



Introduction of Bio Pharmaceutics in Novel Drug Delivery System

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Introduction

Biopharmaceutics is a major branch in pharmaceutical sciences which relates between the physicochemical properties of a drug in dosage form and the pharmacology, toxicology, or clinical response observed after its administration. Biopharmaceutics includes the stability of the drug, liberation of the API from dosage form, rate of extent of drug release and rate of conversion of drug to solution.

It is not sufficient to know what the drug does to the body; it is also crucial to know what the body does to the drug. As a result, biopharmaceutics has evolved into a broad-based discipline that encompasses fundamental principles from basic scientific and related disciplines, including chemistry, physiology, physics, statistics, engineering, mathematics, microbiology, enzymology, and cell biology.

Applied biopharmaceutics is the most important and recognized parameters of CGMPs. The requirement of process validation appears of the quality system (QS) regulation. The goal of a quality system is to consistently produce products that are fit for their intended use. In preclinical and early clinical stages of drug designing, drug disposition is used to predict drug interaction potential, evaluation and understand population pharmacokinetic variability, and select doses for clinical trials.

Biopharmaceutical classification system

Class-1: High solubility, High permeability.

Class-2: low solubility, High permeability.

Class-3: High solubility, Low permeability.

Class-4: Low solubility, High permeability.

Importance of Biopharmaceutics

- The therapeutic activity of a drug is ultimately due to its ability to modify biological processes at the cellular level. The patient's response to a drug is determined by the amount of free or unbound drug present in the plasma and by its ability to combine with specific receptors at their site in various organs and tissues.

- The preparation of dosage forms of today's drugs is a sophisticated science requiring skilled, highly trained personnel working with complicated machinery and complex analytical apparatus.

Applications of biopharmaceutics in new drug delivery

- To understand the absorption, distribution and elimination of the drug, which effects the onset and intensity of biological response.
- Poor patient compliance- increased chances of missing the dose of the drug with shorter half-life.
- In design and development of the new drug and their appropriate dosage regimen.
- In safe and effective management of the patients by improving the drug therapy.
- The unavoidable fluctuations in the drug concentration may lead to the rise or fall of the c_{ss} values in the therapeutic range.

Properties of biopharmaceutics in novel drug delivery systems

- Molecular weight: Lower the molecular weight, faster the absorption.
- Solubility of the drug: A drug with solubility, serves as the good candidate for novel drug delivery system.
- Partition coefficient: Greater the partition coefficient of the drug, greater the lipophilicity and extent of absorption.
- Drug stability: Drugs are stable in both gastric and intestinal PH.

Role of biopharmaceutics in drug development

Bio pharmaceutics is an integral component of the overall development cycle of the drug.

Evaluation begins during the drug discovery process through,

- Compound selection
- Pre-clinical efficacy
- Formulation development
- Clinical efficacy studies
- Post approval stages.

Conclusion

Bio pharmaceutics aims to provide regulatory tools by replacing certain bioequivalence studies by accurate in vivo dissolution tests. The in-vivo pharmacokinetics of the drug mainly depends on the solubility and permeability.

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