

Biopharmaceutics Classification System: A Regulatory Approach

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ABSTRACT

The Biopharmaceutics Classification System (BCS) is the result of continuous efforts in mathematical analysis for the elucidation of the kinetics and dynamics of the drug process in the gastrointestinal tract (GIT) for NDA (New Drug Application) and ANDA (Abbreviated New Drug Application) filings and bioequivalents. This step reduces timelines in the new drug development process, both directly and indirectly, reduces unnecessary drug exposure in healthy volunteers, and increases impact for the replacement of certain bioequivalence (BE) studies with in vitro dissolution tests.

INTRODUCTION

An ANDA (21 CFR 314) contains data for the review and ultimate approval of a generic drug product. Generic drug applications are termed "abbreviated" because they generally are not required to include preclinical (animal) and clinical (human) data to establish safety and effectiveness. Instead, generic applicants must scientifically demonstrate that their products are bioequivalent (i.e., performs in the same manner as the innovator drug).

Bioequivalence studies are conducted on generic drug products in place of animal studies, clinical studies, or bioavailability studies. In vitro-in vivo correlation (IVIVC) studies can be used in the development of new pharmaceuticals to reduce the number of human studies during formulation development. The main objective of an IVIVC is to serve as a surrogate for in vivo bioavailability and to support biowaivers. IVIVCs could also be employed to establish dissolution specifications and to support and validate the use of dissolution methods. This is because the IVIVC includes in vivo relevance to in vitro dissolution specifications.

The introduction of the Biopharmaceutics Classification System (BCS) in 1995 was the result of continuous efforts on mathematical analysis for the elucidation of the kinetics and dynamics of the drug process in the gastrointestinal (GI) tract (1). Since the BCS was introduced, it has been used as a regulatory tool for the replacement of certain BE studies with accurate in vitro dissolution tests. This step certainly reduces timelines in the drug development process, both directly and indirectly, and reduces unnecessary drug exposure in healthy volunteers, which is the normal study population in BE studies.

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OBJECTIVES AND CONCEPT OF BCS

- The objectives of the BCS are (2):
- To improve the efficiency of the drug development and review process by recommending a strategy for identifying expendable clinical bioequivalence test.
 - To recommend a class of immediate-release (IR) solid oral dosage forms for which bioequivalence may be assessed based on in vitro dissolution tests.
 - To recommend methods for classification according to dosage form dissolution along with the solubility-permeability characteristics of the drug product.
- The BCS, which is based on scientific principles, presents a new paradigm in bioequivalence. According to the tenets of the BCS, certain drug products can be considered for biowaivers (i.e., product approval based on in vitro dissolution tests rather than bioequivalence studies in human subjects). At first, biowaivers were only applied to scale-up and postapproval changes (SUPAC) (3), but later the biowaver principle was extended to the approval of new generic drug products. As a result, unnecessary human experiments can be avoided, and the cost of developing generic products can be significantly lowered (4). It provides drug designers an opportunity to manipulate the structure or physicochemical properties of lead candidates to achieve better "deliverability" (5).

CLASSIFICATIONS

The BCS is a scientific framework for classifying a drug substance based on its aqueous solubility and intestinal permeability (6). It allows for the prediction of in vivo pharmacokinetics of oral immediate-release (IR) drug products by classifying drug compounds into four classes (Table 1) based on their solubility related to dose and intestinal permeability in combination with the dissolution properties of the dosage form (7,8).

The interest in this classification system stems largely from its application in early drug development and then in

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