

Draft Guidance on Praziquantel

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Praziquantel

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover, in vivo
Strength: 600 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: 1) Females should practice abstinence or contraception during the study. 2) The approved label has the following warning: "Patients should be warned not to drive a car and not to operate machinery on the day of Biltricide treatment and the following day." 3) Women should not nurse on the day of praziquantel treatment and during the subsequent 72 hours.

 2. Type of study: Fed
Design: Single-dose, two-way crossover, in vivo
Strength: 600 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Same as above
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Analytes to measure (in appropriate biological fluid): Praziquantel in plasma

Bioequivalence based on (90% CI): Praziquantel

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 each of all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).

For additional information on the evaluation of scored tablets, refer to the Guidance for Industry – Tablet Scoring: Nomenclature, Labeling, and Data at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269921.pdf>