Contains Nonbinding Recommendations

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Draft Guidance on Rilpivirine Hydrochloride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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form: Tablet, for suspension

Route: Oral

Strength: EQ 2.5 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: EQ 2.5 mg Base at the administered dose of EQ 25 mg Base
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments: Prepare and administer the tablets for suspension according to the preparation and administration instructions in the labeling. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of rilpivirine. Alternatively, a parallel study design may be considered.

Analyte to measure: Rilpivirine in plasma

Bioequivalence based on (90% CI): Rilpivirine

Waiver request of in vivo testing of additional strength: Not applicable

Dissolution test method and sampling times: Dissolution test(s) should be included for quality control. 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.

Document History: Recommended February 2026

Unique Agency Identifier: PSG_219016

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