

Draft Guidance on Dexbrompheniramine Maleate and Pseudoephedrine Sulfate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Extended-release tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting

Design: Single-dose, two-way crossover in vivo

Strength: 6 mg; 120 mg

Subjects: Healthy males and nonpregnant females, general population

Additional comments: None

2. Type of study: Fed

Design: Single-dose, two-way crossover in vivo

Strength: 6 mg; 120 mg

Subjects: Healthy males and nonpregnant females, general population

Additional comments: None

Analytes to measure (in appropriate biological fluid): Dexbrompheniramine and pseudoephedrine in plasma

Bioequivalence based on (90% CI): Dexbrompheniramine and pseudoephedrine

Waiver request of in vivo testing: Not applicable

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).

For modified-release products, dissolution profiles on 12 dosage units each of test and reference products using U.S. Pharmacopeia (USP) Apparatus I at 100 rpm and/or Apparatus II at 50 rpm in at least three dissolution media (pH 1.2, 4.5, and 6.8 buffer) should be submitted in the application. Agitation speeds may have to be increased, if appropriate. It is acceptable to add a small amount of surfactant, if necessary. Include early sampling times of 1, 2, and 4 hours and continue every 2 hours until at least 80% of the drug is released, to provide assurance against

premature release of drug (dose dumping) from the formulation. Specifications will be determined upon review of the data submitted in the application.