

Draft Guidance on Pseudoephedrine Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Extended Release Tablet; Oral

Recommended Studies: Two in vivo studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 120 mg
Subjects: Healthy males and non-pregnant females, general population.
Additional Comments: Females should not be pregnant or lactating, and if applicable, should practice abstinence or contraception during the study.
2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 120 mg
Subjects: Healthy males and non-pregnant females, general population.
Additional Comments: See comments above.

Analytes to measure (in appropriate biological fluid): Pseudoephedrine in plasma

Bioequivalence based on (90% CI): 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 website 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).

In addition to the method above, for modified release products, dissolution profiles on 12 dosage units each of test and reference products generated using USP 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. Please 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.