Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Baclofen

February 2026

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Baclofen

Dosage Form: Suspension

Route: Oral

Strength: 25 mg/5 mL

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: 25 mg/5 mL at the administered dose of 20 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Due to drowsiness and sedation, subjects should avoid the operation of automobiles, other dangerous machinery, or activities made hazardous by decreased alertness during study.

Analyte to measure: Baclofen in plasma

Bioequivalence based on (90% CI): Baclofen

Waiver request of in vivo testing of additional strength: Not applicable

Dissolution test method and sampling times: Dissolution test(s) should be included for quality control. Provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method[1] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

Product-specific testing conditions for in vitro enteral tube studies: The approved labeling for the RLD states that the product may be administered by a nasogastric (NG) tube. Conduct the in vitro feeding tube studies, including comparative recovery testing, sedimentation volume and redispersibility testing, and in-use stability, and particle size distribution study. For general procedures of in vitro feeding tube studies, refer to the most recent version of the guidance for industry *Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations.*[a]

Testing tube: NG tube (8 French)

In vitro enteral feeding tube testing:

1. Comparative recovery testing
    - Three different tube materials (e.g., polyvinylchloride, silicone, polyurethane) and/or designs (e.g., various numbers of ports and/or eyes, open or closed distal end)
    - Holding times of 0 and 4 hours
    - Repeated administration
2. Sedimentation volume and redispersibility testing
3. In-use stability testing
4. Particle size distribution study

Document History: Recommended May 2024; Revised October 2024; February 2026

Unique Agency Identifier: PSG_215602

[a] For the most recent version of a guidance, refer to the FDA guidance website at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[1] Applicant-developed, United States Pharmacopeia drug product monograph or Dissolution Methods database, https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm