Original Article

A VALIDATED SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF VILAZODONE HYDROCHLORIDE IN PHARMACEUTICAL DOSAGE FORM

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ABSTRACT

Objective: In the present research work three simple, accurate, precise methods of the UV-visible spectrophotometric method was developed and validated for the estimation of Vilazodone HCl in bulk and tablet dosage.

Methods: Three methods were used for estimation of Vilazodone HCl using methanol. Method A involves zero order spectroscopy at absorption maximum of 241 nm; Method B involves first order derivative at 246.5 nm and Method C involves second-order derivative at 243.5 nm. The developed methods were validated according to ICH guidelines.

Results: The developed methods were found to be linear in the concentration range of 1-5 µg/ml. The mean percentage label claim of Vilazodone HCl was within the acceptable range. The accuracy data showed % recovery and % RSD within the range.

Conclusion: The developed methods were found to be accurate and precise. The % RSD values were within limits. These methods can be used for the routine analysis of Vilazodone HCl in bulk and tablet dosage form.

Keywords: Spectrophotometric Method, Vilazodone HCl, Validation

INTRODUCTION

Chemically Vilazodone HCl (fig. 1) is 2-benzofurancarboxamide, 5-[4-[4-(5-cyano-1H-indol-3-yl) butyl]-1-piperazinyl]-, hydrochloride (1:1) with chemical formula $C_{26}H_{27}N_5O_2$. HCl [1]. Vilazodone HCl is a white to cream coloured achiral powder with molecular mass: 477.9 g/mol. The pKa of the drug is 7.1; the aqueous solubility is 0.32 mg/ml and it is freely soluble in methanol [2]. Vilazodone HCl is a dual-acting and selective serotonin reuptake inhibitor and 5-HT$_1$A receptor partial agonist. It is thought to optimise regulation of 5-HT circuitry at both pre-and postsynaptic sites to augment 5-HT neurotransmission, thereby producing an antidepressant effect [3]. Its clinical indication is for the treatment of the major depressive disorder. Vilazodone HCl is a new chemical entity belonging to the structural chemical group of the indol alkylamines [4].

Literature review [5-8] for Vilazodone HCl analysis revealed there are few methods reported for the detection of Vilazodone HCl in bulk and pharmaceutical formulation by spectrophotometry and RP-HPLC.

The objective of the present research work deals with simple, accurate, precise UV spectroscopic methods for estimation of Vilazodone Hydrochloride in bulk and tablet dosage form, and validated as per ICH guidelines [9].
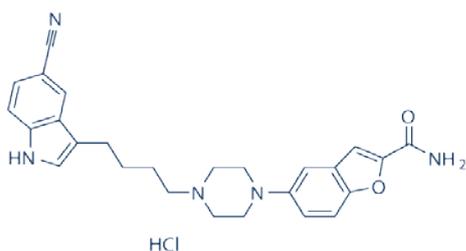

Fig. 1: Structure of vilazodone hydrochloride

MATERIALS AND METHODS

Reagents and chemicals

The pure drug, Vilazodone HCl was procured from Swapnroop Pharmaceuticals, Aurangabad, Maharashtra, India. Marketed formulation Vilano 20 mg was procured from a local pharmacy. All the chemicals and reagents used were of A. R. grade.

Instrumentation

A double beam UV spectrophotometer (UV-1800, Shimadzu, Japan) with UV probe software version (2.31) and 10 mm quartz cells was used. All weights were taken on an electronic balance (Schimadzu-220h).

Method development

Preparation of standard stock solution

The standard stock solution of Vilazodone HCl was prepared by dissolving accurately weighed 10 mg of Vilazodone HCl in 10 ml volumetric flask containing 5 ml of methanol, shaken for 5 min then volume was made up with methanol. The final concentration obtained was 1000 µg/ml with methanol. From the above solution working standard solution of concentration 100 µg/ml was prepared. From this aliquots were prepared to get a concentration range of 1-5 µg/ml.

Preparation of calibration curve [10]

Method A: zero order spectroscopic method

The wavelength was selected by preparing a solution of concentration 2.0 µg/ml by diluting the standard solution with methanol. The solution was scanned under spectrum mode over a wavelength range of 210-400 nm using methanol as blank. The UV spectrum showed λ$_{max}$ at 241 nm in methanol (fig. 2). The calibration curve was plotted taking absorbance on Y-axis against the concentration of standard solution on x-axis over a concentration range of 1-5 µg/ml (fig. 3). The regression equation was calculated.

Method B: first order derivative spectroscopy

The spectra obtained in method A were derivatized to get first-order derivative spectra and the response (dA/dλ) of the spectra were measured at 246.5 nm (fig. 4) and then the calibration curve was constructed by plotting the concentration versus response (dA/dλ) over a concentration range of 1-5 µg/ml (fig. 5). The regression equation was calculated.

Method C: second order derivative spectroscopy

The spectra obtained in method A were derivatized to get second-order derivative spectra and the response (d²A/dλ²) of the spectra were measured at 243.5 nm over a concentration range of 1-5 µg/ml (fig. 6) and then the calibration curve was constructed by plotting the concentration versus response (d²A/dλ²) over a concentration range of 1-5 µg/ml (fig. 7). The regression equation was calculated for this method.

