RAMA UNIVERSITY

Biopharmaceutical Classification System [BCS]

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CONTENT

BIOPHARMACEUTICAL CLASSIFICATION SYSTEM [BCS]

- The Biopharmaceutical Classification System was first developed by in 1995, by Amidon et al & his colleagues.

- **Definition:**

"The Biopharmaceutical Classification System is a scientific framework for classifying a drug substance based on its aqueous solubility & intestinal permeability & dissolution rate".

- To saved time fast screening is required so **drug substances are classified on basis of solubility and permeability.** This classification is called Biopharmaceutical Classification System.

FACTOR AFFECTING ON BCS

The Biopharmaceutical Classification System has been developed to provide a scientific approach to allow for to prediction in vivo pharmacokinetics of oral immediate release (IR) drug product by classifying drug compound based on their,

1. **SOLUBILITY**
2. **PERMEABILITY**
3. **DISSOLUTION**

SOLUBILITY

- The Maximum Amount of solute dissolved in a given solvent under standard conditions of temperature, pressure and pH.
- Solubility is the ability of the drug to be solution after dissolution
- The higher single unit dose is completely soluble in 250 ml at pH 1- 6.8 (37˚C).

PERMEABILITY

- Permeability of the drug to pass the biological membrane which is the lipophilic.
- Permeability is indirectly based on the extent of absorption of a drug substance .
- Drug substance is considered to be highly permeable, when the extent of absorption in human determined to be 90% or more of administered drug or compare to *in vivo* reference dose.

DISSOLUTION

- It is process in which solid substance solubilises in given solvent i.e mass transfer from solid surface to liquid phase.

- Using USP apparatus I at 100 rpm or USP apparatus II at 50 rpm .

- Dissolution Media [900 ml],
  1. 0.1 N HCl **or** simulated gastric fluid (pH 1.2) without enzyme.
  2. pH 4.5 buffer & pH 6.8 buffer.
  3. Simulated intestinal fluid without enzyme.

Biopharmaceutical Classification System for Drug

CLASS	SOLUBILITY	PERMEABILITY	EXAMPLES
Class – I	High	High	Metoprolol , Propranolol
Class – II	Low	High	Nifedipine, naproxen
Class – III	High	Low	Cimitidine, Metformin
Class – IV	Low	Low	Taxol, Clorthiazole

CLASS - I

- Ideal for oral route administration.
- Drug absorbed rapidly.
- Drug dissolved rapidly.
- Rapid therapeutic action.
- Bioavailability problem not expected for immediate release drug product.
- e.g. Metoprolol , Propranolol, Diltiazem.

CLASS - II

- Oral route for administration.
- Drug absorb rapidly.
- Drug dissolve slowly.
- Bioavailability is controlled by dosage form and rate of release of the drug substance.
- e. g. Nifedipine, naproxen.

CLASS - III

- Oral route for administration.
- Drug absorbance is limited.
- Drug dissolve rapidly.
- Bioavailability is incomplete if drug is not release or dissolve in absorption window.
- e. g. Cimitidine, Metformin,Insulin.

CLASS - IV

- Poorly absorbed by orally administration.
- Both solubility & permeability limitation.
- Low dissolution rate.
- Slow or low therapeutic action.
- An alternate route of administration may be needed.
- e. g. Taxol, Chlorthiazole, Cefexime Trihydrate.

APPLICATION

- To predict in vivo performance of drug product using solubility and permeability measurements.
- Aid in earliest stages of drug discovery research.
- To use in biowaiver considerations.
- For research scientist to decide upon which drug delivery technology to follow or develop.
- Also for the regulation of bioequivalence of the drug product during scale up and post approval.

CLASS BOUNDARIES

HIGHLY SOLUBLE

- The highest dose strength is soluble in ≤ 250 ml water over a pH range of 1 to 7.5.
- The volume estimate - a glassful (8 ounce)

HIGHLY PERMEABLE

- When the extent of absorption in humans is determined to be ≥ 90% of an administered dose.

RAPIDLY DISSOLVING

- When ≥ 85% of the labeled amount of drug substance dissolves within 30 minutes using USP apparatus I or II in a volume of ≤ 900 ml buffer solutions.

BIOWAIVER

- **“*in vitro* instead of *in vivo* bioequivalence testing”**

- **Definition:**

It is an exemption from conducting human bioequivalence studies when the active ingredients meet certain solubility and permeability criteria in vitro and when the dissolution profile of the dosage form meets the requirements for an IR dosage form.

CRITERIA OF BIOWAIVER

- Rapid and similar dissolution
- High solubility
- High permeability
- Wide therapeutic window
- Excipient used in dosage form are same as those present in approved drug product

CONCLUSION

- Biopharmaceutical classification system aims to provide regulatory tools for replacing certain bio-equivalence studies by accurate *in vivo* dissolution tests.
- The *in vivo* pharmacokinetics of drug depends largely on the solubility and permeability.
- Many laboratories are engaged to find better means to estimates *in vivo* behavior of the drug after oral administration by using simple *in vitro* dissolution tests.

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Thank you!