

## Draft Guidance on Naldemedine Tosylate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

**Dosage Form; Route:** Tablet; oral

**Recommended Studies:** Two studies

1. Type of study: Fasting  
Design: Single-dose, two-way crossover in-vivo  
Strength: Eq 0.2 mg base  
Subjects: Males and non-pregnant, non-lactating females, general population.  
Additional Comment: None

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2. Type of study: Fed  
Design: Single-dose, two-way crossover in-vivo  
Strength: Eq 0.2 mg base  
Subjects: Males and non-pregnant, non-lactating females, general population.  
Additional Comment: None

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**Analyte to measure (in appropriate biological fluid):** 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 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 the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).