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Draft Guidance on Lenalidomide

October 2024

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Active Ingredient: Lenalidomide

Dosage Form: Capsule

Route: Oral

Strengths: 2.5 mg, 5 mg, 10 mg, 15 mg, 20 mg, 25 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: 25 mg
   Subjects: Healthy males
   Additional comments: Lenalidomide capsule is under a Risk Evaluation and Mitigation Strategy (REMS) with Elements to Assure Safe Use (ETASU), which restricts its use. All pertinent elements of the REMS/ETASU must be incorporated into the protocol and informed consent.

Analyte to measure: Lenalidomide in plasma

Bioequivalence based on (90% CI): Lenalidomide

Waiver request of in vivo testing: 2.5 mg, 5 mg, 10 mg, 15 mg, and 20 mg strengths, based on (i) acceptable bioequivalence study on the 25 mg strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all 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 all 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 June 2010; Revised November 2012, November 2013, October 2024

Unique Agency Identifier: PSG_021880

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