

Research Article

UV Spectrophotometric Method Development and Validation for Quantitative Estimation of Venlafaxine hydrochloride

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ABSTRACT

Aim: UV Spectrophotometric Method Development and Validation for quantitative estimation of Venlafaxine hydrochloride. **Objective:** U.V Spectrophotometric method have been widely employed for determination of analyte in a mixture. Our aim is to develop spectroscopic method for estimation of the Venlafaxine hydrochloride in ternary mixture by using U.V spectrophotometry. **Methodology:** The method was validated as per ICH guidelines. The recovery studies confirmed the accuracy and precision of the method. **Conclusion:** It was successfully applied for the analysis of the drug in bulk and could be effectively used for the routine analysis.

Key words: Venlafaxine hydrochloride, UV spectrophotometric method, Validation.

Introduction

Venlafaxine hydrochloride is an anti-depressant agent and chemically it is a cyclohexanol hydrochloride derivative. Its IUPAC name is [R/S]-1-[2-(dimethylamino)-1-[4-Methoxyphenyl]ethyl] cyclohexanol hydrochloride or (+)-1-[2-[(dimethyl amino) methyl] p-Methoxybenzyl] cyclohexanol hydrochloride. Venlafaxine is official drug in British Pharmacopoeia.

The review of literature revealed that no method is reported for the Venlafaxine hydrochloride in fixed dosage products by UV-spectroscopy. The present paper describes a simple and accurate UV-spectrophotometric method can be highly useful for routine analysis of bulk, formulations and dissolution samples. (Baldania et al., 2008; Savale et al., 2017)

Material and Method

Material

Venlafaxine hydrochloride supplied as a gift sample from Lee Pharma Pvt. Ltd (Hyderabad, India) used as working standard.

Instrumentation

A double beam UV-VIS spectrophotometer (UV-1700, Shimadzu, Japan) connected to a computer loaded with spectra manager software UV Probe was used. The spectra were obtained with the instrumental parameters as follows: Wavelength range: 200–400 nm. All weights were taken on an electronic balance (Model Shimadzu AUX 120).

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Reparation of standard stock solution

According to British Pharmacopoeia, 10 mg of Venlafaxine hydrochloride was dissolved in 100 mL of phosphate buffer (pH 6.4) (100 µg/mL). Out of this stock 0.1-2.4 ml was pipetted and diluted up to 10 mL by phosphate buffer (pH 6.4) (1-24 µg/mL) and examined between 200-400 nm. The maximum absorbance was determined using UV-Vis Spectrophotometer (UV-1700, Shimadzu, Japan) to confirm the λ_{max} of the drugs (Savale et al., 2017).

Validation of analytical method

(Figure 1).

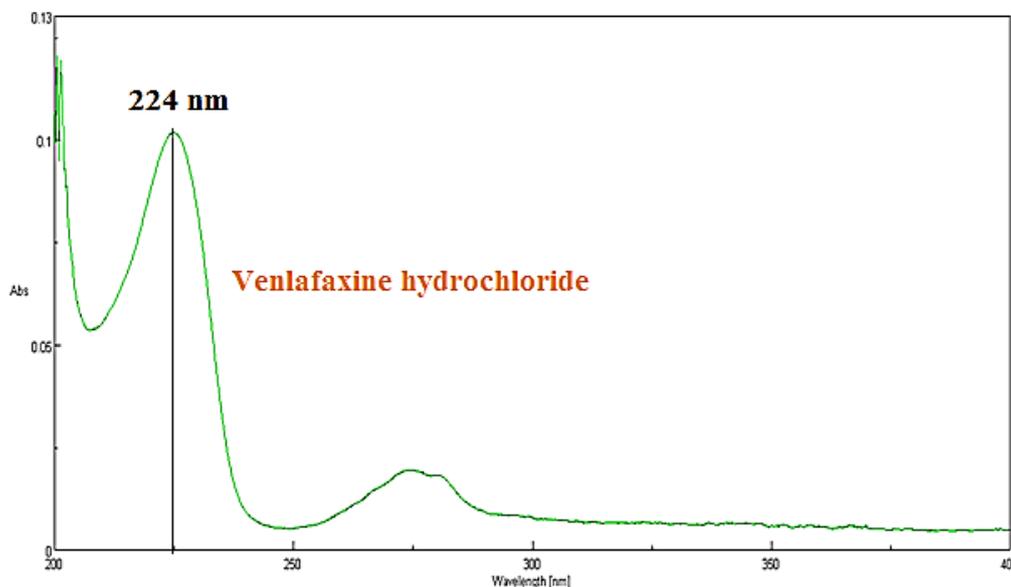


Figure 1. UV spectra of Venlafaxine hydrochloride

Validation of analytical method

Linearity

Accurately weighted Venlafaxine hydrochloride (10 mg) was dissolved in 100 ml of phosphate buffer (pH 6.4) to obtain working standard of 100 µg/ml. Aliquots were pipetted from the stock solution of drug and were transferred to 10 ml volumetric flask, the final volume was adjusted with phosphate buffer (pH

The analytical performance characteristics which may be tested during methods validation: % Recovery, Precision, Ruggedness and sensitivity (Karani et al., 2009; Savale et al., 2017).

