

Contains Nonbinding Recommendations

Draft – Not for Implementation

Draft Guidance on Treosulfan

December 2025

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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: Treosulfan

Dosage Form: Powder

Route: Intravenous

Strengths: 1 gm/vial, 5 gm/vial

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

To qualify for a waiver from the requirement for submission of evidence of in vivo bioequivalence on the basis that bioequivalence is self-evident under 21 CFR 320.22(b)(1), a generic treosulfan 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

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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 $\pm 5\%$ of those used in the RLD.

³ 21 CFR 314.94(a)(9)(iii).