ISSN No:-2456-2165

Development and Validation for Quantitative Estimation of Vericiguat in Bulk and Tablet dosage form by UV Spectrophotometric Method

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Abstract:- Vericiguat (VER) determination in bulk and tablet dosage form has been made possible by the development of sensitive, quick, economical and accurate UV spectrophotometric approach. The 258 nm wavelength was used for quantification. Beer's law was followed at concentrations between 5 and 25 g/ml. ICH guidelines were followed in the method's validation. A statistical analysis demonstrated that the technique was reliable for the analysis of VER in tablet dose form. The proposed technique has been shown to be suitable for routine analysis and quality control assay of tablet due to its wide linearity range, sensitivity, accuracy, and simple procedure.

Keywords:- *Vericiquat, Raw Material, UV Method and Tablet Dosage Form.*

I. INTRODUCTION

Vericiguat is a novel oral soluble guanylate cyclase (sGC) to treat chronic heart failure, and lowers hospitalization rate and ejection fraction [1-2] Therefore, cause vasodilation, which improves heart function by causing smooth muscle relaxation [3-5] No method has been developed for the analysis of Vericiguat, according to a literature review by UV Spectroscopic method. Therefore, the aim of this work is to develop a simple, accurate and reliable UV Spectroscopic method for Vericiguat dosage form determination. The developed method was validated as per ICH norms [6-7].

II. MATERIALS AND METHODS

➢ *Instrumentation*

Shimadzu double beam UV/Visible spectrophotometer (Model UV-1700) with spectral band width of 1 nm was the instrument utilized. The Shimadzu AUX-220 electronic balance was used for all weighing.

➢ *Reagents and chemicals*

Verquvo tablet that were marked to contain 10 mg of VER were the tablet dose form used in this method. The solvent utilized was methanol.

➢ *Selection of solvent*

A crucial step in the development of a method is the choice of solvent for UV analysis. For the quantification of vericiguat for the UV Spectrophotometric technique, methanol was the solvent utilized.

➢ *Preparation of standard stock solutions*

Standard stock solution of Vericiguat (1000µg/ml) was prepared by dissolving 10 mg of Vericiguat in 10 ml of methanol in 10 ml clean volumetric flask with vigorous shaking.

➢ *Selection of wavelengths for estimation*

In UV spectrophotometric method, solution of Vericiguat (10 µg/ml), was prepared by appropriate dilution of standard stock solution with methanol and scanned in the spectrum mode from 200 nm to 400 nm. From the absorption spectrum, the wavelength selected for quantification was 258 nm.

➢ *Preparation of calibration graph*

From the above standard stock solution, pipetted out 1ml of standard stock solution transferred into 10ml clean volumetric flask and made upto 10ml with methanol. From that pipetted out 0.5ml, 1.0ml, 1.5ml, 2ml and 2.5ml and transferred into clean 10ml volumetric flask separately and made upto the mark with methanol to get the final concentration range of 5, 10, 15, 20 and 25 µg/ml absorbances were measured at 258nm.

➢ *Quantification of tablet formulation*

The average weight of twenty tablets, each of which contained 10 mg of VER, was estimated and the tablets were then crushed to create a fine powder. A quantity of powder equal to 10 mg of VER was transferred to a clean 10 ml standard flask. Methanol was added and the mixture was sonicated for 15 minutes. Subsequently, more methanol was added to make upto the mark. Filtered, Pipetted out 1ml of the filtrate and transferred into 10ml volumetric flask and add methanol, made upto the mark. Further pipetted out 1ml of solution and transferred into 10ml volumetric flask and add methanol made the mark to get 10 µg/ml. By analyzing the sample solution absorbance using a UV Spectrophotometric technique at 258.0 nm, the concentration of VER was

determined. Calibration curve were used to determine the concentration of VER in the diluted solution. Following that, the amount of VER in mg/tab was determined by multiplying the measured concentration by the dilution factor. Six times this process was carried out.

➢ *Validation*

The proposed method was validated as per ICH guidelines.

➢ *Accuracy*

Recovery studies were conducted using the standard addition method at three different levels (50%, 100%, and 150%) to evaluate the recovery studies of the suggested approaches. The recovery studies findings, shown in Table 2 as a percent recovery were good.

➢ *Precision*

The reproducibility of this method was determined by analyzing tablet (Intra-day assay precision) at different time intervals on same day in triplicates and (Inter-day assay precision) on three different days. Coefficient of variance for inter-day assay precision coefficient of variance was found to be 0.7214 for VER. Intra-day assay precision was found to be 0.6352 for VER.

