Ph. D. in Pharmaceutical Sciences
Subject: Pharmaceutics

Pharmaceutics is the discipline of pharmacy that deals with all facets of the process of turning a new chemical entity into a safe and effective formulation. It is the science of dosage form design.

Research focus:

The major research areas of the department include:

- Formulation and evaluation of various novel delivery systems and carriers including microparticles, nanomedicine etc.,
- Formulation and evaluation ofMucosal drug delivery systems.
- Formulation and evaluation ofTransdermal drug delivery systems.
- Solubility enhancement techniques.
- Formulation and evaluation of fast dissolving/ disintegrating formulations.
- Taste masking formulations.

The detailed research will be carried out as follows:

- Designing the formulation and optimizing the process parameters using Computer aided dosage form/ delivery system.
- Performing preformulation studies of active pharmaceutical ingredients and the excipients to be used to determine physicochemical properties and compatibility of drug.
- Formulation of dosage form or delivery system with emphasis on novel systems.
- *In vitro* and *In vivo* evaluation of formulations.
- Biopharmaceutics and Pharmacokinetic studies of the formulations.
- Conduction of stability studies of finished formulations as per ICH guidelines.

PHARMACEUTICS SYLLABUS FOR SBSU – PET 2021 ENTRANCE EXAM

UNIT-I: PREFORMULATION STUDIES:

Introduction to preformulation, goals and objectives, study ofphysicochemical characteristics of drug substances, drug-excipient compatibility studies,methods of determination.

a. Physical properties: Physical form (crystal & amorphous), particle size, shape, flowproperties, solubility profile (pKa, pH, partition coefficient), polymorphism.

b. Chemical Properties: Hydrolysis, oxidation, reduction, racemisation, polymerization

c. Product stability: Degradation kinetics, half-life and shelf life, mechanisms, stabilitytesting of drugs and pharmaceuticals, factors influencing stability, accelerated stability studies. Solid statestability and shelf lifeassignment. Stability protocols, reports and ICH guidelines.

UNIT-II: DOSAGE FORMS:

Introduction to dosage forms, classification and definitions.

a. Solid dosage forms:

Tablets:Formulation of tablets, granulation methods, compression and processing problems.Tablet coating: Types of coating, coating materials and defects in coating, Quality control tests. Capsules: Hard gelatin capsules and Soft gelatin capsules: Introduction, size of capsules, fillingof capsules, Quality controltests for capsules.

b. Liquid dosage forms: Monophasic (Definitions and preparations of Gargles, Mouthwashes,Throat Paint, Eardrops, Nasal drops, Enemas, Syrups, Elixirs, Liniments andLotions) and biphasic liquid dosage formsSuspensions: Definition, advantages and disadvantages, classifications,Preparation and stability of suspensions and emulsion.

c. Semisolid dosage forms: Definitions, classification, Preparation of ointments, pastes, creamsand gels. Evaluation of semi-soliddosages forms.

d. Parenteral Production: Area planning & environmental control,wall and floor treatment, fixtures and machineries, change rooms,personnel flow, utilities & utilities equipment location, engineeringand maintenance.

UNIT-III: CONTROLLED DRUG DELIVERY SYSTEMS:

Introduction, terminology/definitions, rationale,advantages, disadvantages, selection of drug candidates.Approaches to design controlledrelease formulations. Physicochemical and biological properties of drugs relevant to controlled releaseformulations.

a. Study of Various DDS: Concepts, design, formulation &evaluation of controlled release oral DDS, Mucoadhesive DDS,Pulsatile, colon specific, transdermal DDS, Ocular delivery systems.

b. Targeted Drug Delivery Systems: Importance, concept,biological process and events involved in drug targeting, design,formulation & evaluation, methods in drug targeting – nanoparticles, liposomes, niosomes, pharmacosomes, resealederythrocytes, microspheres, magnetic microspheres, multiple emulsions, micro-emulsions.

c. Biotechnology in Drug Delivery Systems: Brief review ofmajor areas-recombinant DNA technology, monoclonalantibodies, gene therapy.

UNIT-IV:INTRODUCTION TO BIOPHARMACEUTICS:

a. Absorption: Mechanisms of drug absorption through GIT, factors influencing drugabsorption though GIT.

b. Distribution: Tissue permeability of drugs, binding of drugs, apparent, volume ofdrug distribution, protein binding of drugs, factors affecting protein-drug binding.Kinetics of proteinbinding, Clinical significance of protein binding of drugs.

c. Metabolism: Metabolic pathways and factors affecting metabolism of drugs.

d. Excretion: Renal excretion of drugs, factors affecting renal excretion of drugs,renal clearance, Non renal routes of drug excretion of drugs.

UNIT-V:DRUG REGULATORY AFFAIRS:

Generalconsiderations of Investigational New Drug (IND) Application, New Drug Application (NDA) and Abbreviated New drug Application (ANDA), Clinical research / BE studies, Data Presentation for FDA Submissions, Intellectual Property Rights (IPR).

INDIAN REGULATORY REQUIREMENTS: Central Drug Standard Control Organization(CDSCO) and State Licensing Authority: Organization, Responsibilities, CommonTechnical Document (CTD), Certificate of Pharmaceutical Product (COPP), Regulatoryrequirements and approval procedures for New Drugs.