Active Ingredient: Clemastine fumarate

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 2.68 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: None

2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 2.68 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: None

Analyte to measure (in appropriate biological fluid): Clemastine in plasma

Bioequivalence based on (90% CI): Clemastine

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/](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.

Clemastine fumarate tablets are scored. Therefore, additional split tablet dissolution testing should be conducted. For additional information on the evaluation of scored tablets, refer to the FDA Guidance on “Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation.”