

Contains Nonbinding Recommendations
Draft Guidance on Lanreotide Acetate

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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

Form/Route: Injectable; Subcutaneous

Recommended studies: 2 options

Lanreotide Acetate injection is a parenteral product. According to 21 CFR 314.94(a)(9)(iii), a generic parenteral injection drug product should be qualitatively (Q1) and quantitatively (Q2) the same as the reference product. Based on Q1/Q2 sameness and satisfactory dissolution data, bioequivalence can be demonstrated using one of the two options in this recommendation.

Option 1: biowaiver

A waiver of in vivo bioequivalence study will be granted if the test product demonstrates equivalent molecular, structural, and thermodynamic properties as the reference listed product. Lanreotide conformation, nanotube structure, and thermo stability at different temperature and dilution should be characterized. In addition, acceptable comparative in vitro drug release-rate tests of lanreotide acetate from the test and RLD formulations should be demonstrated. The comparative study should be conducted with at least three lots of both reference and test products.

Option 2: in vivo bioequivalence study

Type of study: Fasting

Design: Single-dose, randomized, parallel in vivo study

Strength: EQ 120mg base (Dose: EQ 120 mg base)

Subjects: Healthy males and females, general population

Additional Comments: The products should be administered as a deep subcutaneous injection at the superior external quadrant of the buttock.

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

Bioequivalence based on (90% CI): Lanreotide

Waiver request of in vivo testing: EQ 60mg base and EQ 90mg base on (i) acceptable bioequivalence studies on the EQ 120mg base strength; (ii) proportional similarity of the formulations across all strengths; and (iii) acceptable in vitro dissolution testing of all strengths.

Dissolution test method and sampling times:

Please design a proper dissolution testing method for this product. 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.