

Contains Nonbinding Recommendations
Draft - Not for Implementation
Draft Guidance on Sodium Chloride
February 2022

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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 sodium chloride.

Active Ingredient: Sodium chloride
Dosage Form; Route: Aerosol, metered; inhalation
Strength: 0.9%
Recommended Studies: Request for waiver of in vivo bioequivalence study

Waiver:

To qualify for a waiver of evidence of in vivo bioequivalence (BE) study requirement under 21 CFR 320.22(b)(3), generic versions of sodium chloride (0.9%) inhalation aerosol metered indicated for dilution of bronchodilator inhalation solutions for nebulization should contain the same active ingredient in the same concentration and dosage form as the Reference Listed Drug (RLD) product and contain no inactive ingredient or other change in formulation from the RLD that may significantly affect systemic or local availability.

For an inhalation aerosol metered product indicated for dilution of bronchodilator inhalation solutions for nebulization that differs from the RLD in inactive ingredients [as permitted by the chemistry, manufacturing, and controls regulations for an Abbreviated New Drug Application (ANDA), 21 CFR 314.94(a)(9)(v)], the regulation specifies that the prospective applicant must identify and characterize the differences and provide information demonstrating that the differences do not affect the safety or efficacy of the proposed drug product.

Analyte to measure: Not applicable

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: See above

Dissolution test method and sampling times: Not applicable

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