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Draft Guidance on Baclofen

December 2025

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Active Ingredient: Baclofen

Dosage Form: Tablet

Route: Oral

Strengths: 5 mg[1], 10 mg, 15 mg[2], 20 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: 20 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: None

Analyte to measure: Baclofen in plasma

Bioequivalence based on (90% CI): Baclofen

Waiver request of in vivo testing: 5 mg, 10 mg, and 15 mg strengths based on (i) an acceptable bioequivalence study on the 20 mg strength, (ii) acceptable in vitro dissolution testing of all strengths and (iii) proportional similarity of the formulations across all strengths

[1] The strength identified is the subject of an approved suitability petition (FDA-2008-P-0325).
[2] The strength identified is the subject of an approved suitability petition (FDA-2020-P-2067).

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.[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 FDA guidance for industry *Referencing Approved Drug Products in ANDA Submissions*.