

Draft Guidance on Primidone

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 50 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional Comments: None

2. Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: 50 mg
Subjects: Males and non-pregnant, non-lactating females, general population
Additional Comments: None

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

Bioequivalence based on (90% CI): Primidone

Waiver request of in-vivo testing: 250 mg strength based on (i) acceptable bioequivalence studies on the 50 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 the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).

Since Primidone Tablets, 50 mg and 250 mg are functionally scored tablets; additional dissolution testing should be conducted on split tablet portions test (i.e. halves). Dissolution

data on split tablet portions should meet finished-product release requirements. For additional information on the evaluation of scored tablets, refer to the FDA Guidance on "Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation" issued in March 2013 at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269921.pdf>.