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Bioequivalence Assessment for Non-oral dosage forms

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Abstract:

Methods for evaluating bioequivalence (BE) of oral dosage forms have been implemented for decades now. Scientific and commercial interests however are leaning towards generic development of non-oral products, primarily owing to enhanced efforts at catering to unmet medical needs through alternate drug delivery routes and a decrease in "blockbuster" oral molecules. Though core principles remain the same, the approaches to establish equivalence vary significantly for non-oral dosage forms and have presented formidable challenges, as opposed to oral drug products. In most cases, a 'case-to-case' approach has been the need, more so if specific regulatory guidelines have not been published. While few products do have pharmacokinetic end-points governing BE criteria, most involve clinical end-point BE studies. However, the latter are difficult to conduct and even upon completion; the clinical end point studies do not necessarily ensure accuracy in differentiating formulation performance. Above reasons have in effect pushed the scientific and regulatory communities to evaluate in vitro options to establish equivalence, an essential factor in most cases being that the formulation composition is at least needed to be qualitatively and quantitatively similar to the reference listed drug product. A multidisciplinary approach to establish bioequivalence involving amalgamation of formulation, analytical, pharmacokinetic and statistical principles is utmost necessary for successful generic development based on Q3 (microstructure) based equivalence methods. This presentation will highlight approaches to establish bioequivalence for non-oral dosage forms, with an emphasis on ophthalmic, nasal and topical products.