

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Dexamethasone

October 2024

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Active Ingredient: Dexamethasone

Dosage Form: Tablet

Route: Oral

Strengths: 0.5 mg, 0.75 mg, 1 mg, 1.5 mg, 2 mg, 4 mg, 6 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 6 mg
Subjects: Healthy males and non-pregnant non-lactating females
Additional comments: None

Analyte to measure: Dexamethasone in plasma

Bioequivalence based on (90% CI): Dexamethasone

Waiver request of in vivo testing: 0.5 mg, 0.75 mg, 1 mg, 1.5 mg, 2 mg, and 4 mg strengths based on (i) acceptable in vivo bioequivalence study on the 6 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity in the formulations of all strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

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¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.