

Draft Guidance on Mycophenolate Mofetil

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Suspension/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 200 mg/mL x 5 mL (1000 mg dose)
Subjects: Healthy adult males, general population
Additional comments: None

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2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 200 mg/mL x 5 mL (1000 mg dose)
Subjects: Healthy adult males, general population
Additional comments: None
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Analytes to measure (in appropriate biological fluid): Mycophenolate mofetil, and the active metabolite, mycophenolic acid (MPA) in plasma.

Please 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.

If mycophenolate mofetil plasma concentrations can be reliably measured and its pharmacokinetics accurately determined, please analyze the data for the parent compound using the confidence interval approach. The data for the active metabolite can be used as supportive evidence. However, if you can demonstrate that it is not possible to measure mycophenolate mofetil in plasma accurately and reliably, please analyze the metabolite using the confidence interval approach.

Waiver request of in vivo testing: Not applicable.

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. Please note that a dosage unit for a suspension is the labeled strength (mL). A total of 12 units from 12 different bottles should be used.