Review Article

Biopharmaceutics Classification System (BCS) - An Overview

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ABSTRACT

The Biopharmaceutics Classification System (BCS) is a scientific framework introduced in 1995 to classify drugs based on their solubility and permeability. This system plays a crucial role in drug development, regulatory approval, and bioequivalence assessment. BCS categorizes drugs into four classes: 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). The system facilitates drug formulation strategies by determining key absorption rate-limiting steps: drug release, dissolution in the gastrointestinal (GI) tract, and permeation through the GI membrane. The significance of BCS lies in its application to waive in vivo bioequivalence studies through biowaivers, particularly for immediate-release solid oral formulations meeting solubility and permeability criteria. Regulatory agencies such as the FDA, EMA, and WHO use BCS guidelines for drug approval processes, including New Drug Applications (NDAs) and Abbreviated New Drug Applications (ANDAs). BCS also aids in predicting drug absorption and optimizing formulation techniques to enhance bioavailability, including micronization, solid dispersions, salt formation, and the use of surfactants. The document further explores advancements in BCS classification, including extensions like the Six-Class Biopharmaceutical Classification System, Quantitative Biopharmaceutical Classification System (QBCS), and Biopharmaceutics Drug Disposition Classification System (BDDCS). Future developments in BCS focus on refining drug absorption predictions, enhancing bioequivalence evaluation, and optimizing formulation strategies for new drug entities.

Keywords: Biopharmaceutics Classification System (BCS), Solubility, Permeability, Drug, Absorption, Bioequivalence, Biowaiver, Formulation Strategies, Regulatory Approval.

INTRODUCTION

The Biopharmaceutics Classification System (BCS) was first introduced in 1995 as a scientific framework to classify drugs based on their solubility and permeability .[1]

The system was developed to improve the **regulatory evaluation of bioequivalence for oral drug formulations** and has since become a key tool in pharmaceutical research and drug regulation [2]. The **BCS classification** has played a crucial role in drug solubility, permeability research 3, and regulatory guidance on bioequivalence assessments [4].

The introduction of **BCS by Amidon et al.** in 1995 provided a systematic way to assess drug absorption and bioavailability, leading to its application in early drug development [5]. Over time, the **FDA, EMA, and WHO** formally adopted BCS guidelines to assist in drug approval process [6].

The **BCS conceptual structure** requirements can be linked to **New Drug Applications (NDAs)** and **Abbreviated New Drug Applications (ANDAs)**, as well as **scale-up and post-approval changes** in medication manufacturing (Committee for Medicinal Products for Human Use, 2008) [7].

BCS Classification & Objectives

The main objectives of BCS classification include:

- Improving drug development efficiency by reducing the need for extensive in vivo studies [8].
- Facilitating drug absorption prediction based on permeability and solubility measurements [9].
- Granting biowaivers, allowing certain drugs to be approved based solely on in vitro data, thus eliminating the need for human bioequivalence studies in specific cases [10].

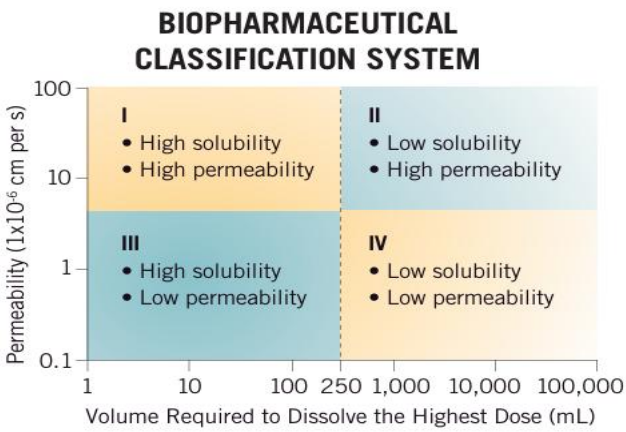

Figure 1: Classification of Drugs Based on BCS[1]

Each **BCS class** has a specific rate-limiting step that can be optimized during drug formulation [9].

The three key rate-limiting phases in oral drug retention include:

- Drug release from the dosage form.
- Dissolution in the gastrointestinal (GI) tract.

