



INTERNATIONAL JOURNAL OF RESEARCH IN PHARMACEUTICAL SCIENCES

Published by JK Welfare & Pharmascope Foundation

Journal Home Page: www.pharmascope.org/ijrps

Fasten, simple, and specific stability of the avant-garde RP-HPLC method for estimation and validation of nystatin in pharmaceutical formulations

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Article History:

Received on: 02.07.2019

Revised on: 15.10.2019

Accepted on: 30.10.2019

Keywords:

Nystatin (NYS),
pharmaceuticals varied,
antifungal medication

ABSTRACT

In this study, a simple and reliable stability-indicating RP-HPLC method was developed and validated for the analysis of Nystatin in the pharmaceuticals. The chromatographic separation was performed in the isocratic mode on an Ion Pac column; Arcus EP-C18; 5 μ m, 4.6 \times 250 mm, 30 °C) using a mobile phase consisting of ammonium acetate 0.05 M buffer/ Methanol mixture (30:70) and a flow-rate of 1.0 mL/min with UV detection at 305 nm. The flow rate was set at 1.0 mL/min. The HPLC analysis method was validated in terms of linearity, precision, accuracy, specificity, and sensitivity, according to International Conference on Harmonization (ICH) guidelines. The results indicated that the retention time was 8 min, and no interferences were observed from the formulation excipients and stress degradation products. The specificity, linearity, precision, accuracy, LOD, and LOQ of the method were validated. The method was linear over the range of 5–500 μ g/mL with an acceptable correlation coefficient ($R^2 = 0.9996$). The method's limit of detection (LOD) and quantification (LOQ) were 0.01 and 0.025 μ g/mL, respectively. The results indicate that this validated method can be used as an alternative method for the assay of nystatin. This validated HPLC method could be used for routine analysis, quality control, and the stability of analysis of Nystatin formulations.



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ISSN: 0975-7538

DOI: <https://doi.org/10.26452/ijrps.v10i4.1760>

Production and Hosted by

Pharmascope.org

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INTRODUCTION

Nystatin is a fungicide belonging to the urine group that has a therapeutic effect on many fungi and yeasts, including Candida. This compound exhibits

toxic effects when administered intravenously while well absorbed through healthy skin or mucous membranes. It is also considered a safe drug when treating fungal oral and intestinal infections, Chemical formula: $C_{47}H_{75}NO_{17}$, Molecular mass: 926.1 g/mol (Ghari *et al.*, 2013; Cione *et al.*, 2010; Groll *et al.*, 1999)

Nystatin that has name According to AUPIC system (*Oxacyclooctatriaconta-6,8,12,14,16, 18-hexaene-23-carboxylic acid*) is an antifungal drug, which was developed at the beginning of the 50 years of the last century. Nystatin is effective for treating superficial infections caused by Candida. There are several forms of this drug, which is used to treat skin, mouth, pharynx, esophagus, and vaginal infections (Pons *et al.*, 1997; Nyst *et al.*, 1992). Since the body is unable to absorb nystamine from the gastrointesti-