

Draft Guidance on Methylprednisolone

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Methylprednisolone

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 32 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional Comments: None

2. Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: 32 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None

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

Bioequivalence based on (90% CI): Methylprednisolone

Waiver request of in-vivo testing: 2 mg, 4 mg, 8 mg, and 16 mg based on (i) acceptable bioequivalence studies on the 32 mg strength, (ii) proportional similarity of the formulations across all strengths and (iii) acceptable in vitro dissolution testing of 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).

All strengths of methylprednisolone tablets are scored. Additional dissolution testing on the scored methylprednisolone tablets is recommended for all strengths. For additional information on the evaluation of scored tablets, refer to the FDA Guidance on "Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation" issued in March 2013 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269921.pdf>.