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Full Length Original Research Paper

Development of validated UV-Spectrophotometric method for the estimation of Vilazodone Hydrochloride

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Abstract:
The present research work discusses the development of UV Spectrophotometric method for the determination of Vilazodone hydrichloride. The present method is simple, rapid, accurate, precise and economical method. The absorption maxima of the drug were found to be 230nm for Vilazodone in Methanol solvent system. The method is applied to tablet dosage form it gives best results of accuracy, precision & linearity over a range of 1-3µg/ml for Vilazodone. The percentage recovery was found to be 99.78%. Results were analysed and validated for various parameters as per ICH guidelines.

Keywords: Vilazodone, UV method development, Validation.

Introduction:

Analytical chemistry is the branch of chemistry involved in separating, identifying and determining the relative amounts of the components making up a sample of matter. It is mainly involved in the qualitative identification or detection of compounds and the quantitative measurement of the substances present in bulk and pharmaceutical preparation.(1) It is the subject of science, which deals with interaction of radiation and matter. All atoms and molecules are capable of absorbing energy in accordance with certain restrictions, these limitations depending upon the structure of the substance. Spectroscopic analytical methods are based on measuring the amount of radiation produced and absorbed by molecular or atomic species. The kind and amount of radiation absorbed depends upon the number of molecules interacting with the radiation. The study of these dependencies is called absorption spectroscopy. Absorption spectroscopy is one of the most valuable analytical techniques; its advantages include simplicity, speed, specificity and sensitivity (2). The parts of the molecule, that is, the atoms or groups of atoms, may move with respect to each other called as vibration and energy called as vibrational energy. The molecule may rotate about an axis; such rotation is characterized by the rotational energy. This mode of movement molecules possesses an electronic energy.(3)

E= E trans+ Evib+ Erot+ Eelect

Vilazodone belongs to the category like serotonergic antidepressant. Vilazodone's antidepressant effects are thought to be due to enhancement of serotonergic activity in the central nervous system (CNS) through selective inhibition of serotonin reuptake. It is unknown if the partial agonism of 5HT1a receptors by vilazodone produces any beneficial effect. It has been hypothesized that vilazodone has a faster onset,

compared to SSRI's alone, as the additional partial agonism of the 5HT1a receptor results in a more rapid and specific desensitization of the somatodendritic 5HT1a autoreceptors.

Chronic administration of a SSRI results in desensitization of presynaptic 5HT1a autoreceptors. Tmax following oral administration is approximately 4 to 5 hrs. Mean terminal half-life is 25 hrs.

Vilazodone is a Selective serotonin re-uptake inhibitor (SSRI) and chemically it is 5-(4-(4-(5-cyano-1*H*indol- 3-yl) butyl)piperazin-1-yl)benzofuran-2-carboxamide with molecular formula $C_{26}H_{27}N_5O_2$. HCl is presented in **Figure No: 1.** Vilazodone is a Indole-Piperazine which acts as SSRI and 5-HT1A receptor partial agonist. [4]

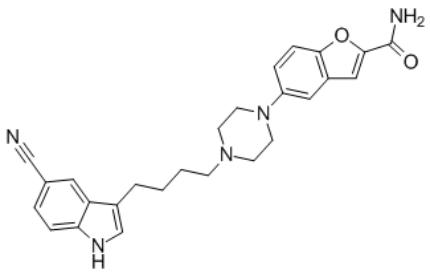

Figure 1: Shows structure of Vilazodone [4]

Literature review [5-6] for Vilazodone analysis revealed there is only one method reported for the detection of Vilazodone in bulk and pharmaceutical formulation by RP-HPLC. The aim of present work is to find out a simple, sensitive, specific, Spectrophotometric method developed and validation for the detection of Vilazodone in bulk drug and pharmaceutical formulation.

Materials and Methods:

Vilazodone working standard was supplied by Mylan Labs Ltd, Hyderabad. Vilazodone (Label claim: 20mg tablet) was manufactured by Forest Pharmaceuticals. All other chemicals used in the analysis were AR grade. A double – beam spectrophotometer LABINDIA UV 3000 was used for the detection of absorbance, Mettler Tremedo (weighing balance) and Bronson sonicator were used for experimental purpose.

Method:

Preparation of standard:

Accurately weigh and transfer 10mg of Vilazodone hydrochloride Working standard into a 100ml volumetric flask add about 70 ml of Diluent (water) and sonicate to dissolve it completely and make volume up to the mark with the same solvent (Stock solution). Further pipette 0.8ml of the Vilazodone hydrochloride stock solution into a 10ml volumetric flask and dilute up to the mark with diluents. Water was used as diluents.