- Permeation through the GI membrane into hepatic circulation [11].

BCS categorizes drugs into four groups based on their solubility and permeability:

- Class I drugs: High solubility and high permeability, meaning they are **easily absorbed** in the body.
- Class II drugs: Low solubility but high permeability, meaning their absorption is limited by solubility rather than permeability.
- Class III drugs: High solubility but low permeability, meaning their absorption is limited by permeability.
- Class IV drugs: Low solubility and low permeability, making them poorly absorbed in the body.

The Apparent Permeability Index (Papp**)** is commonly used to assess the permeability of drug substances. The permeability coefficient is a key parameter used to determine the flow of a drug across membranes. Papp values can be determined through in vitro, ex vivo, in situ, and in vivo techniques [12].

Solubility, Permeability, and Dissolution Rate

- **Solubility**: A drug is considered highly soluble if it dissolves in 250 mL or less of water across a pH range of 1 to 8 [13].
- **Permeability**: A drug is considered highly permeable if more than 90% of the administered dose is absorbed and remains stable in the stomach [14].
- **Dissolution**: A drug is considered to have rapid dissolution if 85% of its labeled amount dissolves within 30 minutes using:
    - **USP Apparatus 1** (at 100 rpm)
    - **USP Apparatus 2** (at 50 rpm)
    - **900 mL buffer solutions** (0.1 N HCl, pH 4.5 buffer, pH 6.8 buffer, without enzymes) (Bala et al., 2005), (Kommuru et al., 2001), (Sharma et al., 2005) [15,16]

Importance of BCS in Drug Development

The BCS classification helps researchers design drug formulations based on scientific principles rather than trial-and-error experiments. Regulatory agencies such as the FDA (2000) use BCS guidelines for:

- New Drug Application (NDA) approvals
- Abbreviated New Drug Application (ANDA) approvals
- Scale-up and post-approval manufacturing changes [17]

Key Factors Affecting Drug Absorption

The BCS framework explains the three rate-limiting steps in drug absorption:

1. Drug release from the dosage form
2. Dissolution in the gastrointestinal (GI) tract
3. Permeation through the GI membrane into hepatic circulation [11].

Determining Permeability and Solubility

- Intestinal permeability is evaluated by comparing drug absorption through oral and intravenous administration.
- Solubility characterization is performed according to the standards set by the United States Pharmacopeia (USP) [18].

Principle of BCS:

BCS follows fick's first law utilized for membrane permeability

$J_f = P_m C_i$

J_f = Drug flux rate (mass/area/time)

P_m = Membrane permeability

C_i = Concentration of the drug at the intestinal membrane surface

BCS acts as a regulatory tool and replaces certain bioequivalent studies, which are have been accurate in vitro dissolution tests and ensure avoiding unnecessary drug exposure to healthy volunteers [19].

Waivers and their importance in BCS studies:

The criteria for BCS direction for biowaiver are given by the United States Food and Drug Administration (FDA or USFDA), World Health Organization (WHO) and European Medicines Agency[20,21]. Waivers (i.e. permission to skip in vivo bioequivalence studies) are reserved for drug products that meet certain requirements around solubility and permeability and also rapidly dissolve in the human body[1]. Biowaiver is most commonly used in the administrative drug approval procedure, when the drug application is confirmed based on the proof of proportionality other than in vivo comparison testing. This waiver applies to both the pre- and post-approval stages. BCS-based biowaiver is applicable for immediate-release solid oral formulations containing the API approved by WHO. Biowaiver acceptance is given to Class I immediate release (IR) solid dosage forms if they fulfill the criteria of high solubility and permeability and also rapid dissolution. It also must not contain any excipients that will affect the rate or extent of absorption. In addition, biowaivers may be granted to products of Class III compounds. In that case, Class III IR solid dosage form must meet the solubility and dissolution criteria of the reference product for Biowaiver granting plus a quantitative and qualitative similarity to the Class III accepted compound. Excipients must be the same, as they can drastically affect the characteristics of low-permeability drugs [22].

