

Contains Nonbinding Recommendations

Draft Guidance on Dexamethasone

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Concentrate (Solution); Oral

Recommended studies: None

Analytes to measure (in appropriate biological fluid): None.

Bioequivalence based on (90% CI): N/A

Waiver request of in-vivo testing: 1 mg/mL strength oral solution based on 21 CFR 320.22 (b)(3).

Dissolution test method and sampling times: N/A