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Review Paper

The Biopharmaceutical Classification System: A Comprehensive review

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ABSTRACT

The Biopharmaceutical Classification System (BCS) is a scientific framework that categorizes drug substances according to their aqueous solubility and intestinal permeability, two key determinants of oral drug absorption from immediate-release solid dosage forms. By integrating dissolution characteristics with permeability data, BCS provides a mechanistic basis for understanding in vivo drug performance and supports rational formulation development. This review outlines the fundamental principles, objectives, regulatory guidance, and defining characteristics of BCS classes, as well as their practical significance in pharmaceutical research and development. It also discusses challenges associated with poor solubility and variable in vivo disposition, which remain major barriers in drug development. BCS classifies drugs into four categories: Class I (high solubility, high permeability), Class II (low solubility, high permeability), Class III (high solubility, low permeability), and Class IV (low solubility, low permeability). These classifications guide formulation strategies and enable the design of optimized dosage forms using predictive, science-based approaches rather than empirical methods. Furthermore, BCS concepts play a critical role in regulatory decision-making, including applications for New Drug Applications (NDA), Abbreviated New Drug Applications (ANDA), biowaivers, and scale-up and post-approval manufacturing changes. By applying BCS principles, pharmaceutical companies can streamline development processes, reduce unnecessary in vivo studies, and achieve significant savings in time and cost while ensuring product quality and therapeutic efficacy.

INTRODUCTION

The Biopharmaceutical Classification System(BCS) provides a scientific structure for categorizing a drug compound according to its solubility in water and ability to permeate the intestines. Amidon et al. conducted the first

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theoretical comparison of in vitro drug dissolution and in vivo bioavailability in 1995.[1-10]

This system mainly focus on drug development and regulatory approval in efficient and cost-effective way. [8]

The three main rate-limiting phases for oral medication retention are:

- Release of drugs from dosage form
- Gastrointestinal (GI) tract arrangement of disintegrated form
- Saturation through GI membrane into hepatic circulation[1-7,12-14]

The BCS considers three main elements that determine the rate and degree of oral medication absorption from IR solid oral-dosage forms: solubility, intestinal permeability, and dissolution rate. These criteria are paired with the drug product's in vitro dissolution characteristics. [20,21]

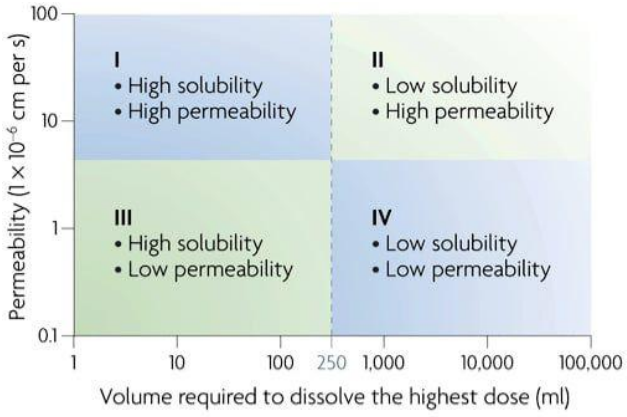

Fig 1: BCS class system [34]

2.SOLUBILITY, PERMABILITY AND DISSOLUTION

SOLUBILITY: when a drug of greatest dosage strength is soluble in 250 mL water over a pH range of 1 to 7.5, it is termed very soluble. [22]

PERMABILITY: When a amount of drug absorption in humans is proven to be > 90% of a given dosage, in comparison to an intravenous reference dosage, a drug substance is termed as extremely permeable. [23]

DISSOLUTION: When more than 85 percent of the labelled amount of drug material dissolves in 30 minutes using USP equipment I (at 100 rpm) or Il (at 50 rpm) in a volume of 900 ml buffer solutions, the drug product is termed as rapid dissolving. [18,24]

3.BCS CLASS:

3.1. CLASS 1-HIGH SOLUBILITY, HIGH PERMEABILITY

The drugs in the category have both high aqueous solubility and permeability which transported to GI mucosa. After oral administration, bioavailability is often nearly 100%, assuming they are not broken down in the gastrointestinal tract and do not experience significant first-pass metabolism. [25] These medications are easily absorbed; thus formulation efforts can prioritize enhancing dosage forms for patient convenience and adherence. Examples are pills and capsules with minimum excipients. [32]

