Contains Nonbinding Recommendations

Draft Guidance on Fexofenadine Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Fexofenadine Hydrochloride

Form/Route: Suspension/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 30 mg/5 ml
   Subjects: Normal healthy males and females, general population
   Additional Comments:

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2. Type of study: Fed
   Design: Single-dose, two-way, crossover *in-vivo*
   Strength: 30 mg/5 ml
   Subjects: Normal healthy males and females, general population
   Additional comments:

Analytes to measure: Fexofenadine in plasma using and achiral assay.

Bioequivalence based on (90% CI): Fexofenadine

Waiver request of in-vivo testing: Not Applicable

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.fda.gov/cder/ogd/index.htm. Please find the dissolution information for this product at this website. Please note that a dosage unit is based on the labeled concentration of the suspension product. Please use the dosage unit (5 ml). A total of 12 units from 12 different bottles should be used. Specifications will be determined upon review of the application.