

Draft Guidance on Apremilast

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way, crossover in vivo
Strength: 30 mg
Subjects: Normal healthy males and nonpregnant females, general population

2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 30 mg
Subjects: Normal healthy males and nonpregnant females, general population

Analytes to measure (in appropriate biological fluid): Apremilast in plasma

Bioequivalence based on (90% CI): Apremilast

Waiver request of in vivo testing: 10 mg and 20 mg base strengths based on (i) acceptable bioequivalence studies on the 30 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths

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 application.