

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Ibexafungerp Citrate

February 2023

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two in vivo bioequivalence studies with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 150 mg Base
Subjects: Healthy non-pregnant, non-lactating females
Additional comments: Female subjects of reproductive potential should use effective contraception during the study and for 4 days after the last dose.
2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 150 mg Base
Subjects: Healthy non-pregnant, non-lactating females
Additional comments: See comments above.

Analyte to measure: Ibexafungerp in plasma

Bioequivalence based on (90% CI): Ibexafungerp

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 and reference products. Specifications will be determined upon review of the Abbreviated New Drug Application (ANDA).

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