

Draft Guidance on Elagolix Sodium

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Elagolix sodium

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 200 mg Base
Subjects: Non-pregnant, non-lactating premenopausal females, general population
Additional comments: None

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2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 200 mg Base
Subjects: Non-pregnant, non-lactating premenopausal females, general population
Additional comments: None
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Analyte to measure (in appropriate biological fluid): Elagolix in plasma

Bioequivalence based on (90% CI): Elagolix

Waiver request of in vivo testing: EQ 150 mg Base based on (i) acceptable bioequivalence Studies on the 200 mg strength, (ii) proportional similarity of the formulations across both strengths, and (iii) acceptable in vitro dissolution testing of both strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each strength of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.