Research Article ISSN:2321-2624

International Journal of Medicine and Pharmaceutical Research
www.pharmaresearchlibrary.com/ijmpr

A Simple UV Spectroscopic Method for the Determination of Sertraline Hydrochloride in Bulk and Tablets

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Received: 24 April 2014, Accepted: 6 June 2014, Published Online: 10 August 2014

Abstract

A simple, economic, accurate UV method was developed for the estimation of Sertraline HCl (SRT) in bulk and tablet dosage form. Water was used as a diluent to dissolve SRT. The drug mixture was sonicated for 3 mins for the enhanced solubility. The absorptions were observed at 228.0 nm, which was selected for the further analysis of SRT in bulk and its tablet dosage forms. The proposed method was validated according to ICH guidelines. The method showed high sensitivity with linearity range from 5 to 30 µg/mL (r2=0.999) at 228.0 nm. The limit of detection (LOD) was found to be 1.22 and the limit of quantization (LOQ) was determined as the lowest concentration was found to be 4.08. The reports expressed that the proposed method was found to be simple, precise, accurate and rapid for the estimation of SRT in bulk and tablet dosage form using UV spectroscopy.

Keywords: Sertraline HCl, Distilled water, UV spectroscopy, ICH guidelines.

Contents

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Manuscript ID: IJMPR2167

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1. Introduction

Sertraline hydrochloride (SRT), chemically known as cis-(1S, 4S)-4-(3, 4-dichlorophenyl)-N-methyl-1, 2, 3, 4-tetrahydronaphthalen-1-amine hydrochloride[1]. Is an antidepressant [2] of the selective serotonin reuptake inhibitor (SSRI) [3] class. It is primarily used to treat major depression in adult outpatients as well as obsessive–compulsive, panic, and social anxiety disorders [4] in both adults and children. The efficacy of Sertraline for depression is similar to that of older tricyclic antidepressants, but its side effects are much less pronounced. Sertraline is slowly absorbed from the gastrointestinal tract with peak plasma concentrations occurring from about 4.5 hours to 8.5 hours after ingestion. It undergoes extensive first-pass metabolism in liver.

The main pathway is demethylation to N-desmethylsertraline, which is inactive; further metabolism and glucuronide conjugation occurs. Sertraline has shown antibacterial activity mainly against gram-positive bacteria. Sertraline demonstrated anti-fungal activity against Candida species in vivo. Sertraline also inhibits dynamin 1 dependent endocytosis.

From the literature survey, it was found that SRT estimated by analytical methods such as spectrophotometric methods [5-6], spectrofluorimetric methods [7], colourimetric method [8], FTIR and Raman spectra method [9] and RP-HPLC method [10]. Hence, the aim of this study was to develop and validate a simple UV method, to quantify SRT in pure form and pharmaceutical formulation (tablets). The proposed method was validated according to ICH guidelines [11]. The validated method was applied to the analysis of tablets containing sertraline Hcl (100 mg).

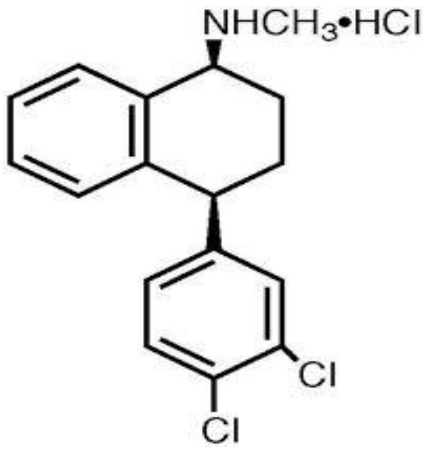

Figure 1. Chemical structure of SRT

2. Materials and Method

Instruments and reagents

An analytically pure sample of SRT was procured as gift sample from MSN laboratories (Hyderabad, India). Distilled water was used as solvent for dilution. Distilled water was prepared in house. A PG Instruments T-60 UV/VIS spectrophotometer was used with 1 cm matched quartz cell. Tablet formulation [Resert 100 mg Aurobindo, India] was procured from a local pharmacy with labeled amount 100 mg per tablet. Distilled Water used as a diluent to dissolve SRT.

Preparation of working standard drug solution

The standard SRT (50 mg) was weighed accurately and transferred to volumetric flask (50 ml). It was dissolved properly and diluted up to the mark with diluent to obtain final concentration of 1000 µg/ml. 15 µg/ml solution was prepared from the stock solution which was used as working standard.

