

Draft Guidance on Acrivastine and Pseudoephedrine Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Capsule; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 8 mg; 60 mg
Subjects: Healthy males and non-pregnant, non-lactating females.
Additional Comments: None

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 8 mg; 60 mg
Subjects: Healthy males and non-pregnant, non-lactating females.
Additional comments: None

Analytes to measure (in appropriate biological fluid): Acrivastine and Pseudoephedrine in Plasma

Bioequivalence based on (90% CI): Acrivastine and Pseudoephedrine

Waiver request of in-vivo testing: N/A

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.