Contains Nonbinding Recommendations

Guidance on Benzonatate

This guidance represents 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: Benzonatate

Form/Route: Capsule/Oral

Recommended studies:

Benzonatate Capsules, 100 mg and 200 mg, may be considered for waiver of in-vivo bioequivalence testing pursuant to 21 C.F.R. 320.22(c) provided the in-vitro dissolution profiles of your Benzonatate Capsules, 100 mg and 200 mg, and the reference listed drugs (RLDs) are comparable.

Analytes to measure (in appropriate biological fluid): Not Applicable

Bioequivalence based on (90% CI): Not Applicable

Waiver request of in-vivo testing: Not Applicable

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.