3.2. CLASS 2-LOW SOLUBILITY, HIGH PERMEABILITY

The drugs in the category have low aqueous solubility and high permeability but easily

transported across the GI mucosa. In order to enhance solubility some techniques are used such as micronization, solid dispersions, nanosizing, and the use of solubilizing agents like cyclodextrins or surfactants are common. The bioavailability of these drugs can also be increased by lipid-based formulations, such as self-emulsifying drug delivery systems (SEDDS) or self-micro emulsifying drug delivery systems (SMEDDS)[25,27]

3.3. CLASS 3-HIGH SOLUBILITY, LOW PERMEABILITY

The drugs in the category have high aqueous solubility and low permeability. This drugs' low membrane permeability prevents them from achieving full bioavailability following oral use. Permeability enhancers are commonly used in formulations to improve medication absorption. Surfactants, co-solvents, and bile salts can be used to increase absorption. To boost medication permeability, consider altering the chemical structure or employing prodrugs. [28,29]

3.4. CLASS4 -LOW SOLUBILITY, LOW PERMEABILITY

Class IV medicines have weak solubility and per meability.
A combination of strategies from Classes II and II I may be required.
Solubility enhancement strategies, such as solid d ispersions and nanosizing, may be used in conjun ction with permeability enhancers.
Advanced drug delivery technologies, including n anoparticles, liposomes, and tailored techniques, may be necessary for optimal bioavailability.
[30,31] The Apparent Permeability Index (Papp) is often used to evaluate drug permeability. The permeability coefficient determines how a medicine flows across membranes. Papp levels can be assessed using in vitro, ex vivo, in situ, and in vivo methods. [26]

Table 1: BCS class

Class	Solubility	Permeability	Rate limiting step (RLS)	Oral dosage form approaches
Class-1	High	High	None	Solid oral dosage form
Class-2	Low	High	Solubility	• Techniques to increase surface area include particle size reduction, solid solution, and solid dispersion. • Solutions containing solvents and/or surfactants
Class-3	High	Low	Permeability	Increase local lumenal concentration and add permeability enhancers.
Class-4	Low	Low	Both solubility and permeability	Combine both 2 &3

4. PRINCIPLE OF BCS(permeability)

BCS applies fick's first law which is used for membrane permeability

Jf= Pm Ci
Where,
Jf = Drug flux rate (mass/area/time)
Pm = Membrane permeability

Ci = Concentration of the drug at the intestinal membrane surface.[13,19]

4.1.PERMEABILITY PROCEDURE

Permeability can be determined using in vitro and in vivo experiments. In vitro investigations typically use the Caco-2 cell model, which involves growing cells on permeable supports to generate a confluent monolayer. The medication solution is applied to the apical side, and samples are taken from the basolateral side at regular intervals to determine the concentration.

In vivo mass balance investigations involve delivering drugs orally and intravenously to human volunteers, collecting blood, urine, and feces samples at different time points, and analyzing them to assess total drug absorption. Absorption is determined by comparing the orally delivered dose to the intravenous reference dose. Highly permeable drugs absorb more than 90% of the supplied dose.[33]

5. PURPOSE OF BCS

Based on the BCS approach, a waiver for bioequivalence studies and in-vivo bioavailability may be granted. The BCS is enlarged for regulatory purposes, and drug classification procedures are advocated. [13]

6. OBJECTIVES OF BCS

The main objectives of the BCS are:

- To enhance medication development and review efficiency, propose an approach for selecting disposable clinical bioequivalence tests.
- To evaluate invivo performance of solid oral dosage forms based on the invitro solubility and permeability data.
- To recommend techniques for categorizing drugs according to dissolution along with the solubility–permeability properties of the drug product. [15-17]

The BCS conceptual structure criteria can be relat ed to

- New Drug Applications (NDAs)
- Abbreviated New Drug Applications (ANDAs) and
- Scale-up and post-approval changes in medication manufacturing [6]

