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Draft Guidance on Valacyclovir Hydrochloride

October 2024

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Active Ingredient: Valacyclovir hydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: EQ 500 mg Base, EQ 1 GM Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 1 gm Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analytes to measure: Valacyclovir and its metabolite, acyclovir, in plasma

Bioequivalence based on (90% CI): Valacyclovir

If valacyclovir plasma concentrations can be reliably measured and its pharmacokinetic parameters accurately determined, applicants should analyze the valacyclovir data using the confidence interval approach. The acyclovir data can be used to provide supportive evidence of comparable therapeutic outcome.

If valacyclovir cannot be reliably measured, applicants should analyze the acyclovir data obtained from the studyusing the confidence interval approach.

Waiver request of in vivo testing: EQ 500 mg Base strength based on (i) acceptable bioequivalence study on the EQ 1 gm Base strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

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 both strengths 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*.