Contains Nonbinding Recommendations

Draft Guidance on Methazolamide

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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: Healthy males and nonpregnant females, general population
   Additional comments: Methazolamide has a long terminal elimination half-life. Ensure adequate washout periods between treatments in the crossover studies. Also consider using a parallel study design.

2. Type of Study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: 50 mg
   Subjects: Healthy males and nonpregnant females, general population
   Additional comments: Same as above

Analytes to measure (in appropriate biological fluid): Methazolamide in whole blood

Bioequivalence based on (90% CI): Methazolamide

Waiver request of in vivo testing: 25 mg based on (i) acceptable bioequivalence studies on the 50 mg strength (ii) acceptable dissolution testing on both strengths; and (iii) proportional similarity in the formulations of both strengths

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 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. Specifications will be determined upon review of the abbreviated new drug application (ANDA).