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Draft Guidance on Elacestrant Dihydrochloride

October 2024

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Active Ingredient: Elacestrant dihydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: EQ 86 mg Base, EQ 345 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 345 mg Base
   Subjects: Healthy males and healthy postmenopausal females
   Additional comments: 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 elacestrant. Alternatively, a parallel study design may be considered.

Analyte to measure: Elacestrant in plasma

Bioequivalence based on (90% CI): Elacestrant

Waiver request of in vivo testing: EQ 86 mg Base strength based on (i) acceptable bioequivalence study on the EQ 345 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.

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[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.*