

Draft Guidance on Halcinonide

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Ointment; topical

Recommended Studies: Two studies

1. Type of study: Pilot vasoconstrictor study
Design: A pilot dose duration-response study using the reference product under un-occluded conditions
Strength: 0.1%
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: Refer to the guidance “Topical Dermatological Corticosteroids: In Vivo Bioequivalence”.

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2. Type of study: Pivotal vasoconstrictor study
Design: A pivotal bioequivalence study under un-occluded conditions
Strength: 0.1%
Subjects: Males and non-pregnant, non-lactating females, general population
Additional comments: See comments above
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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

Applicants intending to propose an alternative approach by which to demonstrate bioequivalence should refer to the guidance for industry *Controlled Correspondence Related to Generic Drug Development* and the guidance for industry *Formal Meetings Between FDA and ANDA Applicants of Complex Products Under GDUFA* for additional information describing the procedures on how to clarify regulatory expectations regarding your individual drug development program.