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Draft Guidance on Thalidomide

May 2025

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Active Ingredient: Thalidomide

Dosage Form: Capsule

Route: Oral

Strengths: 50 mg, 100 mg, 150 mg, 200 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: 200 mg
   Subjects: Healthy males
   Additional comments: Thalidomide 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: Thalidomide in plasma using an achiral assay

Bioequivalence based on (90% CI): Thalidomide

Waiver request of in vivo testing: 50 mg, 100 mg, and 150 mg strengths based on (i) an acceptable bioequivalence study on the 200 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 September 2012; Revised December 2012, May 2025

Unique Agency Identifier: PSG_020785

[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*.