

Draft Guidance on Mycophenolate Mofetil

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Capsule; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 250 mg
Subjects: Males, general population
Additional comments: Males with female partners of reproductive potential should use effective contraception during the study and for at least 90 days after the last dose of mycophenolate mofetil.

-
2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 250 mg
Subjects: Males, general population
Additional comments: See comments above
-

Analytes to measure: Mycophenolate mofetil, and the active metabolite, mycophenolic acid in plasma

Submit the metabolite data as supportive evidence of comparable therapeutic outcome. For the metabolite, 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}.

Bioequivalence based on (90% CI): Mycophenolate mofetil

Waiver request of in-vivo testing: Not applicable

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 for each of the test and reference

products. Specifications will be determined upon review of the abbreviated new drug application.