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Overview of bioequivalence study methods with pharmacokinetics endpoint for topical Ophthalmic Corticosteroid Suspensions (OCS)

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Product-Specific Guidances (PSGs) for generic drugs recommend evaluation of Aqueous Humor (AH) Pharmacokinetics (PK) with or without *in vitro* studies of Physicochemical Properties (PCP) for biowaivers to establish bioequivalence for OCS. However, the relationships among PCP, AH PK, and patient demographics are not well understood. The objective of this research is to provide an overview of the *in vivo* human AH studies submitted to the FDA for OCS and to investigate the impact of patient demographics on the human AH PK. We summarized demographic data, PCP, PK parameters, sampling time points, and sample size per time point to investigate correlations in the studies submitted to the FDA. In the evaluation of patient-specific covariates, the Area Under The Concentration-time curves (AUC) and maximum concentrations (Cmax) were significantly different among ethnicities and age groups, which suggests that the ocular anatomical and physiological differences in various ethnicities and ages of the study population play an important role in the AH PK profiles of OCS. Gender was not primarily associated with differences in AH PK. Considering patient-specific covariate effects in designing bioequivalence studies with AH PK endpoints could reduce bias from covariate imbalance and help identify true effects of formulation differences.

Biography

Dr. Yoriko Harigaya is a clinical pharmacologist at the Division of Bioequivalence, the Office of Generic Drug, FDA. After receiving her Doctor of Pharmacy from the University at Buffalo, School of Pharmacy, New York, she completed a drug development fellowship at Glaxo SmithKline. Prior to joining the Division of Bioequivalence, she also served at the Office of Clinical Pharmacology, the Office of Translational Sciences, FDA.

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