Contains Nonbinding Recommendations

Draft Guidance on Ciclopirox

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Recommended studies:

I. Waiver option:

a. The requirements for in vivo bioequivalence studies for Ciclopirox Shampoo, 1% may be waived as per 21 CFR 320.22(b)(3), provided the generic drug product contains no inactive ingredient or other change in formulation from the RLD that may significantly affect systemic or local availability. The applicant must characterize the differences and provide information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product (21 CFR 314.94(a)(9)(v)). If the generic drug product has different inactive ingredients compared to the RLD, then the Office of Generic Drugs requests a clinical endpoint study to determine bioequivalence between the products.

b. For products applied to the scalp, differences in surfactants or potential penetration enhancers may change the distribution of the product over the scalp or penetration of the drug into the diseased tissues. Therefore, clinical endpoint bioequivalence studies are requested for generic shampoo products with differences in these ingredients that are proportionally more than +/- 5% compared to the RLD.

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: 1%
Subjects: Healthy males and females with seborrheic dermatitis of the scalp.
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