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ORIGINAL ARTICLE

Analytical Method Development and Validation of UV-Visible Spectrophotometric Method for the Estimation of Solriamfetol in bulk and tablet formulation

Sunil Kakad*, Siddhi Sane and Anagha Joshi
[1] Department of Pharmaceutical Chemistry**,** Shree Chanakya Education Society's Indira College of Pharmacy, Pune
Corresponding Author: Email: sunil.kakad21@gmail.com

ABSTRACT
A new, accurate, precise, specific, robust, and first UV spectrophotometric approach for assessing the recently approved by FDA drug Solriamfetol, a first-in-class dopamine and norepinephrine reuptake inhibitor, in bulk and tablet dosage form, was developed and validated as per ICH norms. The UV spectrophotometric observations were taken at 257 nm and water was used as a diluent. The validation of the method was carried out in compliance with the ICH guidelines, and parameters such as linearity, accuracy, precision, limit of detection, limit of quantification, and robustness were evaluated. The linear calibration curve was observed across the concentration range of 100-500µg/ml and with correlation coefficient of r^2 = 0.9998. The accuracy of developed method was indicated through percentage recovery study of drug which was found to be 99.63±0.8088%. The limit of detection and limit of quantitation was demonstrated as 13.72µg/ml and 41.58µg/ml respectively. Results have demonstrated that the procedure is accurate and precise, with relative standard deviation less than 2%, yet also being easy and economical. This new and simple UV spectrophotometric method can be easily implemented for routine estimation of the drug from bulk and pharmaceutical tablet dosage form with no interference from excipients. The study shown that the proposed method can be applied in conventional analysis.
Keywords*: Solriamfetol, Sunosi, UV spectrophotometric method, Validation, Narcolepsy, Obstructive sleep apnea.*

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INTRODUCTION

Solriamfetol, which is currently marketed under the Sunosi ® brand, received FDA approval in March 2019.The solriamfetol is a phenylalanine derivative with the chemical formula (R)-2-amino-3-phenylpropylcarbamate hydrochloride (Figure 1). Solriamfetol is a distinct, approved by the FDA enantiopure drug intended to treat excessive daytime drowsiness caused by obstructive sleep apnea or narcolepsy. R- Solriamfetol, that is only the active R-enantiomer is marketed as a norepinephrine and dopamine reuptake inhibitor for the treatment of daytime drowsiness caused by narcolepsy or obstructive sleep apnea [1]. Solriamfetol, a selective norepinephrine-dopamine reuptake inhibitor, is the first drug of its kind to be evaluated by the USFDA for the treatment of excessive drowsiness in Obstructive sleep apnea and narcolepsy patients. Sleep-wake regulation relies heavily on monoaminergic systems (serotonin, norepinephrine, and dopamine). Solriamfetol can selectively bind to and block reuptake at dopamine and norepinephrine transporters while without increasing monoamine release [2]. The objective of the current study was to develop accurate, reproducible UV spectroscopic approach for detection of the solriamfetol in bulk and pharmaceutical formulation. The method was evaluated for parameters like linearity, accuracy, precision, robustness, LOD, and LOQ in accordance with ICH recommendations.

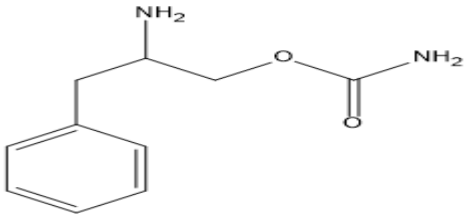

Fig 1: Solriamfetol Structure

MATERIAL AND METHODS

Instruments:

The Jasco V-730 double beam UV Spectrophotometer, with matching 1 cm path length quartz cells and weighing balance Shimadzu A×200 was used for this work.

Materials:

The Solriamfetol pure drug was obtained from Alkem Laboratories, Mumbai. The distilled water used was obtained from institute water purification system.

Preparation of standard stock solution of solriamfetol:

The Standard stock solution of Solriamfetol is prepared by weighing 100 mg of Solriamfetol accurately and then was transferred to 100 ml volumetric flask**.** Then, volume was made up with distilled water to make 1000 µg/ml or 1 mg/ml solution.

Determination of wavelength of maximum absorption:

Using distilled water as a blank solution the 500µg/ml Solriamfetol solution was scanned in UV range of 200-400 nm. The wavelength of maximum absorbance was found to be 257 nm and is selected as an analytical wavelength. The UV spectrum of Solriamfetol is given in figure 2.

