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Draft Guidance on Cinacalcet Hydrochloride

October 2024

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Active Ingredient: Cinacalcet Hydrochloride

Dosage Form: Tablets

Route: Oral

Strengths: EQ 30 mg Base, EQ 60 mg Base, EQ 90 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 90 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Females of reproductive potential should use effective contraception during the study.

Analyte to measure: Cinacalcet in plasma

Bioequivalence based on (90% CI): Cinacalcet

Waiver request of in vivo testing: EQ 30 mg Base and EQ 60 mg Base strengths based on (i) acceptable bioequivalence study on the EQ 90 mg Base strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all 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 all 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*.