This waiver is based on a triple-tier rationale where:

a) high solubility insures that drug solubility will not limit dissolution, and thus absorption,

b) high permeability insures that drug is completely absorbed during the limited transit time through the small intestine, and

c) rapid dissolution insures that the gastric emptying process is the rate-limiting step for absorption of highly soluble and highly permeable drugs[23].

Objectives of BCS:

· The goal of BCS is to evaluate in vivo performance of medicinal products based on in vitro permeability and solubility data.

· To provide techniques for categorizing medicinal products based on solubility and permeability properties as well as dosage form dissolution.

· We improved the efficiency of drug development and review processes by proposing a mechanism to perform clinical bioequivalence tests expandable [24].

Application of BCS:

The BCS places a given API(active pharmaceutical ingredient) in one of four categories depending on its oral dosing solubility and permeability. A drug substance is considered "highly soluble" when the highest clinical dose strength is soluble in 250 mL or less of aqueous media over a pH range of 1–7.5 at 37°C. A drug substance is considered to be "highly permeable" when the extent of the absorption (parent drug plus metabolites) in humans is determined to be ≥90% of an administered dose, based on a mass balance determination or in comparison to an intravenous reference dose[25].

Importance

To replace certain bioequivalent studies, BCS acts as a regulatory tool. It is applicable in both preclinical and clinical examinations. BCS can reduce the time and money for the immediate release orally administered drugs, which meet particular criteria; the FDA will allow a waiver for costly and tedious bioequivalence studies. It acts as a guiding tool for selecting the formulation of new dosage forms, development of various oral drug delivery systems[25].

Figure 2: Examples of Various Drugs according to BCS Class:[26]

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

Various techniques to enhance the solubility of different classes of Drugs:

A. Physical Modification

i. Micronization: Spray drying or use fluid energy or a jet mill to reduce the particle size to 1-10 microns. A reduced particle size will increase the surface area and improve bioavailability. Examples: Griseofulvin, sulfa, and certain steroidal drugs [27].

ii. Nanoionization: Powdered drug is converted to nanocrystals of size 200-600 nm using technologies such as pearl processing, homogenization in water, and homogenization using non aqueous medium. Examples: estradiol, doxorubicin, cyclosporin, and paclitaxel[28].

iii. Sonocrystallization: Ultrasound in the range of 20 KHz-5 KHz is used to induce crystallization in sonocrystallization. Examples: This method increased the solubility of ketoconazole by 5.517 folds [29].

iv. Use of polymorphs, amorphous, solvates, and metastable form: Because the vitality required to transfer the crystal lattice is more than that necessary for amorphous solid, amorphous forms are more soluble than crystal structures. Metastable forms are more soluble than stable ones. Because hydrates are already associated with water, anhydrates are more soluble, so require less energy for crystal separation. Thus, the order of solubility of different solid forms of drugs is Amorphous > Metastable > Stable > Anhydrates > Hydrates > Solvates > Non-solvates Eutectic mixtures: The soluble carrier in the eutectic mixtures dissolves when exposed to water, leaving the drug in a microcrystalline state that solubilize rapidly. They are inexpensive and easily prepared. Examples: paracetamol with urea, griseofulvin with urea, griseofulvin with succinic acid [30].

v. **Solid dispersions**: A hydrophilic matrix (polyvinylpyrrolidone, povidone, polyethylene glycol, surfactant such as sodium lauryl sulfate, tween 80, pluronic F-68) and hydrophobic drug (fats, oils, waxes, alkanes, and other greasy substances) are used in preparing solid dispersions. Methods for preparing solid dispersions including.

vi. **Hot-melt method (fusion method)**: Drug and the carrier are heated directly until they melt and then rapidly cooled with ice by continuous stirring to solidify. After that, it is crushed, pulverized, sieved and compressed into tablets [31].

vii. **Solvent evaporation method:** Medication and the carrier were dissolved in a common solvent and the dissolved content was evaporated under vacuum to form an amorphous precipitate.30 Examples: Meloxicam, naproxen, nimesulide [32].

viii. **Hot melt extrusion**: It is the same as the combination technique, except the extruder does the extreme mix.

It is appropriate for large-scale preparations [32].Examples: Ritonavir[33].

