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Draft Guidance on Cefazolin Sodium

November 2024

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Active Ingredient: Cefazolin sodium

Dosage Form: Powder

Route: Intravenous

Strength: EQ 2 gm Base/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 cefazolin 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 if 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]

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

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