Faculty of Pharmaceutical Science

Syllabus

Final Year B. Pharm. 2013 Course
(With effect from Academic Year 2016 - 17)
4.7.1 T STERILE PRODUCTS
(Theory) (3Hrs/Week)

Learning Objective:
On completion of following theory topics & laboratory experiments, learner should be able to

A. Knowledge:
1. Describe the General requirements, routes of administration, significance of tonicity adjustment and sterility and Pre-formulation of sterile products
2. Describe various packaging materials used, types, choice of containers, official quality control tests and methods of evaluation.
3. Describe the GMP and design and layout of Parenteral Production Facility, environmental control zones, heating ventilation air conditioning (HVAC), HEPA filter and laminar area flow systems.
4. Explain Classification and formulation of SVP, types and selection of vehicles and added substance, processing, manufacturing and Quality control of SVPs along with Special types of SVPs and Pilot plant scale up.
5. Explain Large Volume Parenterals (LVPs), Types, concept of formulation, influence of physiological factors, processing, manufacturing and Quality control of LVPs, along with Parenteral Nutrition, intravenous admixture and Peritoneal dialysis fluid and Pilot plant scale up.
6. Explain General requirements, formulation, types and evaluation of ophthalmic products.
7. Describe Blood Products and Surgical Dressings

B. Skills:
1. Formulation development and Pharmacopoeial evaluation and labeling of SVPs, LVPs, and ophthalmic preparations
2. Expertise in sealing of ampoules
3. Describe use of ingredients in formulation and category of formulation
4. Pharmacopoeial evaluation of packaging materials
5. Importance and validation of aseptic area
6. Evaluation of marketed preparations
7. Significance and Accelerated stability testing of marketed samples.

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<tr>
<th>Sr. No.</th>
<th>Topic</th>
<th>Hrs</th>
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<tr>
<td></td>
<td>SECTION-I</td>
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<tr>
<td>1</td>
<td>Sterile formulations: Pre-formulation: Physicochemical properties of drug substances, General requirements, routes of administration, significance of tonicity adjustment and sterility.</td>
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<tr>
<td>2</td>
<td>Packaging of Parenterals : Various materials used, factors influencing choice of containers, packaging components and types, official quality control tests and methods of evaluation, prefilled syringes, blow-fill-seal technique</td>
<td>05</td>
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<tr>
<td>3</td>
<td>GMP-Design of Parenteral Production Facility: Product characteristics, personnel, batch Vs continuous operation, development of facility layout, environmental control zones, filling area design, heating ventilation air</td>
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conditioning (HVAC), HEPA filter testing and rating, laminar area flow systems.

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<td>4</td>
<td>Small Volume Parenterals (SVPs): Classification, formulation of solutions, 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, Parenterals suspensions, emulsions and Reconstituted products. Quality control for SVP and stability aspects</td>
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SECTION-II

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<tr>
<td>5</td>
<td>Large Volume Parenterals (LVPs): Types of LVPs, concept of formulation, influence of physiological factors, stabilization of LVPs, processing and manufacturing of LVPs, Parenteral Nutrition, intravenous admixture and Peritoneal dialysis fluid. Pilot plant scale up for LVPs. Quality control for LVP and stability aspects</td>
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<td>6</td>
<td>Lyophilization basics: Introduction, Principle, steps involved and Application of Freeze drying process. Component, Parameters, Construction and Working of Lyophilizer/ Freeze dryer</td>
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<td>7</td>
<td>Ophthalmic Products: General requirements, formulation, types of dosage forms, evaluation of ophthalmic product. Contact lens and lens care products,</td>
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<td>8</td>
<td>Blood Products: Collection and storage of whole human blood, fractionation of plasma. Quality control of blood products. Plasma Volume Expanders.</td>
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<td>9</td>
<td>Surgical Products: Definition Sutures and Ligatures of different types, Primary wound dressing, absorbents, surgical cotton, surgical gauzes bandages, advances (Superporous hydrogels) absorbent foam (polyurethane) dressings, Quality control testing.</td>
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4.7.1 PSTERILE PRODUCTS

Practical (3Hrs/Week)

1) Validation of aseptic area.
2) Pharmacopoeial evaluation of glass and plastic containers and rubber closures used for injectable.
3) Formulation and quality control of SVPs as per Indian pharmacopoeia. Any 3 (at least two ampoule sealing)
4) Formulation and quality control of LVPs as per Indian pharmacopoeia. Any 2
5) Accelerated stability testing of a SVP or LVP marketed samples.
6) Formulation, packaging and quality control of ophthalmic: Eye drop and Eye ointment
**Recommended books**

- W. P. Olson, M. J. Groove; Aseptic Pharmaceutical Manufacturing Technology, Interpharmpress.
- Haward.C. Ansel; Pharmaceutical calculations, 13th Ed, Lippincott Williams & Wilkins Publication, 2010
- Cooper and Gunn; Dispensing for Pharmaceutical Students, 12th Ed, CBS Publication
- Leon Lachman and Lieberman; The theory and practice of pharmacy, 3rd Ed, CBS Publication, 1986
- Ray & May; Freeze Drying / Lyophilization of pharmaceutical & Biological Products, Marcel Dekker,
4.7.2 T PHARMACEUTICAL ANALYSIS –V
(Theory) (3 Hrs/Week)

Learning objectives:
On successful completion of following theory topics & laboratory experiments, a learner should

A. Knowledge:
2. Know about electron microscopy.

B. Skills:
1. Independently operate and calibrate various analytical instruments for the separation/isolation and assay of various APIs and formulations as per Pharmacopoeial standards.
2. Independently process, interpret the data obtained through experimentation and report the results as per regulatory requirements.
3. Take appropriate safety measures while handling instruments, chemicals and apparatus.

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<tr>
<th>Topic No</th>
<th>Topics</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, Important spectral regions. <strong>FTIR:</strong> Theory, Instrumentation, sample handling, different attachments used in recording FTIR. Analysis and Interpretation of organic compounds based on FTIR Spectra</td>
<td>14</td>
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<td>2</td>
<td>Introduction to Near Infrared (NIR) &amp; Raman spectroscopy with respect to theory, instrumentation and applications.</td>
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<td>3</td>
<td>Introduction, principle, and applications of Scanning Electron Microscopy (SEM) Travelling Electron Microscopy (TEM)</td>
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<td>4</td>
<td><strong>Gas Chromatography:</strong> Theory, instrumentation, sample handling, columns, detectors, derivatisation and quantitation (area normalization, percent area, Internal standard, and External standard method) and applications.</td>
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<td>5</td>
<td><strong>Flash Chromatography:</strong> Theory, instrumentation and applications.</td>
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<td>6</td>
<td><strong>Super Critical Fluid Extraction and Super Critical Fluid Chromatography:</strong> Theory, instrumentation and applications.</td>
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<td>7</td>
<td><strong>Atomic Emission Spectroscopy:</strong> Theory, instrumentation and applications.</td>
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4.7.2 P PHARMACEUTICAL ANALYSIS -V  
(Practical) (3 Hrs/Week)

