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Draft Guidance on Mitapivat Sulfate

August 2023

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Active Ingredient: Mitapivat sulfate

Dosage Form: Tablet

Route: Oral

Strengths: EQ 5 mg Base, EQ 20 mg Base, EQ 50 mg Base

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: EQ 50 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None
2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 50 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None

Analyte to measure: Mitapivat in plasma

Bioequivalence based on (90% CI): Mitapivat

Waiver request of in vivo testing: EQ 5 mg Base and EQ 20 mg Base strengths based on (i) acceptable bioequivalence studies on the EQ 50 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 and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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