

## **Draft Guidance on Hydrocortisone butyrate**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Lotion; topical

**Recommended Studies:** Two studies

1. Type of study: Pilot vasoconstrictor study  
Design: A pilot dose duration-response study using the reference product under un-occluded conditions  
Strength: 0.1%  
Subjects: Healthy males and non-pregnant, non-lactating females, general population  
Additional Comments: Refer to the guidance “Topical Dermatological Corticosteroids: In Vivo Bioequivalence”
2. Type of study: Pivotal vasoconstrictor study  
Design: A pivotal bioequivalence study under un-occluded conditions  
Strength: 0.1%  
Subjects: Healthy 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 sample times:** Not applicable