

Draft Guidance on Deferasirox

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 360 mg
Subjects: Healthy males and female (non-pregnant), general population
Additional Comments: See comments below.

2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 360 mg
Subjects: Healthy males and females (non-pregnant), general population
Additional Comments: Tablets should not be chewed or crushed; swallow the whole tablet. Fed study should be conducted using a standard high fat meal.

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

Bioequivalence based on (90% CI): Deferasirox

Waiver request of in-vivo testing: 180 mg and 90 mg tablets based on (i) acceptable bioequivalence studies on the 360 mg strength, (ii) proportionally similar 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 all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).