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RESEARCH ARTICLE

Method Development and Validation of Suvorexant in Tablet Formulation by using UV Double Beam Spectrophotometer

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ABSTRACT

This UV-spectrophotometric technique is quite simple, accurate, precise, reproducible, and sensitive. The UV method has been developed for quantification of suvorexant in tablet formulation. The validation procedure confirms that this is an appropriate method for their quantification in the formulation. It is also used in routine quality control of the formulations containing this entire compound.

Keywords: Suvorexant, UV-spectrophotometric technique

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CONTENTS

1. Introduction

Suvorexant, sold under the trade name Belsomra, is a medication for the treatment of insomnia. It is effective for insomnia, at least for four weeks and as compared to a placebo.

Spectroscopy

Definition: Spectroscopy is defined as the study of interaction of EMR with matter. It is used for analysis of wide range of samples.

Spectrum: A plot of the response as a function of wavelength or more commonly frequency is referred to as a spectrum.

Spectrometry: It is the measurement of these responses and an instrument which performs such measurements is a spectrometer or spectrograph.

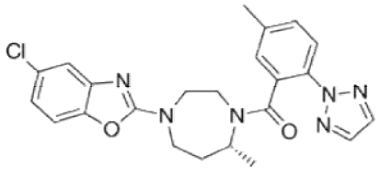

Fig 1: Chemical Structure of Suvorexant

2. Materials and Methods

Materials:

Suvorexant was a gift sample from Dr. Reddys Lab, Hyderabad. All chemicals (distilled water, methanol) and reagents used were of analytical grade and purchased from Qualigens Fine Chemicals, Mumbai, India.

Apparatus:

A Labindia UV–visible spectrophotometer (UV-T60-India) was used for all absorbance measurements with matched quartz cells.

Selection of wavelength for analysis of suvorexant:

During the development phase, the use of ethanol as the diluent resulted in preferable outcome in UV analysis. The pre-determined wavelength of maximum absorption (λmax) was 245 nm.

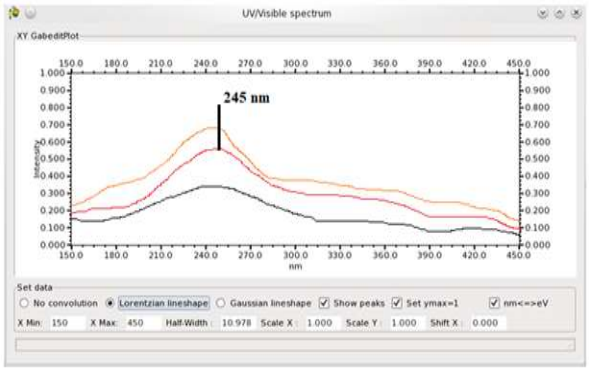

Fig 2: UV spectrum of Suvorexant

Validation of the method

The method was validated in terms of linearity, accuracy, precision, and ruggedness.

Linearity study:

Different aliquots of Suvorexant in the range 0.5–3 ml were transferred into series of 10 ml volumetric flasks, and the volume was made up to the mark with distilled water to get concentrations 5, 10, 15, 20, 25, and 30 µg/ml, respectively. The solutions were scanned on a spectrophotometer in the UV range 200–400 nm. The spectrum was recorded at 245 nm. The calibration plot was constructed as concentration vs. absorbance

Accuracy:

To the preanalysed sample solutions, a known amount of standard stock solution was added at different levels, i.e. 50%, 100%, and 150%. The solutions were reanalyzed by the proposed method.

Precision:

Precision of the method was studied as intraday and interday variations. Intraday precision was determined by analyzing the 10, 15 and 20 µg/ml of suvorexant solutions for three times in the same day. Interday precision was determined by analyzing the 10, 15, and 20 µg/ml of suvorexant solutions daily for 3 days over the period of week.

Sensitivity:

The sensitivity of measurements of suvorexant by the use of the proposed method was estimated in terms of the limit of quantification (LOQ) and limit of detection (LOD). The LOQ and LOD were calculated using equation LOD = 3 × N/B and LOQ = 10 × N/B, where 'N' is standard deviation of the peak areas of the drugs (n = 3), taken as a measure of noise, and 'B' is the slope of the corresponding calibration curve.

Repeatability:

Repeatability was determined by analyzing 20 µg/ml concentration of suvorexant solution for six times.

Ruggedness:

Ruggedness of the proposed method is determined for 20 µg/ml concentration of suvorexant by analysis of aliquots from a homogenous slot by two analysts using same operational and environmental conditions.

