

*Contains Nonbinding Recommendations*

*Draft – Not for Implementation*

**Draft Guidance on Nystatin**

**October 2022**

This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA, or the Agency) on this topic.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

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.

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**Active Ingredient:** Nystatin

**Dosage Form; Route:** Cream; topical

**Recommended Studies:** Characterization tests

Acceptable comparative physicochemical and structural (Q3) characterization of the test product and reference standard should establish that they are the same dosage form, with identical strength. Refer to the most recent version of the FDA guidance for industry on *Physicochemical and Structural (Q3) Characterization of Topical Drug Products Submitted in ANDAs*<sup>a</sup> for additional information regarding appropriate Q3 characterization tests.

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**Revision History:** Recommended May 2010; Revised October 2022

**Unique Agency Identifier:** PSG\_060575

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<sup>a</sup> For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>.