7. DRUGS [18]

Figure 2: Examples of Drugs in BCS class

Class I	Class II	Class III	Class IV
Abacavir	Amiodarone	Acyclovir	Amphotericin
Acetaminophen	Atorvastatin	Amiloride	Chlorthalidone
Acyclovir	Azithromycin	Amoxicillin	Chlorothiazide
Amiloride	Carbamazepine	Atenolol	Colistin
Amitryptyline	Carvedilol	Bisphosphonates	Coenzyme Q10
Antipyrine	Chlorpromazine	Bidisomide	Ciprofloxacin
Atropine	Cisapride	Captopril	Ellagic acid
Buspironec	Ciprofloxacin	Cefazolin	Furosemide
Caffeine	Cyclosporine	Cetirizine	Hydrochlorothiazide
Captopril	Danazole	Cimetidine	Mebendazole
Chloroquine	Dapsone	Cipofloxacin	Methotrexate
Chlorpheniramine	Diclofenac	Cloxacillin	Neomycin
Cyclophosphamide	Diflunisal	Dicloxacillin	Ritonavir
Desipramine	Digoxin	Erythromycin	Saquinavir
Diazepam	Erythromycin	Famotidine	Taxol

BCS: Biopharmaceutical classification system

8.TECHNIQUES FOR IMPROVING DRUG SOLUBILITY ACROSS MANY CLASSES:

8.1. PHYSICAL MODIFICATION

- **MICRONIZATION:** To reduce the particle size to 1–10 microns, utilize a jet mill, fluid energy, or spray drying. Particle size reduction will boost surface area and enhance bioavailability. Examples include sulfa, griseofulvin, and several steroidal medications. (41)
- **NANOIONIZATION:** Using techniques including pearl processing, water homogenization, and non-aqueous medium homogenization, powdered medication is transformed into nanocrystals with a size range of 200–600 nm.(42) Examples include doxorubicin, cyclosporin, paclitaxel2, and estradiol
- **SOLVENT EVAPORATION METHOD:** A common solvent was used to dissolve the medication and the carrier, and the dissolved material was then vacuum-evaporated to create an amorphous precipitate. Examples: Nimesulide, naproxen, and meloxicam (43)
- **HOT MELT EXTRUSION:** With the exception of the extruder performing the intense mixing, hot melt extrusion is identical to the combination process. It works well for extensive preparations. Ritonavir is one example. (44)
- **SOLID DISPERSIONS:** Solid dispersions are made by combining a hydrophilic matrix (e.g. polyvinyl pyrrolidone, povidone, polyethylene glycol), a surfactant (e.g. sodium lauryl sulfate, tween 80, pluronic F-68), and a hydrophobic medicine (e.g. fats, oils, waxes, alkanes, greasy compounds). Methods for preparing solid dispersions including. (44)
- Polymorphs, amorphous, solvates, and metastable forms are used. Amorphous solids are more soluble than crystal structures due to the higher vitality required for crystal lattice transfer. Metastable forms are more soluble than their stable counterparts. Anhydrates require less energy for crystal separation as they are more soluble than hydrates, which are already connected with water. The order of solubility for solid forms of pharmaceuticals is as follows: amorphous, metastable, stable, anhydrates, hydrates, solvates, and nonsolvates.

  Eutectic combinations dissolve the soluble carrier in water, leaving the medication in a microcrystalline condition for fast solubilization. They are affordable and easy to prepare. Examples are paracetamol with urea, griseofulvin with urea, and griseofulvin with succinic acid.(45)
- **HOT-MELT METHOD:** The hot-melt method (fusion method) involves heating the drug and carrier until they melt, then cooling with ice and stirring until solidified. Next, it is crushed, pulverized, sieved, and compacted into tablets. (46)

8.2. CHEMICAL MODIFICATIONS:

- **CHANGE IN pH:** The simplest approach to enhance the solubility of organic ionized solutions is to change the pH of the formulation. A pH change can be done by-Use of buffers & In situ salt formation. (47)
- **PRODRUDS:**
  Prodrugs are created by transforming inactive substances into active ones, increasing drug solubility.
  Examples include: acyclovir, fluorouracil, cy clophosphamide, captopril, and carisoprodol. (48)
- **SALT FORMS**:
  Salt versions are more soluble than pure API medicines.
  Examples include antacid metal salts of acidi c drugs like penicillin, and solid corrosive sal ts of critical pharmaceuticals like atropine. .(47)

- **DERIVATIZATION:** Derivatization is the process of converting a chemical molecule into a product with a similar chemical structure but differing solubilities compared to the adduct. [49]
- **WITH CYCLODEXTRINS:** Beta and gamma ray cyclodextrins can create sub-atomic structures by accommodating lipophilic drugs and having a hydrophilic outside. This results in a significant increase in dissolving rate and solubility. This approach enhances the bioavailability of medicines such as thiazide diuretics, barbiturates, and benzodiazepines [48]

8.2. MISCELLENAOUS MODIFICATION:

- **COSOLVENTS:** Co-solvents have low solubility in weak electrolytes and non-polar molecules. Adding organic co-solvents (miscible or partially miscible solvents) to water can significantly boost medicine solubility by modifying the polarity of molecules. Examples include: etoricoxib, glipizide, glyburide, glimepiride, and pioglitazone. **[50]**
- **USE OF SURFACTANTS:** When used in the focus beneath their basic micelle fixation, surfactants speed up the wetting and infiltration of disintegration liquid into the medication particles because the drug trapped in the micelle structure was unable to partition in the dissolution fluid above the critical micelle concentration. For instance, this method has improved the bioavailability of steroids like spironolactone. [51]
- **PRECIPITATION**: A hydrosol is created when poorly water-soluble drug is first dissolved in an appropriate organic solvent and then rapidly combined with a non-dissolvable substance to precipitate the medication in nanoparticle form. For instance, cyclosporine. [52]
- **RECRYSTALLIZATION OF SUPER CRITICAL FLUID (SCF):** These fluids display the properties of both gases and liquids and have temperatures and pressures above their critical temperature. At close basic temperatures, SCFs exhibit substantial compressibility, enabling for weight adjustment to alter thickness and mass power. The drug particles crystallized with smaller molecular sizes after dissolving in SCF.[53]
- **SOLVENT DEPOSITION:** Solvent deposition involves dissolving and depositing poorly soluble pharmaceuticals on an inert, hydrophilic, solid substrate through evaporation of organic solvents like alcohol. For example, consider nifedipine. [52]

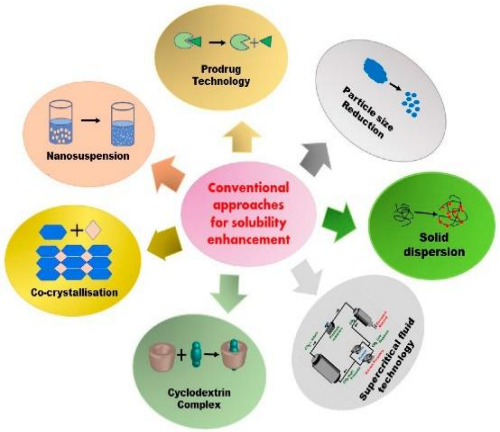

Figure 3: Techniques for improving drug solubility

9. BIOWAIVER

Biowaivers are regulatory measures that allow for the exemption of in vivo bioavailability and bioequivalence studies, which are normally necessary for generic drug product approval, under certain circumstances. The BCS-based biowaiver is an important application of the BCS, which aims to reduce the need for comprehensive clinical testing by relying on in vitro data. [35]

9.1. CRITERIA FOR BCS CLASS-BASED BIOWAIVER

A medication product must fulfill the following r equirements in order to be eligible for a BCS-based biowaiver

- **Classification:** The drug should be classed as BCS Class I (high solubility and permeability)
- **Dissolution:** The drug product must dissolve at least 85% in 30 minutes across three pH levels (1.2, 4.5, and 6.8)
- **Excipients**: The excipients in medication formulations should not significantly impact absorption. [36-38]

9.2. ADVANTAGES OF BIOWAIVER

Biowaivers have various advantages. Eliminating in vivo bioequivalence studies can greatly speed up medication development. Using in vitro data can help pharmaceutical companies cut clinical trial expenditures. Biowaivers also streamline the regulatory review process, allowing generic medications to be approved more quickly. [39-40]

CONCLUSION

In conclusion, the Biopharmaceutics Classification System serves as a scientifically grounded regulatory framework that can substitute certain in vivo bioequivalence studies with reliable in vitro dissolution testing during generic drug development. Although the application of BCS principles to Class II and Class III drugs presents specific scientific and regulatory challenges, it also offers meaningful opportunities to reduce regulatory requirements when supported by strong mechanistic justification.

By integrating solubility and permeability data, BCS enables better prediction of drug disposition, including absorption, transport, and elimination processes, thereby linking physicochemical properties with in vivo pharmacokinetic behavior. This approach supports the rational design of drug delivery systems tailored to optimize therapeutic performance and maintain bioequivalence during scale-up and post-approval changes.

Looking ahead, broader implementation of BCS concepts in the early stages of drug discovery and development-such as candidate selection and preliminary formulation design-has the potential to enhance efficiency, reduce development risks, and promote more science-based decision-making across the pharmaceutical lifecycle.

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