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Reverse engineering in meeting BCS class III biowaivering requirements

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In 2010, European Medicine Agency (EMA) has adopted the biowaiver for BCS class III for the sake of simplifying approval procedures to get more and cheaper generic versions in the markets. However, meeting the current BCS class III biowaiver requirements is highly challenging where the formulation should be comprehensively investigated to meet the EMA criteria: "Excipients that might affect bioavailability are qualitatively and quantitatively the same and other excipients are qualitatively the same and quantitatively very similar."

Reverse engineering/De-formulation is the best approach to meet such criteria, in which innovative analytical techniques could be applied as: a-data Collection from literature , SmPC , innovator product label as well as patents, b-direct or indirect quantitative analysis of excipients used in formulation, c-more experimental work could be done to elaborate the grade of some functional excipients, PSD of the API, polymorphic structure, process and their role in drug release and consequently the BA/BE of the drug product.

An interesting case study will be presented to demonstrate how the BCS class III biowaiver criteria can be met utilizing the reverse engineering approach.

In- conclusion, meeting BCS class III biowaiver criteria is: a-challenging but achievable, b-provide comprehensive understanding of drug quality attributes where QbD concepts would be intensively applied, c -avoiding volunteers from unnecessary exposure to medications in BE studies, d-and most importantly is enabling generic manufacturers to reduce their development cost and provide more economic generic versions of drug products to the market.

Biography

Ala' Abu Ruqa'a earned his Bachelor in Pharmacy and Masters Degree from University of Jordan in the year 2001 and 2003 respectively. He is occupying a position of research & development manager at Hayat Pharma since 2008 with over 13 years of experience in pharmaceutical industry and research. He has special interest in biopharmaceutics including biopharmaceutical classification systems and *in-vitro* bio-assays and its applications in generic pharmaceutical development. He was capable of biowaivering of over 20 generic products which were subjected for evaluation by different health authorities.

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