reserpine, Guanethidine;

**Adrenergic receptor agonists:** Epinephrine, norepinephrine, dopamine, phenylephrine, Clonidine, methyldopa\*, dobutamine, Isoproterenol, Metaraminol, Terbutaline, Ephedrine;

**Adrenergic receptor antagonists:** tolazoline, Phenoxybenzamine, prazosin, Yohimbine, Propranolol\*, Atenolol, Metoprolol, Labetolol, Phenylpropanolamine, Salbutamol\*

#### 3. Cardio Vascular Drugs:

**Antianginal agents and vasodilators:** Amyl nitrite, Nitroglycerin, isosorbide dinitrite;

**Calcium antagonists:** Verapamil, Diltiazem, Nifedipine\*, Amlodipine

**Antiarrhythmic drugs:** Quinidine, Procainamide\*, Flecainide, Amiodarone;

**Antihypertensive drugs:** Enalapril, Captopril, Losartan, Telmisartan, Hydralazine, Diazoxide, minoxidil;

**Positive inotropic agents:** Digitalis;

**Antihyperlipidemic drugs:** Clofibrate, Gem fibrozil, atorvastatin, Pravastatin, Lovastatin, Simvastatin, Cholestyramine

#### 1. Drug Design:

**Computer Aided Drug Design (CADD)**

Quantitative Structure Activity Relationship (QSAR)- Introduction to various methods of QSAR – Physicochemical parameters – lipophilic, electronic and steric. Hansch LFER model and Free Wilson analysis.

**Prodrugs**

**Reference Books:**

1. Chemistry by Ashutosh Kar, 1st edition, New Age International Publications.
2. Vogel's Elementary M.E. Wolf: Burger's Medicinal Chemistry, John Wiley and Sons, New York.
3. R.F. Doerge, Wilson & Gisvold's: Textbook of Organic Medicinal and Pharmaceutical Chemistry, Lippincott.
4. W.O.Foye: Principles of Medicinal Chemistry, Lea & Febiger, Philadelphia.
5. D.Lednicer and L.A. Mitschier: Ale Organic Chemistry of Drug synthesis Vol. 1, II & III John Wiley and Sons, New York.
6. S.N.Pandeya: A Textbook of Medicinal chemistry, Vol-I, S.G.Publishers, Varanasi.
7. Ashutosh Kar: Medicinal Chemistry, Wiley Eastern, Ltd., New Delhi
8. Wilson and Gisvold's Textbook of Organic Medicinal and Pharmaceutical Chemistry by Wilson and Gisvold, J. Lippincot Co. Philadelphia.
9. Medicinal Chemistry-A Biochemical Approach by Nogrady T, Oxford University Press New York, Oxford.
10. Antibacterial Chemotherapeutic Agents by SL Dax, Blackie Academic and Professional Publications, Chapman and Hall, 1997.
11. Principles of Medicinal Chemistry by Kadam SS, Mahadik KR, Bothara KG, Vol. I & II, 10 th Edition, Nirali Prakashan.
12. Introduction to Medicinal Chemistry' – How Drugs Act and Why by Alex Gringauz, Willey-VCH Publication 1997.
13. Practical Organic Chemistry by Mann FC & Saunders BC, The English Language Book Society and Longman Group Limited, London.
14. Vogel's A Text book of Practical Organic Chemistry by Vogel, 3rd edition, The English language book society and Longman group limited, London.
15. Advanced practical Medicinal Practical Organic Chemistry Small Scale Preparation by Arthur I., 2nd Edition, Part-I, CBS Publication.

