

Draft Guidance on Fluvoxamine Maleate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Extended Release Capsule/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover *in-vivo*
Strength: 150 mg
Subjects: Healthy males and non-pregnant females, general population.
Additional Comments: Volunteers should be carefully screened to avoid potential drug-drug interactions and conditions that would put them at greater risk of serotonin syndrome.

2. Type of study: Fed
Design: Single-dose, two-way crossover *in-vivo*
Strength: 150 mg
Subjects: Healthy males and non-pregnant females, general population.
Additional Comments: Please see comment above. Please refer to the Amantadine Tablets guidance for recommendations regarding fed studies.

Analytes to measure (in appropriate biological fluid): Fluvoxamine in plasma

Bioequivalence based on (90% CI): Fluvoxamine

Waiver request of in-vivo testing: 100 mg based on (i) acceptable bioequivalence studies on the 150 mg strength, (ii) acceptable *in-vitro* dissolution testing of 100 mg and 150 mg strengths, and (iii) proportional similarity of the formulations of 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.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.