Contains Nonbinding Recommendations

Draft Guidance on Fluticasone Propionate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 the 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: Fluticasone Propionate

Form/Route: Cream/Topical

Strength: 0.05%

Recommended studies: 2 studies

1. Type of study: Pilot Vasoconstrictor Study
   Design: A pilot dose duration-response study using the reference product
   Strength: 0.05%
   Subjects: Healthy males and 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.

---

2. Type of study: Pivotal Vasoconstrictor Study
   Strength: 0.05%
   Subjects: Healthy males and females, general population
   Additional comments: Refer to the guidance above

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

Bioequivalence based on (90% CI): Vasoconstrictor assay studies (pilot dose duration-response study followed by the pivotal in vivo bioequivalence study)

Waiver request of in vivo testing: Not Applicable

Dissolution test method and sampling times: Not Applicable