

Draft Guidance on Oxycodone Hydrochloride

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

Dosage Form; Route: Capsule; oral

Recommended Study: Two options: BCS waiver option or in vivo option

I. BCS Waiver Option:

Upon request, it may be possible to receive a waiver of in vivo testing of this product, provided that you submit in the application the appropriate documentation regarding high solubility, high permeability, and rapid dissolution, as detailed in the guidance for industry *Waiver of In Vivo Bioavailability and Bioequivalence for Immediate-Release Solid Oral Dosage Forms Based on the Biopharmaceutics Classification System* (Aug, 2000). You may use the information contained in the approved labeling of the reference product. Peer-reviewed articles may not contain the details on the testing necessary for the Agency to make a judgment regarding the quality of the studies. A decision regarding the acceptability of the waiver request can only be made upon review of the data submitted in the application.

II. In Vivo Option:

Recommended studies: two studies

1. Type of study: Fasting
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 5 mg
Subjects: Healthy males and nonpregnant females, general population
Additional comments: A naltrexone blockade should be used to remove the risk of any opioid-related adverse events. Naltrexone should be administered well in advance of dosing to achieve adequate blockade of opioid receptors. The most common approach is to administer 50 mg of naltrexone at the following times: (1) 12 hours prior to dosing; (2) at the time of study drug dosing; and (3) 12 hours after the last dose of study drug. Consult with a physician who is an expert in the administration of opioids for an appropriate dose of narcotic antagonist.

2. Type of study: Fed
Design: Single-dose, two-treatment, two-period crossover in vivo
Strength: 5 mg

Subjects: Healthy males and nonpregnant females, general population
Additional comments: Same as above

Analytes to measure (in appropriate biological fluid): Oxycodone in plasma

Bioequivalence based on (90% CI): Oxycodone

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 all strengths of the test and reference products. Specifications will be determined upon review of the abbreviated new drug application (ANDA).