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<td>PY801</td>
<td>Pharmaceutics – X</td>
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<td>Max Marks 70</td>
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Course : B.Pharmacy VIII Semester.

**PY801: PHARMACEUTICS – X**  
**PHARMACEUTICAL TECHNOLOGY-II**


Sustained and controlled drug delivery systems: concept of sustained release, designing of sustained release products, zero order and first order approximation concept. Matrix and reservoir based techniques. Product evaluation and testing.


Packaging of Pharmaceutical Products: Objective of packaging, packaging components, types, functions, containers and closures, foil and blister packaging. Packaging equipment, legal and official requirements for containers and closures. Package testing.

Pilot plant scale-up techniques: General considerations, personnel requirements, space requirements, review of formula and raw materials. Processing equipments. Process evaluation. GMP considerations.

**Books & References Recommended:**

1. Leon Lachman, Herbert A. Lieberman and Joseph L.Kanig., The Theory and Practice of Industrial Pharmacy.
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<td>PY802</td>
<td>Pharmaceutics – XI</td>
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**Course:** B.Pharmacy VIII Semester.

**PY802 : PHARMACEUTICS-XI (Pharmaceutical Jurisprudence)**

Review of Indian regulatory legislations for drug and pharmaceutical industries, and pharmaceutical education.

*An elaborated study of the following:*
- a. Pharmacy Act 1948
- b. Drugs and Cosmetics Acts 1940 and Rules 1945
- c. Medicinal and Toilet Preparations (Excise Duties) Act 1955
- d. Narcotic Drugs and Psychotropic Substances Act 1985 and Rules
- f. Essential Commodities and Drug Price Control Order
- g. Drugs and Magic Remedies Act (Objectionable Advertisement Act 1954)

*A brief study of the following:*
- b. AICTE Act 1987
- d. Poison Act and rules
- e. MRTP Act
- f. Minimum Wages Act 1948
- g. State Shops and Establishment Act and Rules
- h. Factories Act 1948
- i. Insecticides Act 1968.

Brief Study of various prescription and non-prescription products, medical and surgical accessories, diagnostic aids and appliances marketed in India.

**Books Recommended:**
4. The Gazette of India. The Drugs and Cosmetics act and rules.
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<tr>
<td>PY803</td>
<td>Pharmaceutical Analysis-III</td>
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Course: B. Pharmacy VIII Semester.

**PY803: PHARMACEUTICAL ANALYSIS-III**


Validation of analytical methods: Parameters of validation, pharmacopoeial requirements of analytical method validation.

Validation of analytical instruments: UV/visible spectrophotometer and HPLC as per Indian Pharmacopoeia.

ICH guidelines for impurities in drug substances and drug products, Residual solvents.

Water analysis: Validation and qualification of water purification systems. Total organic carbon, pH, and conductivity test. Moisture content analysis in drug and dosage forms.

Quality control testing: Dosage form evaluation as per monograph with special reference to Indian Pharmacopoeia. Drug identification test, drug content and assay, content uniformity. Sampling considerations.

Good laboratory practices.

**Books and References recommended:**

1. Indian Pharmacopoeia, 2007.
3. Vogel’s, Quantitative Inorganic Analysis.
PY804A : PACKAGING TECHNOLOGY

Packaging material science: Basic materials used in packaging, their properties, method of manufacturing and applications-Paper, Plastics, Glass, Metal, and Elastomers.


Introduction and applications of Form-Fill-Seal (FFS) technology.

Tamper resistant and child resistant packages: Introduction, method of preparation, and applications of Blister and Strip packs, Film Wrappers, Bubble packs, Shrink seals, Sachet and Pouches, Tape seals, Breakable caps, Sealed tubes, Aerosol containers, etc.

Quality control and quality assurance of packaging materials: Detection of defects in packaging materials, Quality testing of formed packs, Quality testing of containers and closures, Testing of child resistance and temper evidence property of packaging materials. Quality control tests for containers and closures as per Indian Pharmacopoeia.

Legal and regulatory requirements: Requirements of labels and labeling as per Drug & Cosmetics act and rules. Product / patient information literatures. Regulatory aspects of storage, handling and distribution of packaging materials with special emphasis on cGMP and cGLP requirements.

Suggested Books:

1. Dean, D.A.; Evans, E.R.; and Hall I.H., Pharmaceutical Packaging Technology.
3. Drug and cosmetic Act and Rules.
Course : B.Pharmacy VIII Semester.

**PY804C : FOOD AND NUTRACEUTICAL TECHNOLOGY**

Functional foods and nutraceuticals:
(a) Sources and role of Tocotrienols, polyunsaturated fatty acids, sphingolipids, lecithin, choline, terpenoids. Vegetables, Cereals, milk and dairy products as Functional foods.
(b) Nutritive and Non-nutritive food components with potential health effects. Effect of processing on Nutrients. Soy proteins and soy isoflavones in human health; Functional foods from wheat and rice and their health effects. Role of Dietary fibers and nuts in disease prevention. General ideas about role of Probiotics and Prebiotics as nutraceuticals.
(c) Properties, structure and functions of various Nutraceuticals: Glucosamine, Octacosanol, Lycopene, Carnitine, Melatonin and Ornithine alpha ketoglutarate. Use of proanthocyanidins, grape products, flaxseed oil as Nutraceuticals.

