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RP-HPLC Method For The Determination Of Sertraline Hydrochloride In Bulk And In Pharmaceutical Dosage Forms

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ABSTRACT

A reverse phase HPLC method was developed for the estimation of Sertraline HCl in bulk and in pharmaceutical dosage forms. Sertraline HCl was chromatographed on a reversed phase C_{18} column in isocratic mode with a mobile phase comprising of acetonitrile, methanol and buffer (pH adjusted to 7.5 with triethyl amine) in the ratio of (35: 20 :45 v/v).The mobile phase was pumped at a flow rate of 1ml/min and the eluents were monitored at 235nm. Due to its simplicity, rapidness, high precision and accuracy, the proposed HPLC method is useful for estimation of Sertraline HCl in bulk and pharmaceutical dosage forms

KEYWORDS

RP- HPLC;
Sertraline HCl.

INTRODUCTION

Sertraline HCl (STL) is a selective serotonin reup take inhibitor and is chemically known as (1S)-cis-4-(3, 4-dichlorophenyl)-1, 2, 3, 4-tetrahydro-N-methyl-1-naphthalenamine hydrochloride. STL helps in correcting the chemical imbalance of serotonin in the brain. The effectiveness of STL is presumed to be linked to its inhibition of CNS neuronal uptake of serotonin (5HT).

STL is used medically mainly to treat the symptoms of depression and anxiety. It has also been prescribed for the treatment of obsessive-compulsive disorder, post-traumatic stress disorder, premenstrual dysphoric disorder, panic disorder, and bipolar disorder. Literature survey reveals that few HPLC[1-6] methods have been reported for the estimation of STL in biological fluids. The authors have developed a simple, rapid, accurate and precise method for the estimation of Sertraline HCl in bulk and in pharmaceutical dosage forms.

EXPERIMENTAL

Instrumentation

An isocratic high performance liquid chromatograph using Shimadzu LC - 10AT provided with ODS reverse phase column (250x4.6 mm ID) and supported by class - VP software was employed in the study.

Chemicals and reagents

Sertraline HCl was a gift sample from Dr.Reddy's labs Ltd., Hyderabad. HPLC grade Acetonitrile (E.Merck India), HPLC grade methanol (E. Merck India). Milli - Q water, ammonium acetate AR grade, triethyl amine AR grade were used for preparing the mobile phase.

Chromatographic conditions

The mobile phase used was acetonitrile, methanol and ammonium acetate (3.5 g of ammonium acetate in 1000 ml of distilled water, pH adjusted to 7.5 with triethyl amine) in the ratio of (35: 20:45 v/v). The mobile phase was filtered through 0.45μ membrane filter and sonicated before use and then it was pumped from the solvent reservoir at a flow rate of 1mL/min and the eluents were monitored at 235nm. The run time was set at 15 min. The column was maintained at 30^0C and the volume of each injection was 20μl. Prior to injecting solutions, the column was equilibrated for at least 30 min with the mobile phase flowing through the system. The detector sensitivity was set at 0.0001 A.U.F.S and eluent monitored at 235nm.

Assay procedure

About 100 mg of pure sample of Sertraline HCl was weighed accurately and transferred to a 100ml volumetric flask and dissolved in 75ml of mobile phase and the solution was sonicated for 10 min and the volume was made up with a further quantity of mobile phase to get 1mg/ml solution. Subsequent dilutions of this solution ranging from 0.5 -100 μg/ml were made in 10ml volumetric flasks. The solutions prepared as above were filtered through 0.45μ membrane filter and then 20μl of filtrate was injected each time into the column at a flow rate of 1ml/min. Each concentration was injected six times into the column and corresponding chromatograms were obtained. Detection of the drug was performed at 235nm. From the chromatogram, the retention time and mean peak area was recorded for all the concentrations. The plot of peak area versus the respective concentrations gives the calibration curve. The regression of drug concentration over the peak area was computed using least squares method of analysis. This regression equation was used to estimate the amount of Sertraline HCl in pharmaceutical formulations.