Estimation of vilazodone HCl in tablet dosage form

Preparation of sample solution

For the estimation of Vilazodone HCl in the commercial formulations, 20 tablets each containing 20 mg of Vilazodone HCl were weighed and the average weight was calculated. The tablets were crushed and powdered in a glass mortar. Powder equivalent to 10 mg of Vilazodone was transferred into a 10 ml volumetric flask and dissolved in sufficient quantity of methanol and sonicated. The final volume made up to the mark with methanol and the solution was filtered through whatman filter paper no.41. Further dilutions of the stock solution were made in methanol to get required concentration of 2 µg/ml. The concentration of Vilazodone HCl in the formulation was determined by above-developed methods. Results of tablet analysis are shown in table 1. The assay procedure was repeated six times (n= 6) for each method.

Method validation

The methods were validated according to ICH guidelines [10] to study linearity, precision and accuracy.

Linearity

The linearity of the proposed UV spectroscopic methods were evaluated by analysing different concentrations of standard solutions of Vilazodone HCl and by plotting absorbance of analyte against concentrations of the analyte. Beer's law was obeyed for all three methods in the concentration range of 1-5 µg/ml. A good linear relationship (R^2=0.999) was observed between the concentrations of Vilazodone HCl and the corresponding absorbance. The regression analysis was made for slope, intercept and correlation coefficient values. The slope, intercept and the correlation coefficient of the drug were shown in table 2.

Accuracy

Accuracy is expressed as the degree of closeness of experimental value to the true value. To study the accuracy of the proposed method and to check the interferences from excipients used in the dosage forms, recovery experiments were carried out by the standard addition method. This parameter is evaluated by percent recovery studies at concentration levels of 80,100 and 120% which includes the addition of known amounts of Vilazodone HCl working standard to a pre-quantified sample solution. Each of the dilutions was observed six times. The samples were reanalyzed by proposed methods. The amount of Vilazodone HCl was estimated by applying obtained values to the regression equation. The percentage recovery of the drug was calculated. The results were shown in table 3.

Precision

Precision is the level of repeatability of results as reported between samples analysed on the same day (Intra-day) and samples run on three different days (Inter-day). To check the intra-day and inter-day variation of the methods, solutions containing 2, 3 and 4 µg/ml concentrations of Vilazodone HCl were subjected to the proposed spectrophotometric methods of analysis and the recoveries obtained were noted. The precision of the proposed method i.e. the intra and inter–day variations in the absorbance of the drug solutions was calculated in terms of % RSD. Statistical evaluation revealed that the relative standard deviation of drugs at different concentration levels for three times was less than 2.0. The values were shown in table 4.

Table 1: Assay results of vilazodone HCl by 3 methods

Analysis method	Label claim (mg/tablet)	Amount found (mg) (n= 6)	% Amount found	% RSD
A	20	20.12	100.60	1.38
B	20	20.28	101.44	1.23
C	20	20.00	100.00	0.00

Table 2: Linearity studies of the proposed method

Parameter	Method A	Method B	Method C
Absorption maxima	241	246.5	243.5
Linearity Range µg/ml	1-5	1-5	1-5
Regression equation (Y = a+bc):	Y=0.194x+0.007	Y=0.023x	Y=0.006x
Correlation coefficient (r2)	0.999	0.999	0.999
Slope (a)	0.194	0.023	0.006
Intercept (b)	0.007	0	0

Table 3: Accuracy studies of vilazodone HCl by 3 methods

Concentration taken (µg/ml)	Spiked level (%)	Amount added (mg)	Amount found (mg)(n = 5)			% Recovery		
			A	B	C	A	B	C
2	80	1.6	1.57	1.608	1.60	98.68	100.54	100
2	100	2.0	1.99	2.0	2.04	99.74	100	102
2	120	2.4	2.40	2.43	2.44	100.22	101.44	101.66

Table 4: Precision studies of vilazodone HCl

Concentration taken (µg/ml)	Intra-day precision		Inter-day precision	
	*mean±SD	% RSD	*mean±SD	% RSD
2	0.378±0.003	0.81	0.397±0.005	1.38
3	0.572±0.002	0.44	0.597±0.004	0.68
4	0.761±0.004	0.60	0.787±0.005	0.67

*RSD of five independent determinations

Table 5: Summary of optical characteristics and validation parameters

Parameter	Method A	Method B	Method C
λmax	241	246.5	243.5
Beer's limit (µg/ml)	1-5	1-5	1-5
Linearity indicated by correlation coefficient	0.999	0.999	0.999
Accuracy indicated by % recovery	98.68-100.22	100-100.54	100-102

