Contains Nonbinding Recommendations

Draft Guidance on Tinidazole

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 500 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: None

---

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 500 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: None

Analyte to measure (in appropriate biological fluid): Tinidazole in plasma

Bioequivalence based on (90% CI): Tinidazole

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

Dissolution testing to document bioequivalence:
Apparatus: USP Apparatus 1 (basket)
Rotation speed: 100 rpm
Medium: 0.1N HCl (or 0.1N HCl with NaCl) at pH 1.2, pH 4.5 acetate buffer, pH 6.8 phosphate buffer, and water
Volume: 900 mL
Temperature: 37°C
Sample times: 5, 10, 15, 20, 25, 30, and 40 min or as needed for profile comparisons
Additional comments: All raw data (test and reference products) should be submitted with means at each sampling point, the range (minimum and maximum values), the percentage of coefficient

of variation (%CV), and f2 value tabulated (if appropriate). The dissolution testing should be conducted on 12 units from the same lot numbers that are used in the in vivo bioequivalence study.

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.