

Draft Guidance on Minocycline Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Tablet/Oral

Recommended Study: 1 study

Type of study: Fasting

Design: Single-dose, two-way crossover in-vivo

Strength: 100 mg

Subjects: Health 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: 50 mg and 75 mg based on (i) acceptable bioequivalence study on the 100 mg 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:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/index.cfm>. Please find the dissolution information for this product at this website. Please 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 application.