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Sunita Dahiya

Globus College of Pharmacy, India

BCS: A scientific and regulatory tool in drug development process

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. Since the BCS was introduced, it has been used as a regulatory tool for the replacement of certain bioequivalence (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. BCS also plays a very significant role for the formulation pharmacist in the task of developing a new dissolution method during early investigational stages of formulation design and optimization. Furthermore, BCS based biowaiver can be requested by the sponsor during ANDAs, INDs/NDAs or for significant post approval changes. The BCS enables pharma manufacturers to reduce the cost of approving scale-up and post approval changes (SUPAC) to certain oral drug products and also replacing certain BE studies with accurate *in vitro* dissolution tests during the process of generic drug development and thus favoring the drug development process by reducing regulatory burden. In this context, BCS seems to be a systematic scientific and regulatory tool that definitely seeking attention in developing the optimal strategies from drug discovery to development.

Biography

Sunita Dahiya completed PhD in Pharmacy from UP Technical University, Lucknow. Presently, she is General Secretary, Association of Pharmacy Professionals (APP) and working as Associate Professor and HOD, Department of Pharmaceutics, Globus College of Pharmacy, Bhopal, MP, India. She has 13 years of experience in academics and guided 30 M.Pharmacy projects. She has published 25 papers in peer reviewed international and national journals and delivered lectures in workshops, conferences and staff development programs. She is reviewer in many international journals including AAPS Pharm SciTech and Clinical Therapeutics, executive editor of APP journal 'Bulletin of Pharmaceutical Research' and Editor-in-Chief of scientific newsmagazine 'APP Scientific Updates'. She has been honored with "Young Teacher Award" by SPER Women Forum for the year 2014.

drsunitadahiya@gmail.com