Commentary
Volume 13:8, 2022

Chemical Sciences Journal

ISSN: 2150-3494 Open Access

Analytical Method for Determination of Amphotericin

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Abstract

By utilising RP-HPLC with UV detection, a straightforward, sensitive, and precise analytical has been established to estimate amphotericin in pharmaceutical effluents that the pharmaceutical industry are discharging into aquatic environments. The devised approach is extremely accurate and sensitive to detect amphotericin at concentrations of less than 0.1ppm-5ppm. For the measurement of Amphotericin in effluents or pharmaceutical industry washouts, a reversed-phase high performance liquid chromatography (RP-HPLC) method was created and validated. On a Symmetry C-18 column (250mm 4.6mm i.d., 5.0m), the separation was accomplished using a citrate buffer with a pH of 4.5 as the buffer, and a combination of 400mL buffer and 600mL acetonitrile in isocratic mode as the mobile phase, all at a flow rate of 1.2 mL/min. A UV detector operating at 383 nm was used for detection. Amphotericin eluted at a retention period of approximately 5.0 min, taking around 12.0 min of total chromatographic analysis time per sample. For accuracy, precision, specificity, linearity, and sensitivity, the procedure was validated. Validation tests proved the accuracy, specificity, speed, dependability, and reproducibility of this HPLC method. The limit of detection (LOD) and limit of quantitation (LOQ) for amphotericin were discovered to be 0.0100 g/ml and 0.0500 g/ml, respectively, and the method was validated in accordance with ICH guidelines. Linearity was observed for amphotericin in the concentration range of 0.05-10 g/mL (R2>0.95). It was discovered that the RSD for intra-day and inter-day precision was less than 5%. The approach is straightforward, definite, exact, and accurate for determining amphotericin in pharmaceutical industry washouts, and the percentage recovery was in good agreement.

Keywords: Amphotericin • Estimation of residual amount • Liquid chromatography

Introduction

Despite the fact that pharmaceutical production [1] started in earnest many years ago, modern scientific research has placed a greater emphasis on waste generation and its effects on the environment. The presence of pharmaceutical compounds in various aquatic habitats, such as lakes and drinking water, has been proven by numerous investigations. The need for clean water has grown even more as a result of increasing urbanisation and population growth, which also increases the amount of effluent that has to be treated. On the other hand, when the demand grows for new medications across a range of therapeutic fields, such as antibiotics, anti-retrovirals, and cancer treatments, the contaminating effects of pharmaceutical products on domestic water sources increase. Recent research has established that due to their high toxicity to bacteria and algae, even at low concentrations, antibiotics and anti-retrovirals are among the pharmacological compounds that pose the greatest risk. These hazards don't just include a rise in the number of deadly hospital-acquired infections caused by microorganisms that become resistant to antibiotics.

Studies on the published databases of several environmental agencies reveal inconsistent waste management monitoring and noncompliance with the restrictions on effluent discharge. It was discovered during inspections in various businesses that waste management is still in its early stages and that high volume production is increasing the variability in effluent composition. The treatment systems and the many analytical techniques used for their estimate during effluent treatment are greatly impacted by the inconsistent composition of waste. The author chose Amphotericin, one of the most widely used drug substances in the pharmaceutical therapeutic category, and developed a straightforward, efficient reverse phase chromatographic analytical method because there is a dearth of published scientific [2,3] work for the determination of pharmaceutical substances. Similar techniques can be used to estimate the drug substance in a variety of pharmaceutical washouts or effluents.

There aren't many techniques in the literature for analysing amphotericin in pharmaceutical dose forms and in bulk from a qualitative and quantitative standpoint. The approach was created and validated in accordance with the International Conference on Harmonization (ICH) recommendations, and standards guidelines were used for the statistical evaluation of outcomes [4,5]. Therefore, our goal was to develop a high-pressure liquid chromatography (HPLC) technology that is simple to use and convenient for both researchers and the analysts who work in pharmaceutical quality control labs. However, no HPLC analytical approach for estimating residual Amphotericin in industrial wastes has been published.