1. Spectrophotometric estimation of two-component formulations by simultaneous analysis. (minimum three)
2. Spectrophotometric analysis of two components by Q-Method. (minimum two)
3. Recording of IR spectra of compounds with different functional groups (-COOH, -COOR, -CONHR, -NH2, -NHR, -OH, -CHO, -CO etc.) (minimum two)
4. IR-Spectral interpretation of aliphatic and aromatic compounds (minimum two)
5. Demonstration experiments: Gas Chromatograph/Atomic Absorption Spectrophotometer / SEM

Recommended books

1. Indian Pharmacopoeia, 2014, Indian Pharmacopoeia Commission, Govt. of India
3. United States Pharmacopeia, 2016, US Pharmacopoeial Convention, USA
6. Pharmaceutical Analysis by Higuchi, Reprint 2004, CBS Publisher & Distributors.
7. The quantitative analysis of drugs by Garrat DC, 3/Ed., CBS Publisher & Distributors.
11. Handbook of Instrumental Techniques for Analytical Chemistry by Frank Settle, First Indian Reprint 2004, Pearson Education
12. Instrumental Methods of Analysis by Willard Merit, Dean Settle, 7th edition, CBS Publisher & Distributor

4.7.3 T MEDICINAL CHEMISTRY-III
(Theory) (3 Hrs/Week)

Learning objectives:
On completion of following theory topics & laboratory experiments, a learner should be able to

A. Knowledge:
Know general aspects of the design & development of drugs including history, classification, nomenclature, structure activity relationship (SAR), mechanism of action, adverse effects, therapeutic uses and recent developments in therapeutic categories such as NSAIDs, steroidal anti-inflammatory drugs, narcotic & non-narcotic analgesics, antipyretics, autacoids and drugs acting on respiratory & GI tract.

B. Skills:
1. Make correct use of various equipments & take safety measures while working in medicinal chemistry laboratory.
2. Develop skills involved in thin layer chromatography techniques and purification of synthesized compounds by column chromatography.
3. Synthesize, recrystallize and understand reaction mechanisms involved in synthesis of medicinally important organic compounds.
4. To interpret the spectral characterizations made by IR and $^1$H-NMRs of synthesized compounds.

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<tr>
<td></td>
<td>History and general aspects of the design &amp; development of drugs including classification, nomenclature, structure activity relationship (SAR), mechanism of action, adverse effects, therapeutic uses, scheme of synthesis of drugs mentioned in bracket and recent developments of following categories.</td>
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<td></td>
<td><strong>SECTION-I</strong></td>
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<tr>
<td>1</td>
<td><strong>Narcotic analgesics</strong>: Opiods, receptor subtypes and opioid antagonists (Methadone, Propoxyphen, Dextromethorphan)</td>
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<td>2</td>
<td>NSAIDs, steroidal anti-inflammatory agents, analgesics &amp; antipyretics (Ibuprofen, Diclofenac, Paracetamol, Piroxicam, Nambutone)</td>
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<td>3</td>
<td><strong>Autacoids</strong></td>
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<td></td>
<td>3.1 Antihistaminic agents: Structural features of Histamine receptor and its Subtypes and their structural features, H1 blockers and H2 blockers.</td>
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<td>3.1 Eicosanoids: history and discovery, eicosanoids biosynthesis, drug action mediated by eicosanoids, eicosanoids approved for human clinical use</td>
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<td>3.2 Prostaglandin analogs (Prolidine, Ranitidine, Diphenhydramine, Cetrizine, Chlorpheniramine, Promethazine)</td>
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<td><strong>SECTION-II</strong></td>
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<td>4</td>
<td><strong>Drugs Acting on Respiratory Tract</strong></td>
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<td></td>
<td>1.1 Antiasthematics</td>
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<td>1.2 Expectorants</td>
<td>1.3 Antitussive agents</td>
<td>1.4 Mucolytics</td>
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**Drugs Acting on Gastrointestinal Tract**

- a. Antisecretory agents
- b. Proton pump inhibitors
- c. Antiemetics
- d. Antidiarrheals
- e. Laxatives
- f. Prokinetics
- g. Antispasmodics and drugs modifying intestinal motility
- h. Drugs Used for Irritable Bowel Syndrome (Omeprazole)

4.7.3 **P MEDICINAL CHEMISTRY-III**

(Practical) (3 Hrs/Week)

I. Synthesis of following medicinally important compounds/drug intermediates with recrystallization of each compound and motoring reactions over TLC.

1. Ibuprofen
2. 4-Fluoro acetophenone
3. Methyl benzoate
4. 2-Methyl benzimidazole
5. Biginelli Reaction
6. Caprolactam
7. Benzyl alcohol

II. Techniques in synthesis

1. Purification of above synthesized compounds by Column chromatography (Any two)
2. Interpretation of IR spectra of synthesized compounds (Any three)
3. Interpretation of $^1$H-NMRs Standard spectra of organic compounds (Any two)

**Recommended Books**

17. Spectrometric identification of organic compounds by R. M. Silverstein, John Wiley and sons USA.
19. Analytical profiles of drug substances by Klaus Florey(All Volumes)
4.7.4 T PHARMACOLOGY-IV
(Theory) (3Hrs/Week)

Learning objectives:
On completion of following theory topics and laboratory experiments, a learner should be able to

1. Get in-depth knowledge about pharmacology and pharmacotherapy of drugs used in infectious
diseases, cardiovascular disorders etc.
2. Understand the involvement of oxidative stress and role of antioxidants along with some safety
issues in pharmacology.

Skill:
1. Understand the importance of isolated preparation, mechanism of action of drugs on isolated
tissues, expertise in performing bioassay of drugs.
2. Analyze the rational and irrational fixed dose combinations based on various parameters.
3. Understand the prescription pattern and rational use of drugs by performing case study or doing
hospital visit.

