

Draft Guidance on Etravirine

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Etravirine

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 200 mg
Subjects: Normal healthy males and non-pregnant females, general population.
Additional Comments: Females should not be lactating, and if applicable, should practice abstinence or contraception during the study.

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2. Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: 200 mg
Subjects: Normal healthy males and non-pregnant females, general population.
Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Guidance for additional information regarding fed studies.

Analytes to measure (in appropriate biological fluid): Etravirine in plasma.

Bioequivalence based on (90% CI): Etravirine

Waiver request of in-vivo testing: 25 mg and 100 mg based on (i) acceptable fasting and fed BE studies on the 200 mg strength, (ii) proportional similarity in the formulations across both strengths, and (iii) acceptable dissolution testing across both strengths.

Dissolution test methods and sampling times: Please note that a Dissolution Method Database is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please 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 application.