

Contains Nonbinding Recommendations
Draft – Not for Implementation
Draft Guidance on Safinamide Mesylate
October 2024

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Active Ingredient: Safinamide mesylate

Dosage Form: Tablet

Route: Oral

Strengths: EQ 50 mg Base, EQ 100 mg Base

Recommended Study: One in vivo bioequivalence study with pharmacokinetic endpoints

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 100 mg Base
Subjects: Healthy male and non-pregnant, non-lactating females
Additional comments: The use of safinamide mesylate is contraindicated with some drugs, including but not limited to monoamine oxidase inhibitor class, potent inhibitors of monoamine oxidase, opioid drugs, serotonin-norepinephrine reuptake inhibitors, dextromethorphan, etc. The concomitant use of safinamide mesylate with these drugs may cause clinically significant drug-drug interactions that could be potentially life-threatening. Applicants should avoid recruiting subjects who are taking these drugs. In addition, female subjects should not be pregnant, and should practice abstinence or contraception during the study, if applicable.

Analyte to measure: Safinamide in plasma

Bioequivalence based on (90% CI): Safinamide

Waiver request of in vivo testing: EQ 50 mg Base based on (i) acceptable bioequivalence study on the EQ 100 mg Base strength, (ii) acceptable in vitro dissolution testing of both strengths, and (iii) proportional similarity of the formulations between both strengths

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

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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*.