

Contains Nonbinding Recommendations
Draft – Not for Implementation
Draft Guidance on Doxycycline Calcium
October 2024

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- Active Ingredient:** Doxycycline calcium
- Dosage Form:** Suspension
- Route:** Oral
- Strength:** EQ 50 mg Base/5 mL
- Recommended Study:** One in vivo bioequivalence study with pharmacokinetic endpoints
1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 50 mg Base/5 mL
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None
- Analyte to measure:** Doxycycline in plasma
- Bioequivalence based on (90% CI):** Doxycycline
- Waiver request of in vivo testing:** Not applicable

Dissolution test method and sampling times: The dissolution information for this drug product can be found in the FDA’s Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution>. Conduct comparative dissolution testing on 12 dosage units each of the test and reference listed drug (RLD) products.¹ Specifications will be determined upon review of the abbreviated new drug application.

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¹ If the RLD is not available, refer to the most recent version of the FDA guidance for industry on *Referencing Approved Drug Products in ANDA Submissions*.