#### 4.8.11 Medicinal Chemistry-IV

Synthesis, M.P & TLC of following drugs & intermediates;

1. Benzocaine
2. Phenytoin
3. Aspirin/ Paracetamol /N-phenylanthranilic acid
4. Benzhydrol
5. Barbituric acid
6. Phenothiazine

Reference Books:

1. Practical Organic Chemistry by Mann FC & Saunders BC, The English Language Book Society and Longman group limited, London.
2. Vogel's a text book of Practical Organic Chemistry by Vogel, 3<sup>rd</sup> edition, The English language book society and Longman group limited, London.
3. Advanced practical Medicinal practical Organic Chemistry Small Scale Preparation by Arthur I, 2<sup>nd</sup> edition, Part-I, CBS Publication.
4. Text book of Medicinal Chemistry-I, 1st edition, PV books Publication.

## 4.8.4 Pharmaceutical Analysis-VI

### 1. Mass Spectrometry:

Principle, theory, ion sources, mass analyzer, types of ions and applications.

### 2. NMR Spectroscopy:

Basic principles, theory, chemical shift, factors affecting chemical shift, spin-spin coupling & applications.

### 3. Quality Assurance & Quality Control:

Introduction to Q.A. & Q.C, Components of Q.A, Q.C & quality management. Documents and formats in Quality policy (quality manual & SOP).

### 4. Analytical method development and validation according to ICH for UV and HPLC and application in the analysis of API and formulations. Introduction to process and equipment validation

### 5. Packaging Material Testing (PMT):

Quality Control test of packaging material used for pharmaceutical products-Glass bottles, Metals, Plastics, Aluminium foils, Rubber closure, Paper board cartons, Corrugated box. (Permeability of plastics, burst and tensile strength, cartons drop test, folding endurance test, hydrolytic resistance test, grammage, leakage test etc.)

### 6. Bio-Statistics:

Statistics in quality control: Definition of terms- mean, median, mode, normal distribution. Standard deviations, t-test, f-test, Chi ( $\psi$ ) square test, Linear regression & non-linear regression, ANOVA & Statistical Quality Control Charts.

### Reference Books:

1. A.H.Beckett, J.B.Stenlake, practical pharmaceutical chemistry, IVth edition, CBS publications.
2. Vogel's textbook of quantitative chemical analysis, J Mendham, R.C.Denney, J.D.Barnes, M.Thomas, B,Sivasankar, VI th edition, pearson.
3. Principles of instrumental analysis, Vth edition, Skoog, Holler, Nieman, Thomson
4. Gurdeep R. Chatwal, Sham K. Anand, Instrumental methods of chemical analysis, Himalay Publishing House.
5. William Kemp, Organic spectroscopy, ELBS.
6. Y.R.Sharma, elementary organic spectroscopy –principles & chemical applications, S.Chand & company Ltd.
7. Manohar A. Potdar, pharmaceutical quality assurance, nirali prakashan.
8. Remington Pharmaceutical Sciences, Vol-1
9. Theory & Practice of Industrial Pharmacy, Lachmann.
10. Walter Soroka, Fundamental's of Packaging technology.
11. D. A. Sawant, The Pharmaceutical sciences pharma pathway, Nirali Prakashan.
12. R M Silverstein and F X Webster, Spectrometric identification of organic compounds 6<sup>th</sup> Edition
13. Dixie A, Dean, Roy Evans, Ian Hall Pharmaceutical Packaging Technology

## 4.8.5 Pharmacology-IV

Classification, mechanism of action, pharmacokinetics, pharmacological actions, adverse effects, contraindications, therapeutic uses, drug interaction, dosage, symptoms and treatment of poisoning of drugs acting on following categories:

### I. Chemotherapy of Infection:

1. General principles
2. Antimicrobial resistance: introduction, types, mechanisms and its importance
3. Sulfonamides, cotrimoxazole and quinolones
4. Beta lactam antibiotics: penicillins, cephalosporins and carbapenems
5. Tetracycline and chloramphenicol
6. Aminoglycoside antibiotics
7. Macrolides
8. Antitubercular drugs
9. Antileprosy drugs
10. Antifungal drugs
11. Antiviral drugs
12. Antiprotozoal (antimalarial, antiamoebic etc.) drugs
13. Anthelmintic drugs

### II. Chemotherapy of cancer

### III. Drugs used in the disorders of eye, ENT and skin:

- Eye - Glaucoma, keratitis, conjunctivitis
- ENT- Allergic rhinitis, otitis media, vertigo, menezies disease.
- Skin- Acne, candidiasis, erythema nodosum, eczema, contact dermatitis, pediculosis, psoriasis, pyoderma, scabies, urticaria, pruritis.