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<th>Sr. No</th>
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<tr>
<td>Pharmacology of drug shall includes : classification, mechanism of action, pharmacological actions, pharmacokinetics, therapeutic uses, adverse effects, drug interactions, contraindications, dosages, treatment of poisoning (if any) pharmacotherapy shall include: Pharmacology of drug/s used for clinical management of diseases/ disorders</td>
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<td>1</td>
<td>General principles of chemotherapy of infections.</td>
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<td>Classification, mechanism of action, antibacterial spectrum, resistance, therapeutic uses, adverse effects and contraindications of:</td>
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<td></td>
<td>• Penicillins, cephalosporines and β-lactamase Inhibitors</td>
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<td>• Sulfonamides and cotrimoxazole</td>
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<td>• Amino glycosides and macrolides</td>
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<td>• Quinolones and treatment of urinary tract infection.</td>
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<td>• Tetracycline and chloramphenicol</td>
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<td>• Tuberculosis and leprosy including National TB programmes (DOTS)</td>
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<td>• Antimalarials, anthelmintics and antiamoebics</td>
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<td>• Antiviral drugs including treatment of HIV</td>
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<td>3</td>
<td>Antineoplastic agents</td>
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<td>4</td>
<td>Immunomodulators</td>
<td>02</td>
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<td>5</td>
<td>Pharmacology of Drugs acting on blood &amp; blood forming organs</td>
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<td></td>
<td>• Haemopoeitics</td>
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<td>• Coagulants and anticoagulants</td>
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<td>6</td>
<td>Diuretics and anti-diuretics</td>
<td>03</td>
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<td>7</td>
<td>Pharmacotherapy of Cardiovascular disorders</td>
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<td>Congestive heart failure, Hypertension, Angina, Myocardial infarction, Atherosclerosis and Arrhythmia</td>
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<td>8</td>
<td>Oxidative stress and Antioxidants</td>
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<td>Reactive oxygen intermediates, antioxidants and there therapeutic implications</td>
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<td>Safety Pharmacology</td>
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<td>Introduction, scope and study design of safety pharmacology</td>
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**Recommended Books:**

5. Butterworth S.: Modi’s Textbook of Medical Jurisprudence and Toxicology.
4.7.4 P PHARMACOLOGY- IV

(Practical) (3Hrs/week)

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<tr>
<th>Sr. No</th>
<th>Title of the Experiment</th>
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<tr>
<td>1</td>
<td>To find out the concentration of give drugs using three point bioassay method on suitable isolated tissue preparation (Minimum 02 exercise)</td>
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<td>2</td>
<td>To find out the concentration of give drugs using four point bioassay method on suitable isolated tissue preparation (Minimum 02 exercise)</td>
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<td>3</td>
<td>To study the drug antagonism using suitable isolated tissue preparation (minimum 02 exercise)</td>
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<td>4</td>
<td><strong>Critical appraisal of fixed dose drug combinations of marketed preparations</strong>&lt;br&gt;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, adverse reactions, contraindications, precautions and special instruction to patients. (Minimum 03 rational and 02 irrational combinations to be discussed)</td>
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<td>5</td>
<td><strong>Prescription auditing and standard treatment protocols:</strong>&lt;br&gt;Comment on given prescriptions with reference to case reports mentioning possible indications and contraindications with dose, route of administration and justification of each ingredient. Comments on special instruction, drug interaction and justification of discharge medication (on the basis of available evidences from literature) (Minimum 03 prescriptions to be discussed)</td>
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<td>6</td>
<td><strong>Demonstration of any one of the following:</strong>&lt;br&gt;Study antioxidant activity of standard drugs by any method (DPPH), Superoxide anion, hydrogen peroxide and hydroxyl radical scavenging activity.</td>
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**Recommended Books:**

2. Daniel Wayne W. Biostatistics: A Foundation for Analysis in the Health Sciences, Wiley
4.7.5 T NATURAL DRUG TECHNOLOGY
(Theory) (3 Hrs/Week)

Learning objectives:

A) Knowledge: on completion of theory, learner should be able to:
1. Understand & explain various difficulties in standardization of herbal material, new approaches evolved, and steps in development of plant monograph.
2. Understand & explain need & significance of plant material authentication, new approaches used with their merits & demerits.
3. Comprehend & explain various factors affect on level of secondary metabolites, how these can be minimized to ensure quality in raw material, effect of post harvesting manipulations, and changes during storage etc & methods to control these modification. Explain various guidelines issued by WHO in relation with cultivation, collection, storage etc.
5. Compare & contrast nutraceuticals & functional foods & understand & explain their significance. Explain & classify natural products used as dietary supplements.
6. Understand & explain significance of natural pesticides & explain source, chemistry & applications.
7. Explain source, extraction, processing, chemistry & applications of natural products used in pharmaceutical & allied industry such as bioavailability & skin permeation agents; wound healing agents, biofuels.

B) Skill: on completion of laboratory experiments, learner should be able to:
1. Prepare, label & evaluate herbal/TSM formulations
2. Evaluate marketed cosmetic & nutraceutical formulations
3. Conduct preformulation parameters & understand underlying rationale
4. Conduct in vitro assays for correlation with biological efficacy
5. Able to handle various equipments as per SOPs & learn various demonstrations (of experiments).
6. Listen carefully, raise logical query, draw information, understand rationale during field visits & prepare brief report for evaluation.
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<tr>
<td><strong>SECTION-I</strong></td>
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<td>1</td>
<td><strong>Standardization of herbal drugs:</strong> Current approaches, difficulties &amp; their limitations, overview of new approach such as system biology approach; steps in development of crude drug monograph.</td>
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<td>2</td>
<td><strong>Authentication of plant material:</strong> Need, significance, approaches used; DNA fingerprinting in plants: Principle and applications.</td>
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<td>3</td>
<td><strong>Cultivation &amp; harvesting technology:</strong> meaning &amp; currently practiced approaches; role in quality assurance; factors influencing the level of plant metabolites; WHO guidelines on ‘Good Agricultural and Collection Practices’ (GACP).</td>
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<td>4</td>
<td><strong>Post-harvesting storage of crude drugs:</strong> Overview of modifications during storage, deterioration of crude drugs due to excessive moisture, higher temperature, exposure to light &amp; oxygen; mould &amp; bacterial attack, insect &amp; rodent-mediated deterioration; methods to control of infestation; other approaches to preserve crude drugs; WHO Guide to good storage practices for pharmaceuticals</td>
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<td>5</td>
<td><strong>Traditional systems of medicine (AYUSH):</strong> Historical background, concept of health &amp; pathogenesis, philosophical background, diagnosis &amp; treatment aspects of Ayurveda, Unani, Siddha &amp; Homoeopathic system of medicine; Ayurvedic dosage forms: types &amp; meaning; methods of preparation &amp; evaluation of Vati, Avleha, Asava, Arista, Taila, Bhasma &amp; Churna.</td>
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<td><strong>SECTION-II</strong></td>
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<td><strong>Overview of novel drug delivery systems for herbal drugs.</strong></td>
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<td><strong>Herbal dietary supplements:</strong> Definitions, classification, inorganic mineral supplements, digestive enzymes, probiotics, prebiotics, omega-3-polyunsaturated fatty acids, dietary fibers, Carotenoids, soya products, Spirulina, Ginkgo biloba, garlic, turmeric, grape seed proanthocyanidins, Resveratrol.</td>
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<td><strong>Cosmeceuticals:</strong> overview of herbs used in cosmetics for skin &amp; hair care, general method of preparation &amp; evaluation.</td>
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<td><strong>Natural pesticides:</strong> Methods of pest control, classification, pesticides &amp; environment; pharmacognostic account of Pyrethrum, Neem, Rotenone &amp; Citronella.</td>
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<td><strong>Natural products as</strong></td>
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<td>a)</td>
<td>Oral bioavailability enhancers</td>
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<td>b)</td>
<td>Skin permeation enhancers</td>
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<td>c)</td>
<td>Radiation protection agents</td>
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<td>d)</td>
<td>Natural products used in wound management [Hyaluronic acid; Corn protein (Zein); Hide glue derived from gelatin]</td>
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<td>e)</td>
<td>Biofuels: Overview of biofuels (bioethanol, biodiesel), general method of preparation, significance of biofuels in national economy.</td>
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Recommended Books (Theory):


