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Draft Guidance on Berotralstat Hydrochloride

October 2024

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Active Ingredient: Berotralstat hydrochloride

Dosage Form: Capsule

Route: Oral

Strengths: EQ 110 mg Base, EQ 150 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 150 mg Base
Subjects: Healthy males and non-pregnant and non-lactating females
Additional comments: Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of berotralstat. Alternatively, a parallel study design may be considered.

Analyte to measure: Berotralstat in plasma

Bioequivalence based on (90% CI): Berotralstat

Waiver request of in vivo testing: EQ 110 mg Base strength based on (i) acceptable bioequivalence study on the EQ 150 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 for each of both strengths of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended August 2022; Revised October 2024

Unique Agency Identifier: PSG_214094

¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.