Special Issue

Bioavailability and Bioequivalence Assessment of Topical Drug Products Intended for Local Action

Message from the Guest Editors

Demonstrating bioequivalence (BE) for topical generics remains challenging due to the lack of standardized methods beyond the FDA's vasoconstrictor assay (VCA). While clinical endpoint studies are often required, recent advances focus on surrogate approaches like tape stripping, microdialysis, and in vitro tests (IVRT/IVPT). Regulatory emphasis on Q1/Q2/Q3 sameness further supports alternative BE strategies. This Special Issue on the bioavailability (BA) and bioequivalence (BE) of topical formulations intended for local action will focus on research and review papers discussing applications of validated methods used to assess the BE of topical dosage forms not intended for absorption (i.e., excluding transdermal dosage forms) and will include both in vivo and in vitro methods. We welcome articles dealing with all aspects of the BA/BE of topical dosage forms for local action, and invite researchers and drug developers to submit their original research or review articles with expert opinions and perspectives in this area.

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