

Draft Guidance on Mycophenolic Acid

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Mycophenolic acid

Dosage Form; Route: Delayed release tablets; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 360 mg
Subject: Healthy males
Additional comments: None

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2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 360 mg
Subject: Healthy males
Additional comments: None
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Analytes to measure (in appropriate biological fluid): Mycophenolic acid in plasma

Bioequivalence based on (90% CI): Mycophenolic acid

Waiver request of in vivo testing: 180 mg based on (i) acceptable bioequivalence study on the 360 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations.

Dissolution test method and sampling times: The dissolution information for this drug product can be found on the FDA-Recommended Dissolution Methods web site, 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).