Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Glecaprevir; Pibrentasvir

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form: Pellets

Route: Oral

Strength: 50 mg; 20 mg/packet

Recommended Studies: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 50 mg; 20 mg/packet at the administered dose of 300 mg for glecaprevir and 120 mg for pibrentasvir
   Subjects: Healthy males and non-pregnant, non-lactating females
   Additional comments:
   - Exclude subjects with evidence of current or prior hepatitis B virus infection due to the risk of reactivation.
   - Pellets should be sprinkled on a small amount of soft food with a low water content that will stick to a spoon and should be swallowed without chewing. Follow the administration instructions described in the reference listed drug labeling.

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 50 mg; 20 mg/packet at the administered dose of 300 mg for glecaprevir and 120 mg for pibrentasvir
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: See comments above.

Analytes to measure: Glecaprevir and pibrentasvir in plasma

Bioequivalence based on (90% CI): Glecaprevir and pibrentasvir

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_215110

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