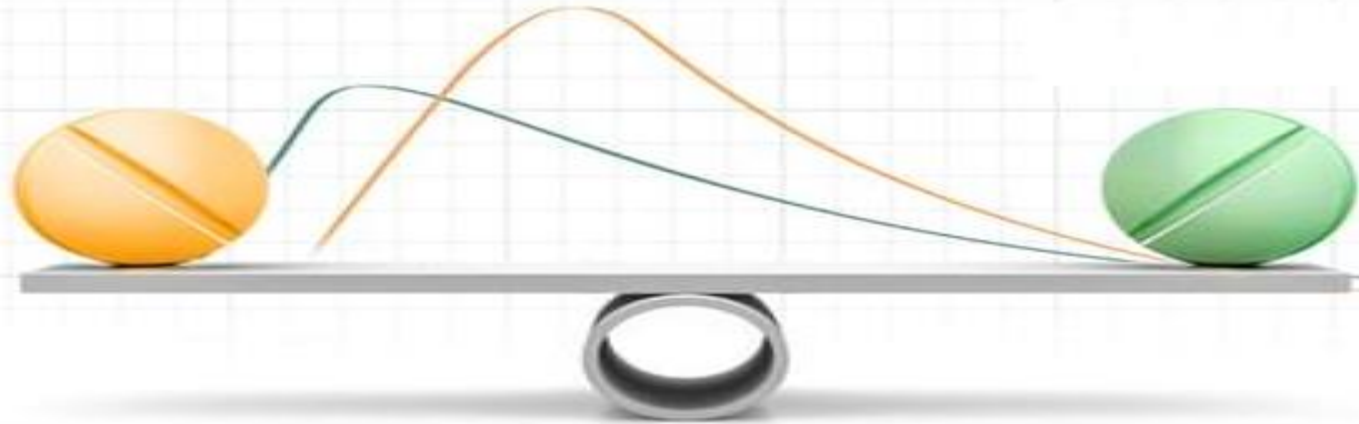# BIOAVAILABILITY & BIOEQUIVALENCE
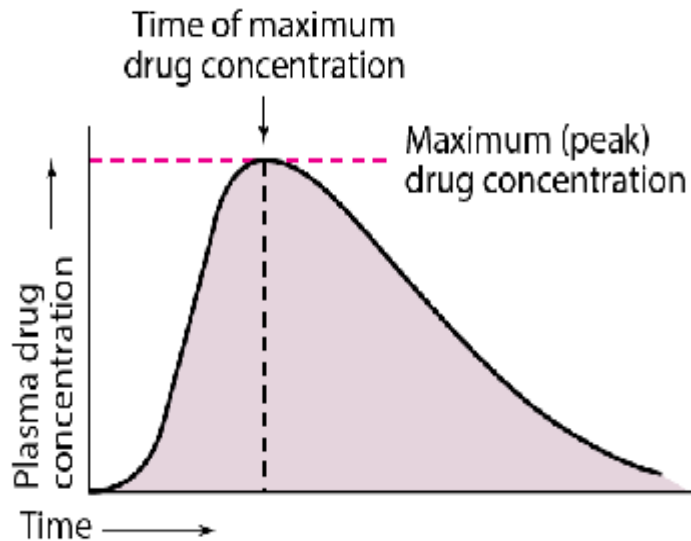
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BIOAVAILABILITY

The <u>extent</u> and the <u>rate</u> to which a drug substance or its therapeutic moiety is delivered from a pharmaceutical form into the general circulation

- **absolute bioavailability**
- **relative bioavailability**

- **For example**, if 100 mg of a drug are administered orally and 70 mg of this drug are absorbed unchanged, the bioavailability is 0.7 or seventy percent.

