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Draft Guidance on Hydrocortisone

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Recommended studies: Acceptable comparative physicochemical characterization of the test and reference standard (RS) formulations of the product to establish that the test product is pharmaceutically equivalent[1] to the RS (Hydrocortisone topical cream, 2.5%) with identical strength.

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

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: Not Applicable

Dissolution test method and sampling times: Not Applicable

[1] Orange book: Approved drug products with therapeutic equivalence evaluations Preface, Section 1.2 which defines "Pharmaceutical Equivalents"