Contains Nonbinding Recommendations

Draft Guidance on Molindone Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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: 25 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Elderly subjects should be excluded from the study. Subjects should be closely monitored for hypotension and dystonia.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 25 mg
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: See comments above

Analyte to measure (in appropriate biological fluid): Molindone in plasma

Bioequivalence based on (90% CI): Molindone

Waiver request of in vivo testing: 5 mg and 10 mg based on (i) acceptable bioequivalence studies on the 25 mg strength, (ii) proportional similarity in the formulations of the 5 mg, 10 mg and 25 mg strengths, and (iii) acceptable in vitro dissolution testing of these strengths.

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.