

Draft Guidance on Albendazole

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 200 mg at the dose of 400 mg (200 mg x 2 tablets)
Subjects: Healthy males and females (non-pregnant and non-lactating), general population
Additional comments: Tablets should be chewed completely before swallowing.
Applicants may consider using a reference-scaled average bioequivalence approach for albendazole. For the method of statistical analysis using the reference-scaled average bioequivalence approach, refer to the Progesterone Capsule Guidance.
2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 200 mg at the dose of 400 mg (200 mg x 2 tablets)
Subjects: Healthy males and females (non-pregnant and non-lactating), general population
Additional comments: See comments above.

Analytes to measure (in appropriate biological fluid): Albendazole and its active 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 C_{max}.

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 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).