

## **Draft Guidance on Clobetasol Propionate**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Ointment; topical

**Recommended Studies:** Two studies

1. Type of study: Pilot vasoconstrictor study  
Design: Pilot dose duration-response study using the reference product under un-occluded conditions  
Strength: 0.05%  
Subjects: Healthy males and nonpregnant, nonlactating 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>.
2. Type of study: Pivotal vasoconstrictor study  
Design: Pivotal in vivo bioequivalence study under un-occluded conditions  
Strength: 0.05%  
Subjects: Healthy males and nonpregnant, nonlactating females, general population  
Additional comments: See comments above.

---

**Analytes to measure (in appropriate biological fluid):** N/A

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

**Waiver request of in vivo testing:** N/A

**Dissolution test method and sampling times:** N/A