International Journal of ChemTech Research
CODEN(USA): IJCRGG ISSN : 0974-4290
Vol.2, No.1, pp 572-575, Jan-Mar 2010

SECOND ORDER DERIVATIVE SPECTROPHOTOMETRIC ESTIMATION OF VENLAFAXINE HYDROCHLORIDE IN BULK AND PHARMACEUTICAL FORMULATIONS

Vimal D. Shirvi*,G.Vijaya Kumar, K.P.Channabasavaraj

Department of Pharmaceutical Analysis, Bharathi College of Pharmacy,

Bharathinagara, Maddur, Karnataka-571422, India

Corres.author: vimalshirvi@gmail.com

ABSTRACT: A simple, precise and economical second order derivative method has been developed for the estimation of Venlafaxine hydrochloride in bulk and pharmaceutical formulations. In this method Venlafaxine hydrochloride showed two sharp peak at 244 and 298 nm when n=1 and linearity was measured at 298 nm. It obeyed Beer's law in the concentration range of 20-100 µg/ml. The LOD and LOQ were found to be 1.46 µg/ml and 4.40 µg/ml, respectively. Recoveries of Venlafaxine hydrochloride in tablet formulations were observed in the range of 98.90-100.29 %. The proposed method is precise, accurate and reproducible and can be extended to the analysis of Venlafaxine hydrochloride in bulk and pharmaceutical formulations.

Keywords: Venlafaxine hydrochloride, Derivative spectrophotometric, Method validation.

1. INTRODUCTION

Venlafaxine hydrochloride is a structurally novel antidepressant for oral administration. Chemically it is designated 1-[(1RS)-2-(dimethylamino)-1-(4-methoxyphenyl) ethyl] cyclohexanol hydrochloride [1-2]. The mechanism of Venlafaxine hydrochloride is referred to as serotonin and noradrenalin reuptake inhibitor (SNRT), because it inhibits uptake of both these amine but, in contrast to older Tricyclic antidepressants (TCAs), Venlafaxine hydrochloride does not interact with cholinergic, adrenergic or histaminergic receptors or have sedative property [3-5]. The minimum dose for antidepressant action, initially 75 mg a day is administered and dose is gradually increased up to 225 mg a day, not to exceed 375 mg a day in severe cases [6-8].

From the literature survey, it was found that Venlafaxine hydrochloride estimated by analytical methods such as spectrophotometric methods [9-14], reversed-phase high-performance liquid chromatographic (RP-HPLC) method [15], and stability indicating LC method [16-17].

Apart from the above no second order derivative spectrophotometric method was reported for the quantitative determination of Venlafaxine hydrochloride in pharmaceutical dosage forms. The developed method was simple, precise, specific and accurate and the statistical analysis proved that method is reproducible and selective for the analysis of Venlafaxine hydrochloride in bulk drug and tablet formulations.

2. EXPERIMENTAL

2.1 Instruments and reagents

An analytically pure sample of Venlafaxine hydrochloride was procured as gift sample from Torrent pharmaceuticals Ltd. (Ahmedabad, India). Analytical grade methanol was used as solvent for dilution. A Shimadzu UV-1800 UV/VIS spectrophotometer was used with 1 cm matched quartz cell. Tablet formulation [VENTAB XL (Brand I), Intas

pharmaceuticals Ltd., Ahmedabad and VEXOR (Brand II), Cadila pharmaceuticals Ltd., Ahmedabad] were procured from a local pharmacy with labeled amount 37.5 mg per tablet.

2.2 Preparation of working standard drug solution

The standard Venlafaxine hydrochloride (100 mg) was weighed accurately and transferred to volumetric flask (100 ml). It was dissolved properly and diluted up to the mark with methanol to obtain final concentration of 1000 µg/ml and the resulting solution was used as working standard solution.

2.3 Analysis of marketed formulations

For the estimation of Venlafaxine hydrochloride in tablets formulations by this method, 20 tablets of brand were weighed and triturate to fine powder. Tablet powder equivalent to 100 mg of Venlafaxine hydrochloride was weighed and transfer into 100 ml volumetric flask than dissolved with methanol and further diluted with methanol. It was kept for ultrasonication for 30 min; this was filtered through Whatman filter paper No. 41 and then final dilution was made with methanol to get the final stock solution of 1000 µg/ml. From this stock solution, various dilutions of the tablet solution were prepared and analyzed.

