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Draft Guidance on Triptorelin Pamoate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: 1 study

Type of study: Fasting
Design: Single-dose, parallel design *in-vivo* with pharmacokinetic endpoints
Strength: 11.25 mg base/vial
Subjects: Advance prostate cancer male patients
Additional Comments:

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

Analytes to measure: Triptorelin in serum

Bioequivalence based on (90% CI): Triptorelin

Waiver request of in-vivo testing: 3.75 mg base/vial based on (i) acceptable bioequivalence studies on the 11.25 mg base/vial strength, (ii) acceptable dissolution testing across all strengths, and (iii) proportional similarity in the formulations across 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.