Method Development

Various mobile phases were used to achieve the best separation and resolution in order to design an appropriate and reliable LC method for the measurement of amphotericin. The first mobile phase used in the method development was Symmetry C-18 (Make: Waters; 250 mm x 4.6 mm I.D; 5 m particle size). Pour 1000 mL of distilled water into a precise scale, Add 4.2 grams of citric acid, and mix. Use a diluted ammonia solution to adjust pH to 4.5 (0.05). Run a 0.45 m membrane filter through the solution to filter it. Prepare a 400:600 v/v combination of buffer and acetonitrile that has been filtered and degassed.

The Amphotericin peak eluted closely with the blank peak, and none of the peaks are separated. The composition of the mobile phase was slightly modified for the following trial. The detected peaks were slightly separated but had a narrow peak shape since the mobile phase's composition was buffer and acetonitrile in isocratic mode. Using water and acetonitrile in isocratic mode at a flow rate of 1.2 mL/min, the mobile phase was once more altered by adjusting the pH. At 383 nm, UV detection was done. Amphotericin had a retention time of approximately 7.0 minutes, and the peak shape was good.

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Received: 09 August, 2022; Manuscript No: CSJ-22-84750; **Editor assigned:** 12 August, 2022, PreQC No: P-84750; **Reviewed:** 23 August, 2022, QC No: Q-84750; **Revised:** 28 August, 2022, Manuscript No: R-84750; **Published:** 02 September, 2022, DOI: 10.37421/2150-3494.2022.13.307

Method validation

Six replicate injections of the standard solution, prepared in accordance with protocol, were made into the HPLC system to show system compatibility. The standard solution was used to test the system suitability characteristics, and it was discovered that they met the requirements. Six replicate injections of standard solution yielded a % RSD for Amphotericin peak regions that was deemed to be within acceptable bounds.

Discussion and Conclusion

It was successful in developing a straightforward, affordable, accurate, and precise HPLC process. The Symmetry C-18 (250 4.6 mm) with a 5 m particle size was used in this procedure. Over an isocratic programme, which is pumped at a flow rate of 1.2 ml/min, an injection volume of 10 l is injected and eluted with the mobile phase in the ratio of buffer, pH 4.5 with diluted ammonia solution and acetonitrile in the ratio of 40:60 v/v. The detection was done at 383 nm. There is no interference from the blank peak and all the chemicals are clearly resolved from it. The outcomes were precise and replicatable. The developed methodology's selectivity, accuracy, linearity, precision, robustness, solution stability, and mobile phase stability were all statistically validated.

Amphotericin standard and sample solutions' chromatograms were obtained for selectivity. The peak is clearly isolated from one another, according to selectivity studies. In order to determine Amphotericin, the procedure is selective. For Amphotericin, the limit of detection (LOD) and limit of quantitation (LOQ) were discovered to be 0.0173 g/ml and 0.0566 g/ml, respectively. With a correlation coefficient greater than 0.95, the linearity results for amphotericin in the designated concentration range are deemed adequate. The calibration curve was drawn, and it was discovered that the correlation coefficient for amphotericin was more than 0.95.

For Amphotericin, the accuracy trials were presented as percentage recoveries at 50%, 100%, and 150%. The findings obtained were deemed to be within the limitations, and the limit of the recovered percentage shown is not less than 80%. As a result, the approach was determined to be reliable. In line with the accuracy studies, there was a % recovery of the amphotericin.

Six duplicate injections were carried for for Precision experiments. From the Amphotericin peak areas, %RSD was calculated. The results were found to be within the acceptable limits, which should not be greater than 10% RSD. The bias for intermediate precision cannot be greater than 1.0. Because of this, the chromatographic techniques created for amphotericin are quick, easy, sensitive, precise, and accurate. As a result, the suggested method can be successfully used to analyse active pharmaceutical compounds on a regular basis to verify their presence in pharmaceutical effluents.

Acknowledgement

None.

Conflict of Interest

None.

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How to cite this article: Swamy, S. Lakshmi. “Analytical Method for Determination of Amphotericin.” Chem Sci J 13 (2022): 307.