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Draft Guidance on Lenacapavir Sodium

February 2024

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Active Ingredient: Lenacapavir sodium

Dosage Form: Tablet

Route: Oral

Strength: EQ 300 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 300 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with abnormal liver function tests. Ensure an adequate washout period between treatments in a crossover study due to long elimination half-life of lenacapavir. Alternatively, a parallel study design may be considered.

2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 300 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: See comments above.

Analyte to measure: Lenacapavir in plasma

Bioequivalence based on (90% CI): Lenacapavir

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 each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended February 2024

Unique Agency Identifier: PSG_215974