### Reference Books:

1. Satoskar R.S. and Bhandarkar S.D.: Pharmacology & Pharmacotherapeutics, Popular Prakashan, Bombay.
2. Tripathi K.D.: Essentials of Medical Pharmacology, Jaypee Brothers, Medical Publishers, New Delhi.
3. Goodman and Gillman: Pharmacological Basis of Therapeutics, McGraw-Hill, Medical Publishing Division, NewYork.
4. Rang H.P. and Dale M.M.: Pharmacology, Churchill Livingstone, Edinbergh.
5. Katzung B.G.: Basic and Clinical Pharmacology, Lange Medical Publications, California.
6. Craig C.R. and Stitzel R.E.: Modern Pharmacology, Little Brown and Co., Boston.
7. Melman K.I. and Morelli H.F.: Clinical Pharmacology: Basic Principles in Therapeutics, Macmillan Press, New York.
8. Pharmacopoeia of India (1985), Controller of publication, Delhi.

## 4.8.6 Herbal Technology

### 1. Introduction:

Role of natural products in herbal medicine, General status and importance of herbal medicine

### 2. Processing of Herbs:

Methods of processing of herbs, Quality assessment, packing and storage of herbs.

### 3. Herbal Formulations:

Introduction to herbal formulations, Principle, methods, single herb formulation, poly-herbal formulation & their merits and demerits.

### 4. Regulatory Requirements of Herbal Medicines:

Safety and efficacy consideration, Regulatory control for Import and Export of herbal products, Herbal drug regulations in India (Brief)

### 5. Introduction to Ayurvedic Dosage Forms:

Definition, Classification, method of preparation and evaluation of following formulations- Asava & Arista, Gutika, Taila, Bhasma, Churna & Leha.

### 6. Herbal Cosmetics:

Introduction and brief history, Skin and hair care products, production and quality control thereof.

### Reference Books:

1. Trease and Evans, Pharmacognosy, Saunders Company, London.
2. Shah and Quadri Text Book of Pharmacognosy.
3. Atal C K, Cultivation and utilization of medicinal and aromatic plant.
4. Chopra, Indigenous drug of India.
5. Wealth of India.
6. Nadkarni, Material Medica.
7. Shehnaz Husain's Beauty Book, Orient Press.
8. Jain Urjita, Beauty through herbs, Institute of Herbs.
9. Chaudhari R D, Herbal Drug Industry, Eastern publication
10. Dr. Pulok K. Mukharjee, "Quality control Herbal Drugs" Business Horizons,
11. Ayurvedic Pharmacopoeia.
12. British Pharmacopoeia.
13. Martindale Extra Pharmacopoeia.
14. Indian Herbal Pharmacopoeia.
15. Wagner, Plant drug analysis.
16. Mohd. Ali, "Pharmacognosy" CBS Publication. New Delhi.
17. Herbal Drug Technology by S.S. Agrawal & M. Paridhavi
18. Kirtikar and Basu Indian Medicinal Plant.
19. Kalia A. N., Industrial Pharmacognosy.
20. Modern Methods of Plant Analysis by Peach & Tracey



#### 4.8.12 Herbal Technology

1. Preparation and Evaluation of Herbal Cosmetics:
  - a) Hair Cosmetics (Any two)
  - b) Skin Cosmetics (Any two)
2. Extraction and Isolation of following phytoconstituents:
  - a) Caffeine
  - b) Citric acid
  - c) Eugenol from Clove oil
3. Study of following Health food with reference to morphology:  
Honey, Brahmi, Shatavari, Spirulina, Guggul, Shankpushpi, Bael fruit, Pipal fruit, Cucumber and Fenugreek
4. Evaluation of marketed herbal and Ayurvedic Formulation: ( Group Experiment)  
Any one herbal and Ayurvedic preparation.