3. Results and Discussions

Linearity:

Table 1: Results for Linearity

Concentration (ug/ml)	Absorbance(nm)
0	0
5	0.265
10	0.492
15	0.706
20	0.933
25	1.141
30	1.365

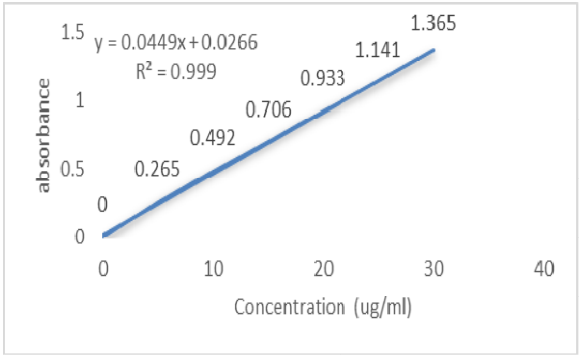

Fig 3: Calibration Graph of Suvorexant

Analysis of Formulation

Preparation of sample solution:

Two tablets are powdered and the average weight was calculated. A quantity equivalent to 40 mg of drug was dissolved in Methanol. Finally the volume was made up to get a working concentration of 10µg/ml each of suvorexant

and absorbances were noted at 245nm respectively. The amounts of suvorexant were calculated using the simultaneous equation given below.

$$\text{At } \lambda_1 \; A_1 = ax_1 bc_x + ay_1 bc_y$$

$$\lambda_2 \; A_2 = ax_2 bc_x + ay_2 bc_y$$

$$C_{fix} = \frac{A_2 ay_1 - A_1 ay_2}{ax_2 ay_1 - ax_1 ay_2}$$

$$C_{qfx} = \frac{A_1 ax_2 - A_2 ax_1}{ax_2 ay_1 - ax_1 ay_2}$$

A_1 =absorbance of formulation at 245nm.
ax_1 = Absorptivity of suvorexant at 245nm.
ay_1 = Absorptivity of suvorexant at 245nm.
C_{fvx} = Concentration of suvorexant.

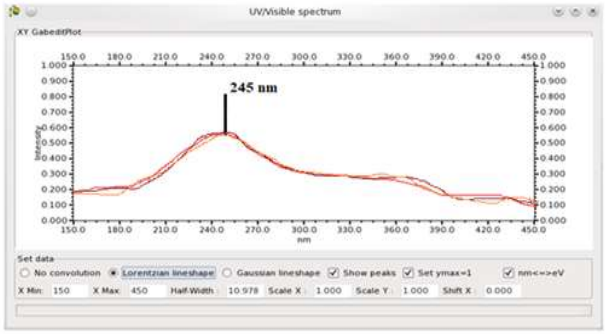

Fig 4: UV spectra of formulation

4. Conclusion

This UV-spectrophotometric technique is quite simple, accurate, precise, reproducible, and sensitive. The UV method has been developed for quantification of suvorexant in tablet formulation. The validation procedure confirms that this is an appropriate method for their quantification in the formulation. It is also used in routine quality control of the formulations containing this entire compound.

Table 2: Results of Accuracy

%Concentration (at specification Level) N=3	absorbance	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	0.354	5.0	4.995	99.9	99.92
100%	0.601	10	9.992	99.92	
150%	0.695	15	14.991	99.94	

Table 3: Intra-day and inter-day precision determined for three different concentrations of suvorexant (n=3)

Concentration (µg/mL)	Intra-day precision			Inter-day precision		
	Absorbance measured	RSD (%)	Average (%)	Absorbance measured	RSD (%)	Average (%)
5	0.357±0.12	1.33	99.15	0.364±0.17	1.21	99.10
10	0.605±0.21	0.91	98.75	0.615±0.25	1.24	99.14
15	0.699±0.25	1.01	99.14	0.684±0.20	1.19	98.95

Table 4: Results of Repeatability

Concentration (µg/mL)	Absorbance measured (Mean ± SD)	Amount Found (%)	RSD (%)
20	0.7154±0.024	99.74	0.05

Table 5: Results of Ruggedness

Analyst	Concentration (µg/mL)	Absorbance measured (Mean ± SD)	Amount Found (%)	RSD (%)
I	20	0.7114±0.0241	98.94	0.04
II	20	0.7215±0.0154	99.16	0.02

Table 5: Analysis of formulation

Drug	Amount (mg/tab)		% label claim	% RSD*
	Labeled	Found		
Suvorexant	200mg	123.5	98.66%	0.95%

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