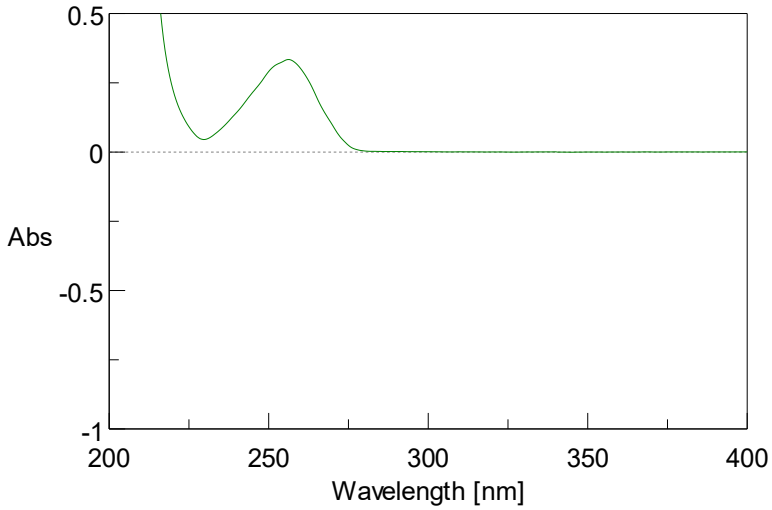

Fig 2: UV Spectrum of Solriamfetol

Preparation of Calibration Graph:

For the calibration graph, 1-5 ml aliquots from stock solution of Solriamfetol (1000µg/ml) were transferred into 10 ml volumetric flask in sequence. The volume was made up with distilled water to get 100-500 µg/ml solutions. At 257nm absorbances were taken and calibration curve was plotted as concentration vs Absorbance.

Table 1: Parameters for Calibration curve

Concentration (µg/ml)	Absorbance
100	0.08219
200	0.16223
300	0.24023
400	0.32546
500	0.40250

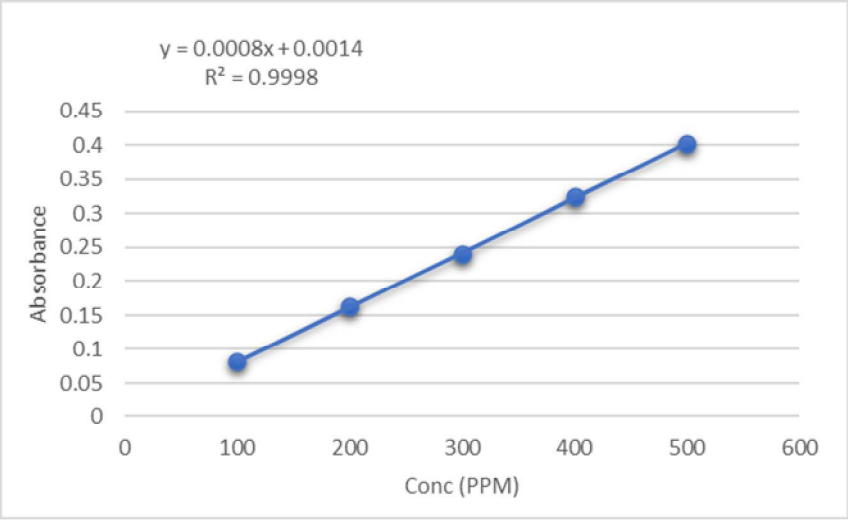

Fig 3: Calibration curve of Solriamfetol

Method Validation Of developed UV Spectrophotometric method

Linearity:

The linearity of an analytical method refers to the method's ability to produce test outcomes that are directly proportional to the concentration of analyte in sample. The calibration curve was created for the concentration range of 100-500µg/ml. The coefficient of correlation and linear regression equation were obtained.

Accuracy:

The analytical method's accuracy shows the degree of closeness of agreement between the accepted value (a conventional actual value or an approved reference value) and the value found. The accuracy of developed method is indicated by % recovery of Solriamfetol by standard addition method. The standard Solriamfetol and In-house prepared tablet formulation was used for this investigation. The dilutions were prepared at three concentration levels 80%, 100% and 120% of standard solution in known quantity of sample.

Precision:

The precision of an analytical process represents the degree of closeness between a set of observations recorded from several samplings of the homogeneous sample under the specified conditions. The developed method was indicated for its precision based on Intra-day and Inter-day variation study. For the intra-day precision study three different solutions of concentration 100, 300, 500µg/ml were prepared in triplicate (n=3) and analysed on same day. For Inter-day precision study three solutions were prepared in triplicate of concentrations 100, 300, 500µg/ml and analysed on two different days. The mean, standard deviation and % RSD were calculated.

