Contains Nonbinding Recommendations

Draft Guidance on Hydrocortisone

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Solution; 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).

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 Hydrocortisone Topical Solution, 2.5% 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. Acceptable physicochemical characterization of the test formulation is recommended for the product to establish that the test product is a comparable hydrocortisone topical solution identical in strength to the RLD.

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.

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

Bioequivalence based on (90% CI): Not 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)(3).

Dissolution test method and sampling times: Not applicable