Rajiv Gandhi Proudyogiki Vishwavidalaya, Bhopal (M.P.)

B. PHARM.-VIII SEMESTER

PY-801- Pharmaceutics –X (Pharmaceutical Technology –II)

Granulation technology: production of granules on large scale by various techniques, evaluation of granules. Compression and consolidation of powdered solids. Heckel plots. Force displacement (F-D) Curves.

Microencapsulation techniques: Coating of particles. Fluidized bed and air suspension coating. Phase separation co-acervation, multiorifice centrifugal, spray drying, spray congealing, polymerization complex emulsion techniques. Top bottom and tangential spray coating machines. Evaluation of microcapsules.

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.

Novel drug delivery systems: Transdermal drug delivery systems. Osmotic drug delivery systems. Liposomes and implants.

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. Liebermann and Joseph L.Kanig., The Theory and Practice of Industrial Pharmacy.

2. Banker G.S. and Rhodes C.D., Modern Pharmaceutics.

3. Remington’s Pharmaceutical Sciences.

4. Aulton M. E., The Science of Dosage Form Design.

List of Practicals :

1. To perform comparison of the tablet by HPMC and PGs Binders.
2. To perform the punching of tablet by slugging process.
3. To prepare and evaluate the floating tablet of paracetamol .
4. Perform and evaluate the fast deliver tablet of diclofenac sodium .
5. To prepare and evaluate diclofenac sodium emulgel formulation .
6. To study the effect of various suspending agents on CaCo3 suspension.
7. To perform the dissolution study of given tablet with curve fitting (zero & firest order)
8. To prepare and microsphere by pan coating
9. Preparation And Characterization of Parcematmol Loaded Liposomes.
10. Preparation And Characterization of Parcematmol Loaded niosomes.
11. To prepare and submit waxes containing microsphere.
12. Preparation and Characterization of microsphere of any model drug by solvent evaporation method
13. Preparation and Characterization of Eudragit Coated Microspheres.
14. To perform phase separation coacervation used for microencapsulation (polymer-polymer interaction).
15. To prepare and submit Carbopol gel
16. Stability evaluation of various dosage forms and their expiration dating.
17. Formulation of oral S.R.Products & their evaluation by in-vitro dissolution profile
18. Evaluation of marketed parenteral suspension and emulsion for parameters like particle size, sterility and rheological parameters.
19. Evaluation of given packaging material (Primary & tertiary packaging).
20. Preparation, filling, sealing, sterilization and evaluation of the injections.
21. Formulation and evaluation of transdermal patch of given drug.
22. To prepare and study of TDDS using different polymer.
23. To prepare and submit buccal patches.
24. To prepare & evaluate gastroretentive floating matrix tablet of atenolol .
25. To prepare and evaluate multiple emulsion .
26. Design and evaluation of mucoadhesive buccal film of paracetamol using aluminium foil and mercury casting method.
27. Development of an osmotic pump system for controlled delivery of diclofenac sodium.
28. Design and evaluation of diclofenac sodium ocusert.

PY -802- 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
e. Patent Act 1970
f. Essential Commodities and Drug Price Control Order
g. Drugs and Magic Remedies Act (Objectionable Advertisement Act 1954)

A brief study of the following:

a. Medical Termination of Pregnancy Act 1970 and Rules 1975
b. AICTE Act 1987
c. Prevention of Cruelty to Animal Act 1960
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:

1. Jain N. K., A Textbook of Forensic Pharmacy.
2. Mittal, B.M., A Textbook of Forensic Pharmacy.
3. Malik V., Drug & Cosmetic Act.
4. The Gazette of India. The Drugs and Cosmetics act and rules.
5. The Gazette of India. The Patent act 1970 and its latest amendments.

PY-803- Pharmaceutical Analysis – III

Analytical method development: Development of new analytical methods for bulk drugs and dosage forms using titrimetry, UV/visible spectrophotometry and HPLC. Development of analytical methods for combination drug products, derivative spectrophotometric methods. Development of stability indicating assay procedures. Drug analysis in biological fluids like blood plasma and urine.