Preparation of sample:

Take 20 tablets and crush to powder. Accurately weigh the sample equivalent to 10mg and transfer into a 100mL volumetric flask add about 70 mL of diluent and sonicate to dissolve it completely and make volume up to the mark with the same solvent (Stock solution). Further pipette 0.8ml of the Vilazodone hydrochloride stock solution into a 10ml volumetric flask and dilute up to the mark with diluent.

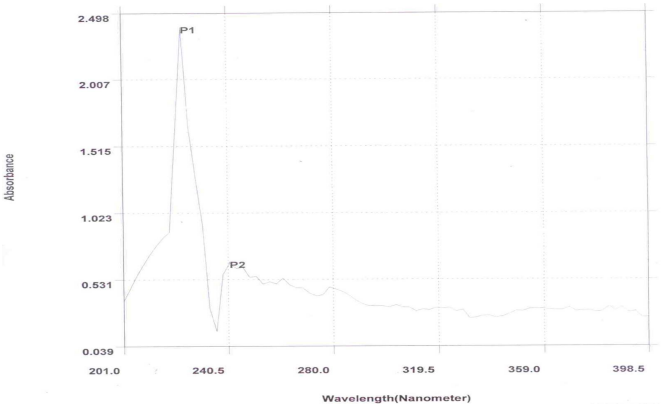

Figure 2: Shows spectrum of Vilazodone

Method validation:

Various methods for analysis of Vilazodone in bulk and pharmaceutical formulation were carried out as per ICH guideline.

Linearity:

The method was validated according to ICH Q2B guidelines for validation of analytical procedures in order to determine the linearity, sensitivity, precision and accuracy of the analyte. For Vilazodone, five point calibration curves were generated with the appropriate volumes of the working standard solutions for UV methods.

Precision and accuracy:

Precision is the degree of repeatability of an analytical method under normal operational conditions. The precision and accuracy were determined with standard quality control samples (in addition to calibration standards) prepared in triplicate at different concentration levels covering the entire linearity range. The precision of the assay was determined by repeatability (intraday) and intermediate precision (inter-day) and reported as RSD % for a statistically significant number of replicate measurements. The intermediate precision was studied by comparing the assays on three different days and the results are documented as the standard deviation and RSD %. Accuracy is the percent of analyte recovered by assay from a known added amount. Data from nine determinations over three concentration levels covering the specified range were obtained.

Limit of detection:

The limit of detection (LOD) is defined as the lowest concentration of an analyte that an analytical process can reliably differentiate from back-ground levels. In this study, LOD is calculated by signal to noise ratio method.

Recovery study:

Recovery of the analyte of interest from a given matrix can be used as a measure of the accuracy or the bias of the method. The same range of concentrations, as employed in the linearity studies, was used. To study the accuracy, precision and reproducibility of the proposed method and dosage forms, recovery experiments were carried out using the standard addition method. These studies were performed by the addition of known amounts of pure RIL to the pre-analyzed tablet formulation and the mixtures were analyzed using the proposed techniques. After parallel analyses, the recovery results were calculated using the related calibration equations.

Results and Discussion:

The development of a simple, rapid, sensitive and accurate analytical method for the routine quantitative determination of samples will reduce unnecessary tedious sample preparations and the cost of materials and labour. Vilazodone is a UV-absorbing molecule with specific Chromophores in the structure that absorb at a particular wavelength and this fact was successfully employed for their quantitative determinations using the UV spectrophotometric method. The λ-max of the drug for analysis was determined by taking scans of the drug sample solutions in the entire UV region. It was found to be that only one peak was observed in this method at the wavelength of 230 nm (λ-max).

Calibration curve data were constructed in the range of the expected concentrations of 1µg/ mL to 3µg/ mL. Beer's law was obeyed over this concentration range. The correlation coefficient (r) of the standard curve was found to be greater than 0.999. The stock solutions and working

standards were prepared using methanol and water. Calibration curve & Linearity table is presented in Figure No: 3 & Table No: 1 respectively.

