Contains Nonbinding Recommendations

Draft Guidance on Fexofenadine Hydrochloride

Active ingredient: Fexofenadine Hydrochloride

Form/Route: Orally Disintegrating Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two-way crossover *in vivo*
Strength: 30 mg
Subjects: Normal healthy males and females, general population
Additional Comments: Females should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study.
The whole tablet should be placed on the tongue and allowed to disintegrate for 30 seconds. After 30 seconds, all subjects should consume 240 mL of water.

Analytes to measure (in appropriate biological fluid): Fexofenadine in plasma

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 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.