

Draft Guidance on Betamethasone Acetate; Betamethasone Sodium Phosphate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Betamethasone Acetate; Betamethasone Sodium Phosphate

Form/Route: Injectable Suspension/Injection

Recommended studies: 1 study

Type of study: Fasting

Design: Single-dose, two-way crossover *in-vivo*

Strength: 3 mg/mL; Eq 3 mg Base/mL

Subjects: Healthy males and nonpregnant females, general population.

Additional Comments:

Analytes to measure (in appropriate biological fluid): Betamethasone, Betamethasone Acetate, and Betamethasone Phosphate in plasma.

Bioequivalence based on (90% CI): Betamethasone

Please submit data for the pro-drugs (Betamethasone Acetate and Betamethasone Phosphate) as supportive evidence of comparable therapeutic outcome. For the pro-drugs, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and C_{max}.

Waiver request of in-vivo testing: Not Applicable

Dissolution test method and sampling times:

Please note that **Dissolution Method Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm>. 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.