

Special Issue

Bioavailability and Bioequivalence of Locally Acting Colon-Targeted Products: In Vivo and In Vitro Considerations

Message from the Guest Editors

Targeting drug release to the colon has been a major research topic over the past three decades. Potential applications for colon-targeted products include localized therapy of colonic pathologies (e.g., inflammatory bowel disease and colon cancer). Multiple approaches to colonic delivery exist, such as pH-dependent, microbe-dependent, time-dependent and pressure-dependent drug delivery systems. One of the aspects that sets localized drug delivery apart from systemic drug delivery is the fact that the site of action is located before systemic circulation, making the value of traditional bioavailability and bioequivalence studies questionable. This is sometimes compounded by the poor colonic permeability of many drug substances, resulting in drug release and availability at the site of action being poorly reflected by the drug plasma concentration profile (if observable), which is then shaped by the strong rate-limiting permeation step. Therefore, research into alternative in vivo approaches as well as into in vitro testing methods that exhibit satisfactory in vivo predictivity (preferably without entailing high complexity) is often needed.

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