

## Draft Guidance on Baclofen

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Orally disintegrating tablet; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 20 mg  
Subjects: Males and non-pregnant, non-lactating females, general population  
Additional comments: Females subjects of child-bearing potential should practice abstinence or use contraception during the study. The orally disintegrating tablet should be placed on the tongue, allowed to disintegrate, and swallowed without water.

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2. Type of study: Fed  
Design: Single-dose, two-treatment, two-period crossover in vivo  
Strength: 20 mg  
Subjects: Males and non-pregnant, non-lactating females, general population  
Additional comments: See comment above.

**Analyte to measure (in appropriate biological fluid):** Baclofen in plasma

**Bioequivalence based on (90% CI):** Baclofen

**Waiver request of in vivo testing:** 10 mg based on (i) acceptable bioequivalence study on the 20 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 all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application.