**4.7.5 P NATURAL DRUG TECHNOLOGY**  
*(Theory) (3 Hrs/Week)*

1. Preparation of Ayurvedic formulations (Min 2 Exp.)
2. Evaluation of prepared/marketed Ayurvedic formulations (Min 2 Exp.)
3. Preparation of herbal formulations (Min 2 Exp.)
4. Evaluation of prepared/marketed herbal formulations (Min 2 Exp.)
5. Preparation of skin/hair care cosmetic products (Min 1 Exp.)
6. Evaluation of prepared/marketed skin/hair care cosmetic products (Min 2 Exp.)
7. Evaluation of marketed nutraceutical product
8. Preformulation study of isolated compounds
9. Determination of free radical scavenging acidity by spectrophometric method
10. Determination of alcohol content in *Asava/Aristha*
11. Preparation of Biodiesel (Demonstration) [Caution: prepare under due care since it involve corrosive chemicals & inflammable materials]

**Recommended Books:**


11. The Ayurvedic Pharmacopoeia of India, Government of India, Ministry of Health and Family Welfare, Department of AYUSH.
4.7.6 T BIO-PHARMACEUTICS & PHARMACOKINETICS
(Theory) (3Hrs/Week)

Learning objectives:
• Understanding the concept of biopharmaceutics and its applications in formulation development.
• Studying pharmacokinetic processes and their relevance in efficacy of dosage form.
• Learning the concepts of bioavailability and bioequivalence studies.
• Learning various compartmental models and non compartmental analysis methods.
• Understanding concept and mechanisms of dissolution and in vitro in vivo correlation.

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<tr>
<th>Sr. No.</th>
<th>Topic</th>
<th>No of Hrs</th>
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<tbody>
<tr>
<td></td>
<td><strong>SECTION-I</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Introduction to biopharmaceutics and its importance in dosage form design.</td>
<td>02</td>
</tr>
</tbody>
</table>
| 2       | **Absorption**: Factors affecting, mechanisms  
**Distribution**: physiological barriers, factors affecting, apparent volume of distribution.  
**Metabolism**: Phase I & phase II, factors affecting.  
**Elimination**: Routes renal & non renal, factors affecting, clearance concept. | 10        |
| 3       | **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 | 03        |
| 4       | Biopharmaceutical classification system, theories of dissolution, dissolution test apparatus, in vitro in vivo co-relation.                                                                        | 08        |
|         | **SECTION-II**                                                                                                                                                                                          |           |
| 5       | **Bioavailability and Bioequivalence**:  
Definition and concept of absolute & relative bioavailability. Methods of assessing bioavailability. Measures of bioavailability, bioequivalence study and introduction to various study designs. Single dose bioequivalence study, Review of regulatory requirements for conducting bioequivalence study, bio-waivers. | 08        |
| 6       | **Compartment models**:  
Introduction to compartmental and non compartmental analysis. 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 and elimination rates based on one compartment model. Introduction to two compartment model. | 14        |

Recommended books:
• Niazi S, Textbook of biopharmaceutics and clinical pharmacokinetics, Appleton-century-crofts.
• Milo Gibaldi, Biopharmaceutics and clinical pharmacokinetics, Ed 4.
• Venkateshwarulu V, Biopharmaceutics and pharmacokinetics, Ed 2, Pharmamed Press, Hyderabad.
Learning objectives:
1) To understand Basic principles, purpose and dimensions of the laws
2) To understand the significance and relevance of Pharmaceutical laws in India
3) Important rules and regulations and procedures made to execute the laws
4) To discuss the purpose of the Board
5) To explain the definitions in the Act;
6) To describe the qualifications for membership and the make-up of the Board
7) To explain the rule-making authority of the Board;
8) To discuss the responsibilities of the Board;
9) To discuss inspections by the Board or its representative;
10) To learn the various laws governing the manufacturing, sale, research & usage of drugs
11) To understand significance of Schedule M and Schedule Y related Manufacturing & clinical trials
12) Identify potential fraud and abuse legal issues of narcotic & psychotropic substance.
13) To study quality & prices of essential medicine
14) Learner knowledge about Patents, procedure for patent application and IPR.
15) To understand the regulatory system for safety and effectiveness of medicine and quality of product

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<tr>
<th>Sr. No.</th>
<th>Topic</th>
<th>No of Hrs.</th>
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<tbody>
<tr>
<td>1</td>
<td>History of Pharmaceutical Legislation in India Code of Pharmaceutical Ethics</td>
<td>02</td>
</tr>
<tr>
<td>3</td>
<td>Pharmacy Act 1948: Objectives, definition and composition of PCI, State Councils and Joint State Council. Functions like Education Regulations, preparation of registers and qualifications for entry into registers, Approval of Courses and Institutions. Corresponding offences and penalties</td>
<td>03</td>
</tr>
<tr>
<td>4</td>
<td>The Drugs Price Control Order with latest amendments: Objectives, definitions, schedules to the order, sales prices of bulk drugs, prices and price list MAPE calculations.</td>
<td>03</td>
</tr>
<tr>
<td>5</td>
<td>Narcotic Drugs &amp; Psychotropic substances act 1985: Definition. Prohibited and controlled operation. Cultivation of poppy plants,</td>
<td>03</td>
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<tr>
<td>6</td>
<td><strong>The prevention of cruelty to Animals Act, 1960</strong></td>
<td>01</td>
</tr>
<tr>
<td>7</td>
<td><strong>Aim, Objectives and Salient features of following legislations</strong></td>
<td>02</td>
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**SECTION-II**

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<tr>
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<tbody>
<tr>
<td>8</td>
<td><strong>Intellectual Property Rights (IPR)</strong></td>
<td>04</td>
</tr>
<tr>
<td></td>
<td>Introduction of IPR &amp; Overview of Patents, Design, Trademarks, Copyrights, Geographical Indications etc.</td>
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<tr>
<td>11</td>
<td>An Introduction to Standard Institutions and Regulatory Authorities such as ICH, WHO, USFDA, MHRA, TGA, BIS, ASTM, ISO.</td>
<td>05</td>
</tr>
</tbody>
</table>

**Recommended books:**

- Education Regulations, Pharmacy Council of India, New Delhi
- The Drugs and Cosmetics Act and the rules by IDMa Publications, Mumbai
- Pharmaceutical regulatory affairs. Subrahmanyam C.V.S, Thimmasetty J. Vallabh Prakashan.
- A Textbook of forensic pharmacy. Mithal B.M. Vallabh Prakashan
- [www.fda.gov](http://www.fda.gov)
SAVITRIBAI PHULE PUNE UNIVERSITY

Faculty of Pharmaceutical Science

Syllabus

Final Year B. Pharm. 2013 Course
(With effect from Academic Year 2016 - 17)
Learning Objective:
On completion of following theory topics & laboratory experiments, learner should be able to

A. Knowledge:
1. Describe the Fundamental Concept of Modified Drug Release and Pre requisites of drug candidates, along with various approaches and classification
2. Describe Polymers with respect to introduction to polymers, classification, types, selection, application and examples.
3. Describe. Introduction, formulation, merits, demerits, application and evaluation of Novel Drug Delivery Systems
4. Explain Therapeutic Aerosols along with typical formulations from, metered dose, intranasal and topical applications,
5. Explain concept of microencapsulation, merits, demerits and application, Types of Microencapsulation and Evaluation of microcapsules
6. Explain Basic concept of optimization

B. Skills:
1. Formulation development and evaluation of sustained release, transdermal, gastro retentive formulations
2. Micro encapsulation techniques
3. Evaluation of marketed preparations
4. Optimization studies using 2^3 factorial design

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<thead>
<tr>
<th>Sr. No.</th>
<th>Topic</th>
<th>Hrs</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Fundamental Concept of Modified Drug Release:</strong> Definitions of controlled release, sustained release time release drug delivery Systems. Pre requisites of drug candidates, various approaches and Classification, dose calculation for controlled release.</td>
<td>04</td>
</tr>
<tr>
<td>2</td>
<td><strong>Polymers</strong>— introduction to polymers, classification (biodegradable /nonbiodegradable), types, environment responsive polymers, parameters affecting selection of polymers for modified release systems, application and examples.</td>
<td>04</td>
</tr>
<tr>
<td>3</td>
<td><strong>Novel Drug Delivery Systems:</strong> Introduction, formulation, merits, demerits, application and evaluation of following— Mucosal drug delivery system, Transdemal drug delivery system (TDDS), Parenteral implants, Ophthalmic inserts, Intrauterine drug delivery system (IUDs), Liposomes, Probiotics and Prebiotics. Gastrro retentive drug delivery system, Colon targeted drug delivery system, Externally modulated devices and delivery; iontophoresis and sonophoresis</td>
<td>15</td>
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<tr>
<td>4</td>
<td><strong>Formulation And Processing of Therapeutic Aerosols:</strong> 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</td>
<td>10</td>
</tr>
</tbody>
</table>
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

|   | Microencapsulation: Introduction, concept of microencapsulation, merits,
demerits and application. Types of Microencapsulation: chemical encapsulation
processes, complex, coacervation, polymer-polymer incompatibility, interfacial
polymerization, and in-situ polymerization. Mechanical encapsulation process:
Pan coating, spray drying, spray congealing, fluidized bed coaters, extrusion, and
Spheronization techniques, rotational suspension separation, solvent evaporation.
Evaluation of microcapsules |
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<td>5</td>
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</table>

|   | Optimization Techniques in Pharmaceuticals:  
Basic concept of optimization, factors variable and design of experiment,
introduction to two level factorial design with suitable pharmaceutical samples. |
<table>
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<td>6</td>
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</tbody>
</table>
4.8.1 P ADVANCED DRUG DELIVERY SYSTEM  
(Practical) (3hrs/Week)

1) Evaluation of polymers – DSC, XRD, FTIR, viscosity, swelling index. (atleast 2)
2) Micro encapsulation (using one solid and one liquid drug) by coacervation evaluation of microcapsules
3) Formulation & Evaluation of sustained release formulations tablet
4) Evaluation of marketed sustained release tablets/capsules.
5) Formulation and evaluation of matrix type transdermal drug delivery system.
6) Formulation & Evaluation of Enteric coated tablet formulations
7) Evaluation of marketed sustained release tablets/capsules.
8) Preparation of beads using ionic gelation.
9) Formulation and evaluation of Effervescent gastro retentive tablet
10) Formulation and evaluation of swellable gastro retentive tablet
11) Optimisation of any one formulation using $2^3$ factorial designs.

**Recommended books:**

- Y. W. Chien ; Controlled drug delivery, Fundamentals and Applications,, 2nd Ed. Marcel Dekker.
4.8.2 T COSMETIC SCIENCE
(Theory) (3 Hrs/Week)

**Learning Objectives:** On completion of following theory topics & laboratory experiments, learner should be able to:

**Knowledge:**
- Understand the concepts of cosmetics, anatomy of skin v/s hair, general excipients used in cosmetics.
- Explain formulation of cosmetics for skin, manufacturing, equipments & evaluation of creams like cold cream, vanishing cream etc. & powder cosmetics.
- Explain formulation of cosmetics for hair, manufacturing & evaluation of hair shampoos, tonics etc.
- Describe formulation of cosmetics for eyes, manufacturing & evaluation of eye mascara, shadow etc.
- Understand formulation of manicure products like nail lacquer, remover etc.
- Learn formulation, manufacture & evaluation of baby cosmetics like baby oils, powders etc.
- Explain the concept of cosmeceuticals, history, difference between cosmetics & cosmeceuticals & cosmeceutical agents.

**Skills:**
- State the correct use of various equipments in Pharmaceutics laboratory relevant to cosmetics.
- Perform formulation, evaluation and labelling of cosmetics like moisturising cream, vanishing cream etc.
- Perform formulation, evaluation of eye cosmetics, nail lacquer & shampoo.
- Perform formulation, evaluation & labelling of shaving cream, after shave & baby products.
- Describe use of ingredients in formulation and category of formulation.
- Prepare labels as per regulatory requirements.

