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Draft Guidance on Valganciclovir Hydrochloride

October 2024

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Active Ingredient: Valganciclovir hydrochloride

Dosage Form: Tablet

Route: Oral

Strength: EQ 450 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 450 mg Base at a dose of EQ 900 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Females of reproductive potential should use effective contraception during the study and for at least 30 days after the last dose. Males should practice barrier contraception during the study and for at least 90 days after the last dose.

Analytes to measure: Valganciclovir and ganciclovir in plasma

Bioequivalence based on (90% CI): Valganciclovir

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution. Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

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[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*