RJC
http://www.rasayanjournal.com

RASĀYAN *J. Chem.*
Vol.2, No.2 (2009), 276-279
ISSN: 0974-1496
CODEN: RJCABP

ESTIMATION OF VENLAFAXINE IN COMMERCIAL DOSAGE FORMS USING SIMPLE AND CONVENIENT SPECTROPHOTOMETRIC METHOD

Mandava V. Basaveswara Rao*, B.C.K. Reddy, T. Srinivasarao and V. Prasanthi

* Department of Chemistry, Sadineni Chowdaraiah College of Arts & Science, Maddirala, Chilakaluripet, Andhra Pradesh - 522 611, India.
* Email: vbrmandava@yahoo.com

ABSTRACT

In this study, UV spectrophotometric method at 276nm was developed for the determination of Venlafaxine in commercial dosage forms. Optical Density (OD) measurement was used in calculating the concentration of the drug samples drawn from dissolution test (temp 37 ± 0.5˚C) at intervals of 2, 4, 8 and 12hrs. The results correlated well with the values obtained from HPLC and LC-MS methods. The proposed method was validated in terms of linearity, reproducibility and accuracy. Linearity was in the range 0.5-2.5 mg of Venlafaxine, while the repeatability (%RSD 2.5) was satisfactory.

Keywords: Venlafaxine; Linearity; Reproducibility; Accuracy; Optical Density; Antidepressant Drug

INTRODUCTION

Venlafaxine Hydrochloride is an established antidepressant drug. Chemically it is known as [2-(Dimethylamino)-1-(4-methoxyphenyl)ethyl]cyclohexanol hydrochloride. A survey of literature reveals that HPLC/MS methods[1-5] are reported for the determination of HPLC Analysis of Venlafaxine and its application to drug quality control studies, development and validation of a flow-injection assay for dissolution studies of the anti-depressant drug Venlafaxine, postmortem tissue concentrations of Venlafaxine, Bioavailability of once-daily Venlafaxine extended release compared with the immediate-release formulation in healthy adult volunteers, Simultaneous stereoselective analysis of Venlafaxine and O-desmethylvenlafaxine enantiomers in human plasma by HPLC-ESI/MS using a vancomycin (mention the name of the column like pirkle, inclusion complex or diacel etc.,) chiral column, simultaneous stereoselective analysis of Venlafaxine and O-desmethylvenlafaxine enantiomers in clinical samples by capillary electrophoresis using charged cyclodextrins, simultaneous stereoselective analysis of Venlafaxine and O-desmethylvenlafaxine enantiomers in human plasma by HPLC-ESI/MS using a vancomycin chiral column, and in clinical samples by capillary electrophoresis using charged cyclodextrins. However there is no UV method reported so for its estimation in commercial dosage form. Hence a UV method for the determination of Venlafaxine in pharmaceutical solid dosage forms is described.

EXPERIMENTAL

Process used and Ingredients:

Venlafaxine hydrochloride 35g(API), sucrose 30g, mannitol 15g**, h**ydroxy propyl cellulose 2g, microcrystalline cellulose 15g, ethyl cellulose N50 3.5g, and Talc 0.5mg.
Total mass 101.0g

Method:

Instrument: UV-VIS spectra, Shimadzu 2010. LC solution computer based data station.

Chemicals and reagents:
Reference standard Venlafaxine Hydrochloride is procured from M/S.RA Interchem, Water (Distilled water), Absolute alcohol AR grade.

Drug release:
Apparatus: 2; 100 rpm
Medium : 1000ml Water
Time: 2, 4, 8 and 12hours

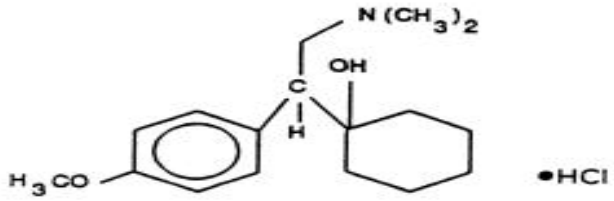

Fig. 1: Venlafaxine hydrochloride

Place the stated volume of dissolution medium in the vessel of apparatus specified in the individual monograph, assemble the apparatus. Equilibrate the dissolution medium to 37 ±0.5^{0}C, and remove the thermometer. Place the 6 samples in the apparatus, taking care to exclude air bubbles from the surface of dosage-form unit, and immediately operate the apparatus at the rate specified in the individual monograph. with in the time interval specified, withdraw a specimen from a zone midway between the surface of dissolution medium and the top of rotation blade, not less than 1 cm from the top of the rotation blade, not less than 1 cm from the vessel wall. Replace the aliquots withdrawn for analysis with equal volumes of fresh dissolution medium at 37^{0}C. Determine the amount of $C_{17}H_{27}NO_2$·HCl; dissolved, using the following method UV spectra:
The spectra are equipped with a 276nm the standard preparation and the record the spectra as directed for procedure: the relative standard deviation for replicate injection is not more than 2.0%.

Procedure:
Placebo solution: Weigh Equivalent to 50 mg Placebo pellets in a 50ml volumetric flask, dissolve and makeup to volume with ethanol. Dilute 5ml of this solution to 50 ml with water. Further dilute 5 ml of this solution to 50 ml with water.
Reference solution: Weigh accurately about 50 mg Venlafaxine Hydrochloride working standard (WS) in a 50ml volumetric flask, dissolve and makeup to volume with ethanol. Dilute 5ml of this solution to 50 ml with water. Further dilute 5 ml of this solution to 50 ml with water.
Test solution: Weigh Equivalent to 50 mg Venlafaxine Hydrochloride pellets in a 50ml volumetric flask, dissolve and makeup to volume with ethanol. Dilute 5ml of this solution to 50 ml with water. Further dilute 5 ml of this solution to 50 ml with water. Record the spectrum and absorbance measurement at the wave length 276nm. The results are tabulated as follows (Table-1)-

RESULTS AND DISCUSSION

Dissolution:
10ppm of standard and sample solutions checked into an UV spectra. The amount of Venlafaxine calculated by comparing the absorbance with that of the standard.