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.
2. Current ICH guidelines.
3. Vogel's, Quantitative Inorganic Analysis.
4. Beckett, Pharmaceutical Analysis.

List of Practicals :

1. To perform the validation of Analytical balance.
2. To perform the validation of UV instrument.
3. To perform the validation of HPLC instrument.
4. To perform assay of Paracetamol by single point estimation method, calibration curve method and Absorptivity method. And compare them.

5. To perform assay of Nimesulide by single point estimation method, calibration curve method and Absorptivity method. And compare them.

6. To perform assay of norfloxacin by single point estimation method, calibration curve method and Absorptivity method. And compare them.

7. To perform assay of two component dosage forms by Dual wavelength method. (combination of any two drugs)

8. To perform simultaneous determination of two components in dosage forms by derivative spectroscopy. (combination of any two drugs)

9. To perform simultaneous determination of two component in dosage forms by simultaneous equation method. (combination of any two drugs)

10. To perform simultaneous determination of two component in dosage forms by isoabsorptive method. (combination of any two drugs)

11. To perform the spectrophotometric estimation of PCM and lomifloxacin by using Q- analysis. (combination of any two drugs)

12. To perform the HPLC determination of given drugs.

13. To perform simultaneous HPLC determination of two drugs . (combination of any two drugs)

14. To perform and interprate IR spectra of given drug. (minimum 4 drugs should be studied)

15. To evaluate tablets as per IP.

16. To evaluate film coated tablet of given drug.
17. To evaluate hard gelatin capsule of given drugs (tetracycline etc.)
18. To evaluate uncoated tablet of given tablet (paracetamol etc.)
19. To perform the evaluation sustained release tablet.
20. To perform the evaluation of enteric coated tablet.
21. To find out diffusion rate of drug from diff. base by using egg membrane.

PY-804 (A) – Packaging Technology (Elective –I)

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

Containers and closures: Introduction and applications of Glass containers, Plastic containers, Collapsible tubes, Plastic tubes, Aerosol containers, Closures, Liners, and Rubber stoppers.

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*.
2. Leon Lachman, Herbert A. Lieberman, Joseph L. Kanig, *The Theory and Practice of Industrial Pharmacy.*
3. *Drug and cosmetic Act and Rules.*

PY-804 (B) – Drug Discovery and Development (Elective –I)

Drug discovery:

- Historical perspective
- Drug discovery without a lead like *penicillin and Lead discovery*
- *Lead modification approaches.*
  - *Identification of the active part; Pharmacophore*
  - *Functional group modification*
  - *Privileged structure and drug like molecules*
  - *Structure modification to increase potency and therapeutic index.*
  - *Structure modification to increase Oral Bioavailability.*

2. Quantitative Structure Activity Relationship: Free Wilson analysis**,** Hansch analysis, Physicochemical properties, Craig Plot, Application of Hansch analysis, Statistical methods in QSAR

3. Drug receptor interactions, Theories of drug-receptor interactions, Membrane and Receptor- Structure, Functions and the mechanism of drug action (Receptor Response), Design of agonist and antagonists, Receptor theories, Models and their types,

4. Computers Aided Drug design: Basic concept of Computational chemistry like Quantum Mechanics, Molecular Mechanics, Force fields, Energy minimization, Conformational search, Molecular dynamics, SBDD(Structure Based Drug Design) LBDD (Ligand Based Drug Design), analog approach, pharmacophore mapping, Molecular-modeling and Virtual screening.

5. Molecular Modeling Software: Introduction to molecular modeling software, brief information on academic freeware and commercial software and their applications in drug discovery.

6. **Introduction to Bioinformatics and Structural Biology:** Knowledge of various databases and bioinformatics tools available at these resources, the major content of the databases like Nucleic acid databases and Protein databases. Current advancements in bioinformatics, introduction to system biology, structural biology, structural bioinformatics. Applications of bioinformatics and system biology in drug discovery.