## Elective (Any one)

### 4.8.7 Structural Elucidation of Organic Molecules

#### 1. IR Spectroscopy :

Idea of the functional groups or groups present or absent, identify functional group such as-OH,-NH,C≡N, C=C,C≡C,C=O,NO<sub>2</sub> & aromatic rings. Determination of the type of C=O group & identification of conjugation with double bond or aromatic ring.

#### 2. Proton NMR Spectroscopy:

The proton NMR spectrum gives the information on the numbers & types of hydrogen items attached to the carbon skeleton. See the expected chemical shift values for organic molecules having various functional groups. Determine the integral ratios for the proton by using the integral traces. See number of protons attached to the carbon chain. Check multiplicities of peaks such as doublet, triplet, quartet, quintet and sextet. Calculate coupling constants which helps in relative position of hydrogen items in alkene (cis/trans isomers).

Following points should be considered for proton NMR spectrum of organic molecules.

- Number of signals/peaks
- Position of signals/peaks
- Integration of signals/peaks
- Chemical shift values of signals/peaks

#### 3. Mass Spectrometry:

Use mass spectra to obtain molecular formula by performing rule of thirteen calculation on the molecular ion peak. Convert hydrogen formula to one containing a functional group. Fragmentation pattern for common functional group is discussed.

Following points should be considered for mass spectrum of organic molecules.

- Identification of various ion peaks
- Identification of molecular ion peaks
- Rule of thirteen, nitrogen rule, hydrogen deficiency index
- General rule of fragmentation pattern

#### 4. UV visible spectrum :

Correlation between Wavelength of Absorbed Radiation and Observed Color, Simple Chromophores, Woodward–Fieser rule for estimating the  $\lambda_{\text{max}}$  in nm.

#### 5. Structural Elucidation (5 organic molecules):

A complete analysis of the information provided in the problems should lead to a unique structure for the unknown compound.

#### References:

- 1) Pavia, Lampman, Kriz & Vyvyan, Introduction to Spectroscopy, 5<sup>th</sup> edition, Cengage Learning.
- 2) Robert M. Silverstein & Francis X. Webster, Spectrometric Identification of Organic Compounds, 6<sup>th</sup> edition, Wiley Publications.
- 3) William Kemp, Organic Spectroscopy 3<sup>rd</sup> edition, Macmillan Publications.
- 4) Y.R Sharma, Elementary Organic Spectroscopy, 5<sup>th</sup> edition, S.Chand Publications.
- 5) Vogel's textbook of Quantitative Chemical Analysis, J.Mendham, R.C. Denney, J.D.Barnes, M.Thomas, B.Sivasankar, 5<sup>th</sup> edition, Pearson Publications.

## 4.8.8 Clinical Research, Pharmacovigilance & Data Management

1. **Introduction to Clinical Research-** Definition, Good Clinical Practice (GCP)-history, principles, guidelines, clinical process, ethics in clinical research, informed consent, clinical trial application, requirements in India.
2. **Introduction to Pharmacovigilance-** History and development, importance of safety monitoring of medicine, WHO international drug monitoring programme, pharmacovigilance Program of India.
3. **Introduction to adverse drug reactions-** Definitions and classification of ADRs, Detection and reporting, Methods in Causality assessment, Severity and seriousness assessment, Predictability and preventability assessment, Management of adverse drug reactions.
4. **Basic terminologies used in pharmacovigilance:** Terminologies of adverse medication related events, Regulatory terminologies.
5. **Drug and disease classification:** Anatomical, therapeutic and chemical classification of drugs, International classification of diseases, Daily defined doses, International Non proprietary Names for drugs.
6. **Drug dictionaries and coding in pharmacovigilance-** WHO adverse reaction terminologies, MedDRA and Standardised MedDRA queries, WHO drug dictionary, Eudravigilance medicinal product dictionary.
7. **Introduction to Clinical Data Management-** Data management activities, Case Report Form (CRF), eCRF and Development of data validation plans (DVP).

