

Draft Guidance on Haloperidol

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting

Design: Single-dose, two-way, crossover *in-vivo*

Strength: 2 mg

Subjects: Normal healthy males and females, general population

Additional Comments: To prevent severe dystonia, subjects should be premedicated with benztropine (Cogentin®) tablets, 1 mg every 10 to 12 hours beginning 4 to 6 hours before dosing with haloperidol and continuing for a total of 4 doses to provide coverage during periods of substantial haloperidol levels. In the event of breakthrough acute dystonia, diphenhydramine (Benadryl®) 50 mg could be administered IM or IV.

Analytes to measure: Haloperidol in plasma

Bioequivalence based on (90% CI): Haloperidol

Waiver request of in-vivo testing: 0.5 mg, 1 mg, 5 mg, 10 mg and 20 mg based on (i) acceptable bioequivalence studies on the 2 mg strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across all 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.fda.gov/cder/ogd/index.htm>. 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.