

Contains Nonbinding Recommendations

Draft Guidance on Erythromycin

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Swab/Topical 2%

Recommended study: Request for Waiver of In vivo Bioequivalence Study Requirements

Bioequivalence study recommendations:

To qualify for a waiver of the in vivo bioequivalence (BE) study requirements under 21 CFR 320.22(b)(3), a generic erythromycin topical solution product must have the same active ingredient in the same concentration as the reference listed drug product (RLD) and no inactive ingredient or other change in formulation from the RLD that may significantly affect local or systemic availability of the active drug.

All ingredients in the test and reference formulations are to be compared using the same units, either %w/w or %w/v.

In 21 CFR 314.94(a)(9)(v), the regulation specifies that the applicant must identify and characterize any formulation differences and provide information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product. In addition, adequate information must be provided to ensure that the composition of the pledgets will not affect the performance of the product.