

Draft Guidance on Bedaquiline Fumarate

October 2024

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Bedaquiline fumarate

Dosage Form: Tablet

Route: Oral

Strength: EQ 100 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 100 mg Base (Dose = 100 mg)
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: Due to QT prolongation associated with bedaquiline, electrocardiography (ECGs) should be closely monitored. Ensure an adequate washout period between treatments in the crossover study due to the long elimination half-life of bedaquiline. Alternatively, a parallel study design may be considered.

Analyte to measure: Bedaquiline in plasma

Bioequivalence based on (90% CI): Bedaquiline

Waiver request of in vivo testing: Not applicable

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 the test product and reference listed drug (RLD).¹ Specifications will be determined upon review of the abbreviated new drug application.

Document History: Recommended November 2013; Revised October 2024

Unique Agency Identifier: PSG_204384

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*.