

Contains Nonbinding Recommendations

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Draft Guidance on Naldemedine Tosylate

October 2024

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Active Ingredient: Naldemedine tosylate

Dosage Form: Tablet

Route: Oral

Strength: EQ 0.2 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: EQ 0.2 mg Base
Subjects: Healthy males and non-pregnant, non-lactating females
Additional comments: None

Analyte to measure: Naldemedine in plasma

Bioequivalence based on (90% CI): Naldemedine

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 product and reference listed drug (RLD).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*.