Draft Guidance on Mycophenolate Mofetil

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 Cmax.

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.