Contains Nonbinding Recommendations

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Draft Guidance on Eprosartan Mesylate; Hydrochlorothiazide

October 2024

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Active Ingredients: Eprosartan mesylate; Hydrochlorothiazide

Dosage Form: Tablet

Route: Oral

Strengths: 600 mg; 12.5 mg, 600 mg; 25 mg

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: 600 mg; 25 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Females of reproductive potential should use effective contraception during the study. Include provisions for appropriate monitoring and intervention in the case of possible drug-related adverse events (e.g. subjects complaining of dizziness/lightheadedness should have blood pressure/heart rate assessed).

Analytes to measure: Eprosartan and hydrochlorothiazide in plasma

Bioequivalence based on (90% CI): Eprosartan and hydrochlorothiazide

Waiver request of in vivo testing: 600 mg; 12.5 mg strength based on (i) acceptable bioequivalence study on the 600 mg; 25 mg 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.

Document History: Recommended April 2008; Revised October 2024

Unique Agency Identifier: PSG_021268

[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*.