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Draft Guidance on Sparsentan

May 2024

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Active Ingredient: Sparsentan

Dosage Form: Tablet

Route: Oral

Strengths: 200 mg, 400 mg

Recommended Studies: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 400 mg
   Subjects: Healthy males and healthy females not of reproductive potential
   Additional comments: Exclude subjects with abnormal liver function tests. Sparsentan tablet is approved under a Risk Evaluation and Mitigation Strategy (REMS) with Elements to Assure Safe Use (ETASU), which restricts its use. All pertinent elements of the REMS/ETASU must be incorporated into the protocol and informed consent.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 400 mg
   Subjects: Healthy males and healthy females not of reproductive potential
   Additional comments: See comments above.

Analyte to measure: Sparsentan in plasma

Bioequivalence based on (90% CI): Sparsentan

Waiver request of in vivo testing: 200 mg strength based on (i) acceptable bioequivalence studies on the 400 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 and reference products. Specifications will be determined upon evaluation of the abbreviated new drug application.

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