

Draft Guidance on Molindone Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Tablet/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Randomized, single-dose, two-way crossover, *in-vivo*
Strength: 25 mg
Subjects: Healthy adult males and nonpregnant females, general population.
Additional Comments: Elderly subjects should be excluded from the study. Subjects should be closely monitored for hypotension and dystonias.

-
2. Type of study: Fasting
Design: Randomized, single-dose, two-way crossover, *in-vivo*
Strength: 50 mg
Subjects: Healthy adult males and nonpregnant females, general population.
Additional Comments: See comments above.
-

Analytes 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) an acceptable bioequivalence study 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:

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.