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Review Article

A Review On The Analytical Method Development And Validation Of Sertraline tablet By UV Spectroscopy

Ashishkumar Panpatil*, Vedant Salunke, Snehal Jadhav, Faisal Shaikh, Pravin Jadhav, Vinod Bairagi, Kaushik Kamble

K. B. H. S. S. Trust's Institute of Pharmacy & Research Centre, Bhayegaon, Malegaon, Nashik, Maharashtra, India.

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ABSTRACT

Sertraline HCl (SRT) in tablet and bulk dose form was estimated using an easy-to-use, reasonably priced, and precise UV technique. We dissolved SRT using water as a diluent. To increase the solubility of the medication combination, it was sonicated for three minutes. The absorptions at 228.0 nm were chosen for additional examination of SRT in tablet and bulk dose forms. The suggested approach was verified in compliance with ICH regulations. At 228.0 nm, the technique demonstrated great sensitivity, with a linearity range of 5 to 30 µg/mL ($r^2=0.999$). The lowest concentration was found to be 4.08, indicating the limit of quantization (LOQ) and the limit of detection (LOD) to be 1.22. According to the findings, utilising UV spectroscopy to estimate SRT in bulk and tablet dosage form proved to be an easy, precise, accurate, and quick process.

INTRODUCTION

Cis-(1S, 4S)-4-(3, 4-dichlorophenyl)-N-methyl-1, 2, 3, 4-tetrahydronaphthalen-1-amine hydrochloride is the chemical name for sertraline hydrochloride (SRT)[1]. belongs to the selective serotonin reuptake inhibitor (SSRI) family of antidepressants [2]. Major depressive disorder in adult outpatients as well as panic, social anxiety, and obsessive-compulsive disorders in adults and children are the main conditions it treats. Sertraline's effectiveness in treating depression is

comparable to that of earlier tricyclic antidepressants, but its adverse effects are far milder. The gastrointestinal tract absorbs sertraline gradually, with peak plasma concentrations happening between 4.5 and 8.5 hours after consumption. The liver goes through a lengthy first-pass metabolism of it.[3]

***Corresponding Author:** Ashishkumar Panpatil

Address: K. B. H. S. S. Trust's Institute of Pharmacy & Research Centre, Bhayegaon, Malegaon, Nashik, Maharashtra, India.

Email ✉: ashishkumarpanpatil@gmail.com

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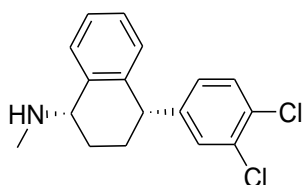


Figure 1: Chemical structure of Sertraline.

The primary route involves demethylation to the inactive form N-desmethylsertraline; further metabolism and glucuronide conjugation take place. Sertraline mostly inhibits gram-positive bacteria in its antibacterial activity studies. In vivo, sertraline exhibited antifungal efficacy against species of *Candida*. Moreover, dynamin 1 dependent endocytosis is inhibited by sertraline.

According to a review of the literature, SRT was calculated using analytical techniques such as spectrophotometric techniques, spectrofluorimetric techniques [4], colorimetric techniques, FTIR and Raman spectra techniques [9–10], and RP–HPLC techniques. Therefore, the purpose of this work was to create and verify a straightforward UV technique for measuring SRT in both pure form and pharmaceutical formulation (tablets). In compliance with ICH criteria, the suggested approach was validated [5]. The 100 mg sertraline HCl tablets were analysed using the approved technique.

