Contains Nonbinding Recommendations

Draft Guidance on Hydrocortisone Valerate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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 condition
   Strength: 0.2%
   Subjects: Healthy males and non-pregnant, non-lactating females, general population
   Additional comments: 1. Female subjects should not be pregnant or lactating, and if applicable, should practice abstention or contraception during the study. 2. 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: Pivotal in vivo bioequivalence study under un-occluded condition
   Strength: 0.2%
   Subjects: Healthy males and non-pregnant, non-lactating females, general population
   Additional comments: See the comments above.

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