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Draft Guidance on Tepotinib Hydrochloride

November 2022

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Active Ingredient: Tepotinib hydrochloride

Dosage Form; Route: Tablet; oral

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 225 mg Base
   Subjects: Healthy males and females not of reproductive potential
   Additional comments: Exclude subjects with abnormal liver function tests. Male subjects with female partners of reproductive potential should use effective contraception during the study and for two weeks after the last dose. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of tepotinib. 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 225 mg Base
   Subjects: Healthy males and females not of reproductive potential
   Additional comments: See comments above.

Analyte to measure: Tepotinib in plasma

Bioequivalence based on (90% CI): Tepotinib

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 (ANDA).

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