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Understanding Q hypotheses for developing topical generic drugs

Hima Bindu Gottam
TOLMAR Inc, USA

Topical drug delivery is considered one of the safest and easiest drug delivery approaches for many reasons. Topical formulations are designed to deliver drugs to the skin to treat skin disease conditions or to alleviate symptoms. Developing a dermatology generic drug product involves many regulations and needs the critical understanding of the test product as well as reference product in order to make the test formulation structurally and functionally similar to the reference product. Current regulations require conducting clinical endpoint trials for demonstrating bioequivalence (BE) between topical generic and reference listed drug (RLD) products. A variety of surrogate methods have been explored but with limited success. FDA has been continuously coming up with new regulatory standards to make high quality and affordable medicines available to public and the generic industry is trying to adapt to the new requirements. Bioequivalence studies on topical products still remained one of the challenging topics in the generic industry because of two reasons: i) due to high complexity of topical dosage forms ii) due to lack of proper design of BE studies. The new GDUFA II guidance gives a clear pathway to assist generic pharmaceutical industry with identifying the most relevant methodologies for developing drugs and generating evidence needed to support ANDA approval. To develop a therapeutically equivalent drug product to a specific reference product, it is necessary to identify the key scientific principles for consistent and efficient identification of BE methods. Availability of product quality matrices i.e. Q1 (qualitatively the same), Q2 (quantitatively the same) and Q3 (microstructure/ physical attributes of the topical dosage form) is critical to demonstrate that generic topical product is therapeutically equivalent.

Biography

Bindu has completed her Bachelors in Pharmacy at the age of 21 years from Acharya Nagarjuna University, India and M.S. in Chemistry (Thesis) from Western Illinois University, US. She started her career as an Associate Scientist and worked on a variety of dosage forms including oral solutions, transdermal patches, topical dosage forms and parenteral dosage forms. She worked in generic dermatology industry for over 8 years and has more than 18 ANDA approvals in the US within the short span and 8 more products are currently under filing with the agency. She has 2 publications in reputed journals and also completed her Regulatory Affairs Certification (RAC).

bindu.gottam@tolmar.com

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