2.4 Second order derivative spectroscopic method

The second order derivative spectra showed two sharp peak at 244 and 298 nm when n=1 and linearity was measured at 298 nm (Figure 1). The absorbance difference at n=1 (dA/dλ) is calculated by the inbuilt software of the instrument which was directly proportional to the concentration of the standard solution. The standard drug solution was diluted so as to get the final concentration in the range of 20-100 µg/ml and scanned in the second order derivative spectra. The calibration curve of dA/dλ against concentration of the drug showed linearity. Similarly absorbance of sample solution was measured and amount of Venlafaxine hydrochloride was determined from standard calibration curve.

3. RESULT AND DISCUSSION

As the drug Venlafaxine hydrochloride showed a broad spectrum, the derivative spectroscopy method applied has the advantage that it locate the hidden peak in the normal spectrum when the spectrum is not sharp and it also eliminate the interference caused by the excipients and the degradation products present, if any, in the formulation.

The method was validated according to International Conference on Harmonization guidelines for validation of analytical procedures [18-20].

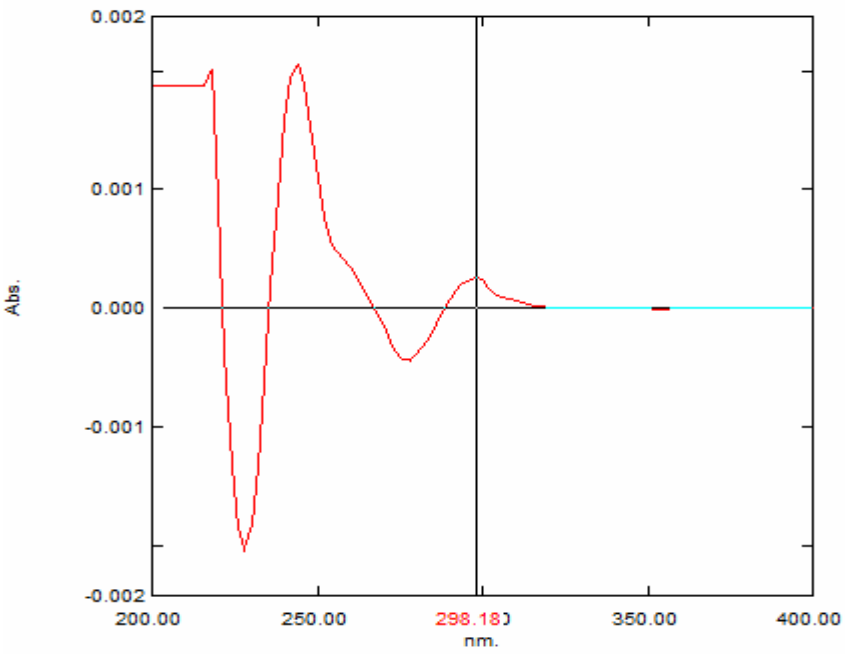

Figure 1: Second order derivative spectrum of Venlafaxine hydrochloride with n=1

The second order derivative spectra showed two sharp peak at 244 and 298 nm when n=1 and linearity was measured at 298 nm. The polynomial regression data for the calibration plots showed good linear relationship in the concentration range of 20-100 µg/ml with r^2=0.999 and given in Table 1.

Recovery studies were carried out at three different levels i.e. 80 %, 100 %, and 120 % by adding the pure drug to the previously analysed tablet powder sample and shown in Table 2. The percentage recovery value indicates non interferon from excipients used in formulation.

The result of analysis of marketed formulation is shown in Table 3. The reproducibility and accuracy of the method was found to be good, which was evidenced by low standard deviation.

Table 1: Calibration Parameters

S.No	Parameter	Results
1	Absorption Maxima (nm)	298
2	Beer's Law limits(µg/ml)	20-100
3	Regression equation (y)* Slope (b) Intercept (a)	 0.000006 0.00002
4	Correlation coefficient	0.998
5	Limit of detection (µg / ml)	1.46
6	Limit of quantification (µg / ml)	4.40

*y = a + bx; when x is the concentration in µg/ml and y is absorbance unit.