TYPES OF BIOAVAILABILITY

Absolute Bioavailability :-

If the systemic availability of a drug administered orally is determined by doing its comparison with I.V. administration, it is known as absolute bioavailability.

$$F = \frac{AUC_{extravascular}}{AUC_{intravenous}} \times \frac{Dose_{intravenous}}{Dose_{extravascular}}$$

Relative Bioavailability :-

If the systemic availability of a drug administered orally is determined by doing its comparison with that of an oral standard of the same drug, it is known as a relative bioavailability.
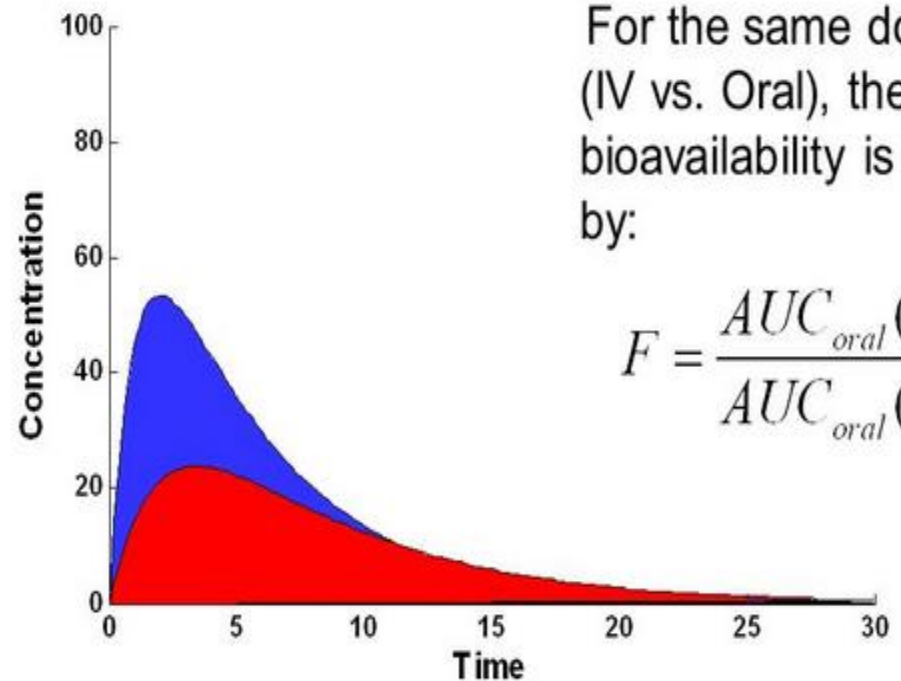
$$F_{rel} = \frac{AUC_{extravascular1}}{AUC_{extravascular2}} \times \frac{Dose_{extravascular2}}{Dose_{extravascular1}}$$

