Contains Nonbinding Recommendations

Draft Guidance on Albendazole

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 200 mg, at a dose of 400 mg (2x 200 mg)
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: Applicants may consider using a reference-scaled average bioequivalence approach for albendazole. If using this approach, provide evidence in the studies of high variability in the bioequivalence parameters of area under the plasma concentration time curve (AUC) and/or peak concentration (Cmax) (i.e., within-subject variability ≥ 30%). For detailed information on this approach, refer to the guidance for Progesterone Oral Capsules.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 200 mg, at a dose of 400 mg (2x 200 mg)
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: See comments above

Analytes to measure (in appropriate biological fluid): Albendazole and its metabolite, albendazole sulfoxide, in plasma

Submit the metabolite data as supportive evidence of 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.

Bioequivalence based on (90% CI): Albendazole

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