

## Guidance on Doxepin Hydrochloride

This guidance represents 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:** 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.
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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).