Draft Guidance on Dichlorphenamide

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting Design: Single-dose, two-way crossover in-vivo Strength: 50 mg Subjects: Males and non-pregnant, non-lactating females, general population

   Additional Comments: Due to the long elimination half-life of Dichlorphenamide Tablets, applicants may conduct a single-dose, crossover study provided an adequate washout period is used. If the crossover study is problematic, applicants may use a BE study with a parallel design. For either a crossover or parallel study, sample collection time should be adequate to ensure completion of gastrointestinal transit of the drug product and absorption of the drug substance. Applicants may use C_max and a suitably truncated AUC to characterize peak and total drug exposure, respectively. For drugs that demonstrate low intrasubject variability in distribution and clearance, applicants may use an AUC truncated at 72 hours (AUC_0-72 hr) in place of AUC_0-t or AUC_0-inf.

2. Type of study: Fed Design: Single-dose, two-way crossover in-vivo Strength: 50 mg Subjects: Males and non-pregnant, non-lactating females, general population

   Additional Comments: Same as above

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

Bioequivalence based on (90% CI): Dichlorphenamide

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 web site, available to the

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public at the following location:  http://www.accessdata.fda.gov/scripts/cder/dissolution/.
Conduct comparative dissolution testing on 12 dosage units each of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).