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Research Article

DEVELOPMENT AND VALIDATION OF A NEW RP-HPLC METHOD FOR ESTIMATION OF SALSALATE

N. Bujji Babu, P. Srinivasa Rao and R. Ramesh Raju*

Department of Chemistry, Acharya Nagarjuna University, Nagarjuna Nagar, Guntur, Andhra Pradesh, India.

*Corresponding Author: rrraju1@gmail.com

ABSTRACT

A Simple High performance liquid chromatographic method (HPLC) was developed for the Analysis of Salsalate drug was carried out by 296 nm wave length. This method was found 99% of accuracy. According to International conference on Harmonization (ICH) guidelines Analytical parameters such as accuracy and precision have been established for the method for Salsalate tablets and statically to assess the application of the method. It can be successfully applied for the best analysis of Salsalate drug.

Keywords: Salsalate drug, RP HPLC Method, Method validation, Diabetic disease.

INTRODUCTION

Salsalate is an intermediate in dopamine and it is using for prevent the diabetic disease. Salsalate[1-6] is chemically known as 2-(2–Hydroxy benzoyl) oxybenzoic acid. (Figure: 1). Molecular formula is $C_{14}H_{10}O_5$

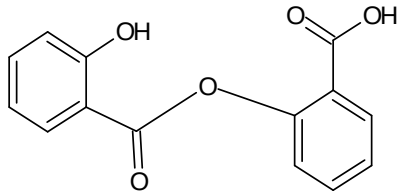

Fig. 1: Chemical Structure of Salsalate

In Most of researchers are reported HPLC methods for different drugs, but no reports on the Salsalate drug. In this paper, we reported the development and validation of accurate HPLC [7-10] method for analysis and formulations of Salsalate drug.

MATERIALS AND METHODS

Salsalate drug was purchased in Dr. Reddy's Laboratory, Hyderabad. HPLC grade methanol, acetonitrile, orthophosporic acid and HPLC water were commercially available.

Experimental conditions

The HPLC system consisted peak series LC-UV 7000 and isocratic pump with UV visible detector. The data acquisition was performed by peak 1.7 software. Analysis of Salsalate drug was carried out at 296 nm. Using a chromosil C_{18} reverse phase column of 250x4.6 mm. The mobile phase consisted of methanol, orthophosphoric acid and acetonitrile in the ratio of 55:30:15, and flow rate of 1 milliliter / 1minute. The column parameters and values have been summarized in Table 1.

Table 1: Column parameters and values

Retention Time	6.0minutes
Column Length	25 cm
Theoretical Plates	3927 number
Tailing Factor	1.82

Preparation of standard Solution

10 mg of Salsalate drug was dissolved in 10 ml of mobile phase to obtain a solution of strength is 1mg/1ml. Now 1 ml of this solution was taken from above solution and

again it dissolved in 10ml of mobile phase and it is known the standard solution.

Preparation of sample solution

From the standard solution of Salsalate drug appropriate detections are prepared in mobile phase to get the final concentration in the range of 0.1-0.5 mg/ml. for the analysis of Salsalate drug pharmaceutical dosage form ten capsules are weighed and powdered. 10 mg of powder was weighed and transferred to 10 ml of volumetric flask containing 10 ml of mobile phase. This solution was ultra sonicated about 10 minutes and then filtered through 0.45 micro meter membrane. In each of the solution is 20 micro litre is injected five times into the C_{18} column in HPLC.

RESULTS AND DISCUSSION

In this paper, we developed the reverse phased column procedure for a suitable method for the pharmaceutical analysis of Salsalate drug. A typical Chromatogram obtained (Figure-2) by using the mobile phase. The precision and accuracy of the method was determined from Salsalate dosage form and obtained. Inter and Intra-day studies were performed in three concentrations of the drug was repeated on three consecutive days.

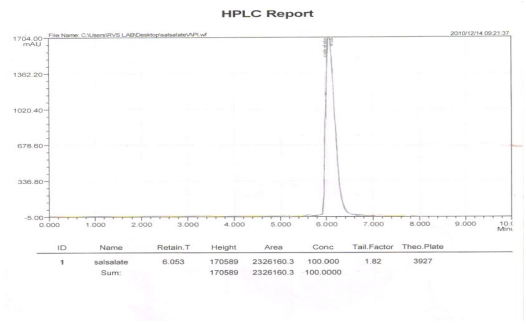

Fig. 2: Typical Chromatogram

Method validation

The method was validated for linearity, range, precision and accuracy parameters [11].Linearity of the method was studied by injecting five concentrations of drug prepared in the mobile phase in the range of 0.1-0.5 mg/ml and solutions are analyzed through the high pressure liquid chromatographic technique. The peak area were plotted against concentration was subjected to linear plot. (Figure: 3) and the results presented in Table 2.

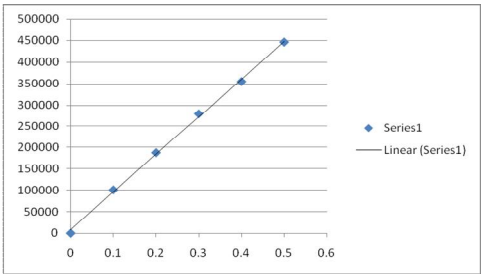

Fig. 3: Method validation Peak

Table 2: The values of peak area with concentrations

S. No.	Retention Time Minutes	Concentration mg/ml	Peak Area mAU*
1	6.1	0.1	100613.1
2	6.1	0.2	187080.5
3	6.1	0.3	279395.5
4	6.1	0.4	354522.2
5	6.1	0.5	445996.1

*mAU : milli Angstrom Units

Precision of this method was studied in inter day and intra day variation. The precision of intraday studies of three different concentration of the drug was repeated thrice in a day and in the inter day variation studies of three different concentration of the drug was repeated on three consecutive days. The developed method was found to be precise as the percentage of RSD values for inter-day and intra-day precision studies were found to be less than 2%. Good recoveries (98 - 100%) of the drug were obtained at each added concentration, indicating that the method was accurate. These results are represented in Table 3 and Table 4. Accuracy and percentage of drug recovery were calculated from chromatographic methods and the data is shown in Table 5.

Table 3: Precision data of Salsalate drug of Intra day

Concentration of Salsalate drug mg/ml	Area mAU	Relative standard deviation (RSD)
0.5	750765.2	0.78

0.6	752363.4	0.88
0.7	757532.5	1.10

Table 4: Precision data of Salsalate drug of Inter day

Concentration of Salsalate drug mg/ml	Area mAU	Relative standard deviation (RSD)
0.5	194270.5	1.02
0.6	196126.9	1.12
0.7	194203.6	1.32

Table 5: Recovery of Salsalate drug

Amount of Salsalate drug mg/ml	Recovery from drain Solution (area) mAU	% drug recovery
0.3	2139938.7	98.0
0.3	2138761.2	99.0
0.3	2137573.2	100.0

CONCLUSIONS

The developed method is accurate, precise and reliable for the analysis of Salsalate in pharmaceutical formulations. This method was validated for linearity, accuracy and precision of Salsalate drug. The RSD values for all parameters were found to be less 2, which indicates the validity of method and results obtained by this method are in fair agreement. Finally this method can be used for better analysis and pharmaceutical formulations of Salsalate drug.

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