

Draft Guidance on Triamcinolone Acetonide

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Paste; dental

Recommended Studies: Acceptable comparative physicochemical characterization of the test and reference standard (RS) formulations of the product to establish that the test product is a comparable triamcinolone acetonide dental paste and of identical strength as the RS paste.

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