DISCIPLINE SPECIFIC ELECTIVE COURSE - (BIOMED-DSE-) – ADVANCES IN PHARMACEUTICAL SCIENCE

CREDIT DISTRIBUTION, ELIGIBILITY AND PRE-REQUISITES OF THE COURSE

Course title & Code	Credits	Credit distribution of the course			Eligibility criteria	Pre-requisite of the course (if any)
		Lecture	Tutorial	Practical/ Practice		
Advances in Pharmaceutical Science	**4**	**2**	**-**	**2**	**XII Passed**	**Basic Knowledge of Chemistry and Biology**

Learning Objectives:

- The course emphasizes the interdisciplinary nature of pharmaceutical research, integrating concepts from chemistry, biology, and biotechnology.
- Students will be introduced to the latest advancements in pharmaceutical research, including drug design principles, biotechnology-derived medications, and the use of biosensors in pharmaceutical industries.
- Knowledge of ethical considerations in clinical trials and pharmacovigilance ensures students are well-prepared to conduct responsible and ethical research.

Learning Outcomes:

Upon successfully completing this course, students will be able to:

- Understand the history and development of pharmaceutical research, including principles of drug design and the various phases of pharmacokinetics and pharmacodynamics.
- Recognize the importance of pharmacognosy and the application of herbal drugs in treating various ailments.
- Gain insights into pharmaceutical biotechnology, including the development and application of therapeutic proteins and monoclonal antibodies.
- Comprehend the principles and classification of drug formulations, including regulatory norms.
- Understand the processes and regulations involved in the approval of new drugs and the role of regulatory affairs in the pharmaceutical industry.
- Develop the foundational knowledge and skills for advanced studies and careers in pharmacology, pharmaceutical sciences, and related fields.

SYLLABUS **(30 hours)**

Unit I: Introduction **(4 hours)**

History and development of Pharmaceutical Research, Principles of drug design (QSAR-Hansch, Topliss, Lipinski, Computer aided drug design), Pharmacokinetics (ADME- Routes of drug administration, Absorption, Bioavailability, Distribution) Metabolism (biotransformation)-microsomal/P450, first pass metabolism, Excretion - kinetics of elimination), Pharmacodynamics (Enzymes-competitive/non-competitive inhibitors, Ion channels, Transporters, Receptors-agonist/antagonist, inverse agonist, partial agonist, Drug receptor interaction, Dose response relationship)

Unit II: Pharmacognosy and herbal drugs **(10 hours)**

Importance of Pharmacognosy in herbal drug industry: Treatment of ailments related to- Central Nervous System (CNS)- Reserpine, Cardiovascular system (CVS)-Digoxin, GIT-Glycyrrhizin, Gymnema, Respiratory system -Codeine. Development of lead compound into effective drugs (Opium to pain killer, Cinchona bark to antimalarial, Taxus Baccata to taxol).

General methods of extraction (simple extraction with separatory funnel, industrial extraction using Soxhlet apparatus, isolation (steam distillation) and purification of phytoconstituents using column chromatography, HPLC.

Primary metabolites: General introduction and pharmaceutical applications of primary metabolites in therapy of CNS, CVS, Liver, Kidney, Intestine and Lung diseases and their pharmaceutical preparations. Carbohydrates (Acacia as emulsifying and stabilizing agent, Agar as surgical lubricant and stabilizer in preparation of suspensions, capsules etc.) Proteins and Enzymes (Gelatin as shell for capsules, Casein as therapeutic agent in dressing wounds, cosmetics) Lipids and Waxes/Oils (Castor oil as stiffening agent and laxative)

Secondary metabolites: General introduction -therapeutic application of secondary metabolites in CNS, CVS, Liver, Kidney, Intestine and Lung diseases and their pharmaceutical preparations.(Ephedrine as bronchodilator and decongestant, Morphine for pain management), Glycosides (Digitoxin in heart failure and treatment of arrhythmias) Polyphenols, Tannins, Flavonoids (Quercetin as antioxidant for treatment of heart conditions).

Nutraceuticals as health care products: General introduction and their formulations, classification and importance of nutritional supplements such as Vitamin supplements, Digestive enzymes, Probiotics, Prebiotics, Dietary fibers, Cereals, Health drinks for the treatment of ailments (as adjuvants) and lifestyle disorders.

Unit III: Pharmaceutical Biotechnology **(8 hours)**

Introduction to Pharmaceutical Biotechnology, DNA sequence to therapeutic proteins, Production and Downstream processing, Interferons, Interleukins.

Monoclonal Antibodies: From structure to therapeutic applications in Cancer and Organ Transplantation.

Biologics and Biosimilars, Biosimilars as low cost treatment options in various ailments (eg. Humira for curing autoimmune diseases) and Regulatory framework for biosimilars. Personalized Medicine and applications.

Process of developing Biotechnology Derived Medications: Vaccines (Hepatitis Vaccine), oligonucleotides, Recombinant engineered protein -Insulin, Recombinant engineered hormones-Follicle Stimulating Hormone, Human Growth Hormone, Recombinant Coagulation factors and

Thrombolytic agents. Biosensors- Working and applications of biosensors in Pharmaceutical Industries for sensing enzymes, small molecules such as blood gases, glucose etc.

Unit IV : Drug Formulation, Release & Regulatory Framework (8 Hours)

(a) : Pharmaceutical formulation, drug release and dissolution

Introduction to drug formulations and their classification with suitable examples (Simple and compound powders; Monophasic and Biphasic liquids; Emulsions; Semisolid Dosage forms- Pastes, Ointments, Creams and Gels; Oral solid dosage forms- Tablets, Capsules; Aerosols). Pharmaceutical excipients. Pharmaceutical coating processes and equipment.

