

Draft Guidance on Dexamethasone

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient Dexamethasone

Form/ Route: Tablet/Oral

Recommend studies: 2 studies

1. Type of study: Fasting
 Design: Single-dose, two-way crossover in-vivo
 Strength: 6 mg
 Subjects: Healthy males and nonpregnant females, general population.
 Additional Comments:

2. Type of study: Fed
 Design: Single-dose, two-way crossover in-vivo
 Strength: 6 mg
 Subjects: Healthy males and nonpregnant females, general population
 Additional Comments:

Analytes to measure (in appropriate biological fluid): Dexamethasone in plasma

Bioequivalence based on (90% CI): Dexamethasone

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

Dissolution test method and sampling times:

Please note that a Dissolution Methods Database is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.