Research in Pharmaceutical Sciences, 2012;7(5)
School of Pharmacy and Pharmaceutical Sciences
Isfahan University of Medical Sciences

Development and validation of high performance liquid chromatography for determination of nystatin in pharmaceutical formulations

F. Shokraneh[1,*], A. Abdollahpour[2], R. Asgharian[1]

[1]Department of Pharmaceutics, Pharmaceutical Sciences Branch, Islamic Azad University, Tehran, Iran.
[2]Department of Pharmaceutics, Pharmaceutical Sciences Branch, Islamic Azad University, Tehran, Iran and Quality Assurance Lab, Jaber Ebne Hayyan Pharmaceutical Company, Tehran, Iran.

Background and Aims: Nystatin is efficient antimicrobial agent against a broad spectrum of saprophytic and pathogenic fungi. Pharmacopeia methods for Nystatin assay, as well for other antibiotics, are traditionally microbiological (USP, 2010, BP, 2010) and yield the potency of the drug. One of the challenging aspects of Nystatin assay method according to the Pharmacopeias method (Microbial assay) is the complexity and time consuming the analysis.
Methods: A simple, rapid and sensitive isocratic High Performance Liquid Chromatography with ultraviolent detection (HPLC-UV) was developed and validated for the assay of Nystatin in bulk and pharmaceutical samples. The method validation demonstrated the specificity, lower limit of quantification (LOQ), recovery, linearity, precision and accuracy of measurements. Separations were performed on a Symmetry 300 TM C18 column (5 µm particle size, 4.6×150 mm. ID) with mobile phase of ammonium acetate buffer: Methanol (20:80) mixture respectively. Validation of this method was performed according to the accepted international recommendation.
Results: Under optimum conditions, the limit of detection (LOD) and quantification (LOQ) were 0.01 and 0.03 mg/L respectively. The method was linear over the range of 0.01 – 500 mg/L with a good correlation coefficient (R2 = 0.9992).Recovery and intra- and inter-day precision showed good reproducibility. The proposed method was applied to determination of Nystatin in bulk and pharmaceutical samples and satisfactory result were obtained (Relative error < 5.0 %). The result showed that the proposed method is simple and could be conducted by different operators and in different Labs.
Conclusions: The results clearly indicate that our proposed validated method can be used as an alternative method for assay of Nystatin. The application of each method as a routine analysis should be investigated considering cost, simplicity, speed and time consuming of analysis.

Keywords: Nystatin; High Performance; Liquid Chromatography; Validation