

Contains Nonbinding Recommendations

Guidance on Benzphetamine Hydrochloride

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: Benzphetamine Hydrochloride

Form/Route: Tablet/Oral

Recommended studies:

Benzphetamine Hydrochloride Tablets, is a DESI-effective drug product without known bioequivalence problems. Therefore, *in-vivo* bioequivalence testing is not requested. Comparative dissolution testing on 12 dosage units of all strengths of the test and reference products is requested. You may request a waiver of *in-vivo* bioequivalence study requirements on this product under 21 CFR 320.22(c).

Analytes to measure: Not Applicable

Bioequivalence based on (90% CI): Not Applicable

Waiver request of in-vivo testing: 50 mg

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.