

Draft Guidance on Buspirone Hydrochloride

February 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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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:	Buspirone hydrochloride
Dosage Form:	Tablet
Route:	Oral
Strengths:	2.5 mg, ¹ 5 mg, 7.5 mg, 10 mg, 12.5 mg, ¹ 15 mg, 30 mg
Recommended Studies:	Two options: (1) Biopharmaceutics Classification System (BCS)-based biowaiver, or (2) one in vivo bioequivalence study with pharmacokinetic endpoints

I. Option 1: BCS Class I-based biowaiver

A waiver request of in vivo testing for all the strengths of this product may be considered provided that the appropriate documentation regarding high solubility, high permeability and rapid dissolution as detailed in the most recent version of the guidance for industry *M9 Biopharmaceutics Classification System-Based Biowaivers*^a is submitted in the application. Applicants may use the information contained in the approved labeling of the reference listed drug (RLD). Peer reviewed articles may not contain the necessary details of the testing for the Agency to make a judgment regarding the quality of the studies. A decision regarding the acceptability of the waiver request can only be made upon assessment of the data submitted in the application.

¹ Strengths identified are the subject of an approved suitability petition (FDA-2022-P-1039).

II. Option 2: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 15 mg
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None

Analyte to measure: Buspirone in plasma

Bioequivalence based on (90% CI): Buspirone

Waiver request of in vivo testing of additional strengths: Justification based on (i) an acceptable bioequivalence study on the 15 mg strength, (ii) acceptable comparative in vitro dissolution studies between additional strengths and the 15 mg strength using 12 units per strength, and (iii) proportional similarity of the formulations across all strengths

Dissolution: Dissolution test(s) should be included for quality control and to support waiver request of in vivo testing of additional strengths.

Dissolution test method and sampling times: Provide a dissolution method development report for the test product containing information and data that demonstrate appropriateness of the selected dissolution method² 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 most recent version of 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 most recent version of the guidance for industry *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation*.^a

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^a For the most recent version of a guidance, refer to the FDA guidance website at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.

² Applicant-developed, United States Pharmacopeia drug product monograph or Dissolution Methods database, <https://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm>