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Development and Validation of UV-Visible Spectrophotometric Method for Estimation of 'Valsartan'

Vaishnavi Patil[1], Ritesh Pujari[1], Snehal Patil[1], Pruthviraj Patil[1], Mr. Prafull Patil[2*]

1. Research Student, Department of B Pharmacy, School of pharmaceutical Science, Atigre, Kolhapur Maharashtra, India- 416118
2. Assistant Professor, Department of School of pharmaceutical Sciences, Atigre Maharashtra,, India- 416118

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ABSTRACT

UV-Visible spectroscopy is a widely used analytical technique for the quantitative determination of various compounds in pharmaceutical, environmental, and chemical applications. Method validation is a critical aspect of ensuring the accuracy, precision, and reliability of UV-Visible spectroscopy result. New simple, accurate and economical UV-spectrophotometric method has been developed for estimation of valsartan in pure form. The λ_{max} of valsartan in methanol was found to be 250.80nm. The drug exhibited the linearity in the concentration range 5.0-25µg/ml with correlation coefficient of 0.997. The limit of detection and limit of quantification was found to be 0.234% and 0.00709 respectively. The method was validated as per ICH guidelines. The developed method was successfully employed for estimation of valsartan in pure form.

Keywords: Valsartan, UV-Spectrophotometry, Validation, Wavelength, absorbance

INTRODUCTION

Spectroscopy

Spectroscopy is the management and interpretation of electromagnetic radiation that molecules, atoms and ions in a sample absorb and emit as they move from one energy level to another energy state[1].

UV-Visible Spectroscopy

Ultraviolet and visible spectroscopy, also known as electronic spectroscopy, is used to measure the number of double bonds and aromatic conjugation in a molecule. UV spectroscopy is a type of absorption spectroscopy in which a molecule absorbs light in the ultraviolet range (200-400 nm), as a result of which electrons are excited from the ground state to a higher energy state. The ultraviolet range correspondence to 400-200 nm and the visible range to 800-400 nm[1].

Apparatus and chemical

Spectral and absorbance measurements were carried out by using Shimadzu UV/Visible spectrophotometer model UV-2450 equipped with 1.0cm thickness matched quartz cells were used for the entire experimental work.

Heart failure (HF), a public health concern, remains a leading cause of morbidity and mortality worldwide. Heart failure with reduced ejection fraction present in approximately 50% of all cases of heart failure.

Application of UV- Spectroscopy

UV-Visible Spectroscopy has many Applications, including in the pharmaceutical, food and beverages, environmental, and chemical industries[2].

Food and beverage

1. Used to assess sensory attributes, nutritional components, and chemical composition.

2. Used to determine the purity of olive oil.

Environmental

1. Used to monitor the progress of a reaction.

2. Used to detect impurities in a sample.

Chemical

1. Used to identify and characterize molecule.

2. Used to measure the concentration of molecule in solution.

3. Used to determine the purity of a sample.

Other applications

1. Used to Analyse the dyes and pigments in textile fibres, paint chips, and glass fragments.

2. Used in kinetic and monitoring studies to ensure certain dyes or dye.

3. UV- Vis Spectroscopy Application range from chemical analysis in teaching and industrial materials science labs to pharmaceutical research.

Valsartan

Chemically Valsartan is [1-4], N-[p-(o-1H-tetrazol-5-ylphenyl) benzyl]-N-valeryl-L-valine1. Valsartan is a specific blocker of the angiotensin II receptor, exhibiting a strong affinity for the angiotensin type I receptor. It is commonly utilized in the management of hypertension, post myocardial infraction, and congestive heart failure[3]. Classified as BCS class IV weak acid drug, Valsartan has low solubility and permeability, which means that its systemic exposure is influenced by both these factors[4].

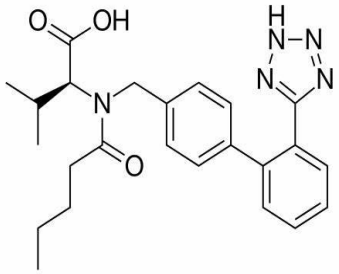
It exhibits greater solubility in specific organic solvents, including ethanol, methanol, and dimethysulfoxide (DMSO). Recent research has presented by UV Spectrophotometric technique for estimation of Valsartan, utilising a solvent 'methanol'. From the literature survey, it was found that valsartan was estimated by analytical method as Spectrophotometry. The objective of this study was to develop and validate a simple, precise and accurate spectrophotometric method for estimation of valsartan as per ICH guidelines[5].

Use of Valsartan

Valsartan is used alone or together with other medicines to treat high blood pressure. (hypertension)[6].

Need and Objective

The objective of the present study was to develop a simple, precise, accurate, economical, and validated analytical method for the estimation valsartan. The analytical method developed was validated as per ICH guidelines and USP requirements.



Structure of Valsartan

Material and Method

Preparation of standard stock solution

Weigh and transfer 50mg of valsartan working standard into 100ml volumetric flask, add 40ml of diluent (Methanol) and sonicate to dissolve and dilute to volume with diluent. The volume was adjusted with the same up to mark to give final strength i.e. 500µg/ml.