Table 1: Drug profiles Sertraline[6]

Name of Drug	Chloramphenicol
Chemical Structure	
Molecular Formula	$C_{17}H_{17}NC_{12}HCl$
Molecular weight	342.7
Chemical Name	(1S, cis)1,2,3, 4-tetrahydro-N-methyl-4-(3,4-dichlorophenyl)1- naphthalenone hydrochloride
Description	Fine crystalline powder in the colours white, grey, or yellow, or fine crystals in the form of needles or elongated plates. between the four potential stereoisomers.
Melting point	242°C to 248°C
Dose	150 mg
Half-life	2.5 – 4 Hrs
Bioavailability	80% oral bioavailability
Spectroscopy data	Ultraviolet, infrared, nuclear magnetic resonance and mass spectra are reported.
Solubility	Slightly soluble in water, methanol and ethanol.
Adverse effect	Nausea, vomiting, and abdominal distension.
Category	Antidepressant

Sertraline tablet:

Sertraline is an antidepressant medication that falls under the category of selective serotonin reuptake inhibitors (SSRIs). Here are some key points about sertraline:

Uses:

1. Depression: Sertraline is commonly used to treat depression.
2. Anxiety: It can also be effective in managing anxiety.
3. Obsessive-Compulsive Disorder (OCD): Sertraline helps alleviate symptoms associated with OCD.

4. Post-Traumatic Stress Disorder (PTSD): It is used to address PTSD symptoms.
5. Premenstrual Dysphoric Disorder (PMDD): Sertraline can provide relief from PMDD symptoms.
6. Panic Disorder: It is prescribed for panic disorder as well.[7]

Method development and validation of Sertraline by UV spectroscopy

The analytical method known as UV-Vis spectroscopy counts the various UV or visible light wavelengths that a sample absorbs or transmits in comparison to a reference or blank sample. These characteristics have an impact on the sample's composition and reveal information about the components and their concentrations. Since the usage of light is necessary for this spectroscopy method, let's first examine the characteristics of light. The amount of light is according to its wavelength. As a result, light has more energy at short wavelengths and less at long wavelengths. The energy needed to take an electron out of a material and transfer it to a higher energy state. For electrons to transition to higher energy states, different bonding conditions within a material require different specific energies. As a result, the wavelengths at which different materials absorb light vary. The visible light spectrum, which appears blue-green at 380 nm and red at 780 nm, is visible to humans. Light may therefore be characterised by its wavelength, and in UV spectroscopy, determining the wavelength that corresponds to the maximum absorption can aid in the analysis or identification of various chemicals (see applications in the UV spectroscopy section) [8].

General procedure for calibration:

The optimal technique for analysing Sertraline residues should be specific, sensitive, and accurate. It should also yield consistent results on the analyte's identity. It should also be as dependable and affordable as feasible. Developing a method that combines all these features is challenging in practice. As a result, the initial application of the test technique is frequently followed by a confirmatory analysis of materials that test positive for the test method in the analytical strategy used to monitor Sertraline residues in animal tissues. [9].

EXPERIMENTAL WORK:

Preparation of standard stock solution:

Precisely weigh out 10 milligrammes of Sertraline, the active ingredient in medicine, and transfer it to a 100 millilitre dry volumetric flask. Then, add 5 millilitres and 10 millilitres of water, sonicate to dissolve with distilled water, cool, and repeat. Combine 10 ml with 1 ml of this solution and stir.

Preparation of sample solution:

Ten tablet weights To a 100 ml volumetric flask, add 700 ml of solvent, sonicate, let cool, then dilute to 100 ml and mix. A 10 ml volumetric flask should be filled with 1 ml of this solution, mixed, and made up to volume. If necessary, filter. Take note of the wavelength, which is 274 nm. Determine the percentage of sertraline in tablets based on market formulations for Zotral-50. [10].

Solutions of pharmaceutical preparations:

Tablet samples:

Combine the tablet's contents. In a volumetric flask, 50 mg of Zotral, or 50 mg of chloramphenicol, was dissolved in 100 ml of water. To obtain 500 µg/mL-1 reduced Sertraline solution, transfer this solution to a 100 ml beaker, lower the volume as previously mentioned, and mix with 100 ml of distilled water. [11].

