Contains Nonbinding Recommendations

Draft Guidance on Baclofen

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Baclofen

Form/Route: Orally Disintegrating Tablets/ Oral

Recommended studies: 1 study

Type of study: Fasting

Design: single-dose, two-way crossover *in-vivo*
Strength: 20 mg
Subjects: Normal healthy males and females, general population.
Additional Comments: Females should not be pregnant, and if applicable, should practice abstention or contraception during the study.

Analytes 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 (1) acceptable bioequivalence study on the 20 mg strength, and (ii) proportional similarity in the formulations and (ii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at http://www.fda.gov/cder/ogd/index.htm. Please find the dissolution information for this product at this website. Please 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 application.