

Contains Nonbinding Recommendations
Draft Guidance on Prednisolone Acetate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Suspension/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in vivo*
Strength: 15 mg/5 mL, prednisolone base
Subjects: Healthy males and females, general population.
Additional Comments:

2. Type of study: Fed
Design: Single-dose, two-way crossover *in vivo*
Strength: 15 mg/5 mL, prednisolone base
Subjects: Healthy males and females, general population.
Additional Comments: Please see Additional Comments above.

Analytes to measure (in appropriate biological fluid): Prednisolone in plasma.

Bioequivalence based on (90% CI): Prednisolone

Waiver request of *in-vivo* testing: 5 mg (base)/5 mL (see below) based on (i) acceptable bioequivalence studies on the 15 mg (base)/5 mL strength, (ii) proportional similarity in formulation across all strengths, and (iii) acceptable *in vitro* dissolution testing across 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.

5 mg (base)/5 mL = Discontinued Strength

Please note that Prednisolone Acetate Oral Suspension, 5 mg (base)/5 mL, has been discontinued from the market. If you would like to market the 5 mg (base)/5 mL strength, please submit a Citizen Petition pursuant to 21 CFR. 314.122, requesting that the FDA determine whether this strength was discontinued due to safety and/or effectiveness reasons. Please follow the Citizen Petition format outlined in 21 CFR 10.20 and 10.30. If the FDA determines that it was not withdrawn for safety and/or effectiveness reasons, you may request a waiver of *in-vivo* bioequivalence testing for the 5 mg (base)/5 mL strength based on (1) acceptable bioequivalence studies on the 15 mg (base)/5 mL strength, (2) acceptable dissolution testing on the 5 mg (base)/5 mL and 15 mg (base)/5 mL strengths, and (3) proportional similarity in the formulations of the 5 mg (base)/5 mL and 15 mg (base)/5 mL strengths.