Active ingredient: Loratadine

Form/Route: Capsules; Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way, crossover in vivo
   Strength: 10 mg
   Subjects: Healthy males and females, general population.
   Additional Comments:

2. Type of study: Fed
   Design: Single-dose, two-way, crossover in vivo
   Strength: 10 mg
   Subjects: Healthy males and females, general population.
   Additional Comments: Please refer to the Amantadine Hydrochloride Tablet Draft Guidance for additional information regarding fed studies.

Analytes to measure: loratadine and its metabolite, descarboethoxyloratadine, in plasma

Bioequivalence based on (90% CI): Loratadine

Please submit the metabolite data as supportive evidence of the comparable therapeutic outcome. For the metabolite, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and Cmax.

Waiver request of in-vivo testing: Not Applicable

Dissolution test method and sampling times:
Please note that a Dissolution Methods Database is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. Please 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 application.

Recommended Apr 2013