Analysis of marketed formulations

For the estimation of Sertraline HCl in tablets formulations, 20 tablets were weighed and triturate to fine powder. Tablet powder equivalent to 50 mg of SRT was weighed and transfer into 50 ml volumetric flask than dissolved in diluent. It was kept for sonication for 3 min; this was filtered through Whatman filter paper No. 41 and then final dilution was made with diluent to get the final stock solution of 1000 µg/ml. From this stock solution, various dilutions of the sample solution were prepared and analysed.

Validation

Method validation was performed in terms of specificity and selectivity, precision and accuracy, linearity, LOD & LOQ.

Linearity and range

Calibration standards of SRT, covering the range 5-30 µg/mL were prepared with the suitable dilution made from SRT stock solution. The calibration curves were obtained by plotting the intensity of absorbance against of concentration of SRT. The slope and intercept of the calibration line were determined by linear regression using the least squares method.

Specificity and selectivity

The interference from endogenous compounds was investigated by the analysis of tablets of various concentrations.

Precision

The intra & inter-day precision was evaluated by analyzing six sample solutions (n = 6), at the final concentration of analyses (15 µg/ml) of SRT. The SRT concentrations were determined and the relative standard deviations (RSD) were calculated.

Accuracy

SRT reference standards were accurately weighed and added to a mixture of the tablets excipients, at three different concentration levels (7.5, 15 and 22.5 µg/ml of Sertraline HCl). At each level, samples were prepared in triplicate and the recovery percentage was determined.

Detection and quantitation limits

Limit of detection LOD and limit of quantification LOQ were calculated by using the standard deviation from the precision and the slope of linearity.

3. Results and Discussion

SRT has the zero order absorbance spectra maxima (figure 2 and 3) at 228.0 nm. The polynomial regression data for the calibration plots showed good linear relationship in the concentration range of 5-30 µg/ml with correlation coefficient (r^2) was found to be higher than 0.999 and the linearity curve was shown in figure 4. Recovery studies were carried out at three different levels i.e. 50 %, 100 %, and 150 % by adding the pure drug to the previously analysed tablet powder sample. Percentage recovery for Sertraline HCl was determined by all the methods and they were found to be under acceptance criteria which are 98% to 102 % according to ICH guidelines [9]. The results of accuracy were in table 2. The percentage recovery value indicates noninterference from excipients used in formulation. The precision was carried out as described in method and the results were presented in table 1. The values obtained in the repeatability (precision) shows that there is no significant difference in the precision values; hence the developed method can be used to analyze the SRT in tablet formulation. The mean assay of the precision value is 100%. The LOD determined as the amount drug was found to be 1.22 µg/mL and the LOQ was determined as the lowest concentration was found to be 4.08 µg/mL in formulation. The summary of all the optical characterizes were shown in table 2.

