Contains Nonbinding Recommendations

Draft Guidance on Mometasone Furoate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Lotion; topical

Recommended Studies: A waiver of the requirement for the submission of evidence obtained in vivo measuring bioavailability or demonstrating bioequivalence may be requested in situations where the proposed drug product meets all the requirements specified in 21 CFR 320.22(b)(3). Alternatively, in situations where the proposed drug product contains a change in formulation from the Reference Listed Drug (RLD) product that may significantly affect the systemic or local availability of the active ingredient, two vasoconstrictor studies are recommended.

I. Waiver option:

a. To qualify for a waiver of the in vivo bioequivalence study requirement under 21 CFR 320.22(b)(3), generic versions of Mometasone Furoate Topical Lotion, 0.1% must be a solution and contain the same active drug ingredient in the same concentration and dosage form as the Reference Listed Drug (RLD) and must not have an inactive ingredient or other change in formulation from the RLD that may significantly affect systemic or local availability.

b. For a topical drug product with inactive ingredients that differ from the RLD or are present in significantly different amounts [as permitted by the chemistry, manufacturing and controls regulations for abbreviated new drug applications, 21 CFR 314.94(a)(9)(v)], the regulation specifies that the applicant must identify and characterize the formulation differences and provide information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.

II. In Vivo option:

1. Type of study: pilot vasoconstrictor study
   Design: Pilot dose duration-response study using the reference product under un-occluded conditions
   Strength: 0.1%
   Subjects: Healthy males and females (non-pregnant, non-lactating), general population
   Additional comments: 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
   Design: Pivotal in vivo bioequivalence study under un-occluded conditions
   Strength: 0.1%
   Subjects: Healthy males and females (non-pregnant, non-lactating), 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, when applicable

Waiver request of in vivo testing: A waiver of the in vivo studies listed above may be requested in accordance with 21 CFR 320.22(b).

Dissolution test method and sampling times: Not Applicable