Contains Nonbinding Recommendations

Draft Guidance on Deferasirox

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Deferasirox

Dosage Form; Route: Granule; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 360 mg
   Subjects: Males and non-pregnant, non-lactating females, general population.

   Additional Comments: None

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 360 mg
   Subjects: Males and non-pregnant, non-lactating females, general population.

   Additional Comments: Fed study should be conducted using a standard high fat meal.

Analyte to measure (in appropriate biological fluid): Deferasirox

Bioequivalence based on (90% CI): Deferasirox

Waiver request of in-vivo testing: 90 mg and 180 mg strengths based on (i) acceptable bioequivalence studies on the 360 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).