

Draft Guidance on Benzonatate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Capsule; oral

Recommended Studies:

Benzonatate capsules, 100 mg, 150 mg, and 200 mg, may be considered for waiver of in vivo bioequivalence (BE) testing pursuant to 21 C.F.R. 320.22(c), provided the in vitro dissolution profiles of the test benzonatate capsules, 100 mg, 150 mg, and 200 mg, and the reference listed drugs (RLDs) are comparable.

Analytes to measure (in appropriate biological fluid): Not applicable (N/A)

Bioequivalence based on (90% CI): N/A

Waiver request of in vivo testing: 100 mg, 150 mg, and 200 mg oral capsules pursuant to 21 CFR 320.22 (c).

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 (ANDA).