

Contains Nonbinding Recommendations
Draft Guidance on Triptorelin Pamoate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Triptorelin Pamoate

Form/Route: Injectable/Intramuscular

Recommended studies: 3 studies

1. Type of study: Fasting
Design: Single-dose, parallel design in vivo with pharmacokinetic endpoints
Strength: 3.75 mg base/vial
Subjects: Advanced prostate cancer male patients

2. Type of study: Fasting
Design: Single-dose, parallel design in vivo with pharmacokinetic endpoints
Strength: 11.5 mg base/vial
Subjects: Advanced prostate cancer male patients

3. Type of study: Fasting
Design: Single-dose, parallel design in vivo with pharmacokinetic endpoints
Strength: 22.5 mg base/vial
Subjects: Advanced prostate cancer male patients

As per 21 CFR § 314.94, the proposed parenteral drug product should be qualitatively (Q1) and quantitatively (Q2) identical to the reference product for all strengths (22.5 mg base/vial, 11.25 mg base/vial and 3.75 mg base/vial).

Analytes to measure: Triptorelin in serum

Bioequivalence based on (90% CI): Triptorelin

The 90% confidence intervals of the following PK parameters must meet the acceptable limits of [80.00-125.00]: Log-transformed AUC_{7-t} , AUC_t , $AUC_{0-\infty}$, and C_{max} ,

where AUC_{7-t} is the area under the plasma-concentration vs. time curve from 7 days to the last sampling time point, AUC_t is the area under the curve from 0 to the last sampling time point, $AUC_{0-\infty}$ is the area under the curve from 0 to infinity, and C_{max} is the maximum plasma concentration.

Waiver request of in vivo testing: N/A

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.