Drug release and dissolution: Theoretical Concepts for the Release of the Drug from drug formulations.

(b) : The New Drug Approval Process and regulatory affairs

Drugs and Cosmetics Act (1940) and Rules (1945). Pharmacy Act 1948. Investigational New Drug Applications (INDs): Approval processes and timelines involved, Preclinical testing, Clinical testing - Phase I, II, III and IV, Clinical trial protocols, Institutional Review Board / Independent Ethics committee - formation and working procedures, Informed consent process. Pharmacovigilance - Safety monitoring in clinical trials.

Practical: (60 hours)

(Wherever wet lab experiments are not possible, the principles and concepts can be demonstrated through any other material or medium including videos/virtual labs etc.)

1. Preparation of alcohol from rectified spirit by distillation.
2. Extraction of vasicine (quinazoline alkaloid) from the leaves of *Adhatoda vasica* by modified acid-base extraction and purification by column chromatography and purity check by TLC.
3. Extraction of curcuminoids (phenolics) from *Curcuma longa* using ethanol and purification by column chromatography and purity check by TLC.
4. Extraction of Eugenol oil from steam co-distillate of cloves using dichloromethane.
5. Screening of the natural products for biological activity like antidiabetic (by inhibition of alpha-amylase) or anti-microbial (Gram+/Gram- bacteria) (by MIC/Disc-diffusion method).
6. Study the effect of polarity of solvents (water/ethanol/ethyl acetate/ether/hexane) and pH (buffer/water - pH 4, 7, 8.5) of the solution on the solubility of drugs (aspirin/penicillin/ sulphonamides) using UV spectroscopy.
7. Disintegration/Dissolution studies of different formulations (Capsule, tablet, syrup) of the drugs (e.g., paracetamol) using UV spectroscopy.
8. Visit to a pharmaceutical industry to understand how drug formulations are prepared.
9. Synthesis of paracetamol, preparation of paracetamol tablets by wet granulation method and virtual demonstration of formulation of film coated tablets of paracetamol.

Essential Readings:

- Roche, V.F., Zito, S.W., Lemke, T.L., & Williams, D.A. (2019). 8th Edition. *Foye's Principles of Medicinal Chemistry*. Philadelphia, PA: Lippincott Williams & Wilkins. ISBN-13: 9781496385024.
- Shah, B. (2018). *Textbook of Pharmacognosy and Phytochemistry*. New Delhi, India: CBS Publishers & Distributors. ISBN-13: 978-9386217738.

- Wildman, R.E.C., & Bruno, R.S. (2020). 3rd Edition. *Handbook of Nutraceuticals and Functional Foods*. CRC Press. ISBN-13: 978-1498703727.
- Gupta, R.C., Lall, R., & Srivastava, A. (2021). 2nd Edition. *Nutraceuticals: Efficacy, Safety and Toxicity*. Cambridge, MA: Academic Press. ISBN-13: 978-0128210383.
- Crommelin, D.J.A., Sindelar, R.D., & Meibohm, B. (2013). *Pharmaceutical Biotechnology: Fundamentals and Applications* (4th ed.). New York, NY: Springer. ISBN-13: 978-1461464860, ISBN-10: 1461464862.
- Adejare, A. (Ed.). (2020). *Remington: The Science and Practice of Pharmacy* (23rd ed.). Elsevier. ISBN-13: 978-0128200070 (hardback), ISBN-13: 978-0128223895 (eBook)
- Kokate, C.K. (2017). *Practical Pharmacognosy* (18th ed.). Nirali Prakashan. ISBN-13: 978-8185790367.
- Sreelekshmi U, Sarathchandra G, Vijayarani K, Sp P. Isolation & purification of vasicine from leaves of *Adhatoda vasica* by modified acid-base extraction method. J Pharm. Innov. 2021;10(1):171-3.
- Kulkarni SJ, Maske KN, Budre MP, Mahajan RP. Extraction and purification of curcuminoids from Turmeric (*Curcuma longa* L.). International Journal of Pharmacology and Pharmaceutical Technology. 2012;1(2):81-4.
- https://assets.thermofisher.com/TFS-Assets/CAD/Vector-Information/pS45-pS80-Extraction-of-Eugenol-from-Cloves.pdf

Suggestive Readings:

- Patrick, G.I. (2017). *Introduction to Medicinal Chemistry* (6th ed.). Oxford, UK: Oxford University Press. ISBN-13: 978-0198749691.
- Tripathi, K.D. (2018). 8th Edition. *Essentials of Medical Pharmacology*. New Delhi, India: Jaypee Brothers Medical Publishers. ISBN-13: 978-9352704996.
- Evans, W.C. (2009). 16th Edition. *Trease and Evans' Pharmacognosy*. Edinburgh, UK: Elsevier. ISBN-13: 978-0702029349.
- Kokate, C.K., Purohit, A.P., & Gokhale, S.B. (2007). *Textbook of Pharmacognosy* (37th ed.). New Delhi, India: Nirali Prakashan. ISBN-13: 978-8190791136.
- Gupta, S.K. (2019). *Textbook of Pharmacovigilance* (2nd ed.). Jaypee Brothers Medical Publishers. ISBN-13: 978-9352707034.
- https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/acts_rules/2016DrugsandCosmeticsAct1940Rules1945.pdf