UTTARANCHAL UNIVERSITY

(Established vide Uttaranchal University Act, 2012, UGC Approved)
(Uttarakhand Act No. 11 of 2013)
Arcadia Grant, P.O. Chandanwari, Premnagar, Dehradun, Uttarakhand

Programme Name	Pre-Ph.D Course Work	Programme Code	
Course Code	DSE704	Credit	3
Year/Sem	1/1	L-T-P	3- 0- 0
Course Name	Advance Pharmaceutical Sciences Paper I		

Objectives of the Course:

After completion of course student is able to know,

•the stage of development during which the physicochemical properties of the drug substance.

•provides the foundation for development of a robust dosage form.

UNIT-I

a. Pre-formulation Studies: Introduction, pre-formulation testing criteria, regulatory requirements, testing systems, solid-state characterization, transport across biological membranes

b. Optimization: Introduction to statistical methods and factorial design, quality by design

Pharmaceutical Process Validation: Basic concept, regulatory basis of validation , benefits of validation, types of process validation related to prospective retrospective and concurrent process validation , revalidation of validation process and scale-up and post approval changes (SUPAC), analytical Validation

UNIT II

Definition, need for patenting, types of patents, conditions to be satisfied by an invention to be patentable, introduction to patent search.

Parts of patents, filling of patents, the essential elements of patent, guidelines for preparation of laboratory note book, non-obviousness in patent

Brief introduction to CDSCO, WHO, USFDA, EMEA, TGA, MHRA, MCC, ANVISA

Brief introduction to trademark protection and WHO Patents, IPR's and its types, major bodies regulating Indian pharmaceutical sector

UNIT- III

Polymer: Polymer classification, physiochemical properties and polymer solutions, biodegradable and non-biodegradable polymers, application of polymers in controlled release of drugs, transport of small molecules in polymers, ionic polymers as drug carriers, polymer drug interactions

Stereochemistry: Optical isomerisim: chirality and molecular symmetry; stereochemical designation of chiral centre(s) (R& S); chiral axis; resolution of racemic mixture-techniques including chiral chromatography, geometric Isomerisim: cis, trans; E, Z ,conformational analysis: boat-chair conformations; staggered, gauche, eclipsed conformations

UNIT-IV

Natural Products: Drugs of natural origin: from plants, micro-organisms, animal source, marine products, biosynthesis of natural products, approaches of structure elucidation: degradation and synthetic approaches; spectral analysis (UV, IR, NMR, Mass), hyphenated techniques: GC-MS, LC-MS, chemical modifications of natural products; opiod analgesics, antineoplastic agents, anti-malarials

Techniques of Quantitative Estimation of Drugs for Determination of Purity

UNIT-V

Molecular Aspects of Drug Action: Receptor occupancy, types of drug targets, main families of receptors and ion channels, signal transduction mechanisms coupling receptors to cellular function

In-vitro Experimentation Techniques: Animal cell lines and their uses, radioligand binding assay, patch clamp, ELISA

Molecular Techniques: PCR, blotting, immunostaining, cloning, RIA

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Programme Name	Pre-Ph.D Course Work	Programme Code	23
Course Code	DSE704 (i)	Credit	3
Year/Sem	1/1	L-T-P	3 - 0 - 0
Course Name	Advance Pharmaceutical Sciences Paper II		

Objectives of the Course:

Upon completion of the course the student shall be able to

1. Understand the chemistry of drugs with respect to their pharmacological activity
2. Understand the drug metabolic pathways, adverse effect and therapeutic value of drugs
3. Know the Structural Activity Relationship (SAR) of different class of drugs
4. Observe the effect of drugs on animals by simulated experiments

UNIT-I

Central Drug Standard Control Organisation (CDSCO) : Functions and responsibilities Investigational New Drug : Need of an IND, Content and Format of an IND application, Submission of an IND, FDA review of IND. The New Drug Application: Overview, Law regulations and Guidance, new drug development and approval, NDA development preclinical investigation, new drug application (phase I, phase II, phase IV and post marketing surveillance), contents of the NDA (chemistry, manufacturing, testing, packaging, labelling, controls, preclinical, clinical data), Human Pharmaco-kinetic and bioavailability testing requirements, Common technical document (CTD) for NDA, Submission, review and maintenance of NDA.

UNIT II

Oral Controlled drug delivery systems: Design and fabrication of diffusion controlled, dissolution controlled, osmotic, gastro-retentive delivery systems, biodegrable polymeric delivery systems. Controlled drug delivery polymers, roles of polymers in drug delivery, pharmacokinetic/ pharmacodynamic basis of oral controlled drug delivery.

UNIT- III

Drug Design: Analogue synthesis versus rational drug design, discovery of lead compounds, pharmacophore identification, structure modifications of lead compound (prototype), physicochemical alterations, pro-drug approach, quantitative structure activity relationship, computer aided drug design, molecular modelling, combinatorial chemistry and high throughput screening, biochemical and physiological approaches.

Lead compound: Search & Optimization: Search of lead compound from natural products and other sources, selection of test compounds. Methods of lead optimization – synthesis of analogs, variation of substituents, extension of structure, ring versus chain structures, bioisosterism, ring contraction and expansion. Hansch analysis, Free-Wilson analysis, Craig plot, Topliss scheme, CoMFA analysis.

UNIT-IV

Natural Products: Drugs of natural origin: from plants, micro-organisms, animal source, marine products, biosynthesis of natural products, approaches of structure elucidation: degradation and synthetic approaches; spectral analysis (UV, IR, NMR, Mass), hyphenated techniques: GC-MS, LC-MS, chemical modifications of natural products; opiod analgesics, antineoplastic agents, anti-malarials

Extraction: Different techniques adopted for the extraction of phytoconstituents like Maceration, percolation, sonication, soxhlet assisted extraction, and ultrasound assisted extraction, super critical carbon dioxide extraction and Microwave assisted extraction.

UNIT-V

Molecular Aspects of Drug Action: Receptor occupancy, types of drug targets, main families of receptors and ion channels, signal transduction mechanisms coupling receptors to cellular function

Common animal models for selected categories of drugs: anti-hypertensive, anti-inflammatory, anti-diabetic, anti-ulcer.

Antioxidants: Reactive oxygen intermediates , antioxidants and their therapeutic implications

Toxicity Studies :Acute, sub-acute, sub-chronic, chronic toxicity