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Original Article

Method Development and Its Validation for Estimation of Sertraline Hydrochloride by Using UV Spectroscopy

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ABSTRACT

The present study was aimed at developing simple, rapid, specific, reproducible and reliable UV Spectrophotometric method with following objectives. Method Development and its Validation for Estimation of Sertraline HCL by using UV Spectroscopy. To validate the proposed method in accordance with USP and ICH guidelines for the intended analytical application i.e. to apply the method for analysis of the drug in bulk and its dosage form. Literature survey revealed that few methods have been reported Sertraline HCL individually or in Combination with other drugs in pharmaceutical dosage forms or in biological fluids. So far only one Stability Indicating LC method has been reported for in pharmaceutical dosage form. However no UV method has been reported for the Sertraline HCL in tablet formulation.

Key Words: UV Spectrophotometric, Sertraline, Stability.

1. INTRODUCTION

Analytical chemistry may be defined as the science and art of determining the composition of material in terms of elements or compounds contained in it. Analytical chemistry is divided into two branches quantitative and qualitative. A qualitative analysis provides information

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about the identity of atomic or molecular species or functional groups in sample. A quantitative analysis is performed to establish the proportion of the essential component in the raw material. The final manufactured product is analyzed to ensure that its essential component is present within a predetermined range of composition and impurities do not exceed certain specified limit.

UV-VIS Spectrophotometer:

Ultraviolet and visible spectrometers have been in general use for the last 35 years and over this period have become the most important analytical instrument in the modern day laboratory. In many applications other techniques could be employed but none rival UV-Visible spectrometry for its simplicity, versatility, speed, accuracy and cost-effectiveness [2,3].

Lambert's (or Bouguer's) Law:

Lambert's law states that each layer of equal thickness of an absorbing medium absorbs an equal fraction of the radiant energy that traverses it. The fraction of radiant energy transmitted by a given thickness of the absorbing medium is independent of the intensity of the incident radiation, provided that the radiation does not alter the physical or chemical state of the medium. If the intensity of the incident radiation is Io and that of the transmitted light is I, then the fraction transmitted is:

$$I/Io = T$$

The percentage transmission is:

$$\%T = I/Io \times 100$$

The Beer-Lambert's Law:

The Beer-Lambert law states that the concentration of a substance in solution is directly proportional to the absorbance, A, of the solution.

Absorbance, A = Constant x Concentration x Cell length

Or, Molar Absorptivity, $\varepsilon = A/ c\ l$

Where, A= absorbance, c = sample concentration in moles/liter and l = length of light path through the sample in cm.

The law is only true for monochromatic light that is light of a single wavelength or narrow band of wavelengths, provided that the physical or chemical state of the substance does not change with concentration. When monochromatic radiation passes through a homogeneous solution in a cell, the intensity of the emitted radiation depends upon the thickness (l) and the concentration (c) of the solution.

Criteria for selection of UV-Visible spectroscopy:

a) Compounds must fall in absorbance range 200-800 nm.

b) Compound should have a chromophore or the chromophore should be reactive to some derivatizing agents.

c) Compound should be unsaturated.

d) Compound should follow Lambert-Beer's law

e) To follow Lambert-Beer's law, concentration of the compound should be very low.

f) All molecules have absorption bands; therefore solvent taken must be transparent within the wavelength range being processed [3].

Purpose of validation:

The principal purpose of analytical method validation is to ensure that test methods, which are used for assessing compliance of pharmaceutical products with established specifications, will give accurate, reliable and reproducible results [6, 9-13].

The real goal of the method validation process is to challenge the method and determine limits of allowed variability for the conditions needed to run the method. It is important to have a well-conceived validation plan for testing the method and acceptance criteria before starting the validation process. Included in this plan should be detailed procedure describing the entire method (including

calibration standard and sample preparation, separation, data handling and calculations) that can conveniently be executed by others.

Typical validation characteristics which should be considered are listed below,

(a) Specificity or selectivity (b) Linearity (c) Range (d) Accuracy (e) Precision

(f) Detection Limit (g) Quantification Limit (h) Ruggedness (I) Robustness

(j) System suitability testing

2. EXPERIMENTAL WORK

Weighing balance, Ultrasonic bath, Digital pH meter, FTIR, UV Visible Spectrophotometer, Sertraline HCL as Reference Standard Morpan pharma ltd.