Food processing and preservation:
(a) General principles and techniques of food processing and food preservation, shelf life of food and nutraceutical products. Food stability: methods to enhance stability- freezing, lyophilization, and air drying techniques.
(b) Contamination and microbial spoilage of food products: Milk and milk products, eggs and poultry, fish, breads and cereals, meat, canned foods, vegetables and fruits. Food borne infections and intoxications.
(c) Methods of food preservation, approved preservatives, Radiation and food preservation: Role of radiation in food preservation. Principles underlying destruction of micro-organisms by irradiation. Effect of irradiation on food constituents. Legal status of food irradiation.

Regulatory affairs:
(b) Regulatory certifications: FPO regulations, Manufacturing guidelines, Manufacturing and marketing licenses, AGMARK, Green Label certification, Organic food certifications.

**Books recommended:**
1. Essentials of Food and Nutrition by Swaminathan M., Ganesh and Co, 1985
**Course :** B.Pharmacy VIII Semester.

**PY805A : PERFUMES AND COLOURS**

**Perfumes:**

Historical background & present scenario of perfumery industry.  
Definition of odour, its classification. Definition of perfumes, attars, cologne, deodorants, aromatic waters. Chemical classification of perfumes obtained from plant and animal sources.  

Formulation of perfumes, formulation excipients, manufacturing methods of perfumes, deodorants, colognes, and aromatic waters.

Regulatory considerations: Analysis & standardization of perfumes. Toxicological aspects of use of perfumes, safety study of perfumes on naked skin including various dermatological tests.

Application of perfumes in various cosmetic products like skin cosmetics, hair cosmetics, men’s toiletries etc.

**Colours:**

Definition of colour, lake, dye, pigment. Theory of color formation at molecules level including Hund’s Rule of multiplicity volume band approach & molecular orbital approach to colour.

Detailed classification of colour obtained from natural sources like plant & animal sources, colours obtained from mineral sources, synthesis colours, dyes & pigments. FDA classification of colours. Various physiochemical properties of dyes & colours.

Manufacturing of colors: manufacturing methods of colours, dyes, lakes, and pigments.


Applications of colours in various cosmetics like skin, nail, and hair cosmetics, etc.

**Suggested Books:**

2. Harry’s Cosmetology.
Course : B.Pharmacy VIII Semester.

**PY805B : CLINICAL RESEARCH**

Introduction: Clinical pharmacy, duties and activities of a clinical pharmacist in hospital, monitoring of pharmacotherapy (patient chart review, medication counseling, clinical output review), ward round participation, patient relevant history (diseases and medication), prescriptions, drug prescribing guidelines, therapeutic drug monitoring.

Patient data analysis: Introduction to common medical terminologies and abbreviation used in clinical pharmacy. Patient case history & case history formats, use of case history in evaluation of drug therapy.

Clinical laboratory tests: Interpretation of laboratory tests used in evaluation of disease state: Tests for hormones, body organ function, blood, urine, microbial culture, etc.


Clinical trial: Designs of clinical trials, Good clinical practices (ICH & GCP guideline for safety and efficacy), Institutional Ethical Committee and its function.

Various phases of clinical trials, introduction to monitoring and auditing of clinical trials. Basic concepts of biostatistics.

Clinical research organization (CRO): Organizational structure, present status and future prospects of clinical research organizations in India.

**Books Recommended**

1. Hefindal, E. T., Clinical Pharmacy & Therapeutics-. Williams & Wilkins.
2. Katzung, B., Basic and Clinical Pharmacology, Lange Medical Publication, California
3. Laurence D.R. and Bennet, P.N., Clinical Pharmacology, Churchill Livingstone
6. Green and Harris, Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall Publications.
Course : B.Pharmacy VIII Semester.

PY805C : HERBAL DRUG TECHNOLOGY

Introduction: Definition, source of herbal raw materials, identification, authentication, Collection and processing of herbal drugs. Seasonal & geographical variations, natural & artificial drying methods. Packaging & labeling of herbal drugs prior to extraction.


Herbal Formulations: Principles of Ayurveda, Ayurvedic dosage forms and their evaluation as per Ayurvedic pharmacopoeia. Formulation considerations of herbal infusion, decoction, lotion, washers, insect repellents, tincture, syrups, compresses, poultice, plasters, ointments, oils and salves, tablets and capsules.

Plant Tissue Culture Techniques & its Application in Pharmacy: Introduction, techniques of initiation and maintenance of various types of cultures for industrial level production of phyto-constituents. Immobilized cell techniques & biotransformation studies including recent developments in production of biological active constituents in static, suspension and hairy root cultures.

Brief account of plant based industries of India and world involved in R & D work on medicinal and aromatic plants and manufacturing herbal medicine. Regulatory requirements for herbal medicine industries: Infrastructure, Quality control, safety and stability, import and export of herbal products. Analytical Pharmacognosy – drug adulteration and detection.

Books Recommended:

2. Modern Methods of Plant Analysis by Peach & Tracey
3. Biotechnology by S.S. Purohit.
5. Pharmacognosy by C.K. Kokate, A.P. Purohit and S.B. Gokhale
6. Ayurvedic Pharmacopoeia of India