

AREA UNDER CURVE UV SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF VALSARTAN IN BULK.

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ABSTRACT:- The simple, precise and accurate UV Spectrophotometric method has been developed and validated for the estimation of valsartan (VAL) in bulk. In that work is carried out to for estimation of Valsartan bulk by utilizing Area Under Curve (AUC) method using UV – Visible Spectrophotometry. For this purpose the wavelength range 200-400 nm was selected. Methanol was used as solvent throughout the work. Linearity was observed in concentration range 5-25 µm/ml ($R^2 = 0.996$) for the method. The present method was found which can be used for routine quality control analysis for spectrophotometric estimation of Valsartan in bulk.

Keywords: Valsartan, AUC, Methanol, UV Spectrophotometric.

INTRODUCTION:

Valsartan is a non - peptide, orally active and specific angiotensin II receptor blocker acting on the AT1 receptor subtype. The Valsartan is chemically described as (Figure 1) [1] N-(1-Oxo pentyl)-N- [Z(1H-Tetrazol-5yl)(1,1'biphenyl) 4-yl methyl]L-valine. Valsartan is used for treatment of hypertension, can be used alone or in combination with other antihypertensive drugs for treatment of high blood pressure. It is not official in any of the pharmacopoeia. The pharmacokinetics properties of valsartan have been investigated in healthy volunteers after oral administration of the sample. The aim of this work is to develop simple, accurate, precise spectrophotometric method for the routine determination of valsartan in bulk. [2, 3, 4, 5]

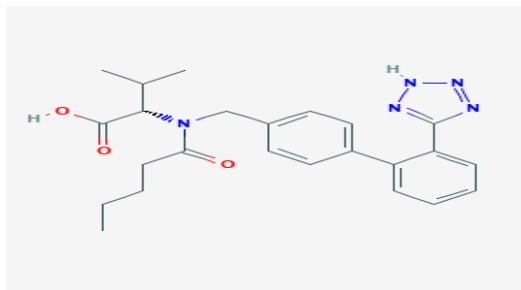


Figure 1: Chemical Structure of Valsartan.

MATERIALS AND METHODS:

Chemicals:

Valsartan was obtained at gift sample from alembic pharmaceuticals, Vadodara. Methanol analytical reagent (AR) grade was used as solvent throughout the experimentation. A pharmaceutical preparation was purchased from local pharmacy.

Instrumentation:

A Shimadzu (Kyoto, Japan) model UV- 1800 double beam UV- Visible spectrophotometer attached with computer operated software UV probe 2.33 with spectral width of 2 nm, wavelength accuracy of 0.5 nm and pair of 1 cm matched quartz cells was used to measure absorbance of the resulting solutions. Analytical balance of make Mettler Toledo (Model JL 1503- C) was used for weighing purpose.

METHOD:

Experimental Work-

A) To check the solubility of Valsartan:

25 mg of Valsartan was weighed and solubility of this sample was checked in 25 ml distilled water, methanol, ethanol. [11]

B) To identify the λ max of Valsartan:

Weigh 1 gm of the pure drug and dissolve it in small portion of methanol and make up the volume upto 10 ml using distilled water to give a standard stock solution of 1000 μ m/ml. From above solution 2.5 ml of the standard solution was withdrawn in volumetric flask and diluted to 25 ml to prepare 100 ppm solution. Suitable dilutions were made with distilled water to get standard solutions of concentrations: 5, 10, 15, 20, 25 μ m/ml. [6,7] Spectrum peak details are shown in Figure 2 Spectrum peak pick.

Table 1: Calibration curve of Valsartan.

Concentration	Absorbance
5	0.222
10	0.400
15	0.607
20	0.839
25	1.046

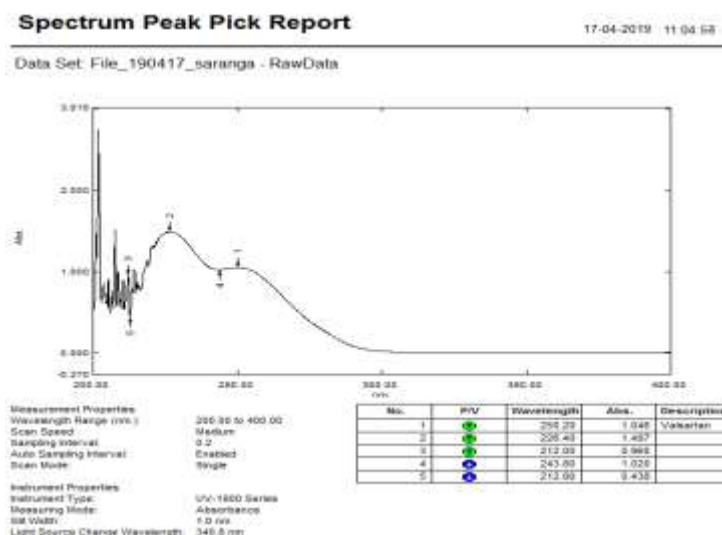


Figure 2: Spectrum Peak Pick.

