Contains Nonbinding Recommendations

Draft Guidance on Megestrol Acetate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Megestrol Acetate

Form/Route: Suspension/Oral

Recommended study: 2 studies

1. Type of study: Fasting
   Design: Single-dose, two way crossover *in-vivo*
   Strength: 125 mg/mL (125 mg dose)
   Subjects: Healthy male subjects, general population
   Additional Comments: Due to safety concerns, women should be excluded.

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2. Type of study: Fed
   Design: Single-dose, two way crossover *in-vivo*
   Strength: 125 mg/ml (125 mg dose)
   Subjects: Healthy male subjects, general population
   Additional Comments: See comment above.

Analytes to measure (in appropriate biological fluid): Megestrol acetate in plasma.

Bioequivalence based on (90% CI): Megestrol acetate.

Waiver request of *in-vivo* testing: Not applicable

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at http://www.accessdata.fda.gov/scripts/cder/dissolution/. Please find the dissolution information for this product at this website. 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 application.

Please note that a dosage unit for a suspension is the labeled strength (ml). A total of 12 units from 12 different bottles should be used.