Contains Nonbinding Recommendations

Draft Guidance on Desoximetasone

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Desoximetasone

Form/Route: Ointment/Topical

Recommended studies: 4 studies

1. Type of study: Vasoconstrictor Study
   Design: Pilot dose duration-response study under un-occluded conditions.
   Strength: 0.05%
   Subjects: Healthy males and nonpregnant 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: Vasoconstrictor Study
   Design: Pivotal in vivo bioequivalence study under un-occluded conditions.
   Strength: 0.05%
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: Please see comment above.

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3. Type of study: Vasoconstrictor Study
   Design: Pilot dose duration-response study under un-occluded conditions.
   Strength: 0.25%
   Subjects: Healthy males and nonpregnant females, general population.
   Additional Comments: Please see comment above.

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4. Type of study: Vasoconstrictor Study
   Design: Pivotal in vivo bioequivalence study under un-occluded conditions.
   Strength: 0.25%
   Subjects: Healthy males and nonpregnant females, general population.

Additional Comments: Please see comment above.

Analytes to measure (in appropriate biological fluid): Not Applicable

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

Waiver request of in vivo testing: Not Applicable

Dissolution test method and sampling times: Not Applicable