Results and Discussion

Method Development

The solution of Venlafaxine hydrochloride in phosphate buffer (pH 6.4) was found to exhibit **maximum absorption at 224 nm** after scanning on the UV-Vis spectrophotometer which was reported as λ_{max} in the literature and the procured drug sample of Venlafaxine hydrochloride complies with the reference spectra.

6.4) so that concentration of 1-24 µg/ml could be made. Absorbance of the above solution were taken at 224 nm by using UV-Vis spectrophotometer (UV-1700, Shimadzu, Japan) against the blank solution prepared in the same manner without adding the drug. A graph of absorbance vs concentration was plotted (Figure 2) and R^2 was found to be 0.9986.

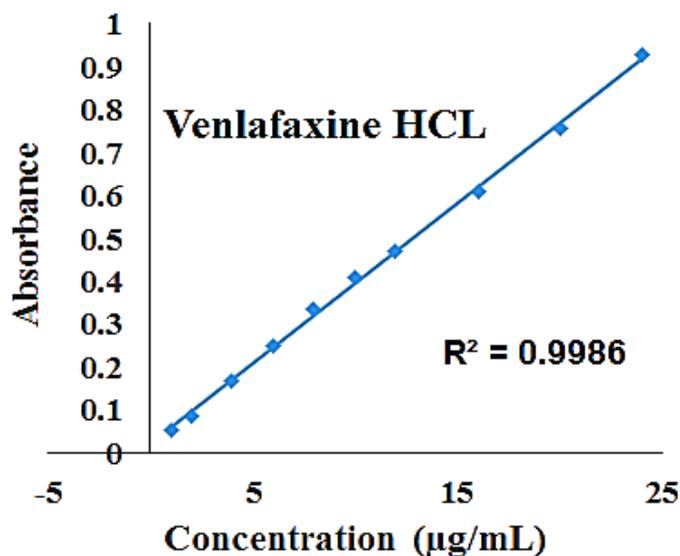


Figure 2. Calibration curve of Venlafaxine hydrochloride

Recovery

Recovery study is performed by standard addition method by adding the known amount of Venlafaxine hydrochloride(Working standard) at two different concentration levels i.e 80%, 100% of assay concentration and % recovery for all

these drug were calculated. Result was reported in Table 1.

Table 1. Recovery study

	Drug	Initial amount (µg/ml)	Added Amount (µg/ml)	% Recovery	% RSD (n = 3)
Precision Intra-day was	Venlafaxine hydrochloride	2	1.8	100.77	0.03
		2	2	100.01	0.01

precision

determined by analysing, the two different concentrations 2 mg/ml, 3 mg/ml containing Venlafaxine hydrochloride, for three times in the same day (n = 3) Table 2. Inter-day variability

was assessed using above mentioned three concentrations analysed on three different days, over a period of one week (n = 3) Table 2.

Table 2. Precision study

Drug	Con. ($\mu\text{g/ml}$)	Intra - Day		Inter - Day	
		Mean \pm SD	% RSD	Mean \pm SD	% RSD
Venlafaxine hydrochloride	2	2.0 \pm 0.0044	0.08	2.0 \pm 0.0088	0.01
	3	3.0 \pm 0.0075	0.02	3.0 \pm 0.0041	0.09

similar operational and environmental conditions (Table 3) (n = 3).

Ruggedness

From stock solution, sample solution containing Venlafaxine hydrochloride (2 $\mu\text{g/ml}$) was prepared and analyzed by two different analysts using

Table 3. Ruggedness study

Drug	% Amount Found		% RSD	
	Analyst I	Analyst II	Analyst I	Analyst II
Venlafaxine hydrochloride	100.74	100.95	0.01	0.05

Sensitivity

Sensitivity of the proposed method were estimated in terms of Limit of Detection (LOD) and Limit of Quantitation (LOQ) (Table 4).

Table 4. Sensitivity study

Drug	LOD	LOQ
Venlafaxine hydrochloride	0.48 \pm 0.001	0.98 \pm 0.016

Conclusion

The proposed UV spectrophotometric method was found very simple, rapid and economical. The method is validated in compliance with ICH guidelines is suitable for estimation of Venlafaxine hydrochloride with excellent recovery, precision and linearity.

Reference

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