GRAPHICAL COMPARISION BETWEEN ABSOLUTE AND RELATIVE BIOAVAILABILITY

Absolute bioavailability
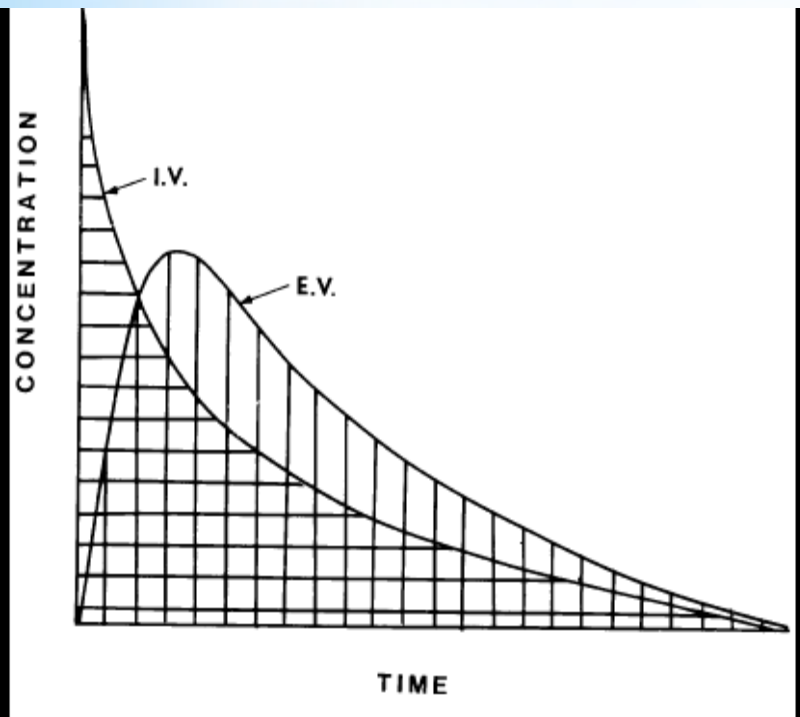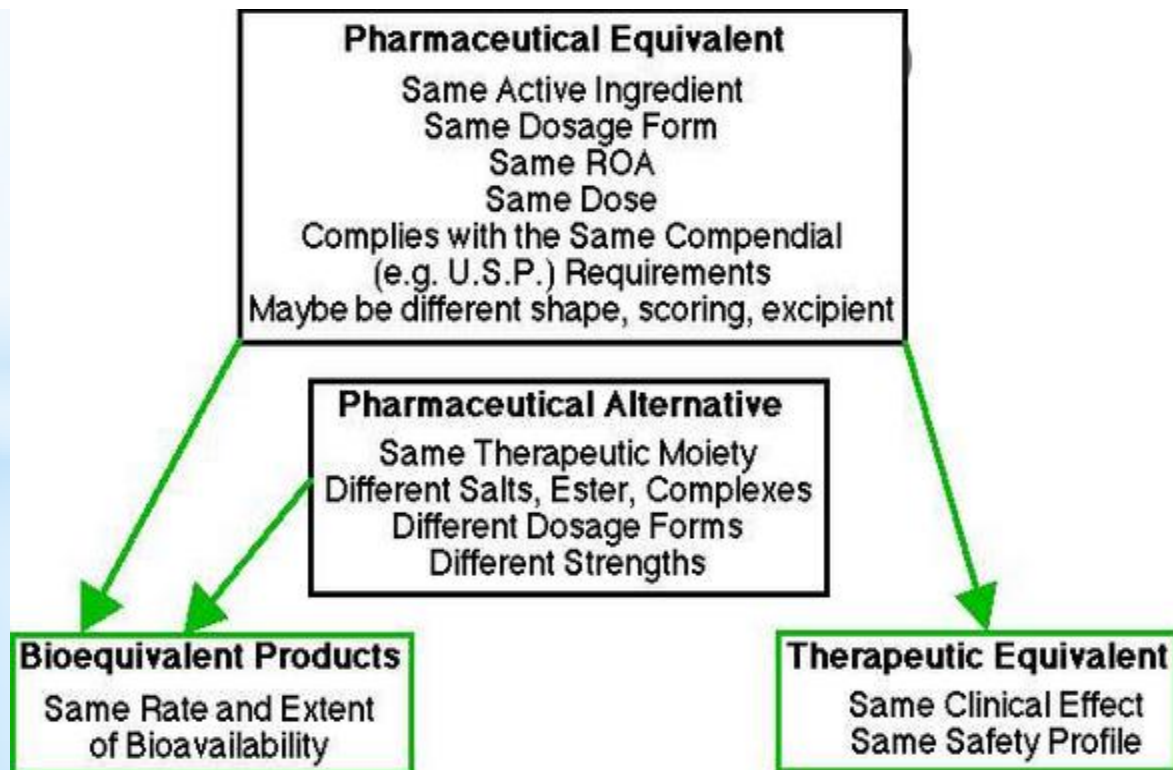

Relative bioavailability

For the same dose (IV vs. Oral), the bioavailability is given by:

$$F = \frac{AUC_{oral}(A)}{AUC_{oral}(B)}$$

BIOEQUIVALANCE

According to Food and Drug Administration (FDA) Guidance, bioequivalence is defined as, —the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study

Pharmaceutical Equivalent
Same Active Ingredient
Same Dosage Form
Same ROA
Same Dose
Complies with the Same Compendial (e.g. U.S.P.) Requirements
Maybe be different shape, scoring, excipient

Pharmaceutical Alternative
Same Therapeutic Moiety
Different Salts, Ester, Complexes
Different Dosage Forms
Different Strengths

Bioequivalent Products
Same Rate and Extent of Bioavailability

Therapeutic Equivalent
Same Clinical Effect
Same Safety Profile

OBJECTIVES OF BIOEQUIVALENCE

- To compare the bioavailability of the generic drug product to the brand-name product.

- Bioequivalent drugs that have same systemic bioavailability will have same predictable drug response.

- Still, variable response may occur due to age, drug tolerance, drug interactions or disease states.