Contains Nonbinding Recommendations

Draft Guidance on Minocycline Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: Two studies

1. Type of study: Fasting
   Design: Single-dose, two-way crossover in-vivo
   Strength: EQ 100 mg BASE
   Subjects: Males and nonpregnant females, general population
   Additional Comments:

2. Type of study: Fed
   Design: Single-dose, two-way crossover in-vivo
   Strength: EQ 100 mg BASE
   Subjects: Males and nonpregnant females, general population
   Additional Comments:

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

Bioequivalence based on (90% CI): Minocycline

Waiver request of in-vivo testing: EQ 50 mg BASE and EQ 75 mg BASE based on (i) acceptable bioequivalence study on the EQ 100 mg BASE strength, (ii) acceptable in-vitro dissolution testing of all strengths, and (iii) proportional similarity in 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 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).