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Draft Guidance on Triamcinolone Acetonide

October 2022

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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Active Ingredient: Triamcinolone acetonide

Dosage Form; Route: Ointment; topical

Recommended Studies: Characterization tests

Acceptable comparative physicochemical and structural (Q3) characterization of the test product and reference standard should establish that they are the same dosage form, with identical strength. Refer to the most recent version of the FDA guidance for industry on *Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs*[a] for additional information regarding appropriate comparative Q3 characterization tests.

Revision History: Recommended April 2016 (0.10% Strength)
Recommended October 2016 (0.50% Strength)
Recommended July 2017 (0.025% Strength)
Merged October 2022

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[a] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.