<table>
<thead>
<tr>
<th>Unit</th>
<th>Topic</th>
<th>Hrs</th>
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<tbody>
<tr>
<td></td>
<td><strong>SECTION-I</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td><strong>Fundamentals and Scope of Cosmetic Science</strong></td>
<td>08</td>
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<tr>
<td></td>
<td>• <strong>Additives in Cosmetics:</strong> emollients, waxes, oils, humectants, preservatives, binders, surfactants, colours and perfumes.</td>
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<tr>
<td></td>
<td>• Cosmetics v/s drug formulation. Anatomy and composition of skin and hair. Types of cosmetics.</td>
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<td></td>
<td>• Quality of Water in cosmetic Industry</td>
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<td></td>
<td>• Packaging, Cleanliness, Hygiene and Microbial control in Cosmetic manufacturing</td>
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<td></td>
<td>• Perfumes- Source, classification, blending and fixation</td>
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<tr>
<td>2</td>
<td><strong>Formulation, manufacturing &amp; evaluation of following cosmetics</strong></td>
<td>10</td>
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<tr>
<td>A)</td>
<td><strong>Skin care Products</strong></td>
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<tr>
<td></td>
<td>a) <strong>Cosmetics for skin:</strong> Moisturising cream, cleansing cream, cold cream, vanishing cream, anti ageing and anti wrinkle, antiperspirants, deodorants,</td>
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<td></td>
<td>b) <strong>Powder cosmetics:</strong> Heavy, medium and light powders, compacts</td>
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<td>c) <strong>Face mask and packs</strong></td>
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<td></td>
<td>d) <strong>Face make up:</strong> Face powder, compact powders, Cake makeup, Liquid makeup, Stick preparation</td>
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</table>
**4.8.2 P COSMETIC SCIENCE**

(Practical 0 (3 Hrs/week)

Formulation and evaluation of following cosmetics:

<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Cosmetic preparation</th>
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<tbody>
<tr>
<td>1</td>
<td>Cold cream</td>
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<tr>
<td>2</td>
<td>Vanishing cream</td>
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<tr>
<td>3</td>
<td>Moisturising cream</td>
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<td>4</td>
<td>Sunscreen cream/lotion</td>
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<td>5</td>
<td>Lip stick</td>
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<td>6</td>
<td>Shampoo</td>
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<td>7</td>
<td>Shaving cream</td>
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<td>8</td>
<td>After shave lotion</td>
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<td>9</td>
<td>Face pack</td>
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<tr>
<td>10</td>
<td>Face powder</td>
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<td>11</td>
<td>Eye cosmetics: Eye shadow, Eye liner, Eye Mascara</td>
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<td>12</td>
<td>Tooth powder</td>
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<tr>
<td>13</td>
<td>Baby products - Baby powders, lotions</td>
</tr>
<tr>
<td>14</td>
<td>Nail lacquer</td>
</tr>
</tbody>
</table>

**Recommended Books:**
- Barel Andre O., Paye Marc, Maibach Howard I., Handbook of Cosmetic Science and Technology, Marcel Dekker, Inc.
- Poucher W.A., Perfumes, Cosmetics and Soaps by, Vol. I, II, III
• E.G. Thossssen” Modern cosmetics Universal Publishing Corporation.
• Elsner Peter, Howard I. Maibach. Cosmeceuticals. Marcel Dekker, Inc.
• Dr. Laba “Rheological properties of cosmetics and toiletries” Marcel Dekker.
• Appell L. “The formulation and preparation of cosmetics, fragrance and flavours” Micelle press
• J. Knowlton and S. Rearce “Handbook of cosmetic science and technology” 1st edition; Elsevier science publisher; Oxford, UK, 1993
• Mithal BM, Saha RN, A handbook of Cosmetics. VallabhPrakashan, Delhi.
Learning objectives:
On successful completion of following theory topics & laboratory experiments, a learner should get the

Knowledge:
1. Understand principles, instrumentation of NMR and ESR spectroscopy, HPLC and their applications in Pharmaceutical research, quality control of APIs & formulations.
2. Understand the basic principle, instrumentation of Mass Spectrometry.

Skills:
1. Independently operate and calibrate various analytical instruments for the assay of various APIs and formulations as per Pharmacopoeial standards.
2. Independently process, interpret the data obtained through experimentation and report the results as per regulatory requirements.
3. Take appropriate safety measures while handling instruments, chemicals and apparatus.

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<tr>
<th>Sr. No.</th>
<th>Topics</th>
<th>No. of hrs.</th>
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<tbody>
<tr>
<td></td>
<td>The following topics 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</td>
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<tr>
<td></td>
<td><strong>SECTION-I</strong></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td><strong>Nuclear Magnetic Resonance (NMR) Spectroscopy</strong>: Theory, Chemical shift, shielding-deshielding, Spin-Spin Coupling (Splitting), Coupling Constant, Chemical and Magnetic Equivalence, Double resonance, Shift reagents, Solvents, Factors affecting chemical shift, Anisotropy, Instrumentation, application and simple structure determination. Introduction to C$^{13}$ NMR</td>
<td>15</td>
</tr>
<tr>
<td>2</td>
<td><strong>ESR</strong>: Introduction, principle &amp; instrumentation</td>
<td>02</td>
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<tr>
<td>3</td>
<td><strong>Ion Exchange Chromatography</strong>: Theory, instrumentation and applications. Capillary electrophoresis: Theory, instrumentation and applications</td>
<td>04</td>
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<td></td>
<td><strong>SECTION-II</strong></td>
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<tr>
<td>4</td>
<td><strong>High performance Liquid Chromatography (HPLC)</strong>: Theory, instrumentation and applications, Isocratic &amp; Gradient types, Pumps, Columns, Detectors, Tubings, Degassing techniques, Quantitation techniques, Trouble shooting in brief and System suitability testing, <strong>UPLC</strong>: Introduction and advantages over HPLC</td>
<td>12</td>
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<tr>
<td>5</td>
<td><strong>Mass spectrometry</strong>: Introduction, theory, instrumentation, resolution, different methods/techniques of ionization (EI,CI,FAB,ESI and MALDI) and their applications. Introduction to GC-MS, LC-MS and MS-MS</td>
<td>12</td>
</tr>
</tbody>
</table>
4.8.3 P PHARMACEUTICAL ANALYSIS-VI
(Practical) (3 Hrs/Week)

1. Validation of analytical methods (Spectrophotometry & HPLC) as per USP or ICH guidelines (minimum two)
2. Study of system suitability parameters as per IP/BP/USP protocol for HPLC methods.
3. Study of Quantitation Techniques in HPLC (% Area / Area Normalization, Internal Standard addition)
4. Interpretation of UV, IR, NMR, MS spectras of simple organic compounds for structure elucidation (minimum four compounds)

**Recommended books for Theory and Practicals**
1. Indian Pharmacopoeia, 2014, Indian Pharmacopoeia Commission, Govt. of India
6. Pharmaceutical Analysis by Higuchi, Reprint 2004, CBS Publisher & Distributors.
7. The quantitative analysis of drugs by Gرار DC, 3/Ed., CBS Publisher & Distributors.
11. Handbook of Instrumental Techniques for Analytical Chemistry by Frank Settle, First Indian Reprint 2004, Pearson Education
12. Instrumental Methods of Analysis by Willard Merit, Dean Settle, 7th edition, CBS Publisher & Distributor
4.8.4 T MEDICINAL CHEMISTRY-IV
(Theory) (3 Hrs/Week)

**Learning objectives:** On completion of following theory topics & laboratory experiments, a learner should be able to

**A. Knowledge:**
Know general aspects of the design & development of drugs including history, classification, nomenclature, structure activity relationship (SAR), mechanism of action, adverse effects, therapeutic uses and recent developments in categories such as chemotherapeutic agents, antibiotics, hormones & anti-fertility agents.

