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Draft Guidance on Leniolisib Phosphate

August 2024

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Active Ingredient: Leniolisib phosphate

Dosage Form: Tablet

Route: Oral

Strength: EQ 70 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 70 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Females of reproductive potential should use non-hormonal contraception during the study and continue to use effective contraception for one week after the last dose. Subjects should be informed not to use live attenuated vaccines immediately prior to or during the study.

Analyte to measure: Leniolisib in plasma

Bioequivalence based on (90% CI): Leniolisib

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: Recommend August 2024

Unique Agency Identifier: PSG_217759