

Draft Guidance on Naloxegol Oxalate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Tablet; oral

Recommended Studies: One in vivo study

1. Type of study: Fasting
Design: Single-dose, two-way crossover in vivo
Strength: EQ 25 mg base
Subjects: Healthy males and nonpregnant females, general population
Additional comments: None
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Analytes to measure (in appropriate biological fluid): Naloxegol in plasma

Bioequivalence based on (90% CI): Naloxegol

Waiver request of in vivo testing: EQ 12.5 mg base based on (i) acceptable bioequivalence studies on the EQ 25 mg base strength, (ii) acceptable in vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across 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).