

Draft Guidance on Mycophenolic Acid

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Delayed Release Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting

Design: Single-dose, two-treatment, two-period crossover in vivo

Strength: 360 mg

Subjects: Healthy adult males, general population

Additional comments: None

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:

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.