Recovery studies:
To study the linearity, accuracy and precision of proposed method, recovery experiments were carried out. Known quantities of standard at two different levels were added to the pre-analyzed sample, the recovery was estimated to be more than 99%.

Table-1

Semi formulation	Release rate in Hours	Bowl	% Drug Release	% Drug Release6 bowls average value	SD	RSD
P E L L E T S	2nd hour	1,2,3,4,5 and 6	21.2,23.4,22.3,21.8 22.02 and 22.4	22.18	0.73232	3.30
	4th hour	1,2,3,4,5 and 6	44.2,43.4,42.9,44.8,43. 7 and 44.5	43.91	0.7139	1.62
	8th hour	1,2,3,4,5 and 6	65.3,66.1,66.8,64.963.8 and 65.9	65.46	1.048	1.60
	12th hour	1,2,3,4,5 and 6	89.7,91.2,90.8,91.590.3 and 92.8	91.05	1.070	1.17

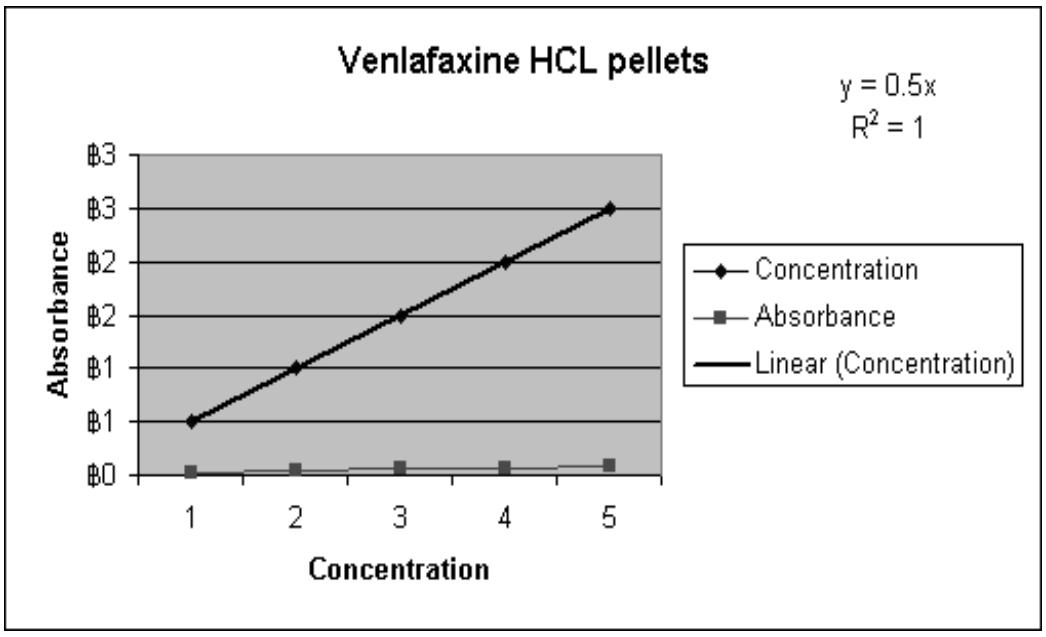

Fig.-2: Graph of absorbance of standard solutions versus concentration

Linearity:

The linearity of Venlafaxine is established by plotting a graph of absorbance of standard solutions versus concentration (Fig.-2). The linearity is found to be between 0.5-2.5mg.

Table-2

Concentration	Absorbance
0.5	0.018
1.0	0.036
1.5	0.054
2.0	0.072
2.5	0.091

The concentration of venlafaxine found to be with in limits and the RSD values are reasonably low.

Table-3

S.NO	Parameter	Venlafaxine HCl
1	RSD Of 6 samples	1.08

The precision of the method is studied by making 5 samples of standard and very low RSD values indicate good precision. The reproducibility and reliability of the method has been tested by performing recovery studies which showed good results.

CONCLUSION

The proposed method is very simple, rapid and no where involves use of complicated sample preparation. High percentage of recovery shows that the method is free from interferences of the excipients used in the semi formulations. Therefore the method can be useful in routine quality control analysis.

REFERENCES

1. P. D. Tzanavaras, A. Verdoukas and D.G. Themelis, *Analytical Sciences*, **21**, 1515 (2005).
2. K.E. Goeringer, I.M. Mc Intyre, O.H. Drummer, *Forensic Science International*, **121**, 70 (2001).
3. *Current Therapeutic Research*, **58,** 492 (1997).
4. S.M. Troy, C. Dilea, P.T. Martin, A.S. Rosen, R.J. Fruncillo, S.T. Chiang, W. Liu, F. Wang and H.-D., L, *Journal of Chromatography B*, **850**, 183 (2007).
5. S. Rudaz, C. Stella, A.E. Balant-Gorgia, S. Fanali and J.-L. Veuthey, Laboratory of Pharmaceutical Analytical Chemistry, University of Geneva, 20 Bd d'Yvoy, 1211 Geneva 4, Switzerland.

(Received: 16 February 2009 Accepted: 23 March 2009 RJC-323)