Active ingredient: Nystatin
Form/Route: Cream/Topical
Recommended studies: None

Nystatin Topical Cream is a DESI - 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

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1 Drug Efficacy Study Implementation

Recommended May 2010