

Draft Guidance on Ciclopirox

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Solution/Topical

I. Waiver option:

- a. To qualify for a waiver of the in vivo bioequivalence study requirement under 21 CFR 320.22(b)(3), generic versions of Ciclopirox Topical Solution, 8% must contain the same active drug ingredient in the same concentration and dosage form as the Reference Listed Drug (RLD) and contain no inactive ingredient or other change in formulation from the RLD that may significantly affect systemic or local availability.
- b. For a topical drug product that differs from the RLD in inactive ingredients [as permitted by the chemistry, manufacturing and controls regulations for abbreviated new drug applications, 21 CFR 314.94(a)(9)(v)], the regulation specifies that the applicant must identify and characterize the differences and provide information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.
- c. Since the resin imparts important characteristics to the formulation and hence the nail coat, it is important that data be provided showing the polymeric resin has similar physico-chemical properties as the RLD (e.g., molecular weight distribution, number of butyl groups/g of resin).

II. In Vivo option:

Recommended studies: 1 study

Type of study: Bioequivalence (BE) with Clinical Endpoint Study

Design: Randomized, double blind, parallel, placebo-controlled in vivo

Strength: 8%

Subjects: Healthy, immunocompetent males and females with mild to moderate onychomycosis of fingernails and/or toenails

Additional comments: FDA recommends submitting a protocol for review and comment prior to conducting the study.

Analytes to measure (in appropriate biological fluid): Not Applicable.

Bioequivalence based on (90% CI): Clinical endpoint (in vivo option).

Dissolution test method and sampling times: Not Applicable.