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Draft Guidance on Elacestrant Dihydrochloride

May 2024

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Active Ingredient: Elacestrant dihydrochloride

Dosage Form: Tablet

Route: Oral

Strengths: EQ 86 mg Base, EQ 345 mg Base

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 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.

2. 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: See comments above.

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 studies 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 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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