

Draft Guidance on Amphetamine Sulfate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies:

Amphetamine sulfate tablet is a DESI¹ effective drug for which there are no known or suspected bioequivalence problems.

Analytes to measure: Not Applicable

Bioequivalence based on (90% CI): Not Applicable

Waiver request of in vivo testing: 5 mg and 10 mg pursuant to 21 CFR 320.22 (c) provided the in-vitro dissolution profiles of the proposed product are comparable to those of the reference product

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).

¹ Drug Efficacy Study Implementation