Table 1: Analytical parameters for UV spectroscopy of Sertraline

Parameters	Method A
λ max (nm)	274nm
Linearity range ($\mu\text{g ml}^{-1}$)	5-30



Molar absorptivity ($\text{L mol}^{-1} \text{ cm}^{-1}$)	1.355×10^4
Sandell's sensitivity ($\mu\text{g} \cdot \text{cm}^{-2}$)	0.0297
Limit of detection ($\mu\text{g ml}^{-1}$)	1.22
Limit of quantification ($\mu\text{g} / \text{ml}$)	4.08
Relative standard deviation (RSD %)*	1.905
Stability (hr)	2.5
Assay of tablets	98.17

VALIDATION METHOD:

Only analytical quality control can guarantee a drug's efficacy and safety. Thus, it is necessary to assess drug purity, distribution, storage, and use. The goal of validation is to ensure that the specification can demonstrate a qualitative relationship between the chemical being studied and the substance that needs to be assessed first for pharmacological, toxicological, and medicinal purposes. Effective quality control is always dependent on applying appropriate analytical techniques. Pharmaceutical submission proposals, government-controlled laboratories, or method validation companies. The process of recording or demonstrating that an analytical method produces analytical data that is appropriate for its intended use is one of the common validation features to take into account. Making sure that manufacturers implement this technique is crucial[12].

Specificity and Selectivity:

Analysing analytes for the existence of elements that are anticipated to be present in the sample matrix is the process of characterization. The method of qualitatively identifying analytes in the presence of items predicted to be present in the sample matrix is known as sampling. Calculations are performed to determine the amount of medicine, absorption is evaluated, and pre-weighed pharmaceuticals are added to the formulation. [13]

Linearity:

The standard mixed solution made according to procedure 2.4 was injected into the capillary and examined to assess the linearity of the approach. The least square linear regression approach was used to evaluate the linearity between each analyte's concentration and peak level. If $P < 0.07$, a one-way analysis of variance test was used to establish the linear regression's significance. [14].

Sensitivity:

According to the most recent ICH Q2R1 recommendations, limit of detection (LOD) and limit of quantification (LOQ) are not required for quantitative procedures. However, the approach must maintain the working concentration of each analyte below the limit of quantitation (LOQ). Thus, by examining solutions with various doses of sertraline, the limit of quantification (LOQ) for each analyte was ascertained. The concentration with a signal-to-noise ratio of 10:1 and a triple analysis RSD of less than 10% is known as the limit of quantitation (LOQ). [15]

Accuracy:

Applying unlabeled Sertraline (standard dose method) to a sample of the drug's formulation was how the recovery test was carried out. A biological sample (blood) with a precise quantity of sertraline equivalent to two milligrammes of the patient's preparation is used for the recovery test. Using the recommended standard addition procedure, 2 mg is applied. Transfer the contents to a 100 ml volumetric flask and let the standard to dissolve in the solution after adding it. At last, I registered to give a speech. Using filter paper, the "Whatman

No. 41" solution was filtered. After measuring and analysing the mixed sample solution, absorbance was determined. Every recovery and current stage involves five decisions [16] .

Precision:

Interval accuracy, repeatability, and system consistency were used to evaluate the accuracy of the CZE approach [36, 37]. Six times a day, mixed standard solutions containing each analyte at 100% concentration were measured to assess the appropriateness of the system [19]. Using six measurements taken on the same day and on two different days at around 100% working concentration containing an analyte, repeatability and accuracy intervals were calculated. [17,18].

Repeatability:

Sertraline blank standard solution was made in order to compare the absorbance to the solution. Five measurements of adherence to solutions at the

same concentration were made, and the standard deviation was computed and reported. [19,20] .

Robustness:

An analytical method is considered robust if it can show reliability when used regularly and can withstand slight, deliberate changes in method parameters. These pertinent controls should be mentioned in the method notes if the measurements are susceptible to variations in the analytical conditions. Several options are available to you; these are enumerated below. A percentage is used to express the analyte concentration. [21] .

