

## Draft Guidance on Oxymorphone Hydrochloride

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

**Active ingredient:** Oxymorphone Hydrochloride

**Form/Route:** Tablets/Oral

**Recommended studies:** 1 study

Type of study: Fasting

Design: Single-dose, two-treatment, two-period crossover *in-vivo*

Strength: 10 mg

Subjects: Normal healthy males and females, general population.

Additional Comments: Please use a narcotic antagonist such as naltrexone if the study involves healthy subjects. You should consult a physician who is an expert in the administration of opioids for an appropriate dose of narcotic antagonist.

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**Analytes to measure (in appropriate biological fluid):** Oxymorphone and its metabolite, 6-OH-oxymorphone in plasma.

For 6-OH-oxymorphone, the following data should be submitted: individual and mean concentrations, individual and mean pharmacokinetic parameters, and geometric means and ratios of means for AUC and C<sub>max</sub>.

**Bioequivalence based on (90% CI):** Oxymorphone

**Waiver request of in-vivo testing:** 5 mg, based on acceptable (i) bioequivalence studies on the 10 mg strength (ii) proportional similarity of the formulations and (iii) acceptable in vitro dissolution testing of all strengths.

**Dissolution test method and sampling times:**

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.fda.gov/cder/ogd/index.htm>. Please find the dissolution information for this product at this website. Please 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 application.