

Contains Nonbinding Recommendations
Draft Guidance on Doxycycline Hyclate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet, delayed-release; oral

Recommended Studies: Three studies

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: EQ 200 mg base at a dose of 200 mg (1x200 mg)
Subjects: Healthy males and nonpregnant females, general population
Additional comments: None
2. Type of study: Fed
Design: Single-dose, two-way crossover in vivo
Strength: EQ 200 mg base at a dose of 200 mg (1x200 mg)
Subjects: Healthy males and nonpregnant females, general population
Additional comments: None
3. Type of study: Fasting, sprinkle
Design: Single-dose, two-way crossover in vivo
Strength: EQ 200 mg base at a dose of 200 mg (1x200 mg)
Subjects: Healthy males and nonpregnant females, general population
Additional comments: Administer the dose after sprinkling the entire contents of the tablet on a spoonful of applesauce, in accordance with the approved labeling of the reference listed drug (RLD).

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

Bioequivalence based on (90% CI): Doxycycline

Waiver request of in vivo testing: EQ 50 mg base, EQ 75 mg base, EQ 80 mg base, EQ 100 mg base, and EQ 150 mg base based on (i) acceptable bioequivalence (BE) studies on the EQ 200 mg base strength, (ii) proportionally similar formulation across all strengths, and (iii) acceptable in vitro dissolution testing of 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).

Note that the reference products are scored tablets. For additional information related to scored tablets, refer to the guidance *Tablet Scoring: Nomenclature, Labeling, and Data for Evaluation*, issued in March 2013 at

<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269921.pdf>