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Draft Guidance on Pacritinib Citrate

October 2024

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Active Ingredient: Pacritinib citrate

Dosage Form: Capsule

Route: Oral

Strength: EQ 100 mg 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 100 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with latent tuberculosis, abnormal blood counts or planned surgical or invasive procedures within seven days prior to the study. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of pacritinib. Alternatively, a parallel study design may be considered.

Analyte to measure: Pacritinib in plasma

Bioequivalence based on (90% CI): Pacritinib

Waiver request of in vivo testing: Not applicable

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 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*.