



Spectrophotometric methods for quantitative estimation of sertraline hydrochloride from tablet formulation

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ABSTRACT

Two simple and sensitive visible spectrophotometric methods have been developed for the quantitative estimation of Sertraline Hydrochloride from its tablet formulation. The developed methods are based on formation of chloroform extractable colored complex of drug with alizarin red and tropaeolin ooo. The chloroform extracted complex of drug with alizarin red showed absorbance maxima at 425.0 nm and linearity was observed in the concentration range of 20-90 µg/ml (method-I), with tropaeolin ooo showed absorbance maxima at 485.0 nm and linearity was observed in the concentration range of 3-24 µg/ml (method-II). Results of analysis for both the developed methods were validated statistically and by recovery studies.

Keywords: Sertraline Hydrochloride, Chloroform extract, Alizarin red, and Tropaeolin.

INTRODUCTION

Sertraline¹ chemically is (1S,4S)-4-(3,4-Di-chloro phenyl)-1,2,3,4-tetrahydro-N-methyl-1-1-naphthalenamine. It is used for treating depression and comes under second generation antidepressant drugs in the class of selective serotonin reuptake inhibitor (SSRI)². Literature survey reveals that few analytical methods for estimation of Sertraline Hydrochloride from pharmaceutical dosage forms by using LC-MS³, RP-HPLC⁴ and UV-Visible Spectrophotometre⁵ have been reported. However, there is no work in the literature reported about the visible Spectrophotometric estimation of Sertraline

Hydrochloride in pharmaceutical dosage forms with Alizarin red & Tropaeolin ooo reagents. An attempt has been made in the present study to develop two simple & rapid visible Spectrophotometric methods for analysis of Sertraline Hydrochloride in pharmaceutical dosage forms after referring various analytical methods.⁶⁻⁸

EXPERIMENTAL

A Shimadzu UV/Visible spectrophotometer- 1700 with 1 cm matched quartz cells was used for spectral measurement. All the chemicals used were of analytical

grade, alizarin red solution (0.1% w/v) and tropaeolin ooo (0.03% w/v) was prepared in acid buffer⁹ pH 1.2 and pH 1.6 respectively and extracted several times with chloroform so as to remove chloroform soluble impurities. Buffer solutions were prepared in double distilled water. The tablet samples of Sertraline Hydrochloride were procured from the local market.

For method **I**, in a series of 10 ml volumetric flasks aliquots of standard drug solution of Sertraline Hydrochloride (100 µg/ml) in chloroform were transferred and diluted with the same so as to give several dilutions in the concentration range of 20-90 µg/ml of drug. To 10 ml of each dilution taken in a separating funnel, 10 ml of alizarin red solution was added, shaken and allowed to stand for 10 minutes for the formation of colored complex. The colored chloroform layer was separated out and absorbance was measured at 425.0 nm against a reagent blank. A calibration curve was prepared by plotting concentration versus absorbance.

For method **II**, in a series of 10 ml volumetric flasks aliquots of standard drug solution of Sertraline Hydrochloride (30 µg/ml) in chloroform were transferred and diluted with the same so as to give several dilutions in the concentration range of 3-24 µg/ml of drug. To 10 ml of each dilution taken in a separating funnel, 10 ml of tropaeolin ooo solution was added, shaken and allowed to stand for 10 minutes for the formation of colored complex. The colored chloroform layer was separated out and absorbance was measured at 485.0 nm against a reagent blank. A calibration curve was prepared by plotting concentration versus absorbance.

For analysis of formulation, twenty tablets of Sertraline Hydrochloride were accurately weighed and average weight per tablet was determined. The tablets were powdered and powder equivalent to 100 mg of Sertraline Hydrochloride was accurately weighed and

extracted four times with 20 ml portions of chloroform, the combined extract was filtered through Whatmann filter paper No.41 into 100 ml volumetric flask. The residue was washed with chloroform and the washings were added to the filtrate, final volume of filtrate was made up to the mark with chloroform. From the above filtrate 10 ml was further diluted to 100 ml in a volumetric flask to get a tablet sample stock of 100 µg/ml.

For method **I**, 4 ml of above stock was further diluted to 10 ml with chloroform and for method **II**, 1.5 ml of above stock was further diluted to 10 ml with chloroform. This was treated as per the respective procedure for the calibration curve and absorbance was measured at 425.0 and 485.0 nm respectively and the amount of drug present in sample was computed from respective calibration curve.

RESULTS AND DISCUSSION

Both the developed methods were repeated five times for two different strength of tablet formulation. Results of analysis are reported in Table 2.

Recovery studies were carried out for both the developed methods by addition of known quantity of pure drug solution to pre analyzed tablet sample solution at three different concentration levels. The result of recovery studies is reported in Table 2.

The proposed Spectrophotometric methods for determination of Sertraline Hydrochloride from tablet formulations are based on formation of chloroform extractable colored complex of drug with alizarin red and tropaeolin ooo. The pH required for method **I** and **II** was optimized at pH 1.2 and pH 1.6 respectively. The optical characteristics such as Beer's law limits, sandell's sensitivity, molar extinction coefficient and percent relative standard deviation, (calculated from the eight measurements within the Beer's law limits) were calculated and the results are summarized in Table-1.

Table-I Optical Characteristics And Precision Of Proposed Methods I And II

Parameter	Method-I	Method-II
λ_{\max} (nm)	4255	488
Beer's law limits (µg/ml)	20-90	3-24
Molar absorptivity (Lmole ⁻¹ cm ⁻¹)	0.0545x10 ⁶	0.1595x10 ⁶

Sandell's sensitivity		
($\mu\text{g cm}^{-2}/0.001$ absorbance unit)	0.0063	0.00215
Regression equation (Y=a+bC)		
Slope (b)	0.0161	0.0473
Intercept (a)	-0.0027	-0.0052
Correlation co efficient (r)	0.9999	0.9999
Relative standard deviation (%)*	0.0722	0.1979
% Range of error (confidence limits)*		
0.05 level	0.0604	0.1655
0.01 level	0.0894	0.2448
Y = a + b C, where C is concentration in $\mu\text{g/ml}$ and Y is absorbance unit.		
* Eight replicate samples		

Table - II Assay And Recovery of Sertraline Hydrochloride In Dosage Forms

Sample	Labeled amount (mg/tab)	Amount obtained (mg/tab)		Reference * method	% Recovery**	
		Proposed method	Reference * method		I	II
1	25	24.96	24.97	24.94	99.86	99.88
2	25	24.98	24.97	24.96	99.95	99.95
3	25	25.02	25.04	25.02	100.08	100.12

* Reference U.V. Method developed in our lab ** Average of three determination

Regression characteristics like standard deviation of slope (S_b), standard deviation of intercept (S_a), standard error of estimation (S_c), and percentage ranges of error (0.05 and 0.01 confidence limits) were calculated and are shown in Table-1.

Recovery studies were satisfactory which shows that there is no interference of excipients. The developed methods were found to be simple, rapid and accurate

and can be used for routine analysis of drug from tablet formulations.

ACKNOWLEDGMENTS

The author is thankful to Ajanta Pharma, Mumbai for providing the gift samples of Sertraline Hydrochloride. The author is also thankful to the management of Chilkur Balaji college of Pharmacy, Hyderabad, for providing the additional laboratory facilities.

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