References

1. Comprehensive Medicinal Chemistry Vol-I (Hansch (1990) Pergamon pres.
2. Principle of Drug action-Goldstein.
3. Introduction to medicinal Chemistry, III Edn. Patrick (2001) Oxford
4. Organic Chemistry of Drug Design and Drug Action. R.B.Silverman (1993) Academic
5. Medicinal Chemistry Vol. I Burger.
6. Molecular Modeling, Principles and applications -Andrew Leach(Longman) 1998.
7. Statistical MethodS in Biology-Norman Bailey(1995) Cambridge.
8. A Text book of Drug design and development II nd Edn. Povl..Krogsgaard-Larsen Tommy L. and U Madsen (1996) Harwood Acad. Publishers
9. Introduction to Bioinformatics by Aurther M lesk

PY-804 (C) – Food and Nutraceutical Technology (Elective –I)

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:
(a) Regulatory aspects of food and nutraceutical products. The prevention of Food Adulteration Act 1954, The Food Safety & Standards Act, 2006.
(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
2. Handbook of Nutraceuticals and Functional Foods Edited by Robert E.C. Wildman, Routledge Publishers.
3. Nutraceuticals by L. Rapport and B. Lockwood, Pharmaceutical Press.
4. Dietary Supplements of Plant Origin, M. Maffei (Ed.), Taylor & Francis, 2003.
5. Food packaging principals and practice, Gordon L. Robertson, Marcel and Dekker Inc. New York. 1993.

PY-805 (A) – Perfumes and colours (Elective –II)

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.
Essential oils: Introduction, study of various physical and chemical properties of essential oils. Study of various isolation methods of essential oils.

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.
Regulatory aspects of use of colours in drug and cosmetics as per schedule Q of Drug and Cosmetic Act. Analysis of colours using instrumental methods & chromatographic methods.

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

Suggested Books:

1. Sagarine, Cosmetic Science and Technology, Vol. 1-4.
2. Harry's Cosmetology.
3. The Chemistry and Manufacture & Cosmetics, Vol. IV - Mainson G. De. Nawarre.
4. Colour and Cosmetic colour material - New Cosmetic Science - Mitsui.
5. The Cosmetic Industry - edited by Norman Scientific & Regulatory foundation - F. Estrin.

PY-805 (B) – Clinical Research (Elective –II)

Introduction: Clinical pharmacy, duties and activities of a clinical pharmacist in hospital, monitoring of pharmacotherapy (patient chart review, medication counseling, clinical out put review), ward round participation, patient relevant history (dieses 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.

Drug and poison information: Introduction to information resources and institutes, systemic approach in answering drug information queries, preparation of reports. Detection and assessment of adverse drug reactions and their documentation.

Clinical pharmacokinetic: Individualization of drug therapy, introduction to clinical pharmacokinetics models, determination of drug clearance and volume of distribution, renal and non-renal clearance, hepatic clearance.

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
4 Walker, R. & Edwards, C., Clinical Pharmacy & Therapeutics, Churchill Livingston
5 DiPiro, J.T. et.al., Pharmacotherapy a pathophysiological approach, McGraw-Hill companies, Inc.
6 Green and Harris, Pathology and Therapeutics for Pharmacists: A Basis for Clinical Pharmacy Practice, Chapman and Hall Publications.

PY-805 (C) – Herbal Drug Technology (Elective –II)

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.

Standardization techniques: WHO guidelines for assessing quality of herbal medicine. Analysis of raw herbal extracts and their formulation using TLC, HPTLC, GC, HPLC, UV& IR techniques.

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:

1. Herbal Drug Technology by S.S. Agrawal & M. Paridhavi.
2. Modern Methods of Plant Analysis by Peach & Tracey
3. Biotechnology by S.S. Purohit.
4. Quality control of herbal drugs: an approach to evaluation of botanicals by Pulok K. Mukherjee.
5. Pharmacognosy by C.K. Kokate, A.P. Purohit and S.B. Gokhale
6. Ayurvedic Pharmacopoeia of India