Contains Nonbinding Recommendations

Draft Guidance on Erythromycin

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Active Ingredient: Erythromycin

Dosage Form; Route: Gel; topical

Recommended Studies: Acceptable comparative physicochemical characterization of the test and reference standard (RS) formulations of the product to establish that the test product is pharmaceutically equivalent to the RS with the identical strength

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

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: Not Applicable

Dissolution test method and sampling times: Not Applicable