**B. Skills:**

1. Make correct use of various equipments & take safety measures while working in medicinal chemistry laboratory.
2. Understand and develop skills in various demonstrated experiments such as High Vacuum distillation, recrystallization and pH based amino acid separation.
3. Develop skills involved in thin layer chromatography techniques and purification of synthesized compounds by column chromatography.
4. Synthesize, recrystallize and understand reaction mechanisms involved in synthesis of medicinally important organic compounds.
5. Interpret the spectral characterizations made by IR and $^1$H-NMRs of synthesized compounds.

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<thead>
<tr>
<th>Sr. No</th>
<th>Topic</th>
<th>No. of hrs</th>
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<tbody>
<tr>
<td><strong>SECTION-I</strong></td>
<td>History and general aspects of the design &amp; development of drugs including classification, nomenclature, structure activity relationship (SAR) and recent developments of following categories, therapeutic uses, scheme of synthesis of drugs given in bracket.</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>a. Synthetic antibacterial agents eg. Sulfonamides, Quinolones, Nitrofurans etc.</td>
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<td></td>
<td>b. Antitubercular &amp; Antileprotic agents</td>
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<td>c. Antifungal agents</td>
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<td></td>
<td>d. Antimalarials</td>
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<td>e. Antiamebic agent</td>
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<td>f. Trypanosomicidal drugs, drugs acting against leishmaniasis.</td>
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<td>g. Anthelmintics</td>
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<td>h. Antiviral agents including antiretroviral</td>
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<td>i. Antineoplastic agents including recent drugs and monoclonal antibodies (Metronidazole, Ciprofloxacin, Proguanil, Amodiaquine, PAS, Isoniazid, Clotrimazole, 5-Flocytosine, Nevirapine, Saquinavir, Albindazole, Melphalan,</td>
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<td>Antibiotics:</td>
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<td>β-lactam antibiotics: (Penicillins and Cephalosporins, oxopenams, carbapenams, monobactams and beta lactamase inhibitors)</td>
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<tr>
<td>The aminoglycosides</td>
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<td>The tetracycline</td>
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<td>The macrolides</td>
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<td>The Lincomycins</td>
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<td>The Polypeptides</td>
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<tr>
<td>Unclassified antibiotics</td>
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<tr>
<td>(Amoxycillin Trihydrate, Cephadroxil)</td>
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<tr>
<td>Steroids</td>
<td>06</td>
<td></td>
</tr>
<tr>
<td>a. Sex hormones and their synthetic analogs</td>
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<td>b. Antifertility agents</td>
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**4.8.4 P MEDICINAL CHEMISTRY-IV**

*(Theory) (3 Hrs/Week)*

I. Synthesis of following medicinally important compounds/drug intermediates with recrystallization of each compound and monitoring reactions over TLC.

1. 4-Methyl quinoline
2. Isoniazide
3. Metronidazole/Albendazole
4. Sulphamethoxazole
5. Methyl Salicylate
6. O-Iodo benzoic acid from Phalimide

II. Techniques in synthesis:

1. Purification of above synthesized compounds by Column chromatography (Any two)
2. Preparative TLC (Any Two)
3. Interpretation of IR spectra of synthesized compounds (Any three)

III. Demonstration Experiments (Any one)

1. High Vacuum Distillation
2. pH based amino acid separations

**Recommended Books**

17. Spectrometric identification of organic compounds by R. M. Silverstein, John Wiley and sons USA.
19. Analytical profiles of drug substances by Klaus Florey(All Volumes)
Learning objectives:
On completion of following theory topics and laboratory experiments, a learner should be able to
1. Understand various methods of drug-drug interaction inside the body.
2. Understand the mechanism of adverse drug reactions and pharmacovigilance.
3. Get knowledge about recent development in pharmacology

Skill:
1. Understand the in vivo and in vitro experiments, use of software for the study of preclinical experiments.
2. Brief idea about statistics, its applications and how to solve problems using various statistical tests.

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<tr>
<th>Sr. No</th>
<th>Topic</th>
<th>No of Hrs</th>
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<tbody>
<tr>
<td>1</td>
<td><strong>Drug interactions:</strong> Introduction to Drug-Drug, Drug-food interaction. Classification of Drug-Drug interaction. Basic concepts of mechanisms of drug-drug interactions with suitable examples.</td>
<td>04</td>
</tr>
<tr>
<td>2</td>
<td><strong>Adverse Drug reactions (ADR):</strong> Epidemiology, Classification, Risk factors, Monitoring, Detecting and reporting of ADR. Introduction to Pharmacovigilance.</td>
<td>04</td>
</tr>
<tr>
<td>3</td>
<td><strong>Bioavailability, bioequivalence and Therapeutic Drug Monitoring:</strong> Concept, organization, advantages, special issues, applications.</td>
<td>04</td>
</tr>
<tr>
<td>4</td>
<td><strong>Introduction and recent development in:</strong> Gene therapy Stem cell biology Tissue Engineering</td>
<td>04</td>
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<td>5</td>
<td>Drug abuse and misuse, Drug induced diseases. Interpretation of clinical laboratory tests.</td>
<td>04</td>
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<td>6</td>
<td><strong>Hospital Pharmacy:</strong> Introduction, 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>7</td>
<td>Outpatient and inpatient services, drug distribution system in hospital, floor ward stock system, satellite pharmacy services, bed side pharmacy, distribution of control drugs.</td>
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<td>8</td>
<td>Methods of assessment of compliance, Reason for patient noncompliance, strategies to improve compliance</td>
<td>02</td>
</tr>
<tr>
<td>9</td>
<td><strong>Clinical Trials:</strong> History, important terminologies, Types of clinical research, Phases of clinical research, role of clinical trial in new drug developments</td>
<td>04</td>
</tr>
<tr>
<td>10</td>
<td><strong>Ethical issues in clinical trials</strong> Principle of regulatory requirements, responsible conduct, supervision of ethics, (Informed Consent, Institutional Review Board (Role responsibility, members and auditing).</td>
<td>06</td>
</tr>
</tbody>
</table>
Recommended Books:

4.8.5 P PHARMACOLOGY-V (INCLUDING BIOSTATISTICS)

(Practical) (3 hrs/Week)