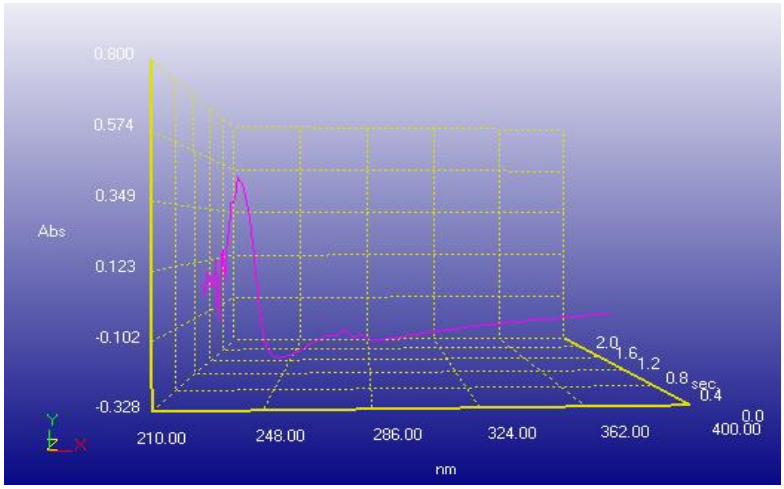

Figure 2: λ max (3-D view) curve of SRT

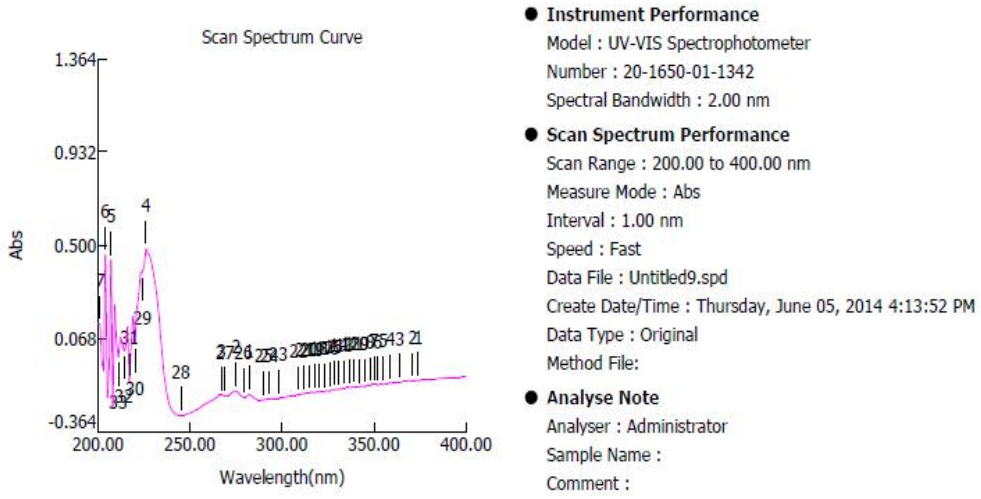

Figure 3: λ max curve of SRT

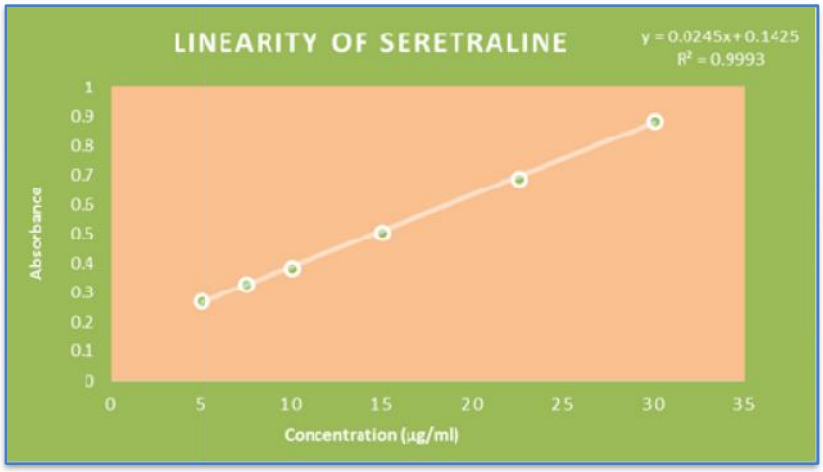

Figure 4: Linearity curve of SRT

Table1: Results of Precision

Sample No.	Sample Abs - 1	% Assay - 1
1	0.505	99.53
2	0.503	98.42
3	0.499	98.42
4	0.505	98.81
5	0.505	99.53
6	0.507	98.54
Avarage Assay:		99.087
STD		0.480
% RSD		**0.485**

Table 2: Summary of Optical characteristics and Other Parameters

S No.	PARAMETERS	RESULTS
1	Absorption Maxima (nm)	228
2	Beer's-Lambert's range (µg/ml)	5-30
3	Regression equation (y)*	Y = 0.0245x + 0.1425
4	Slope (b)	0.0245
5	Intercept (a)	0.1425
6	Correlation coefficient (r^2)	0.999
7	Sandell's sensitivity (mcg / cm^2-0.001 absorbance units)	0.0297
8	Intraday precision (% RSD)**	1.60
9	Interday precision (% RSD)**	1.38
10	Accuracy (% mean recovery)	99.087
11	Limit of detection (µg / ml)	1.22
12	Limit of quantification (µg / ml)	4.08
13	Assay of tablets (%Purity)	98.17

*y = a + bx; when x is the concentration in mg/ml and y is absorbance unit.
**Average of six determinations.

4. Conclusion

The most striking features of the method was its simplicity and rapidity, non- requiring consuming sample preparations such as extraction of solvents, heating, degassing which are needed for HPLC or other procedures. It can be concluded that the proposed methods was fully validated and found to be simple, sensitive, accurate, precise, reproducible, rugged and robust and relatively inexpensive. So, the developed method can be easily applied for the routine Quality Control analysis of SRT in pharmaceutical preparations.

5. Acknowledgement

We would like thank to MSN laboratories, Hyderabad for providing reference sample of SRT to facilitate this work and also to the Principal Dr Hindustan Abdul Ahad, Balaji College of Pharmacy, Anantapur for providing facilities to carry out this research work.

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