

Contains Nonbinding Recommendations
Draft Guidance on Octreotide Acetate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Injectable/Injection

Recommended studies: 1 study

Type of study: Fasting

Design: Single-dose, parallel design in vivo

Strength: 30 mg

Subjects: Healthy males and nonpregnant females, general population.

Additional Comments: Administration should occur as an intramuscular (IM) injection intragluteally.

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

Bioequivalence based on (90% CI): Octreotide

The 90% confidence intervals of the following PK parameters must meet the acceptable limits of [80.00-125.00]: Log-transformed AUC_{0-28} , AUC_{28-56} , AUC_t , $AUC_{0-\infty}$, and C_{max} ,

where AUC_{0-28} is the area under the plasma-concentration vs. time curve from 0 to 28 days, AUC_{28-56} is the area under the plasma-concentration vs. time curve from 28 to 56 days, 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: 10 mg and 20 mg based on (i) acceptable bioequivalence study on the 30 mg strength, (ii) acceptable in-vitro dissolution testing of all strengths, and (iii) proportional similarity of the formulations across all strengths.

The formulation of test and reference products should be qualitatively (Q1) and quantitatively (Q2) the same per CFR 21 314.94 (a)(9)(iii).

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.accessdata.fda.gov/scripts/cder/dissolution/>. 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.

Please note that a dosage unit for a suspension is the labeled strength (mL). A total of 12 units from 12 different bottles should be used. Specifications will be determined upon review of the application.