C) Area Under Curve Method:

In case of AUC (Area under Curve) method is applicable where there is no sharp peak or broad spectra is obtained. In that involves the calculation of integrated value of absorbance with respect to the wavelength between the two selected

wavelengths λ_1 and λ_2 . The Area calculation processing item calculates the area bound by the curve and the horizontal axis. The horizontal axis is selected by the entering the wavelength ranges over which area has to be calculated. This wavelength range is selected on the basis of repeated observation so as to get the linearity between area under curve and concentration. The above mentioned spectrums were used to calculate AUC. Thus, the calibration curve can be constructed by plotting concentration versus AUC.^[8, 9]

D) Analytical Method Development and Validation:

Linearity:

The linearity of an analytical procedure is the interval between the upper and lower concentration of analyte in the sample. For which demonstrated that the analytical procedure is of linearity. The standard solution of Valsartan (5, 10, 15, 20, and 25 $\mu\text{m}/\text{ml}$) was pipette out in a separated series of 10ml volumetric flask. Make up the volume with distilled water and mixed well. The absorbance maxima and area under curve for the solutions was measured at 250 nm and range of nm for two methods respectively against distilled water as blank. Calibration Curve table of Valsartan is shown in Table. 1. Calibration curve of Valsartan.^[8, 10]

RESULTS AND DISCUSSION:

The AUC (Area under Curve) spectra for Valsartan was recorded at the wavelength of 250 nm.

A) Calibration Curve for Drug :

Absorbance maxima method:

Under the Experimental conditions described, the graph obtained for the absorbance maxima for pure drug showed linear relationship (Figure 3). Regression analysis was made for the slope, intercept and correlation coefficient values. The regression equations of calibration curve were $y = 0.0082x - 0.0114$ ($R^2 = 0.996$) at 250 nm for absorption maxima the range was found to be 5 - 25 $\mu\text{m}/\text{ml}$ for the UV spectrophotometric analysis. Calibration Curve is shown in Table. 1. Calibration Curve of valsartan. Calibration curve of valsartan is shown in Figure. 3. Calibration Curve of valsartan.

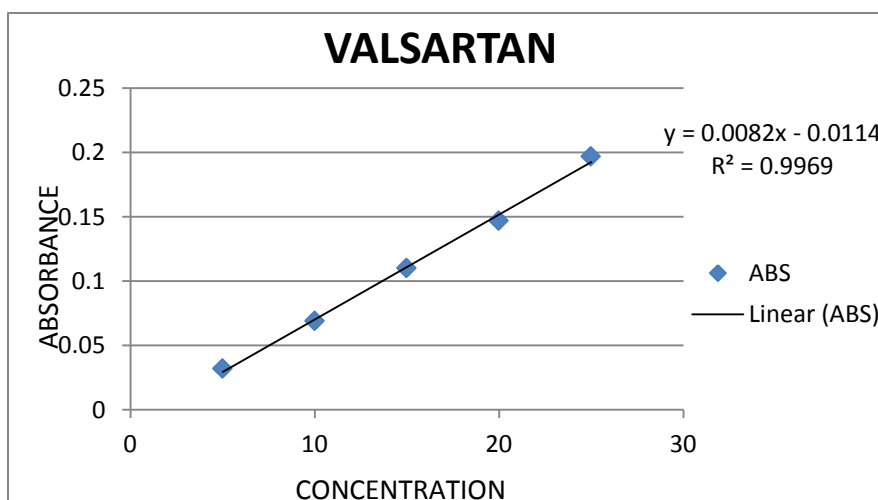


Figure 3: Calibration Curve of Valsartan.

B) Area Under Curve Method :

In the Experimental conditions described, the graph obtained for the Area Under Curve (AUC) spectra showed linear relationship (Figure 4). Regression analysis was made for the slope, intercept and correlation values. The

equation is $y = 0.008x - 0.011$ ($r^2 = 0.996$) at 200 – 400 nm for Area Under Curve spectrophotometry analysis. The range was found to be 5 - 25 $\mu\text{m/ml}$ for the Area Under Curve UV spectrophotometric analysis.