Interferences studies:

Several substances are used in the formulation, which is inert, to test sertraline under ideal circumstances. Despite having more layers than anticipated, none of them obstruct the suggested mechanism in the formulation. [22,23] .

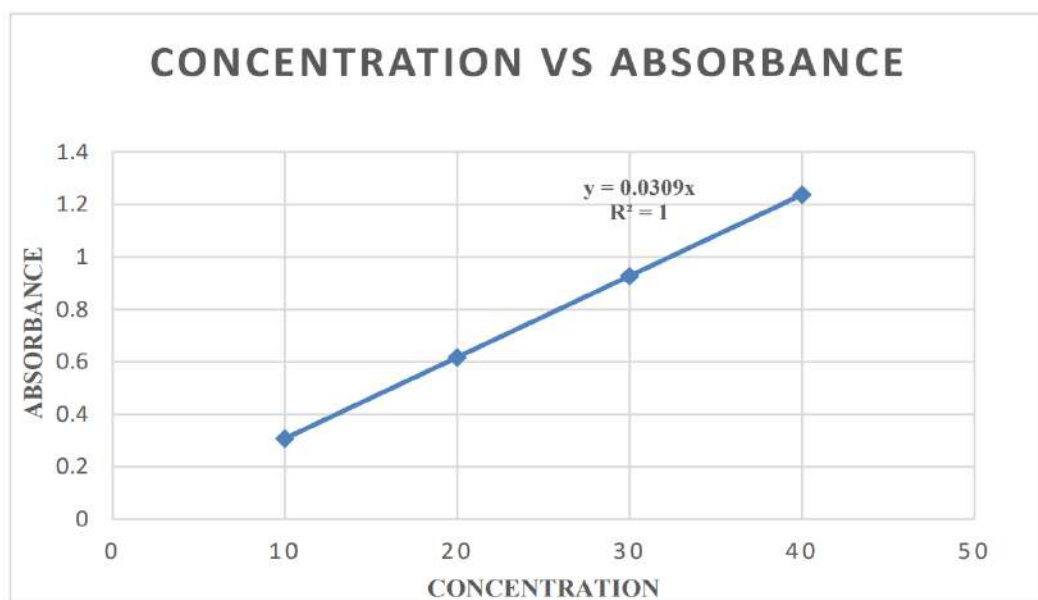


Figure 2: Calibration curve of Sertraline

Pharmaceutical application:

The British Pharmacopoeia for the medication and pure sertraline were successfully compared with the suggested approach [24] . The suggested method's outcomes for the tested formulations are consistent with the body of available literature. Using the F test and t-test, a formal technique [25] with a 95% confidence level produced the results

shown in Table 2. The computed values of F and t for procedures A and B do not go over their corresponding critical levels.. This demonstrates that, in terms of accuracy and precision, there is no discernible difference between the official approach and the suggested method for determining the presence of Sertraline in medications. [27,28,29].

CONCLUSION:

UV Spectroscopy is a simpler, faster, less expensive, and more selective method than other previously published ones. It is precise and has the benefit of not requiring costly reagents or solvents, sample removal, chemical sample preparation, temperature control, pH control, or extraction processes. Sertraline can be analysed using the suggested approach for both routine analysis and pharmaceutical formulations. The British Pharmacopoeia and the suggested procedure for pure and pharmaceutical Sertraline were effectively compared. The results of the suggested procedure agree with published materials for all preparations evaluated. A straightforward, quick, precise, and economical approach for estimating sertraline in medicinal ointment dosages was created and proven. In solution, a stock solution is ready. Sertraline's absorbance was measured at a wavelength of 274 nm. Toxicity was observed in the concentration range of 5-30 ppm for Sertraline. The UV-spectrophotometry method was validated according to ICH guidelines.

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