Active ingredient: Cetirizine Hydrochloride

Form/Route: Orally Disintegrating Tablet; Oral

Recommended studies: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: 10mg
   Subjects: Healthy males and healthy non-pregnant females, general population
   Additional Comments: The whole tablet should be placed in the mouth and allowed to disintegrate for 30 seconds. After 30 seconds, all subjects should consume 240 mL of water.

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

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

Bioequivalence based on (90% CI): Cetirizine

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 drug 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.

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