

*Contains Nonbinding Recommendations*  
**Draft Guidance on Nystatin**

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the Office of Generic Drugs.

**Active ingredient:** Nystatin

**Form/Route:** Cream/Topical

**Recommended studies:** None

Nystatin Topical Cream is a DESI<sup>1</sup> - effective drug for which there are no known or suspected bioequivalence problems, and as such is rated "AT" in FDA/CDER's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book")

**Analytes to measure (in appropriate biological fluid):** Not Applicable

**Bioequivalence based on (90% CI):** Not Applicable

**Waiver request of in-vivo testing:** 100,000 USP Nystatin Units per gram provided the conditions specified in 21 CFR 314.94(a)(9)(v) are met.

**Dissolution test method and sampling times:** Not Applicable

---

<sup>1</sup> Drug Efficacy Study Implementation