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TITLE

BIOEQUIVALENCE METHODS For assessment of Highly Variable Drug – Abe, Sabe, Pbe and ibe

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ighly variable drugs with greater than 30% of within-subject variability have been difficult to meet current regulatory acceptance criteria of bioequivalence using a reasonable number of study subjects. Several strategies for overcoming the challenge of establishing bioequivalence (BE) for highly variable drugs (HVDs; drugs having within-subject variability > 0.3) have been considered in recent years. Previous studies presenting alternative approaches for bioequivalence evaluation of highly variable drugs have been reviewed. The presentation focused on an approach for widening the bioequivalence acceptance limits using within-subject variability. The methods for widening of bioequivalence limits based on reference variability are SABE (scaled average bioequivalence) containing within-subject variability on reference drug (σ WR), PBE (population bioequivalence) derived from total variability on reference drug (σ TR) and test drug (σ TT), and IBE (individual bioequivalence) derived from subject by formulation interaction variability (oD) and within subject variability on reference drug (σ WR) and test drug (σ TR). The switching variability (σ 0) will have to be set by the regulatory authorities for the application of above methods. We investigated whether the doxifluridine is HVDs by determination the within-subject variability of AUCt and Cmax. In addition, average bioequivalence (ABE), scaled average bioequivalence (SABE), population bioequivalence (PBE) were applied and assessed to BE study of doxifluridine for evaluation BE of HVDs. The SABE method is suggested to be the most useful method to resolve the problem of BE evaluation for highly variable drugs, and to satisfy the internationally suggested guideline in bioequivalence.

Keywords: Bioequivalence; SABE; highly variable drug; doxifluridine

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