Contains Nonbinding Recommendations

Guidance on Deferasirox

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: Deferasirox

Form/Route: Tablets for Oral Suspension

Recommended studies: 1 study

Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 500 mg
Subjects: Normal healthy males and females, general population
Additional Comments: The following passage is reproduced from the Dosage and Administration section of the labeling:
Tablets should be completely dispersed by stirring in water, orange juice, or apple juice until a fine suspension is obtained. Doses of < 1 g should be dispersed in 3.5 ounces of liquid and doses of > 1 g in 7.0 ounces of liquid. After swallowing the suspension, any residue should be re-suspended in a small volume of liquid and swallowed. Tablets should not be chewed or swallowed whole.

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

Bioequivalence based on (90% CI): Deferasirox

Waiver request of in-vivo testing: 250 mg and 125 mg tablets based on (i) acceptable bioequivalence studies on the 500 mg strength, (ii) proportionally similar across all strengths, and (iii) acceptable in vitro dissolution testing of 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.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.