

Draft Guidance on Glasdegib Maleate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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: Glasdegib maleate

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 100 mg Base
Subjects: Males, general population
Additional comments: 1) Exclude elderly and subjects with risk factors for prolonged QTc interval and torsade de pointes. 2) Monitor subjects during the study for any electrocardiogram changes. 3) Subjects with pregnant partners or female partners of reproductive potential should use effective contraception during the study and for at least 30 days after the last dose. 4) Subjects should not donate sperm or blood/blood products during the study and for at least 30 days after the last dose of glasdegib.

 2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 100 mg Base
Subjects: Males, general population
Additional comments: See comments above
-

Analyte to measure: Glasdegib in plasma

Bioequivalence based on (90% CI): Glasdegib

Waiver request of in vivo testing: EQ 25 mg Base strength based on (i) acceptable bioequivalence studies on the EQ 100 mg Base strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the two formulations across both 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 for each of both strengths of the test

and reference products. Specifications will be determined upon review of the abbreviated new drug application.