

Draft Guidance on Betamethasone Dipropionate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Lotion (augmented); topical

Recommended Studies: A waiver of the requirement for the submission of evidence obtained in vivo measuring bioavailability or demonstrating bioequivalence may be requested in situations where the proposed drug product meets all the requirements specified in 21 CFR 320.22(b)(3). Alternatively, in situations where the proposed drug product contains a change in formulation from the reference listed drug product that may significantly affect the systemic or local availability of the active ingredient, two vasoconstrictor studies are recommended.

1. Type of study: Pilot vasoconstrictor study
Design: A pilot dose duration-response study using the reference product
Strength: 0.05%
Subjects: Healthy males and nonpregnant, nonlactating females, general population
Additional comments: Please refer to the guidance “Topical Dermatological Corticosteroids: In Vivo Bioequivalence” available at:
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm070234.pdf>.

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2. Type of study: Pivotal vasoconstrictor study
Design: A pivotal bioequivalence study
Strength: 0.05%
Subjects: Healthy males and nonpregnant, nonlactating females, general population
Additional comments: Please refer to the guidance above
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Analytes to measure (in appropriate biological fluid): N/A

Bioequivalence based on (90% CI): Pivotal vasoconstrictor study

Waiver request of in vivo testing: A waiver of the in vivo studies listed above may be requested in accordance with 21 CFR 320.22(b).

Dissolution test method and sampling times: N/A