

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Etelcalcetide

February 2022

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the Office of Generic Drugs.

This guidance, which interprets the Agency’s regulations on bioequivalence at 21 CFR part 320, provides product-specific recommendations on, among other things, the design of bioequivalence studies to support abbreviated new drug applications (ANDAs) for the referenced drug product. FDA is publishing this guidance to further facilitate generic drug product availability and to assist the generic pharmaceutical industry with identifying the most appropriate methodology for developing drugs and generating evidence needed to support ANDA approval for generic versions of this product.

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This is a new draft product-specific guidance for industry on generic etelcalcetide.

Active Ingredient:	Etelcalcetide
Dosage Form; Route:	Solution; intravenous
Strengths:	2.5 mg/0.5 mL, 5 mg/mL, and 10 mg/2 mL
Recommended Study:	Request for waiver of in vivo bioequivalence study requirements
Waiver:	

In vivo bioequivalence (BE) study may be waived on the basis that BE is self-evident (21 CFR 320.22(b)), for a generic etelcalcetide injection solution product that is qualitatively (Q1)¹ and quantitatively (Q2)² the same as the Reference Listed Drug (RLD).

¹ Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the reference list drug product.

² Q2 (Quantitative sameness) means that concentrations of the inactive ingredient(s) used in the test product are within ± 5% of those used in the reference listed product.

A proposed generic drug product may differ from the RLD in preservative, buffer, or antioxidant if the identified differences are characterized and demonstrated to not affect the safety or efficacy of the proposed drug product.³

In addition to ensuring active pharmaceutical ingredient sameness, a comparative assessment of product aggregation including the formation of subvisible aggregates is recommended with at least three batches of the proposed generic etelcalcetide and the RLD aged under various conditions.⁴

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³ 21 CFR 314.94(a)(9)(iii)

⁴ Samples should be aged under conditions consistent with the worst-case label storage conditions.