

Draft Guidance on Clocortolone Pivalate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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