Contains Nonbinding Recommendations

Draft Guidance on Clocortolone Pivalate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Clocortolone pivalate
Dosage Form; Route: Cream; topical
Recommended Studies: Two studies

1. Type of study: Pilot Vasoconstrictor Study
   Design: Pilot dose duration-response study using the reference product
   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”. Occluded study conditions may be used if minimal skin blanching is observed in preliminary pilot dose-duration studies for this drug product

2. Type of study: Pivotal Vasoconstrictor Study
   Design: Pivotal in vivo bioequivalence study
   Strength: 0.1%
   Subjects: Healthy males and non-pregnant, non-lactating females, general population
   Additional comments: See comments 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