Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Dordaviprone Hydrochloride

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form: Capsule

Route: Oral

Strength: EQ 125 mg Base

Reference Listed Drug: NDA 219876

Recommended Study: 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: EQ 125 mg Base
   Subjects: Healthy males and healthy females not of reproductive potential
   Safety recommendations:
   - Males with female partners of reproductive potential should use effective contraception during the study and for one month after the last dose.

Analyte to measure: Dordaviprone in plasma

Bioequivalence based on (90% CI): Dordaviprone

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

Dissolution: 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.

Product-specific testing conditions for in vitro feeding tube studies: Conduct the in vitro nasogastric (NG) or gastrostomy (G) tube studies listed below. For additional information, refer to the guidance for industry *Oral Drug Products Administered Via Enteral Feeding Tube: In Vitro Testing and Labeling Recommendations*.[a]

Testing tube: NG tube (6 French) and G tube (12 French)
Dispersion media: sports drink, apple juice, lemonade, and water

1. Comparative recovery testing
    - Three different configurations of 6 French NG tubes, defined by materials (e.g., polyvinylchloride, silicone, polyurethane) and/or designs (e.g., number of ports/eyes, open or closed distal end)
    - Three different configurations of 12 French G tubes
        - At least one G tube should be tested with an inflated balloon design
    - Reporting of the pH values of the dispersion media
    - Holding times of 0 and 2 hours
2. Sedimentation volume and redispersibility testing
3. In-use stability in designated dispersion media

Document History: Recommended May 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