B. Chemical Modifications:

i. Change in pH: The easiest approach to enhance solubility of organic ionized solutions is to change the pH of the formulation. A change in pH can be done by;

· Use of buffers

· In situ salt formation

ii. Salt formation: When compared with pure API drugs, salt forms have better solubility. Example: Antacid metal salts of acidic medicines, such as penicillin, solid corrosive salts of vital pharmaceuticals, such as atropine[34].

iii. Prodrug: Solubility of the drugs can be increased by converting a pharmacologically inactive substance into a pharmacologically active drug. Examples: acyclovir, fluorouracil, cyclophosphamide, carbamazepine, captopril, and carisoprodol.

iv. Atomic elucidation with cyclodextrins: The beta and gamma ray cyclodextrins can form sub-atomic consideration structures since they have a cavity to accommodate lipophilic medicines as guests and the exterior of the transporter is hydrophilic. As a result, there is a significant increase in dissolving rate and solubility. Thiazide diuretics, barbiturates, and benzodiazepines are examples of drugs with enhanced bioavailability due to this method [35].

v. Derivatization: Conversion of a chemical compound into a product, which shows a similar chemical structure called derivative with different solubilities's that of the adduct[36].

C. Miscellenaous Modification:

i. Super critical fluid (SCF) recrystallization: These fluids have temperatures and pressures that are higher than their critical temperature and exhibit the characteristics of both gases and liquids. SCFs are profoundly compressible at close fundamental temperatures, modifying thickness and mass power by allowing weight modification. When the drug particles were dissolved in SCF, they crystallized with smaller molecule sizes[37].

ii. Use of surfactants: Surfactants increase the disintegration rate by advancing wetting and infiltration of disintegration liquid into the medication particles, when used in the focus beneath their basic micelle fixation because drug captured in the micelle structure failed to partition in the dissolution fluid above the critical micelle concentration. Example: a steroid like spironolactone bioavailability has been enhanced by this technique[38].

iii. Solvent deposition: Poorly soluble medicines are dissolved and deposited on an inert, hydrophilic, and solid matrix by evaporation of the solvent using organic solvents such as alcohol. Example: Nifedipine.

iv. Precipitation: Medication that is poorly water-soluble is first dissolved in a suitable organic solvent, then quickly mixed with a non-dissolvable to precipitate the medication in nanosize particles, and this result is known as a hydrosol. Example: cyclosporine [39].

v. Co-solvents: Solubility is low for weak electrolytes and non polar compounds. Solubility can be increased by altering the polarity of those molecules by adding organic co-solvents (mixing miscible or partially miscible solvents) to water, which drastically affects medication solubility. Example: Etoricoxib, glipizide, glyburide, glimepiride and pioglitazone [40].

vi. Hydrotrophy: The addition of a significant number of additives (hydrotropic agent) to the drug solution increases the medication's water solubility.41 Example: Ethanol, resorcinol, pyrogallol, catechol and procaine hydrochloride [41].

vii. Selective adsorption on insoluble carriers: Adsorbents can enhance solubility by forming weak physical bonding between the drug and adsorbent and can also by hydration and swelling of clay in aqueous media. Example: inorganic clay bentonite can improve the dissolution of drugs like griseofulvin, prednisone, and indomethacin [42].

BCS and trends in Dosage form:

It is commonly recognized that most new drugs present formulation challenges. Older drugs as compared to newer ones generally have higher solubilities. One reference noted that BCS Class II compounds, as a percentage of the total number of compounds in development, has increased from 30% to 60%. BCS Class I compounds have fallen correspondingly from 40% to 20% over that same period [43].

Figure 3: BCS Classification[1]

BCS Class	Solubility	Permeability	Oral Dosage Form Approach
1	High	High	Simple solid oral dosage form
2	Low	High	• Techniques to increase surface area like particle size reduction, solid solution, solid dispersion • Solutions using solvents and/ or surfactants
3	High	Low	Incorporate permeability enhancers, maximize local lumenal concentration
4	Low	Low	Combine 2 and 3

Extension of BCS Classification:

1. Six-class biopharmaceutical classification system:

Bergstrom and co-workers have divided the drugs into six classes considering solubility, permeability, and calculated surface area which is the modified version of the BCS. The solubility was allotted as "high" or "low" and the permeability was classified as "low", "intermediate," or "high". The non–polar portion of the surface area of the molecule terminated in good permeability predictions. It is well suited for early development especially for optimization of the pharmacokinetic parameters [44].

