

## Draft Guidance on Betamethasone Dipropionate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Recommended Studies:** Two studies.

1. Type of study: Pilot vasoconstrictor study  
Design: A pilot dose duration-response study using the reference product  
Strength: EQ 0.05% Base  
Subjects: Males and non-pregnant, non-lactating females, general population

**Additional comments:**

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: EQ 0.05% Base  
Subjects: Males and non-pregnant, non-lactating females, general population  
Additional comments: See comments above
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**Analytes to measure (in appropriate biological fluid):** Not applicable

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

**Waiver request of in vivo testing:** Not applicable

**Dissolution test method and sampling times:** Not applicable