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Draft Guidance on Asciminib Hydrochloride

August 2023

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Active Ingredient: Asciminib hydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: EQ 20 mg Base, EQ 40 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 40 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Exclude subjects with abnormal complete blood counts. Exclude subjects with a history of pancreatitis or abnormal pancreatic enzymes (e.g., amylase and lipase). 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.

Analyte to measure: Asciminib in plasma

Bioequivalence based on (90% CI): Asciminib

Waiver request of in vivo testing: EQ 20 mg Base strength based on (i) acceptable bioequivalence study on the EQ 40 mg Base strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both 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 each of both strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.

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