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Draft Guidance on Pomalidomide

October 2024

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Active Ingredient: Pomalidomide

Dosage Form: Capsule

Route: Oral

Strengths: 1 mg, 2 mg, 3 mg, 4 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: 4 mg
   Subjects: Healthy males
   Additional comments: Pomalidomide capsule is approved 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: Pomalidomide in plasma, using an achiral assay

Bioequivalence based on (90% CI): Pomalidomide

Waiver request of in vivo testing: 1 mg, 2 mg, and 3 mg strengths based on (i) acceptable bioequivalence study on the 4 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.

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[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*.