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Draft – Not for Implementation

Draft Guidance on Nystatin

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

The contents of this document do not have the force and effect of law and are not meant to bind the public in any way, unless specifically incorporated into a contract. This document is intended only to provide clarity to the public regarding existing requirements under the law. FDA guidance documents, including this guidance, should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA guidances means that something is suggested or recommended, but not required.

In May 2010, FDA issued a draft product-specific guidance for industry on generic nystatin. We are now issuing revised draft guidance for industry that replaces the previously issued guidance.

Active Ingredient:	Nystatin
Dosage Form; Route:	Powder; topical
Recommended Study:	Acceptable comparative physicochemical and structural (Q3) characterization of the test and reference products to establish that the test product is the same dosage form as the reference product with the identical strength to support a demonstration of pharmaceutical equivalence.

Analyte to measure: Not applicable

Bioequivalence based on (90% CI): Not applicable

Waiver request of in vivo testing: Not applicable

Dissolution test method and sampling times: Not applicable

Revision History: Recommended May 2010; Revised August 2021

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