

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Ambrisentan

November 2025

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Active Ingredient: Ambrisentan

Dosage Form: Tablet

Route: Oral

Strengths: 5 mg, 10 mg

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 10 mg
Subjects: Healthy males and healthy females not of reproductive potential
Additional comments: None

Analyte to measure: Ambrisentan in plasma

Bioequivalence based on (90% CI): Ambrisentan

Waiver request of in vivo testing: 5 mg strength based on (i) an acceptable bioequivalence study on the 10 mg strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA's Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of both strengths of the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended August 2009; Revised Jun 2013, October 2024, November 2025

Unique Agency Identifier: PSG_022081

¹ If the RLD is not available, refer to the most recent version of the guidance for industry *Referencing Approved Drug Products in ANDA Submissions*.