

Draft Guidance on Nystatin

This draft guidance, once finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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: Suspension/Oral

Recommended studies:

Nystatin Oral Suspension is a DESI¹ effective drug for which there are no known or suspected bioequivalence problems, and as such is rated “AA” in the FDA/CDER’s Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”).

Analytes to measure: Not Applicable

Bioequivalence based on (90% CI): Not Applicable

Waiver request of in-vivo testing: 100,000 Units/mL pursuant to 21 CFR 320.22(c) provided that the in-vitro dissolution profiles of the proposed product are comparable to those of the reference product.

Dissolution test method and sampling times:

Please note that a **Dissolution Methods Database** is available to the public at the OGD website at <http://www.accessdata.fda.gov/scripts/cder/dissolution/>. Please find the dissolution information for this product at this website. Please conduct comparative dissolution testing on 12 dosage units each of all strengths of the test and reference products. Specifications will be determined upon review of the application.

Please note that a dosage unit for a suspension is the labeled strength (mL). A total of 12 units from 12 different bottles should be used. Specifications will be determined upon review of the application.

¹ Drug Efficacy Study Implementation