

Draft Guidance on Ixazomib Citrate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Ixazomib citrate

Dosage Form; Route: Capsule; oral

Recommended Studies: One study

Type of study: Steady-state

Design: Two-way crossover in-vivo

Strength: EQ 4 mg base

Subjects: Multiple myeloma patients who have received at least one prior therapy.

Additional Comments: Submission of a Bio Investigational New Drug Application (BioIND) is required prior to the conduct of a bioequivalence study for a cytotoxic drug product such as ixazomib (see 21CFR § 320.31).

Analytes to measure (in appropriate biological fluid): Ixazomib in plasma

Bioequivalence based on (90% CI): Ixazomib

Waiver request of in-vivo testing: EQ 2.3 mg base and EQ 3 mg base based on (i) acceptable bioequivalence study on the EQ 4 mg base 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 on the FDA-Recommended Dissolution Methods website, available to the public at the following location:

<http://www.accessdata.fda.gov/scripts/cder/dissolution/>. 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 abbreviated new drug application (ANDA).