Selection of wavelength for analysis of valsartan

Convenient volume of 2 ml of standard stock solution of valsartan was transferred into 100ml volumetric flask, diluted to mark with distilled water to give concentration of 20µg/ml. The resulting solution was scanned in UV range (200nm-400nm). In spectrum valsartan showed absorbance maximum at 250.80nm.

Linearity study

Appropriate 1ml of standard stock solution was transferred into 10 ml of volumetric flask and dilute up to mark with diluent to get strength 50µg/ml. Different dilution of valsartan in range 1ml-5ml of 50µg/ml solution and it is transferred into 10ml of volumetric flask and volume make up to mark with diluent (Methanol) to get concentration 5,10,15,20 and 25µg/ml, respectively. The solutions were scanned on spectrophotometer in the UV range 200-400nm. The absorbance spectrum was recorded at 250.80nm.

Accuracy

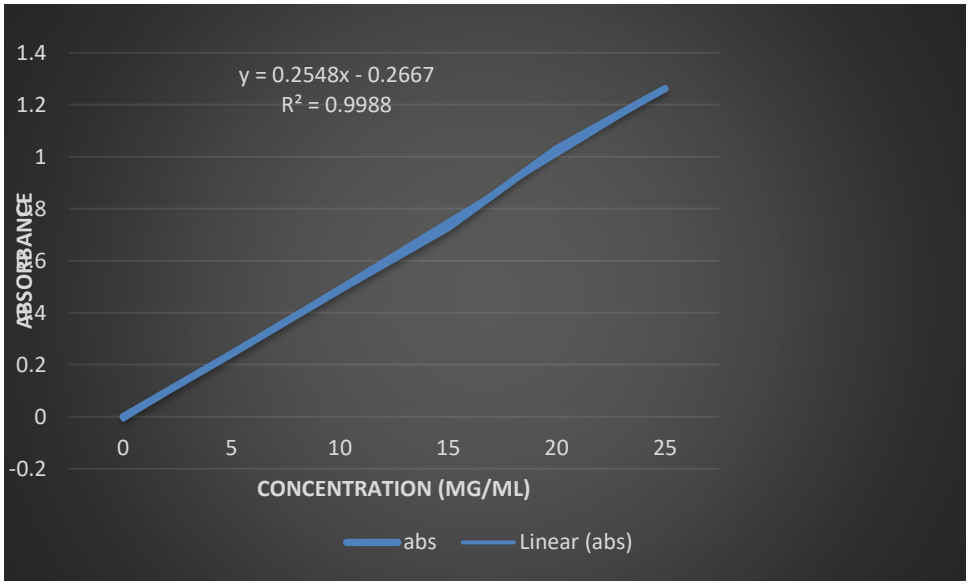
Accuracy of proposed method was determined using recovery studies. The results studies at three different levels, i.e., 50,100,150% The solutions were prepared in triplicates and the % recovery was calculated as[7].

$$\% \text{ Accuracy} = \text{measured concentration} \div \text{Actual added concentration} \times 100$$

Precision

Precision is the measure of how close the data values are to each other for a number of measurements under the same analytical conditions[7].

Result



Calibration data for Analysis of Valsartan in Methanol at λ 250.80

Table.1

S. No	Concentration (µg/ml)	Absorbance
1	5µg/ml	0.24
2	10µg/ml	0.48
3	15µg/ml	0.72
4	20µg/ml	1.03
5	25µg/ml	1.24

Method Validation

Validation Parameters

Table.2

S. No	Parameters	Result
1	Absorption maxima λ max(nm)	250.80 nm
2	Linearity range(µg/ml)	5-25(µg/ml)
3	Standard regression equation	Y= 0.2548x - 0.2667
4	Correlation coefficient	R^2=0.9988

Lowest Limit of detection & lowest limit of quantification

Table.3

LOD (µg/ml)	LOQ (µg/ml)
2.34	7.09

Discussion

Attempt has been made to develop rapid sensitive, economic, precise and accurate analytical method for valsartan. The UV spectrum of standard solution of valsartan was studied in methanol. Maximum absorbance was found to be at 250.80nm. LOD and LOQ were found to be 2.34 and 7.09 respectively. Beer's law was obeyed in concentration ranging from 5-25µg/ml. The correlation co-efficient values were above 0.997 which shows that absorbance was linear with concentration. The optical characteristics such as Beer's law limit correlation coefficient, slope, intercept was calculated and validated. From all the validation parameters, the developed method was found to be simple, economical, precise and accurate. Hence proposed method could be effectively applied for estimation of valsartan in API[8].

Conclusion

UV- spectrophotometric method for determination of Valsartan in methanol by method of external standards was validated for analytical parameters: linearity, LOD, LOQ, accuracy and precision. The method is selective, precise, accurate and linear over the concentration range studied. The method is simple and suitable for the estimation of valsartan.

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Conflict of Interest Statement: All authors have nothing else to disclose.