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Research Article

New Simple UV Spectrophotometric Method For Determination of Venlafaxine Hydrochloride in Bulk And Pharmaceutical Dosage Forms

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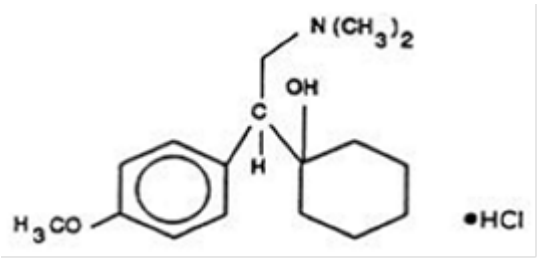
ABSTRACT
Venlafaxine is 1-[2-(dimethylamino)-1-(4-methoxyphenyl) ethyl] cyclohexan-1-ol, used as an antidepressant of the neither serotonin- nor epinephrine reuptake inhibitor (SNRI) class. It is prescribed for the treatment of clinical depression and anxiety disorders. In present work, a simple, sensitive, accurate and economical spectroscopic method has been developed for the estimation of Venlafaxine HCl in Bulk and its pharmaceutical dosage forms. An absorption maximum was found to be at 274 nm with the solvent system 0.1 N HCl. The drug follows Beer law in the range of 10-250 µg/ml with correlation coefficient of 0.9998. The percentage recovery of Venlafaxine HCl ranged from 99.97 to 100.05% in pharmaceutical dosage form. Results of the analysis were validated for accuracy, precision, LOD, LOQ and were found to be satisfactory. The proposed method is simple, rapid and suitable for the routine quality control analysis.

Key Words: Venlafaxine, UV spectrophotometry, estimation, Validation

INTRODUCTION

Venlafaxine is 1-[2-(dimethylamino)-1-(4-methoxyphenyl) ethyl] cyclohexan-1-ol, used as an antidepressant of the neither serotonin- nor epinephrine reuptake inhibitor (SNRI) class. It is prescribed for the treatment of clinical depression and anxiety disorders [1-4]. Molecular basis of Venlafaxine (VNL) reveals that it is a complex molecule for the estimation by UV method and the $-OCH_3$, Tertiary amine, alcoholic groups are the responsible for its therapeutic activity and quality control parameters [2, 3]. A survey of literature also states that there was no specified, simple data reported on UV method for the estimation of Venlafaxine. An absorbance was found to be 274 nm and the spectrum was scanned for the drug dissolved in 0.1N HCl. The method has been validated in and according to ICH guidelines [4, 5].



Structure of Venlafaxine HCL

EXPERIMENTAL WORK

Chemicals and Reagents: The investigated samples, Venlafaxine Hydrochloride capsules were formulated in Aurobindo Pharma Limited, Hyderabad, India. Working standards were procured from the local market. Reagents used for analysis i.e., Hydrochloric Acid (Merck), Distilled Water. Venlafaxine Hydrochloride (VNL) was obtained from Aurobindo Pharma Limited. (India) and was used as such without further purification. The commercial formulations available are Venlafaxine Hydrochloride Capsules (150 mg) were purchased from the local market.

Instruments and Equipments: ESICO 2371 Spectrophotometer, Single beam with M Wave Basic software UV-Visible spectrophotometer with 1cm matched quartz cells, Six Stage Dissolution Apparatus, Weighing Balance, Sonicator, Whatmann Filter Paper.

Method Development: Preparation of 0.1 N Hcl: Preparation of 0.1 N Hydrochloric Acid Solution: 8.5 mL of Concentrated Hydrochloric Acid was added drop by drop with the continuous stirring in about 500 mL of Distilled water and made up the volume with water upto 1000 mL, and filtered through 0.45µ Whatmann filter paper .This buffer solution was used as diluents.

Preparation of diluent: 0.1 N Hcl buffer solution was used as the diluent.

Preparation of standard solution: Stock solution of VNL (1 mg/mL) was prepared by accurately weighed powder equivalent to about 100 mg of Venlafaxine Hydrochloride in to a 100 mL clean dry volumetric flask, and add about 50 mL of diluent and sonicated for 30 minutes, and diluted upto the 100 mL with diluent and mixed. Standards solutions of VNL were prepared in the range of 10 µg/mL to 250 µg/mL by diluting the stock solution with mobile phase.

Assay of Venlafaxine HCl: Twenty capsules were weighed to get the average weight and then the granules from the capsules were removed and weighed. After that the empty capsule shells were subtracted from the total granules weight. The granules, equivalent to 100 mg

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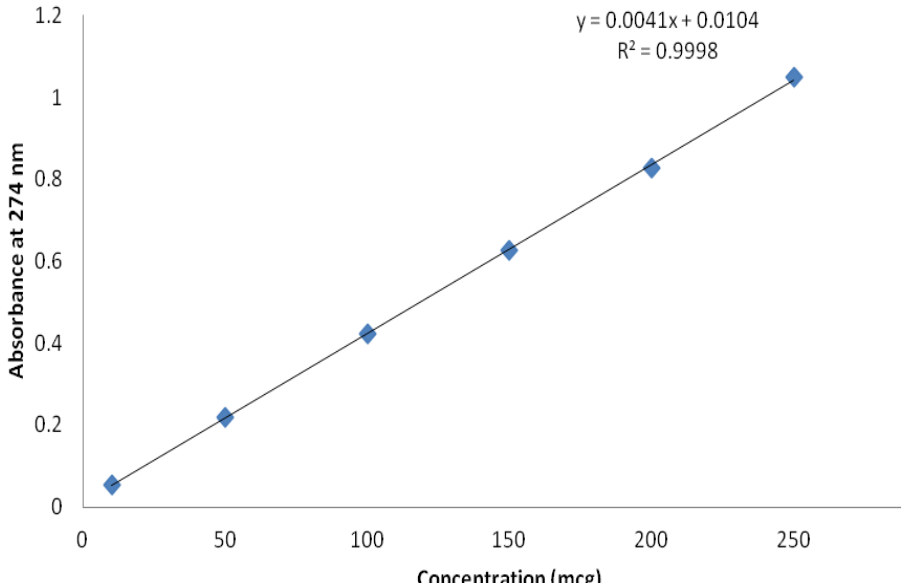

