Draft Guidance on Methylprednisolone Acetate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Dosage Form; Route: Suspension; injection

Recommended Studies: Two studies

1.   Type of study: Fasting
       Design: Single-dose, two-way crossover, in vivo; or single-dose, parallel, in vivo
       Strength: 80 mg/mL (multi-dose vials)
       Subjects: Healthy males and nonpregnant females, general population
       Additional comments: None

2.   Type of study: Fasting
       Design: Single-dose, two-way crossover, in vivo; or single-dose, parallel, in vivo
       Strength: 80 mg/mL (single-dose vials)
       Subjects: Healthy males and nonpregnant females, general population
       Additional comments: None

Analytes to measure: Methylprednisolone in plasma

Bioequivalence based on (90% CI): Methylprednisolone

Waiver request of in vivo testing: 20 mg/mL, 40 mg/mL (multi-dose vials) and 40 mg/mL (single-dose vial) based on (i) acceptable bioequivalence studies on the respective 80 mg/mL strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across all strengths.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods website available to the public at the following location: http://www.accessdata.fda.gov/scripts/cder/dissolution/. 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 abbreviated new drug application (ANDA).