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Draft Guidance on Gabapentin

November 2025

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Active Ingredient: Gabapentin

Dosage Form: Tablet

Route: Oral

Strengths:[1] 100 mg[2], 400 mg[2], 600 mg, 800 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: 800 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Gabapentin in plasma

Bioequivalence based on (90% CI): Gabapentin

Waiver request of in vivo testing: 100 mg, 400 mg, and 600 mg strengths based on (i) an acceptable bioequivalence study on the 800 mg strength, (ii) acceptable in vitro dissolution testing of all the strengths, and (iii) proportional similarity of the formulations across all strengths

[1] The previous version of this PSG contained recommendation on the 300 mg strength. The approval of a 300 mg strength in NDA 022544 means that the suitability petition FDA-2000-P-0409 and NDA 020882 cannot be used as the basis of submission for the 300 mg strength.
[2] Strengths identified are the subject of an approved suitability petition (FDA-2000-P-0409).

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).[3] Specifications will be determined upon review of the abbreviated new drug application.

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