

Draft Guidance on Thalidomide

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active ingredient: Thalidomide

Form/Route: Capsules/Oral

Recommended studies: 2 studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in-vivo
Strength: 200 mg
Subjects: Healthy adult males, general population. Female subjects should be excluded from the bioequivalence studies.
Additional comments: All subjects should adhere to the guidelines of the “System for Thalidomide Education and Prescribing Safety” (S.T.E.P.S®) program and warnings for thalidomide.

2. Type of study: Fed
Design: Single-dose, two-way crossover in-vivo
Strength: 200 mg
Subjects: Healthy adult males, general population. Female subjects should be excluded from the bioequivalence studies.
Additional comments: Please see comments above.

Analytes to measure (in appropriate biological fluid): 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 based on (i) acceptable fasting and fed bioequivalence studies on the 200 mg strength, (ii) proportional similarity of the formulations across all strengths, and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.