

Draft Guidance on Lidocaine

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Ointment; topical

Recommended studies:

1. The test and Reference Listed Drug (RLD) formulations should be qualitatively and quantitatively the same (Q1/Q2). The test product should contain the same inactive ingredients in the same quantitative composition ($\pm 5\%$ of the RLD concentration of that inactive ingredient), and no concentration of any inactive ingredient should exceed the allowed limit listed in the inactive ingredient database for the applicable route of administration.
2. Acceptable comparative physicochemical characterization of the test and RLD formulations of the product to establish that the test product is pharmaceutically equivalent¹ to the RLD with identical strength.

Due to the potential safety concerns, if the generic version of Lidocaine Ointment, 5% is not Q1/Q2 the same as the RLD, the sponsor should clearly characterize the differences in inactive ingredients and provide sufficient scientific evidence that the difference will not change the local or systemic availability of the drug or otherwise change the safety or efficacy of the product.

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

¹ Orange Book Preface, Section 1.2 which defines “Pharmaceutical Equivalents”