Table 2: Recovery study Data

Sample	Label claim (mg)	Amount added (%)	Amount recovered (µg/ml)	Recovery ± SD (%)	% RSD
BRAND I	37.5	0	37.09	98.90 ± 0.78	0.788
	37.5	80	37.34	99.57 ± 0.33	0.331
	37.5	100	37.52	100.05 ± 0.25	0.249
	37.5	120	37.25	99.33 ± 0.45	0.453
BRAND II	37.5	0	37.61	100.29 ± 0.15	0.149
	37.5	80	37.17	99.12 ± 0.52	0.524
	37.5	100	37.38	99.68 ± 0.82	0.822
	37.5	120	37.45	99.86 ± 0.37	0.370

Table 3: Analysis of tablet formulation

Tablet	Label claimed (mg)	Amount found (mg)	%Recovery ± SD
BRAND I	37.5	37.3 ± 0.09	99.46 ± 0.11
BRAND II	37.5	37.6 ± 0.15	100.26 ± 0.26

4. CONCLUSION

A spectrophotometric method for quantifying Bicalutamide in formulation samples has been developed and validated. The proposed method is precise, accurate and reproducible and can be extended to the analysis of Venlafaxine hydrochloride in bulk and tablet formulations.

5. ACKNOWLEDGEMENT

We would like thank to Torrent Pharmaceuticals Ltd, Ahmedabad for providing reference sample of Venlafaxine hydrochloride to facilitate this work and also to the Principle Dr T. Tamizh Mani, Bharathi College of Pharmacy, Maddur for providing facilities.

6. REFERENCES

1. British Pharmacopoeia, Vol. II, HMSO, International edn, Cambridge,2009, 6317
2. The Merck Index – An Encyclopedia of chemicals, Drugs and Biologicals, 12th edn, Merck and Company, USA, 1992, 1695.
3. Tripathi K.D., Essentials of Medical Pharmacology, 6th edn, Jaypee Brothers, New Delhi, 2008, 447.
4. Walker R. and Edwards C., Clinical Pharmacy and Therapeutics, 3rd edn, Elsevier Science, USA, 2003, 447.
5. Harvey R.A. and Champe P.C., Lippincott's Illustrated Reviews- Pharmacology, 2nd edn, Willams and Wilkins, New Jersey, 2000, 123.
6. Seth S.D., Textbook of Pharmacology, 2nd edn, Reed Elsevier, New Delhi, 1999, 883.
7. Hardman J.G. and Limbird L.E., The Pharmacological Basis of Therapeutics, 10th edn, McGraw Hill, New Yourk, 2001, 461.
8. Katzung B.G., Basic and Clinical Pharmacology, 8th edn, McGraw Hill, New Yourk, 2001, 507.
9. Rajasekaran A., Arulkumaran M. and Kannanraj S., Indian J. Pharm Sci., 2004, 66, 101.
10. Pillai S. and Singhvi I., Indian Pharmacist, 2006, 5, 75.
11. Sankar D.G., Vijayasri K., Shehalatha B. and Murthy T.K., Kumar J.M.R. and Reddy M.V.N., Asian J. of Chem., 2002, 14, 1779.
12. Armagan O., Kepekci S.E., Mugecetin S. and Erturk S., J of AOAC Int., 2006, 89, 966.
13. Rathore G.S., Basniwal P.K., Suthar M. and Roop N.G., Asian J. of Chem., 2009, 21, 5908.
14. Basaveswara Rao M.V., Reddy B.C.K. and Prasanthi V., Rasayan J., 2009, 2, 276.
15. Baldania S.L., Bhatt K.K., Mehta R.S. and Gandhi T.R., Indian J of Pharm sci., 2008, 70, 124.
16. Makhija S.N. and Vavia P.R., J. Pharm. Biomed. Anal., 2002, 28, 1055.
17. Asafu-Adjaye E.B., Faustino P.J., Tawakkul M.A. and Erson L.W., J. Pharm. Biomed. Anal., 2007, 43, 1854.
18. International Conference on Harmonization (ICH), Validation of Analytical Procedures:Text on Validation of Analytical Procedures Q2A, 1994.
19. International Conference on Harmonization (ICH), Validation of Analytical Procedures: Methodology Q2B, 1996.
20. International Conference on Harmonization (ICH), Validation of Analytical Procedures: Text and Methodology Q2 (R1), 2005

*****