Contains Nonbinding Recommendations

Guidance on Doxepin Hydrochloride

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

---

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.

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).