Contains Nonbinding Recommendations

Draft Guidance on Terbinafine Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Terbinafine Hydrochloride

Form/Route: Granules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover *in vivo*
   Strength: 187.5 mg, free base
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: The test and reference products should be administered by sprinkling the granules on a spoonful of pudding or other soft, non-acidic food such as mashed potatoes and swallowed in the entirety (without chewing). Do not use applesauce or fruit-based foods.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover *in vivo*
   Strength: 187.5 mg free base
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: Please see comments above. The test and reference products should be administered 30 minutes after start of the meal.

Analytes to measure (in appropriate biological fluid): Terbinafine in plasma.

Bioequivalence based on (90% CI): Terbinafine

Waiver request of *in-vivo* testing: 125 mg (base) based on (i) acceptable bioequivalence studies on the 187.5 mg (base) strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across all strengths.

Dissolution test method and sampling times: Please note that **Dissolution Method 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.