IR Spectrum

The IR spectrum of Sertraline HCL was taken using KBr disc technique and compared with reference spectrum

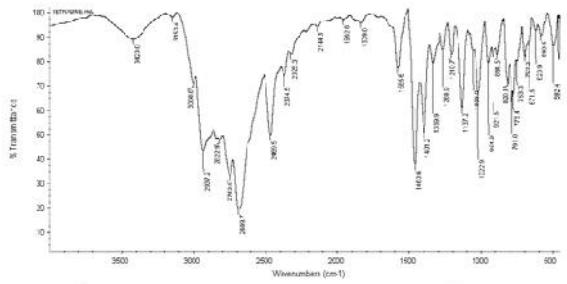

Fig 1: FTIR spectrum of Sertraline HCL Standard

Preparation of calibration curve for Sertraline HCL

Stock solutions of Sertraline HCL (1, 2, 3, 4, 5, 6, 7, 8, 9 and 10 ml) were pipetted, into a series of ten 50 ml volumetric flasks. The volume in each volumetric flask was made up to the mark with 50%v/v aqueous methanol and the content was mixed so as to obtain a final concentration in the range of 2 to 20 µg/ml. The absorbances of the solutions were measured at 273 nm against 50%v/v aqueous methanol used as blank. The calibration curve data and calibration curve.

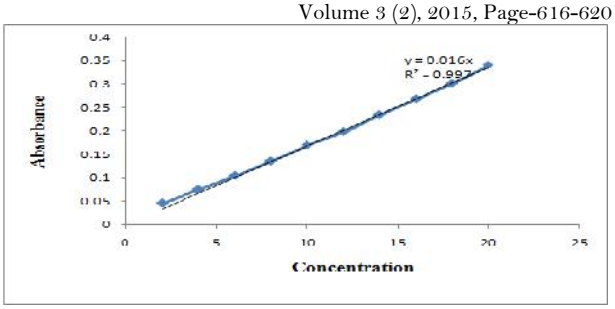

Fig 2: Calibration Curve of Sertraline HCL

The method was found to be linear within the range of 70-130% of the 100% test concentration i.e.10µg/ml. In the linearity study, regression equation and correlation coefficient for Sertraline HCL was found to be y = 0.016x + 0.0002, r=0.997.

Determination of optical parameters

The molecular absorptivity and Sandell's sensitivity were calculated as

$$\text{Molecular absorptivity } (\epsilon) = AM/ct$$

A = Absorbance, M = Molecular weight ,C = Concentration of sample

t = Path length

$$\text{Sandell's Sensitivity} = M/\epsilon$$

M = Molecular weight, ϵ = Molecular absorptivity

Other optical parameters i.e. Beer's limit, slope, intercept and correlation coefficient were calculated from calibration curve.

Table 1: Optical parameters and regression characteristics of Sertraline HCL

Parameters	Observations
Beers's law limit (µg/ml)	2-20
Molar absorptivity (l mole^{-1}cm^{-1})	5.5×10^{-4}
Sandell's sensitivity (mg/cm^2/0.001absorbance unit)	62.2×10^{-3}
Regression equation (y= a + bc) slope	0.016
(b) intercept (a)	2×10^{-4}
Correlation coefficient (r)	0.997

Table 2: Calculation of overall RSD for precision of method

	Day 1	Day 2	Day 3	Mean	SD	RSD
% Recovery for conc. no. 1	107	105.8	105	105.9	1.00	0.944
% Recovery for conc. no. 2	107	108.3	107	107.4	0.751	0.699
% Recovery for conc. no. 3	108.5	107.8	109.1	108.4	0.655	0.604
Overall RSD						0.749

The intra-day and inter-day precision studies which were conducted it showed RSD of 1.856% for Sertraline HCL for intraday analysis and overall RSD of 0.749% for Sertraline HCL for inter day analysis. Thus the data showed that the RSD was below 2% inferring that the analytical technique had a good intraday and inter day precision.

3. RESULTS AND DISCUSSION

A UV-spectroscopic method was developed for the estimation of Sertraline HCL in Pure dosage forms. Solvent used was 50%v/v aqueous methanol. Measurement was done at 273 nm. Method was statistically validated according to ICH guidelines. From these characteristics of the proposed method,

it was found that Sertraline HCL obeys linearity within the concentration range 1-20 mcg. Found that % RSD is less than 2, which indicates that the system & method has good reproducibility. From the result shown in accuracy table it was found that the % recovery value of pure drug from the analyzed solution of formulation were in that the commonly use excipients and additives in the pharmaceutical formulation were not interfering in the proposed method, inter day, intraday of the samples indicated

shows that the intermediate precision is less than 2 and instruments and method are precise.

Table 3: Summary of validation parameters for the estimation of Sertraline HCL by UV-Spectroscopy

Parameter	Observation Sertraline HCL
Specificity	2.3
Linearity (Correlation coefficient r)	0.997
Range	70 to 130%
Accuracy (% Recovery)	100.01%
Precision RSD	
Repeatability (n= 6)	1.169
Intra-day (n=3)	1.856
Inter-day (days=3)	0.749

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