

Draft Guidance on Lurasidone Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

Active Ingredient: Lurasidone hydrochloride

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: 40 mg
Subjects: Healthy males and nonpregnant females, general population
Due to safety concerns, conduct bioequivalence studies using the 40 mg strength (1 x 40 mg tablet).
Additional comments: (a) Study population should consist of healthy subjects at least 18 years of age with no clinically relevant abnormalities identified by a detailed medical history, full physical examination including vital signs (blood pressure, pulse rate, respiratory rate and temperature), 12-lead electrocardiogram (ECG), and clinical laboratory tests. Females should not be pregnant or lactating, and, if applicable, should practice abstinence or contraception during the study. (b) To minimize risks, based on the current knowledge, subjects with any of the following conditions should be excluded from the BE study: (i). A history or diagnosis of any cardiovascular, respiratory, hepatic, renal, gastrointestinal, endocrine, neurological, immunologic, hematologic or psychiatric disorders. (ii). Subjects who are on strong CYP3A4 inhibitors (e.g., ketoconazole, clarithromycin, ritonavir, voriconazole, mibefradil, etc.) or inducers (e.g., rifampin, avasimibe, St. John's wort, phenytoin, carbamazepine, etc.). (c) Blood pressure, heart rate, and body temperature should be monitored during the study and immediate medical care provided for any significant abnormalities.

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2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: 40 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: See comments above.
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Analytes to measure (in appropriate biological fluid): Lurasidone in plasma

Bioequivalence based on (90% CI): Lurasidone

Waiver request of in vivo testing: 20 mg, 60 mg, 80 mg, and 120 mg based on (i) acceptable bioequivalence studies on the 40 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 website 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).