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Draft – Not for Implementation

Draft Guidance on Lactitol

November 2021

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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 lactitol.

Active Ingredient: Lactitol

Dosage Form; Route: For solution; oral

Strength: 10 gm

Recommended Study: Request for waiver of in vivo bioequivalence study

Waiver:

To qualify for a waiver of the in vivo bioequivalence study requirement under 21 CFR 320.22(b)(3), generic versions of lactitol powder for oral solution must contain the same active drug ingredient in the same concentration and dosage form as the reference listed drug (RLD) and contain no inactive ingredient or other change in formulation from the RLD that may significantly affect systemic availability.

Analyte to measure: Not applicable

Waiver request of in vivo testing: See above

Dissolution test method and sampling times: Not applicable

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