Contains Nonbinding Recommendations

Draft Guidance on Haloperidol

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.