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*Draft – Not for Implementation*

## **Draft Guidance on Clindamycin Hydrochloride**

**October 2024**

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**Active Ingredient:** Clindamycin hydrochloride

**Dosage Form:** Capsule

**Route:** Oral

**Strengths:** EQ 75 mg Base, EQ 150 mg Base, EQ 300 mg Base

**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: 300 mg  
Subjects: Healthy males and non-pregnant, non-lactating females  
Additional comments: None

**Analyte to measure:** Clindamycin in plasma

**Bioequivalence based on (90% CI):** Clindamycin

**Waiver request of in vivo testing:** EQ 75 mg Base and EQ 150 mg Base strengths based on (i) acceptable bioequivalence study on the EQ 300 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 in the FDA’s Dissolution Methods database, <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Conduct comparative dissolution testing on 12 dosage units for each of all strengths of the test product and reference listed drug (RLD).<sup>1</sup> Specifications will be determined upon review of the abbreviated new drug application.

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**Document History:** Recommended September 2011; Finalized August 2017; Revised October 2024

**Unique Agency Identifier:** PSG\_050162

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<sup>1</sup> 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*.