*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

# Draft Guidance on Terbinafine Hydrochloride

**October 2024**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

---

**Active Ingredient:** Terbinafine hydrochloride

**Dosage Form:** Granule

**Route:** Oral

**Strengths:** EQ 125 mg Base/packet; EQ 187.5 mg Base/packet

**Recommended Study:** One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 187.5 mg Base/packet
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Sprinkle 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. Administer the drug 30 minutes after start of the meal.

**Analyte to measure:** Terbinafine in plasma

**Bioequivalence based on (90% CI):** Terbinafine

**Waiver request of in vivo testing:** EQ 125 mg Base/packet strength based on (i) an acceptable bioequivalence study on the EQ 187.5 mg Base/packet strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

**Dissolution test method and sampling times:** The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, http://www.accessdata.fda.gov/scripts/cder/dissolution/. Conduct comparative dissolution testing on 12 dosage units for each of the test product and reference listed drug (RLD).[1] Specifications will be determined upon review of the abbreviated new drug application.

---

**Document History:** Recommended April 2009; Finalized October 2011; Revised October 2024

**Unique Agency Identifier:** PSG_022071

[1] If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions.*