Estimation of Sertraline HCl in tablet dosage forms

Two commercial brands of Sertraline HCl tablets were chosen for testing suitability of proposed method to estimate Sertraline HCl in tablet dosage forms. For this, 20 tablets were weighed and powdered. Accurately weighed portion of tablet powder equivalent to 100mg was taken in 100ml volumetric flask and 50 ml of mobile phase was added, shaken well and allowed to stand for 15min with intermittent sonication to ensure complete solubility of the drug. The mixture was thoroughly mixed and made up to the mark with mobile phase and filtered through a 0.45μ membrane filter. From the filtrate, different aliquots were taken in separate 10ml volumetric flasks. The contents of flasks were made up to mark with mobile phase and mixed well. Each of the solutions (20μl) was then injected into the column. All the determinations were conducted five times. The drug content in the tablet was quantified using the regression equation obtained from the peak areas of the pure sample.

RESULTS AND DISCUSSION

The development of an analytical method for the determination of drugs by HPLC has received considerable attention in recent years because of their importance in quality control of drug and drug products. The goal of this study was to develop a simple rapid accurate and precise HPLC method for the analysis of Sertraline HCl in bulk and tablet dosage forms using most commonly employed RP C-18 column with UV detection. A typical chromatogram was shown in figure 1.

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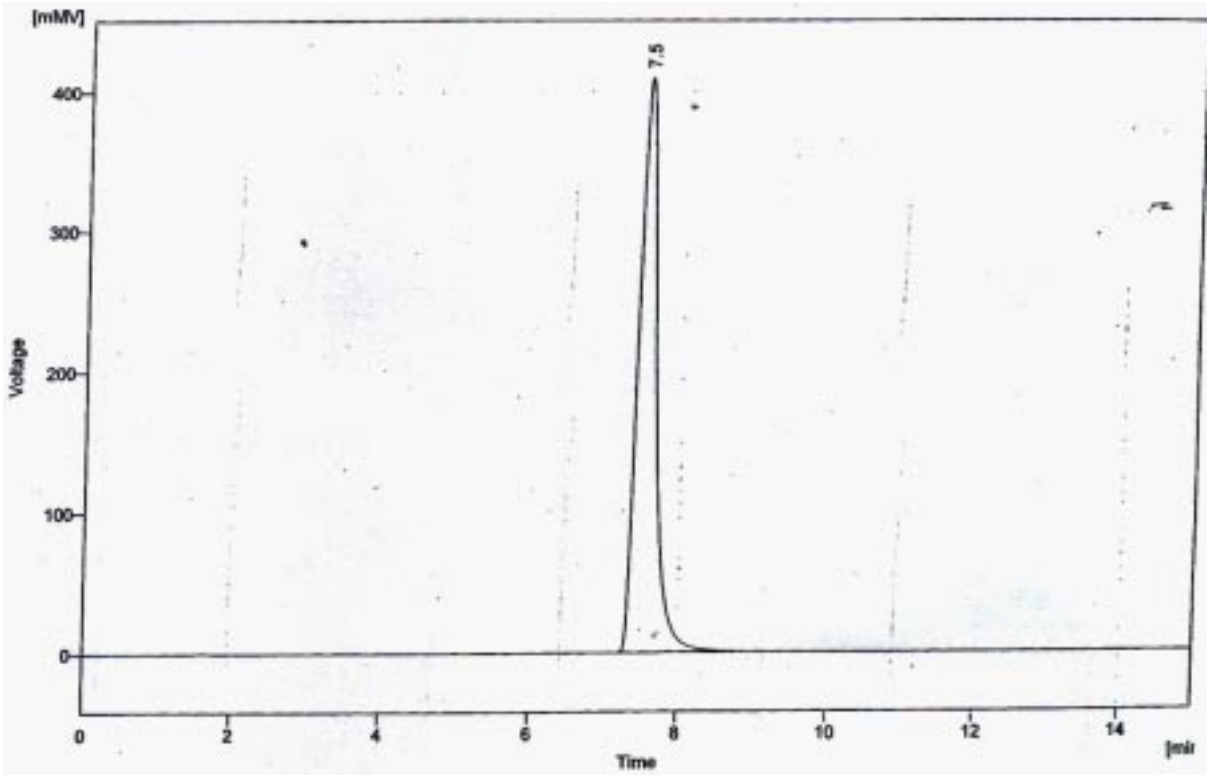

