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Draft Guidance on Pemetrexed Disodium

May 2025

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Active Ingredient:	Pemetrexed disodium
Dosage Form:	Solution
Route:	Intravenous
Strengths:	EQ 100 mg Base/4 mL (EQ 25 mg Base/mL); EQ 500 mg Base/20 mL (EQ 25 mg Base/mL); EQ 1 gm Base/40 mL (EQ 25 mg Base/mL)
Recommended Study:	Request for waiver of in vivo bioequivalence study requirements

To qualify for a waiver from submitting an in vivo bioequivalence study on the basis that bioequivalence is self-evident under 21 CFR 320.22(b), a generic pemetrexed disodium intravenous solution product should be qualitatively (Q1)[1] and quantitatively (Q2)[2] the same as the RLD.

An applicant may seek approval of a drug product intended for parenteral use 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]

[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).

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