### References:

1. Textbook of Pharmacovigilance: S K Gupta, Jaypee Brothers, Medical Publishers.
2. Practical Drug Safety from A to Z by Barton Cobert, Pierre Biron, Jones and Bartlett Publishers.
3. Mann's Pharmacovigilance: Elizabeth B. Andrews, Nicholas, Wiley Publishers.
4. Stephens' Detection of New Adverse Drug Reactions: John Talbot, Patrick Walle, Wiley Publishers.
5. An Introduction to Pharmacovigilance: Patrick Waller, Wiley Publishers.
6. Cobert's Manual of Drug Safety and Pharmacovigilance: Barton Cobert, Jones & Bartlett Publishers.
7. Textbook of Pharmacoepidemiology edited by Brian L. Strom, Stephen E Kimmel, Sean Hennessy, Wiley Publishers.
8. A Textbook of Clinical Pharmacy Practice -Essential Concepts and Skills: G. Parthasarathi, Karin Nyfort Hansen, Milap C. Nahata
9. National Formulary of India
10. Text Book of Medicine by Yashpal Munjal

## 4.8.9 Introduction to Pharmacological Screening

1. Introduction to Pharmacological Screening: laboratory animals, CPCSEA guidelines, anaesthetics and techniques of euthanasia.
2. Dose selection: calculation and conversions
3. Rationale for grouping of animals, selection of animal species and sex for the study.
4. Basic definition and types of toxicology. Regulatory guidelines for conducting toxicity studies OECD, ICH, Principles of Good laboratory practice (GLP)
5. Acute, sub-acute and chronic toxicity studies
6. Acute eye irritation, skin sensitization, dermal irritation & dermal toxicity studies.
7. Carcinogenicity studies, teratogenicity studies, genotoxicity studies
8. Study of pharmacological screening methods for:
  - a) Analgesic, anti-inflammatory, antiulcer, Antidiabetic, antipsychotic, antiepileptic, skeletal muscle relaxants
  - b) Mydriatics, miotics and local anaesthetics
  - c) Diuretics & antihypertensive
  - d) High-throughput screening, cell culture and its applications in screening of anticancer drugs and antimicrobial agents.
9. IND enabling studies (IND studies) - Definition of IND, importance of IND, industry perspective, list of studies needed for IND submission.
10. Safety pharmacology studies- origin, concepts and importance of safety pharmacology.

### Reference Books:

1. Vogel G.H. (Ed.). Drug Discovery and Evaluation: Pharmacological Assays (Second Edition). Springer-Verlag Berlin Heidelberg New York.
2. Fundamentals of Experimental Pharmacology by Ghosh M.N.; Scientific Book agency, Calcutta.
3. Hand book of Experimental Pharmacology, 2<sup>nd</sup> Ed., S.K. Kulkarni., Vallabh Prakashan, Delhi.
4. Handbook of Experimental Pharmacology, 1<sup>st</sup> Ed., by Shivsharan B. Dhadde.; Studium Press (INDIA)., Pvt. Ltd.
5. Sheth, U. K. Dadkar, N. k. and Kamat, U. G. Selected Topics in Experimental pharmacology.
6. Pharmacological Experiments on Isolated preparations. Perry, W. L. M, E & S. Livingstone, Edinburgh & London
7. R. K. Goyal. Practicals in Pharmacology: B.S. Shah Prakashan, Ahmedabad.
8. Pharmacopoeia of India (1985), Controller of publication, Delhi