Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Ceftobiprole Medocaril Sodium

May 2025

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Active Ingredient: Ceftobiprole medocaril sodium

Dosage Form: Powder

Route: Intravenous

Strength: 667 mg/vial

Recommended Study: Request for waiver of in vivo bioequivalence study requirements

To qualify for a waiver of in vivo bioequivalence study requirement on the basis that bioequivalence is self-evident under 21 CFR 320.22(b)(1), a generic ceftobiprole medocaril sodium intravenous powder product should be qualitatively (Q1)[1] and quantitatively (Q2)[2] the same as the reference listed drug (RLD).

An applicant may seek approval of a drug product that differs from the RLD in preservative, buffer, or antioxidant provided that the applicant identifies and characterizes the differences and provides information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.[3]

Document History: Recommended May 2025

Unique Agency Identifier: PSG_218275

[1] Q1 (Qualitative sameness) means that the test product uses the same inactive ingredient(s) as the RLD.
[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 RLD.
[3] 21CFR 314.94(a)(9)(iii)