Contains Nonbinding Recommendations

Draft Guidance on Safinamide Mesylate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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 male and non-pregnant, non-lactating female subjects.

   Additional Comment: 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.

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2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: 100 mg
   Subjects: Healthy male and non-pregnant, non-lactating female subjects.

   Additional Comment: See comments above

Analyte to measure (in appropriate biological fluid): Safinamide in plasma

Bioequivalence based on (90% CI): Safinamide

Waiver request of in-vivo testing: 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 web site, 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).