Contains Nonbinding Recommendations

Draft Guidance on Isocarboxazid

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; Oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 10 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments:

   - During the bioequivalence study, subjects should not receive the following foods: protein foods in which aging or protein breakdown is used to increase flavor, such as cheese (particularly strong or aged varieties), sour cream, Chianti wine, sherry, beer (including non-alcoholic beer), liqueurs, pickled herring, anchovies, caviar, liver, canned figs, raisins, bananas or avocados (particularly if overripe), chocolate, soy sauce, sauerkraut, the pods of broad beans (fava beans), yeast extracts, yogurt, meat extracts, meat prepared with tenderizers, or dry sausage.
   - Subjects on regimens of the following drugs should be excluded from the bioequivalence study: other monoamine oxidase inhibitors, dibenzazepine-related and other tricyclics, Bupropion, selective serotonin reuptake inhibitors, Buspirone, sympathomimetic drugs and related compounds, Meperidine.
   - Study subjects should not consume alcoholic beverages during the study or within 7 days of study initiation.
   - Study subjects should not take dextromethorphan during the study or within 7 days of study initiation.

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2. Type of study: Fed
   Design: Single-dose, two-treatment, two-period crossover in vivo
   Strength: 10 mg
   Subjects: Males and non-pregnant, non-lactating females, general population
   Additional comments: See above

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

Bioequivalence based on (90% CI): Isocarboxazid

Waiver request of in vivo testing: Not applicable

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).

Isocarboxazid tablets are scored. For additional information on the evaluation of scored tablets, refer to the FDA Guidance on "Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation" issued in March 2013 at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269921.pdf.