Special Issue

Bioavailability and Bioequivalence of Topical Formulations

Message from the Guest Editor

The market approval of a generic product requires the demonstration of bioequivalence (BE) against an innovator reference product in order to ensure safety and efficacy. Unlike extravascular dosage forms where well-established methods and regulatory guidelines are available for BE assessment, procedures or guidelines for the BE of topical dosage forms intended for local action, apart from the US FDA's vasoconstrictor assay (VCA), are conspicuously absent. Most regulatory authorities usually require lengthy and expensive comparative clinical endpoint studies in patients. More recently, considerable efforts have been directed towards the development and validation of surrogate models to demonstrate the BE of topical products for local action and facilitate the faster entry of generic products into the market. 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 topical dosage forms not intended for absorption, and will include both in vivo and in vitro methods.

Guest Editor

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Deadline for manuscript submissions

closed (20 August 2023)

Pharmaceutics

an Open Access Journal by MDPI

Impact Factor 5.5
CiteScore 10.0
Indexed in PubMed

mdpi.com/si/136419

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an Open Access Journal by MDPI

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Indexed in PubMed

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