Limit of Detection (LOD) and Limit of Quantitation (LOQ):

The Limit of Detection (LOD) of analytical procedure is the lowest amount of the analyte in the sample that can be detected but not exactly quantified. The Limit of Quantitation of analytical procedure is the lowest amount of analyte in the sample that can be detected and quantified.

$$LOD = \frac{3.3 \times \sigma}{S}$$

$$LOQ = \frac{10 \times \sigma}{S}$$

Where, σ is the mean standard deviation of absorbances of sample solutions of calibration graph and S is the slope of the related calibration curve equation.

Robustness:

The ability of analytical method to obtain the repeatability in test results under the deliberate changes in method parameters is known as robustness. The robustness of the developed method was indicated by switching the analysts. The data was obtained as mean, standard deviation and % RSD.

RESULT AND DISCUSSION

Method Validation of developed UV spectrophotometric method:

Linearity:

The linearity of developed method is demonstrated by triplicate analysis of five concentrations in range of 100-500µg/ml concentrations. The calibration curve shows the linear relationship between concentration and absorbance in rage of 100-500µg/ml with correlation coefficient of 0.9998 and regression equation as Y = 0.0008 X + 0.0014.

Accuracy:

The accuracy was established in triplicate by analyzing the percentage recovery of Solriamfetol using the standard addition procedure. The data for the % recovery and % RSD was obtained. The % recovery obtained demonstrates that there is no interference from the excipients included in the formulation. The % RSD was found to be within the limit of less than 2 %. The table no.2 Shows the data for the accuracy.

Table 2: Data for Accuracy recovery study

Level Of Addition (%)	Standard API (µg/ml)	Formulation Stock (µg/ml)	Total Conc. (µg/ml)	Drug Recovered (µg/ml)	%Recovery	%RSD
80 %	200	160	360	354.6	98.50	0.88
100 %	200	200	400	397.2	99.30	0.69
120 %	200	240	440	444.8	101.09	0.85

Precision:

The Intra-day and Inter-day precision were demonstrated in terms of calculated %RSD. For Intra-day precision, 100, 300, 500 µg/ml concentration solutions were measured three times in a day and % RSD was calculated. For Inter-day precision the observations were measured on two different days and %RSD was calculated. The %RSD calculated were in specified limit of less than 2%. The data for the precision is shown in Table No.3 and 4.

Table 3: Inter-Day precision

Drug Concentration (µg/ml)	Mean Absorbance	Standard deviation	%RSD
100	0.08289	0.00010	0.12
300	0.2379	0.0012	0.53
500	0.3997	0.0024	0.60

Table 4: Intra-Day Precision

Drug Concentration (µg/ml)	Mean Absorbance	Standard deviation	%RSD
100	0.08269	0.00020	0.24
300	0.2375	0.0031	1.32
500	0.3964	0.0038	0.98

Limit of Detection (LOD) and Limit of Quantification (LOQ):

The method sensitivity parameters like limit of detection (LOD) and Limit of Quantitation were estimated with help of calibration curve. The limit of detection and limit of quantitation were estimated to be 13.72 µg/ml and 41.58 µg/ml respectively.

Robustness:

The robustness was indicated based on the %RSD values for the observations obtained by the switching between the analysts. The %RSD was observed to be less than 2 %. The data is given in Table no 5.

Table 5: Robustness

Drug Concentration (µg/ml)	Analyst 1			Analyst 2		
	Mean abs ± SD	%RSD	% Amount found	Mean abs ± SD	%RSD	% Amount found
100	0.08202±0.00061	0.75	102.5	0.08245±0.0002	0.24	103
300	0.23463±0.0041	1.76	97.7	0.2411±0.0021	0.87	100
500	0.3941±0.0027	0.68	98.5	0.4002±0.0012	0.31	100

CONCLUSION

The UV-Spectrophotometric method was developed for determination of Solriamfetol from pure drug and its formulation. The developed method was validated in accordance with the guidelines referring to ICH Q2 (R1). The method was found to be simple, Precise, accurate and reproducible for estimation of Solriamfetol. The method is economic and environmentally friendly because of use of water as a diluent. This method can be effectively utilized for the routine analysis of Solriamfetol in quality control laboratories.

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