2. Quantitative biopharmaceutical classification system (QBCS)

Apart from solubility of drug in the dissolution fluid dissolution can be dependent on the amount of drug present at the site of absorption (dose) considering this fact the quantitative BCS (QBCS) was designed by Rinaki and Co–workers. The classification was based on the solubility: dose ratio as main parameter. According to FDA guidance for the industry, August 2000, the highest dose strength of an immediate release product should be considered for study[10].

The QBCS relies on a permeability and dose/solubility ratio. Permeability estimates, (P app that is the apparent permeability) were derived from Caco–2 cell studies and a constant intestinal volume content of 250ml was used to express the dose solubility ratio as a dimensionless quantity (q) (Figure 4).

Figure 4: Quantitative classification[9#(10)]

Quantitative biopharmaceutical classification system

BCS class	Papp*(cm/sec)	q*
I	Papp>10-5cm/sec	q≤0.5
II	Papp>10-5cm/sec	q > 1
III	Papp<2 C 10-6cm/sec	q≤0.5
IV	Papp<2 C 10-6cm/sec	q > 1

*Papp- apparent permeability and q- Dose/solubility.

Papp is the apparent permeability coefficient, which is the ratio of flux to concentration of drug in the donor compartment. Hence from it in–vitro tissue model can be used to predict in–vivo data.

3. Biopharmaceutics drug disposition classification system (BDDCS)

Factors like efflux transporters, food, absorptive transporters and renal or biliary routes of elimination on drug absorption and bioavailability are considered in this classification system [7].

In the BDDCS, permeability is replaced by extent of metabolism and drugs are classified on the base of solubility and extent of metabolism. According to classification, if the drug is mainly eliminated by metabolism, then the drugs show high permeability. If the drug is mainly eliminated as unchanged drug by biliary or renal route, then the drugs show low permeability. Formerly, "Extensive metabolism" was defined as ≥50% metabolism of an oral dose in humans in vivo but now "extensive metabolism" mean ≥70% metabolism of an oral dose in vivo in humans whereas the "poor metabolism" mean excretion of ≥50% of the dose unchanged.

CONCLUSION

The Biopharmaceutics Classification System is a pivotal tool in modern pharmaceutical research and regulatory science, offering a structured approach to evaluating drug solubility, permeability, and bioavailability. Its implementation streamlines drug development, reduces the need for extensive in vivo studies, and facilitates efficient drug approval pathways. The concept of biowaivers further strengthens its utility by minimizing unnecessary human exposure to drugs while ensuring therapeutic efficacy. With continuous advancements and modifications, BCS remains a cornerstone in pharmaceutical sciences, aiding in the formulation of effective and safe drug products. Further research and refinement of BCS guidelines will enhance its applicability, contributing to the future of drug development and regulatory decision-making.

Future Prospects of BCS:

From the time of introducing BCS classification, modifications of the BCS guidelines resulted in increased chances of applicability in development of drug. Since BCS can be used to determine rate limiting step in the process of oral absorption during early phases of drug development, so it provides information on formulations to scientists about the overall drug development process. BCS is also useful for the early development of molecule [45]. Differences of bio–waiver dossiers and assessments gives us the impression that a common understanding is lacking on a successful use of the BCS concept to support, and hence more research is needed for improving the BCS classification.

The integration of computational modeling, machine learning, and artificial intelligence in BCS assessments is expected to enhance drug classification accuracy. Additionally, regulatory bodies may expand the scope of biowaivers to include more drug classes, reducing the reliance on in vivo studies and expediting drug approval processes. Future research will likely focus on bridging the gap between BCS and personalized medicine, ensuring that drug formulations align with patient-specific needs. These advancements will solidify BCS as an indispensable tool in pharmaceutical innovation and therapeutic optimization.

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