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Draft Guidance on Fluvoxamine Maleate

August 2026

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient:	Fluvoxamine maleate
Dosage Form:	Tablet
Route:	Oral
Strengths:	25 mg | 50 mg | 100 mg
Reference Listed Drug:	NDA 021519
Recommended Studies:	Two options: (I) One in vivo bioequivalence study with pharmacokinetic endpoints or (II) alternative approach to establish bioequivalence

Option I: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Class of study: Bioequivalence
   Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 100 mg
   Subjects: Healthy males and non-pregnant, non-lactating females

Analyte to measure: Fluvoxamine in plasma

Bioequivalence based on (90% CI): Fluvoxamine

Bioequivalence of additional strength: Waiver request of in vivo testing of additional strength based on (i) an acceptable bioequivalence study on the 100 mg strength, (ii) acceptable comparative in vitro dissolution studies between the additional strengths and the 100 mg strength using 12 units per strength, and (iii) proportional similarity of the formulations across all strengths

Dissolution: Dissolution tests should be included for quality control and to support a waiver request of in vivo testing of the additional strengths. For the quality control dissolution method, provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method[1] and sampling times, such as the discriminating ability to detect changes in critical quality attributes that could potentially impact drug product performance.

For drug products containing high solubility drug substances that meet the rapidly dissolving criteria, demonstration of discriminating ability may not be needed. For additional information, refer to the guidance for industry *Dissolution Testing and Acceptance Criteria for Immediate-Release Solid Oral Dosage Form Drug Products Containing High Solubility Drug Substances*.[a]

If any strength of the tablet product has a functional score, additional dissolution profile testing should be conducted for each segment of the split tablet after manual and mechanical splitting as per the guidance for industry *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation.*[a]

Option II: Alternative approach to establish bioequivalence

BCS waiver: Fluvoxamine may be eligible for a Biopharmaceutics Classification System (BCS) class-based biowaiver. A waiver request of in vivo testing for all the strengths of this product may be considered provided that the appropriate documentation as detailed in the guidance for industry: *M9 Biopharmaceutics Classification System-Based Biowaivers*[a] is submitted in the application. A decision regarding the acceptability of the waiver request can only be made upon assessment of the data submitted in the application.

Document History: Recommended August 2026

[a] We update guidances periodically. For the most recent version of a guidance, refer to the FDA guidance webpage at https://www.fda.gov/regulatory-information/search-fda-guidance-documents.

[1] Applicant-developed, United States Pharmacopeia drug product monograph or Dissolution Methods database, https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm