

Draft Guidance on Triamcinolone Acetonide

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Paste/Dental

Recommended studies:

Triamcinolone Acetonide Dental Paste is a DESI¹ effective drug for which there is no known or suspected bioequivalence problem, and as such is rated “AT” in FDA/CDER’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”).

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

Bioequivalence based on (90% CI): Not Applicable

Waiver request of in-vivo testing: The applicant may request a waiver of in-vivo testing under 21 CFR 320.22(c), provided that the ingredient composition of the proposed product is similar to that of the reference product. If the ingredient composition is not similar, then the firm must demonstrate that the changes in the formulation will not impact the safety and efficacy of the proposed product.

¹ Drug Efficacy Study Implementation