

Draft Guidance on Demeclocycline Hydrochloride

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Active ingredient: Demeclocycline Hydrochloride

Form/Route: Tablets/Oral

Recommended studies: 1 study

Type of study: Fasting

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

Strength: 300 mg

Subjects: Normal healthy males and females, general population

Additional Comments:

Analytes to measure: Demeclocycline in plasma

Bioequivalence based on (90% CI): Demeclocycline

Waiver request of in-vivo testing: 150 mg based on (i) acceptable bioequivalence studies on the 300 mg strength, (ii) acceptable dissolution testing across 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.fda.gov/cder/ogd/index.htm>. 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.