

Biopharmaceutics Classification System: A Regulatory Approach

B. Basanta Kumar Reddy^{1,*} and A. Karunakar²

¹Regulatory Affairs Dept., Subhank Health Specialities Pvt. Ltd., (R&D) Research Laboratory, MLDIC, Tolaja, Dharwadgarh, Near Akumbal Moharashtra-430008, India

²Regulatory Affairs Department, PDD, Dr. Reddy's Laboratory, Bachupally, Hyderabad, Andhra Pradesh-502325, India

e-mail:bbasanta@redkyd@gmail.com

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 bioequivalents. 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.

*Corresponding author.

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 bioequivalents (i.e., product approval based on in vitro dissolution tests rather than bioequivalence studies in human subjects). At first, bioequivalents were only applied to scale-up and postapproval changes (SUPAC) (3), but later the bioequivalent 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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Table of Contents Biopharmaceutics Classification System A Regulatory Approach

1. Understanding the eBook Biopharmaceutics Classification System A Regulatory Approach
 - The Rise of Digital Reading Biopharmaceutics Classification System A Regulatory Approach
 - Advantages of eBooks Over Traditional Books
2. Identifying Biopharmaceutics Classification System A Regulatory Approach
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Biopharmaceutics Classification System A Regulatory Approach
 - User-Friendly Interface
4. Exploring eBook Recommendations from Biopharmaceutics Classification System A Regulatory Approach
 - Personalized Recommendations
 - Biopharmaceutics Classification System A Regulatory Approach User Reviews and Ratings
 - Biopharmaceutics Classification System A Regulatory Approach and Bestseller Lists
5. Accessing Biopharmaceutics Classification System A Regulatory Approach Free and Paid eBooks
 - Biopharmaceutics Classification System A Regulatory Approach Public Domain eBooks
 - Biopharmaceutics Classification System A Regulatory Approach eBook Subscription Services
 - Biopharmaceutics Classification System A Regulatory Approach Budget-Friendly Options
6. Navigating Biopharmaceutics Classification System A Regulatory Approach eBook Formats

- ePub, PDF, MOBI, and More
 - Biopharmaceutics Classification System A Regulatory Approach Compatibility with Devices
 - Biopharmaceutics Classification System A Regulatory Approach Enhanced eBook Features
7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Biopharmaceutics Classification System A Regulatory Approach
 - Highlighting and Note-Taking Biopharmaceutics Classification System A Regulatory Approach
 - Interactive Elements Biopharmaceutics Classification System A Regulatory Approach
 8. Staying Engaged with Biopharmaceutics Classification System A Regulatory Approach
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Biopharmaceutics Classification System A Regulatory Approach
 9. Balancing eBooks and Physical Books Biopharmaceutics Classification System A Regulatory Approach
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Biopharmaceutics Classification System A Regulatory Approach
 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
 11. Cultivating a Reading Routine Biopharmaceutics Classification System A Regulatory Approach
 - Setting Reading Goals Biopharmaceutics Classification System A Regulatory Approach
 - Carving Out Dedicated Reading Time
 12. Sourcing Reliable Information of Biopharmaceutics Classification System A Regulatory Approach
 - Fact-Checking eBook Content of Biopharmaceutics Classification System A Regulatory Approach
 - Distinguishing Credible Sources
 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
 14. Embracing eBook Trends
 - Integration of Multimedia Elements
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