III. RESULTS AND DISCUSSION

For our studies, the Vericiguat analysis of a new drug was used. The UV Spectroscopic Method has advantages that it takes less time and consume less solvent when estimating a single dosage form. To ensure the % purity in single dosage form of thedrug, the UV-spectroscopy was developed.

A accurate, fast, simple and precise UV Spectrophotometric method was developed and validated. Methanol was chosen as a solvent for the estimation of VER.

The standard solution of 10 µg/ml of VER in the appropriate solvent were made, and the solution was scanned with methanol in the UV region between 200 and 400 nm to record the spectra, which is shown in Figure 01. 258 nm was selected from the UV spectrum to determine the VER without any intervention.

The aliquots of five different VER concentrations ranging from (5.0 to 25.0 g/ml) were prepared. For the UV spectrum, the absorbances were measured at 258 nm. For the drug at a wavelength of 258 nm, the calibration graph preparation process was done six times. On the calibration graph, absorbance was plotted using absorbance against concentration. For the VER drug, optical parameters like the correlation coefficient, Sandell's sensitivity, LOQ, LOD, standard error and molar absorptivity were calculated. It was found that VER correlation coefficient was found to be 0.9998. Thus, it was showen that the calibration graphs were linear.

Verquvo tablet formulation containing 10 mg of VER was selected for estimation. From the linearity, the nominal concentration of VER i.e. 10 µg/ml was prepared. Six test solution were determined based on the absorbance of the solutions was measured at 258 nm. The % purity found in tablet dosage form was 99.99 ± 0.6352. The % RSD values were found to be very less. Hence the method has good precision. The results of analysis are shown in Table-1.

Precision of the developed UV method was studied by making repeated analysis (Intraday and Interday). The % RSD values for Intraday and Interday analysis were found to be 0.6352 and 0.7214. The results show the developed UV method was very high.

In ruggedness studies, Different Instrument 1 and 2 were found to have % RSD values of 0.7845 and 0.7651, respectively. Different Analyst 1 and 2 were found to have % RSD values of 0.6985 and 0.7124, respectively. Lower % RSD values indicated, method was more rugged.

Accuracy studies of the developed UV method was confirmed. The % recovery ranged from 99.60 to 100.46%. Lower % RSD values indicated that the developed UV spectroscopic method was more accurate. The results was shown in Table-2.

Table I: QUANTIFICATION OF VERQUVO FORMULATION

Sample	Sample number	Label claim (mg/tab)	Amount present (mg/tab)*	% Purity* (% w/w)	% RSD
VER	1	10	9.99	99.90	0.6352
	2	10	10.09	100.09	
	3	10	10.00	100.04	
	4	10	9.98	99.87	
	5	10	9.99	99.95	
	6	10	10.01	100.14	

*Mean of six observation

ISSN No:-2456-2165

TABLE II: RECOVERY STUDY

Sample	% Conc.	Sample amount (µg/ml)	Amount spiked (µg/ml)*	Estimated Amount (µg/ml)*	Recovered Amount (µg/ml)*	Average % recovery
VER	50	10.09	4.995	15.092	5.002	100.14
	100	10.09	10.01	20.14	10.05	99.60
	150	10.09	15.03	25.16	15.10	100.46

*Mean of three observation

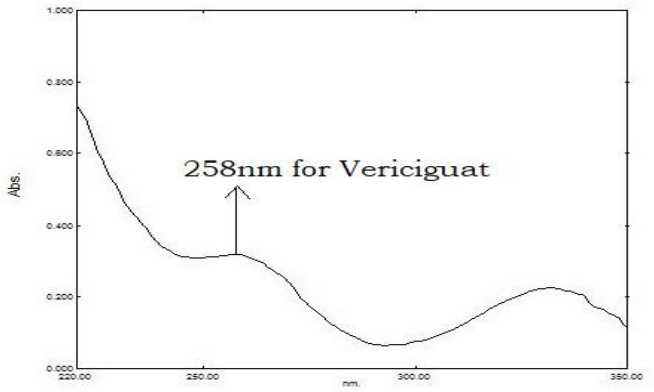

Fig 1. UV spectrum of Vericiguat (10µg/ml)

IV. CONCLUSION

The validated UV Spectroscopic technique used in this study showed to be easy, economical, quick, precise, and accurate. Therefore, Vericiguat tablet dosage estimation can be done regularly using them.

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