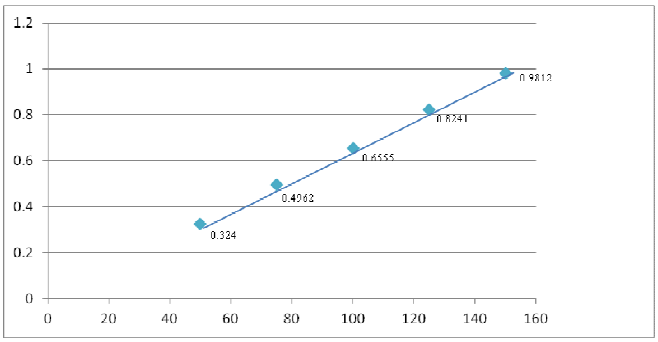

Figure 3: Shows calibration curve for linearity of Vilazodone

Table 2: Linearity Table

CONC%	Absorbance	µg/ml
50	0.324	1
75	0.4962	1.50
100	0.6555	2.00
125	0.8241	2.50
150	0.9812	3.00

Table 2: Data for Method Precision

Reading	Absorbance
Reading-1	0.6557
Reading-2	0.6554
Reading-3	0.6547
Reading-4	0.6547
Reading-5	0.6540
Reading-5	0.6553
Average	0.65495
Standard Deviation	0.000826
%RSD	0.126

Table 3: Data for System Precision

Reading	Absorbance
Reading-1	0.6566
Reading-2	0.6564
Reading-3	0.6562
Reading-4	0.6566
Reading-5	0.6265
Reading-6	0.6263
Average	0.6464
Standard deviation	0.000317
%RSD	0.086

Table 4: Accuracy data of Vilazodone

%Concentration (at specification Level)	Absorbance	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	0.3265	1.0	0.989	98.91%	99.78%
100%	0.6574	2.0	1.985	99.28%	
150%	0.9843	3.0	3.036	101.16%	

Table 5: Summary for assay of Vilazodone UV spectroscopy

S. No	Validation parameters	Acceptance criteria	Observation
1.	Linearity range (µg/ml)	-	1-3
2.	Correlation coefficient	NLT 0.999	0.999
3.	Method precision	% RSD (NMT 2%)	0.126%
4.	System precision	% RSD (NMT 2%)	0.086%
5.	% Recovery	98% to 102%	99.78%
6.	Limit of Detection (µg)	NMT 3	0.1601 µg
7.	Limit of Quantification (µg)	NMT 10	0.1146 µg

Performing replicate analyses of the standard solutions was used to assess the accuracy, precision and reproducibility of the proposed methods. The selected concentration within the calibration range was prepared in Acetonitrile and analyzed with the relevant calibration curves to determine the intra- and inter day variability. The accuracy of the method was shown by analyzing the model mixtures contained 50, 100 and 150% of bulk samples of Vilazodone within

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the linearity ranges were taken. After injected the standard solution, Accuracy -50%, Accuracy -100% and Accuracy -150% solutions, the Amount found, Amount added for Vilazodone, individual recovery and mean recovery values were calculated. The recovery of Vilazodone was evaluated from 50 to 150% of the labeled tablet. The mean percentage recoveries were found to be 98.91%, 99.28% and 101.16% for 50%, 100% and 150% respectively. Accuracy data were present in **Table No: 4**.

The intra- and inter day precision were determined as the RSD %. Intraday precision (repeatability) study was done by measuring absorbance of 5 sample of same concentration, % RSD value was 0.086 which is less than 2% & well accepted according to guideline data is given in **Table No: 3.** Other parameter of assay of Vilazodone by UV-Vis Spectroscopy is given in **Table No: 5.**

The proposed methods can be successfully applied for Vilazodone assay in tablet dosage forms without any interference. The assay showed the drug content of this product to be in accordance with the labelled claim 20mg. The recovery of the analyte of interest from a given matrix can be used as a measure of the accuracy of the method. In order to check the accuracy and precision of the developed method and to prove the absence of interference by excipients, recovery studies were carried out after the addition of known amounts of the pure drug to various pre-analyzed formulations of all drugs. The application of this procedure is explained in the experimental section. The obtained results demonstrate the validity and accuracy of the proposed method for the determination of all drugs in tablets. These results reveal that the developed method have an adequate precision and accuracy and consequently, can be applied to the determination of Vilazodone tablet in pharmaceuticals without any interference from the excipients.

Conclusion:

The developed Spectrophotometric method was simple, sensitive, and specific, for the detection of Vilazodone in bulk & pharmaceutical formulation. It could be precisely quantify and LOD was found to be 0.1601µg and LOQ was found to be 0.1146µg. All the calibration curves shows a linear relationship between the absorbance and concentration and coefficient correlation not less than 0.999. Precision of the method was found to be 0.000826 against the label claim of 20mg. The percentage recovery was found to be 98.91-101.16%. The proposed method will be suitable for the analysis of Vilazodone in bulk and pharmaceutical formulation.

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