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Draft Guidance on Abrocitinib

August 2023

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Active Ingredient: Abrocitinib

Dosage Form: Tablet

Route: Oral

Strengths: 50 mg, 100 mg, 200 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: 200 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with latent tuberculosis or abnormal blood counts. Do not use live attenuated vaccines immediately prior to or during the study.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 200 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: See comments above.

Analyte to measure: Abrocitinib in plasma

Bioequivalence based on (90% CI): Abrocitinib

Waiver request of in vivo testing: 50 mg and 100 mg strengths based on (i) acceptable bioequivalence studies on the 200 mg 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 and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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