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Draft – Not for Implementation

Draft Guidance on Technetium Tc-99m Sodium Pertechnetate Generator

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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 technetium Tc-99m sodium pertechnetate generator.

Active Ingredient:	Technetium Tc-99m sodium pertechnetate generator
Dosage Form; Route:	Solution; intravenous, intravesicular, ophthalmic
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)(1), a generic technetium Tc-99m sodium pertechnetate generator intravenous, intravesicular, ophthalmic product must be 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 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.

An applicant may seek approval of a drug product that differs from the RLD in preservative, or buffer³ 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.

Additional comments: Technetium Tc-99m sodium pertechnetate generator intravenous, intravesicular, ophthalmic products should have comparable physicochemical properties to the Reference Standard (RS) including but not limited to pH, specific gravity, buffer capacity, osmolality, and viscosity, if applicable. Comparative analysis should be performed on three exhibit batches, if available, of both test and RS products.

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³ Refer to 21 CFR 314.94(a)(9)(iii) for product for parenteral use. Refer to 21 CFR 314.94(a)(9)(iv) for product for ophthalmic use. In addition, for ophthalmic route of administration, FDA has determined that, as a scientific matter, any qualitative or quantitative deviations from the RLD, even in inactive ingredients listed in 21 CFR 314.94(a)(9)(iv), should be accompanied by an appropriate in vivo BE study or studies. Refer to the most recent version of the FDA guidance for industry on *ANDA Submissions – Refuse-to-Receive Standards*.