Minimum 15 Experiment to be conducted

<table>
<thead>
<tr>
<th>Sr. No</th>
<th>Title of the Experiment</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>To study the preclinical pharmacological experiments using suitable computer based program (Minimum 02 exercise).</td>
</tr>
<tr>
<td>2</td>
<td>To find out the PA₂ or PD₂ value of given drugs using suitable isolated tissue preparation. (Minimum 02 exercise)</td>
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<tr>
<td>3</td>
<td>Basic concepts of statistics, its application and importance.</td>
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<td>4</td>
<td>To determine the Mean, Mode and Median of the given data (Minimum 02 exercise).</td>
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<td>5</td>
<td>To determine the Standard deviation, Standard error of mean and coefficient of variation of the given data (Minimum 02 exercise).</td>
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<td>6</td>
<td>To determine the Analysis of variance (ANOVA) of the given data (Minimum 02 exercise).</td>
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<tr>
<td>7</td>
<td>To study the problems based on paired and unpaired Student ‘t’ test. (Minimum 02 exercise)</td>
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<tr>
<td>8</td>
<td>To study the problems based on non parametric test. (Minimum 02 exercise)</td>
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<tr>
<td>9</td>
<td>To solve statistical problems using suitable software. (Minimum 01 exercise)</td>
</tr>
</tbody>
</table>

Recommended Books:

Learning objectives:

On completion of theory, learner should be able to:

1. Understand & realize the significance of natural products in daily life. He/she should be able to classify different segments in market, demand & supply position; export & import potential; position of Indian herbal drug industry in global contest; government organizations & policies for promotion; their regulation in India & other countries, various regulatory guidelines, ethical issues etc.

2. Realize the market potential of natural products & explore entrepreneurship skills to grab these opportunities.

3. Understand & explain safe use of natural products, possible toxicities & interaction, toxicities in most vulnerable group (elderly patients), need & significance of pharmacovigilance systems; WHO guidelines in this regard.
<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Topic</th>
<th>No. of Hours</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>SECTION-I</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td><strong>Commerce:</strong> Global &amp; domestic market size/volume of various natural product segments in commerce (crude drugs, phytopharmaceuticals, herbal drug formulations, drug leads, drug intermediates, traditional medicinal products, nutraceuticals, health drinks &amp; beverages, essential oils, flavor, fragrance, perfumes, spices &amp; condiments, cosmetics, colorants, sweeteners, Pharmaceutical excipients, pesticides &amp; insect repellents, veterinary medicinal products, biofuels; demand &amp; supply position; export &amp; import.</td>
<td>07</td>
</tr>
<tr>
<td>2</td>
<td><strong>Industry:</strong> Indian herbal drug industry: Size, turnover, domestic &amp; international share, export potential, domestic &amp; global market for prescription, OTC &amp; TSM products, important plants used in indigenous systems of medicine &amp; in modern medicine; major herbs/extracts exported from India, government agencies involved in development &amp; promotion, promotional policy for entrepreneurship development: technical &amp; funding assistance schemes, Industry oriented R &amp; D institutes, leading manufacturer of herbal drugs, bottlenecks of plant based drug industry.</td>
<td>08</td>
</tr>
<tr>
<td>3</td>
<td><strong>Pharmacovigilance of herbal medicines:</strong> Meaning, need, significance; WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems</td>
<td>06</td>
</tr>
<tr>
<td><strong>SECTION-II</strong></td>
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<tr>
<td>3</td>
<td><strong>Regulation:</strong> Herbal drug regulation in India, licensing requirements for production &amp; sale of herbal drugs in India; documentation; global regulatory status; ethical issues, WHO guidelines for regulation, The International Conference on Harmonization (ICH) guidelines, concepts of Quality by Design (QBD), GMP; Other issues related to export of natural products (such as CITES Certificate, DGFT Notification, Negative list of herbs, TRAFFIC)</td>
<td>12</td>
</tr>
<tr>
<td>4</td>
<td><strong>Toxicity in herbals and their interaction:</strong> Different ways by which herbal preparations cause toxicity, pharmacokinetic &amp; pharmacodynamic interactions, herbal drug interaction of commonly used herbs (Liquorice, Cinchona, Cannabis, Garlic, Digitalis, St John’s wort); special precautions in geriatric patients.</td>
<td>08</td>
</tr>
<tr>
<td>5</td>
<td><strong>Pharmacovigilance of herbal medicines:</strong> Meaning, need, significance; WHO guidelines on safety monitoring of herbal medicines in pharmacovigilance systems</td>
<td>06</td>
</tr>
<tr>
<td>6</td>
<td><strong>Plant Allergens:</strong> definition &amp; classification (inhalants, injectants, contactants, infectants and infestants), plants causing Hay fever, allergy. Applications of allergents in diagnosis &amp; treatment, method of preparation of allergenic extracts.</td>
<td>04</td>
</tr>
</tbody>
</table>


4. Drugs and Cosmetics Act 1940.


4.8.7 T QUALITY ASSURANCE TECHNIQUES (Theory) (3 Hrs/Week)

Learning Objectives:
On completion of following theory topics learner should be able to:
- Describe the significance of quality in pharmaceutical manufacturing
- Explain Current Good Manufacturing Practices
- Describe various aspects of documentation, SOPs and records
- Elaborate on the role of validation in assurance of quality in pharmaceutical industry
- Explain about quality by design
- Explain about ICH guidelines in stability testing and QMS
<table>
<thead>
<tr>
<th>Sr. No.</th>
<th>Name of the topic</th>
<th>No of Hrs</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Quality assurance</strong>: Importance of QA, Concept of quality control, Organization of Quality Assurance department, Quality assurance &amp; total quality controls. Sources of variation, Quality control of raw materials &amp; pharmaceutical process &amp; finished products. Documentation, concepts of statistical quality control. Quality Audits.</td>
<td>09</td>
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<tr>
<td>2</td>
<td><strong>Validation</strong>: Introduction. Basic concepts, types and stages of validation, validation master plan (VMP), equipment validation. Concept of URS, DQ, IQ, OQ &amp; PQ and process-types. Prospective, concurrent and retrospective validation &amp; revalidation. Validation of steam sterilization, membrane filters, tray dryers, compression machine and cleaning method.</td>
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<tr>
<td>3</td>
<td><strong>Introduction to QBD</strong></td>
<td>02</td>
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<tr>
<td>4</td>
<td><strong>Current good manufacturing practices</strong>: Personnel, surrounding, building, equipment.</td>
<td>09</td>
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<tr>
<td>5</td>
<td><strong>Documentation and records</strong>: Introduction, specifications, importance and types. Master Production and Control Record, Batch Production and Control Record. Importance of SOPs and records. Change control. Site Master File.</td>
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<td>6</td>
<td><strong>ICH guidelines for stability testing.</strong> Introduction to Quality management System as per ICH.</td>
<td>05</td>
</tr>
</tbody>
</table>

**Recommended Books:**
6) Pharmaceutical Process Validation, 2nd Ed, Ira R Berry, Robert A Nash
7) Facility Validation, Theory, Practice and Tools, Grahm C Wrigley