Calibration Curve of Venlafaxine HCL at 274nm

Table -1 Assay of Venlafaxine dosage forms

Dosage form	Label claim (mg/tab)	Amount found * ± SD	% Purity of VNL ± %RSD
Velaxin 25	25	25.04 ± 0.07211	100.2 ± 0.36
Effexor	25	24.93 ± 0.055	99.85 ± 0.28

**An average of three samples of each concentration*

Table-2 Optical characteristics and precision of the proposed method

Parameter	value
Absorption maxima (nm)	274 nm
Beer's law limit (µg/ml)	10-250 µg/ ml
Correlation coefficient (r)	0.9998
Regression equation (Y= mX+c)	Y= 0.0041x + 0.0104
Slope (m)	0.0041
Intercept (c)	0.0104
Standard Deviation	0.0075
LOD (µg / ml)	1.53
LOQ (µg / ml)	4.63

Table-3 Linearity range of proposed UV-Visible Spectrophotometric method

S.No.	Linearity Level	Concentration (µg/mL)	Absorbance
1	I	10	0.0539
2	II	50	0.2177
3	III	100	0.4227
4	IV	150	0.6251
5	V	200	0.8286
6	VI	250	1.0491
	Correlation Coefficient		0.9998

of VNL, was weighed and transferred into a 100 mL calibrated volumetric flask and dissolved using diluent. This mixture was sonicated for (45 min) and then filtered through a 0.45 µm Whatman filter paper. After filtration, Aliquots solutions were prepared by taking required mL in volumetric flasks, separately and made up to volume with diluent to yield concentrations of drug in range of linearity previously described. The amount of VNL was calculated from the related linear regression equations Table 1.

Optical characteristics: The optical characteristics such as beer's law limit, molar extinction coefficient, % RSD were calculated. Regression characteristics like slope,

Table -4 Accuracy data of the drug

Sample ID	Concentration µg /ml		(%)Recovery* ± S.D	RSD (%)
	Pure drug mg	Formulation mg		
80%	20	25	101.3±0.308	0.305
100%	25	25	99.4±0.397	0.40
120%	30	25	99.9±0.222	0.223

** An average of three samples of each concentration*

Table -5 Precision of the Venlafaxine HCl working standards

Type of precision	Intra day (%RSD)	Inter day (%RSD)
System Precision [a]	0.188	0.102
Method Precision [b]	0.253	0.410

a, b are a mean of six independent samples

intercept, correlation coefficient, LOD, LOQ, standard deviation were calculated (Table-2).

Method Validation: The method was validated for different parameters like Linearity, Accuracy and Precision.

Linearity: Fresh aliquots Concentrations of ranging from 10-250 µg/ml were prepared from the stock solution. The samples were scanned in UV-Visible spectrophotometer using 0.1 N HCl as blank. It was found that the VNL shows linearity between the 10-250 µg/ml (Table -3).

Accuracy: Accuracy of the method confirmed by studying recovery at 3 different concentrations for 80, 100, and 120% of these expected, in accordance to ICH guidelines, by replicate analysis. Standard drug solution was added to a pre analyzed sample solution and percentage drug content was measured. The results from study of accuracy were reported in table no.3. %Recovery = [(ct –cu)/ ca] × 100. Where ct is the total conc. of the analyte found; cu is the conc. of the analyte present in formulation; and ca is the conc. of the pure analyte added to the formulation. (Table 4)

Precision: Precision (intra-day precision) of the method was evaluated by carrying out the six independent test samples of Venlafaxine. The intermediate precision (inter-day precision) of the method was also evaluated using two different analyst, and different days in the same laboratory. The percent relative standard deviation (%RSD) and assay values obtained by two analysts were found to be Good (Table- 5).

RESULTS AND DISCUSSIONS

The percentage purity and relative standard deviation from the Assay of the tablet dosage forms (Table-1) were found to be within the limits From the optical characteristics (Table-2) of the proposed method, Venlafaxine HCl was shown its λ max at 274 nm in the solvent 0.1 N HCl with a good correlation coefficient 0.9998. From linearity data (Table-3) it was found to be that Venlafaxine HCl obeys beer's law in the range of 10-250 µg / ml. The accuracy data of the drug (Table-4) was shown good percentage recovery and %RSD with the range of 99.97 -100.05 and 0.2-0.4 respectively. The Inter-day and Intra-day(Table-5) precision values were found to be 0.102 to 0.410, which indicates that the proposed method is accurate and also reveals that there is no interference of the commonly used excipients and additives in the formulation.

CONCLUSION

The proposed method for the estimation of Venlafaxine HCl was found to be simple, sensitive and reliable with good precision and accuracy. The method is specific while estimating the commercial formulations without interference of excipients and other additives. Hence this method can be used for the routine analysis of Venlafaxine HCl in pure and pharmaceutical formulations.

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