Contains Nonbinding Recommendations

Guidance on Eletriptan Hydrobromide

This guidance represents 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: Eletriptan Hydrobromide

Form/Route: Tablets/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover in-vivo
   Strength: 40 mg base Eq
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments:

2. Type of study: Fed
   Design: Single-dose, two-way, crossover in-vivo
   Strength: 40 mg base Eq
   Subjects: Healthy males and nonpregnant females, general population.
   Additional comments:

Analytes to measure: Eletriptan in plasma

Bioequivalence based on (90% CI): Eletriptan

Waiver request of in-vivo testing: 20 mg base Eq based on (i) acceptable bioequivalence studies on the 40 mg base Eq strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across all strengths.

Dissolution test method and sampling times:

Please note that a Dissolution Methods 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 all strengths of the test and reference products. Specifications will be determined upon review of the application.

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