

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Primidone

November 2024

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Active Ingredient:	Primidone
Dosage Form:	Tablet
Route:	Oral
Strengths:	25 mg ¹ , 50 mg, 100 mg ¹ , 125 mg ¹ , 250 mg
Recommended Study:	One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 50 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None

Analyte to measure: Primidone in plasma

Bioequivalence based on (90% CI): Primidone

Waiver request of in vivo testing: 25 mg, 100 mg, 125 mg and 250 mg strengths based on (i) an acceptable bioequivalence study on the 50 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths

¹ Strengths identified are the subject of an approved suitability petition (FDA-2009-P-0482).

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA’s Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test product and reference listed drug (RLD).² Specifications will be determined upon review of the abbreviated new drug application.

If any strength of the tablet product has a functional score, additional dissolution profile testing should be conducted for each segment of the split tablet after manual and mechanical splitting as per the most recent version of the FDA guidance for industry on *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation*.^a

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^a For the most recent version of a guidance, check the FDA guidance website at <https://www.fda.gov/regulatoryinformation/search-fda-guidance-documents>.

² If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.