Contains Nonbinding Recommendations

Draft Guidance on Albuterol Sulfate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in vivo
   Strength: EQ 4 mg base
   Subjects: Healthy males and females, general population
   Additional Comments: None

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in vivo
   Strength: EQ 4 mg base
   Subjects: Healthy males and females, general population
   Additional Comments: None

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

Bioequivalence based on (90% CI): Albuterol

Waiver request of in vivo testing: EQ 2 mg base strength based on (i) acceptable bioequivalence studies on the EQ 4 mg base strength, (ii) acceptable dissolution testing across all the strengths, and (iii) proportional similarity in the formulations across all the strengths.

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/. 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 abbreviated new drug application (ANDA).