Figure 1: Model chromatogram for Sertraline HCI

The run time of the method was set at 15min and the Sertraline HCl was appeared on chromatogram at 7.513min. This indicates that the present HPLC method is rapid, which in turn shows that the method consumes less volume of HPLC solvents. When the same drug solution was injected six times, retention time of the drug was found to be same.

The peak areas from such different concentrations set up as above were calculated and shown in TABLE 1. A good linear relationship was observed between the concentration of the Sertraline HCl and the respective peak area. The regression curve was constructed by least squares method and its mathematical expression was Y= 69945.90X +1136.34 (where Y is the peak area and X is the concentration of Sertraline).This regression equation was used to estimate the amount of Sertraline HCl in tablet dosage forms. The intra-day and inter-day variations of the method were determined using five replicate injections of three different concentrations, which were analyzed on the same day and three different days over a period of two weeks, a low coefficient of

TABLE 1: Calibration of the proposed method

Drug concentration (µg/ml)	Peak area*	C.V. (%)
0.5	39980	0.73
2.0	139941	0.42
5.0	349832	1.08
10	699655	0.88
20	1399260	0.92
40	2798498	0.75
60	4197713	0.23
80	5596980	0.18
100	6996194	0.15

***Mean of six determinations**
Regression equation from 0.5 - 100µg/ml
Y= 69945.90X +1136.34 (r = 0.9999)

TABLE 2: Precision of the proposed method

Concentration of Sertraline HCl (µg/ml)	Observed concentration of Sertraline HCl (µg/ml)			
	Intra - day		Inter - day	
	Mean (n= 5)	% C.V.	Mean (n=5)	% C.V.
10	10.01	1.13	9.98	1.21
40	40.08	0.77	40.06	0.64
80	80.19	0.28	80.13	0.17

TABLE 3: Results of recovery study

Amount of drug added (µg)	Recovery from drug solution		Recovery from tablet formulation	
	Mean amount Found (n= 5)	Mean % recovery	Mean amount Found (n = 5)	Mean % recovery
10	10.01	100.1	10.02	100.2
20	20.05	100.25	20.10	100.5
30	30.01	100.03	30.02	100.06

TABLE 4: Assay of Sertraline HCl in tablet dosage Frms

Brand	Labeled amount of drug (mg)	Mean (± s.d.) Amount (mg) recovered (n= 5)	Mean (± s.d.) % of recovery (n= 5)
I	100	99.99±0.21	99.99±0.22
II	100	100.04±0.17	100.04±0.17

variation (C.V.) was observed (TABLE 2). This shows that the present HPLC method was highly precise.

To ensure reliability and accuracy of the method recovery studies were carried out. A fixed quantity of pre analyzed sample was taken and standard was added at three different levels .The values were shown in TABLE 3. About 100.1% of Sertraline HCl could be recovered from the pre analyzed samples indicating the high accuracy of the proposed HPLC method.

The HPLC method developed in the present study has also been used to quantify Sertraline HCl in tablet dosage forms. Sertraline HCl tablets (containing 100 mg of the drug) were quantified using the proposed analytical method and the results were given in TABLE 3. No interfering peaks were found in the chromatogram indicating that the tablet excepients did not interfere with the estimation of the drug by proposed HPLC method. The tablets were found to contain 99.99 - 100.04 % of the drug. It can be concluded that the proposed method was simple, precise, and accurate and hence can be applied for routine quality control analysis of Sertraline HCl in pharmaceutical formulations.

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