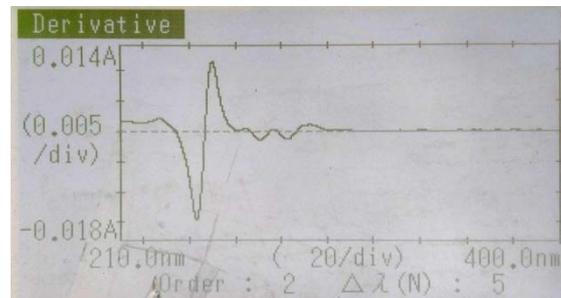Fig. 2: Zero order derivative of vilazodone HCl
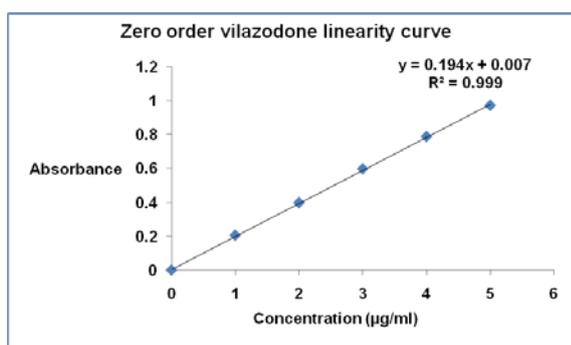

Fig. 6: Second order derivative vilazodone HCl
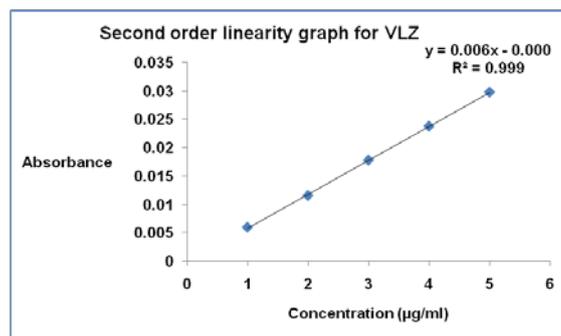

Fig. 3: Calibration graph of vilazodone HCl

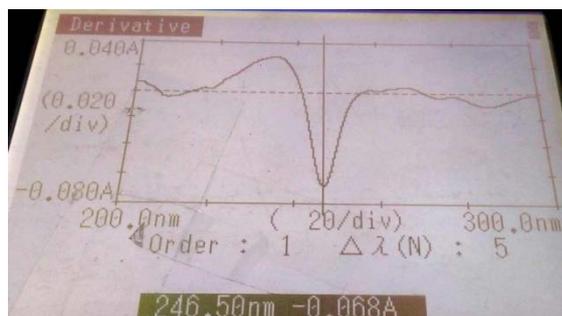Fig. 7: Calibration graph of vilazodone HCl

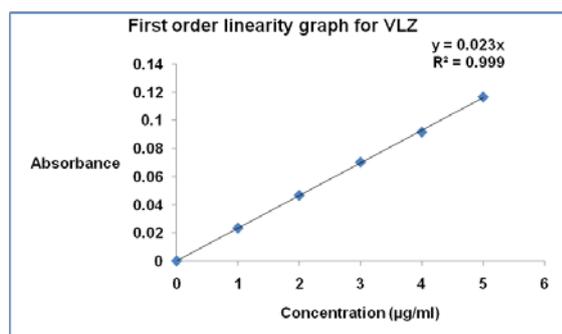
Fig. 4: First order derivative of vilazodone HCl

Fig. 5: Calibration graph of vilazodone HCl

RESULTS AND DISCUSSION

The proposed methods for estimation of Vilazodone HCl were found to be simple, precise, accurate and economical. The Absorption maxima for method A, method B and method C were found to be 241 nm, 246.5 nm and 243.5 nm respectively. The calibration curve was linear in the concentration range of 1-5 µg/ml (table 2). The % assay by the three methods was found to be in the range 98.16-100.3% for Vilazodone HCl (table 1). No interference was observed from the pharmaceutical excipients. The recovery studies showed that the methods were accurate and reproducible. The results revealed that any change in the drug concentration could be accurately determined by the proposed method. Accuracy and reproducibility of the proposed methods were further confirmed by percent recovery values, as shown in table 3. Repeatability results indicated the precision under the same operating conditions over a short interval time and inter-day precision, % RSD not more than 2.0 indicate good intermediate precision which were shown in table 4. Hence, the proposed methods were validated in terms of linearity, precision and accuracy. Characteristic parameters and summary of validation parameters for all the three methods were given in table 5.

By observing the validation parameters, the methods were found to be simple, accurate and precise. Hence these methods can be employed for the routine analysis of Vilazodone HCl in tablet formulations.

CONCLUSION

The three spectrophotometric methods were developed and validated as per ICH guidelines. The standard deviation and % RSD calculated for the proposed methods are within the acceptance limits, indicating a high degree of precision of methods. The results

of the recovery studies performed indicate the methods to be accurate. Hence, it can be concluded that developed spectrophotometric methods are simple, accurate, precise and economical and can be employed successfully in the estimation of Vilazodone HCl in bulk and formulation. There is a good scope for estimation of Vilazodone HCl by these methods to carry out their spectrophotometric analysis. Thus, it can be conveniently adopted for routine quality control analysis.

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CONFLICT OF INTERESTS

Declare none

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