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Regulatory application of BCS based biowaivers and introduction to the recent BDDCS

Lina Nabulsi
The Jordanian Pharmaceutical Manufacturing Co. PLC, Jordan

Biowaivers are waivers for *in vivo* BE studies and not for bioequivalence itself. It is now almost 18 years since Amidon et al. published the theoretical basis for the BCS pharmaceutical sciences. The BCS defines three dimensionless numbers, dose number (Do), dissolution number (Dn) and absorption number (An), to characterize drug substances. These numbers represent physicochemical and physiological parameters, and cover the fundamentals of GI drug absorption. BCS has enabled the regulatory bodies to simplify and improve the drug approval process. FDA is now employing the BCS during IND and NDA approvals as well as in post-approval changes, and accepting Class 1 drug products to be waived. EMA is employing the same in its approvals but extends it approvals to biowaiver class 3 drug products. The WHO states that biowaivers can further apply to Class II weak acids, which are highly soluble at pH 6.8 but not at pH 1.2 or pH 4.5. This discrepancy in the application of the regulatory authorities proves that there are still controversial conclusions that must be resolved. Research in this domain is concentrating on presenting better bioperformance dissolution testing. Evidence is showing that pH 6.8 phosphate buffer, is not biorelevant, and that one of the most important buffers in the human GI tract is bicarbonate. On the other hand, Wu and Benet have published their results of a new classification; Biopharmaceutical Drug Disposition Classification System (BDDCS), which is complimentary to the BCS, but with a different purpose, and is expected to have a big role in the prediction of drug disposition and potential drug-drug interactions in the intestine and the liver.

Biography

Lina Nabulsi is the Technical Director at The Jordanian Pharmaceutical Manufacturing Co. Plc. (JPM) in Jordan. She holds a BSc degree from JU in Jordan and an upper diploma degree in Research Quality Assurance from University of Anglia Polytechnic/ Cambridge/UK. She has an experience of 27 years in pharmaceutical industry, covering various technical positions in the field, including Research and Development. She has various publications in different journals in this field. Her continuous interest is in bioequivalence, biowaivers as well as researching in the various regulatory challenges facing the pharmaceutical industry and its related supporting sectors.