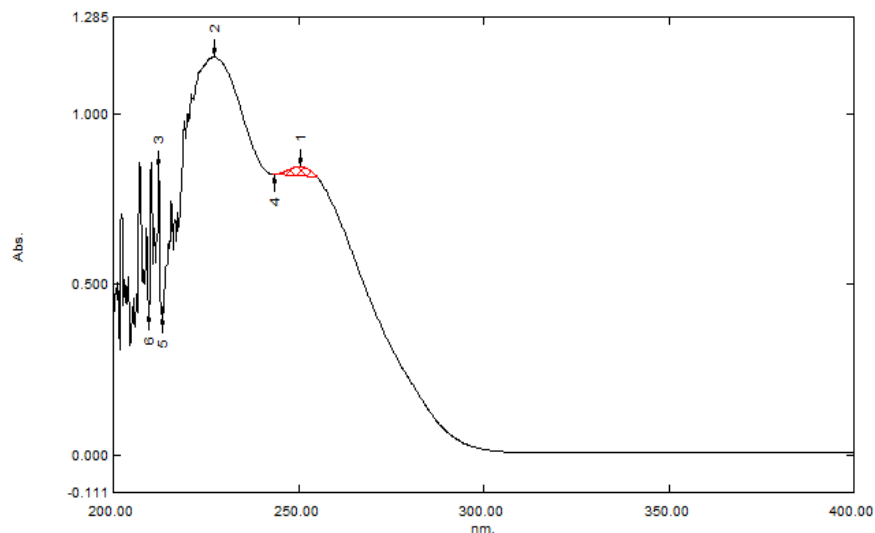
Table 2: Area Under curve of Valsartan.

Parameter	AUC
Wavelength Range (nm)	200 – 400
Concentration Range ($\mu\text{m/ml}$)	5 - 25
Slope (m)	0.008x
Intercept (c)	0.011
Correlation Coefficient (r^2)	0.996

Spectrum Peak Area Report

17-04-2019 11:27:12

Data Set: File_190417_112523 - RawData




Region	Color	Start	End	Divisor	Area	Result	Description
1		243.00	255.00	1.000	0.180	0.180	Valsartan

Figure 4: Area Under Curve Of Valsartan.

CONCLUSION:

The no any spectrophotometric methods have been described for AUC determination of Valsartan. Therefore simple, fast and reliable area under curve UV spectrophotometric methods was developed for the routine analysis of Valsartan. The developed method can be concluded as accurate, sensitive and precise and can be easily applied to the pharmaceutical formulation.

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REFERENCES:

- 1) Satoskar R. S. Pharmacology and pharmacotherapeutics Popular Prakashan, New Delhi, 21st Edition, 587-588, 2008.
- 2) Budavari S., O' Neil M J., Smith A., Heckelman P.E. Ed. The Merck Index, Mary Adele 13th ed. Published By, Merck Research Lab, Division of Merck and Co, White House Station, NJ, USA, 2001, 148.
- 3) Chiralo A. And burnier M., Expert Opinion on investigational Drugs, 1998, 7, 1915.
- 4) Hoang T., Guarria D. And Nichalle J, Valsartan Therapy in heart failure after myocardial infarction the role of endothelial dependent vasorelaxation, journal of Cardiovascular Pharmacology, 2007, 50, 703-707.
- 5) Markham A. And Goa K. L., Valsartan. A review of its pharmacology and therapeutics use in essential hypertension, Drugs 1977, 54, 299-311.
- 6) Brand JJ, Colquhoun WP, Gould AH, Perry WLM. (-)-Hyoscine and cyclizine as motion sickness remedies. Br J PharmacChemother. 1967; 30: 463-469.
- 7) Beckett, A. H., Stenlake, J. B., Practical Pharmaceutical Chemistry, 4th edition, CBS Publishers and Distributors, New Delhi, 2002; 2: 275-295.
- 8) Christian G D. Analytical chemistry 6th edition, John Willey and Sons, PA, 1-2,604-620, 2003.
- 9) Blessy M. A review – development and stability indicating studies. Journal of Pharmaceutical Analysis, 2013.
- 10) Robert A. Nash, et. Al. Pharmaceutical Process Validation, Third Edition, Volume 129, 14, 181.