Contains Nonbinding Recommendations

Draft Guidance on Venetoclax

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: 100 mg
   Subjects: Healthy females with non-childbearing potential (post-menopausal or surgically sterile), general population.
   Additional Comments: Submission of an Investigational New Drug Application (IND) is required prior to the conduct of a bioequivalence study for a cytotoxic drug product. (See 21 C.F.R § 320.31).

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 100 mg
   Subjects: Healthy females with non-childbearing potential (post-menopausal or surgically sterile), general population.
   Additional Comments: See comment above

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

Bioequivalence based on (90% CI): Venetoclax

Waiver request of in-vivo testing: 10 mg and 50 mg based on (i) acceptable bioequivalence studies on the 100 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 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).