

Draft Guidance on Naloxegol Oxalate

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: EQ 25 mg Base
Subjects: Males and non-pregnant females, general population
Additional comments: None

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 both strengths, (iii) proportional similarity of the formulations between both 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 both strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).

Product-specific testing conditions for in vitro feeding tube studies:

The approved labeling for the reference product states that the product may be administered by a nasogastric (NG) tube. Conduct the in vitro feeding tube studies including comparative recovery testing and sedimentation volume testing. Refer to the Lansoprazole Delayed-Release Orally Disintegrating Tablet Draft Guidance for additional information regarding procedures of in vitro feeding tube studies.

Testing tube: NG tube (8 French)

Testing strength: 25 mg

Dispersion medium: 60 mL water