

Draft Guidance on Doxepin Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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 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: Doxepin hydrochloride

Dosage Form; Route: Capsule; oral

Recommended Studies: Two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 150 mg base
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Due to the potential for serious adverse events, monoamine oxidase inhibitors should be discontinued at least two weeks prior to study initiation. Subjects should be monitored for adverse events for at least 24 hours after dosing or until resolution of adverse events
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2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 150 mg base
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Please see comments above. Refer to the amantadine hydrochloride tablet draft guidance for additional information regarding fed studies
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Analytes to measure (in appropriate biological fluid): Doxepin, and its active metabolite nordoxepin, in plasma

Bioequivalence based on (90% CI): Doxepin

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).