TWO EXTRACTIVE SPECTROPHOTOMETRIC METHODS FOR DETERMINATION OF VALSARTAN IN TABLETS

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ABSTRACT

Two simple and sensitive visible spectrophotometric methods have been developed for the estimation of Valsartan in pure and pharmaceutical dosage forms. These methods are based on the formation of ion-pair complexes of the drug with acidic dye Bromo Thymol blue (BTB: λ_{max} 440 nm) and with basic dye Saffranine (SFN: λ_{max} 510 nm). The absorbance of the chloroform extracts is measured against the corresponding reagent blanks. The methods have been statistically evaluated and found to be precise and accurate.

1.INTRODUCTION

Valsartan which is chemically N-(1-0xopentyl)-N-[(2[1]–(1H-tetrazol-5-yl) [1,1[1]–biphenyl]-4-yl]methyl]-L-valine is a Anti-hypertensive which blocks the vasoconstrictor and aldosterone-secreting effects of angiotensin II by selectively blocking the binding of angiotensin II to the AT_1 receptor in many tissues, such as vascular smooth muscle and the adrenal gland. It is used for treatment of high blood pressure, congestive heart failure (CHF), or post-myocardial infarction (MI). Methods like HPLC, Mass Spectrometry and Nuclear Magnetic Resonance spectroscopy were reported for the estimation of Valsartan, in its pure form. Literature survey reveals that visible spectrophotometric methods have not been reported for its quantitative determination in its pure form and pharmaceutical formulations. In the present investigation, two simple and sensitive visible spectrophotometric methods have been developed for the determination of Valsartan. The developed methods involve the formation of colored extractable complexes with BTB and SFN. Extractable complexes showed absorption maximum at 440 and 510 nm respectively. Beers law is obeyed in the concentration ranges of 5-10µg/ml and 5-10µg/ml respectively. The results of analysis for the two methods have been validated statistically and by recovery studies.

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2.EXPERIMENTAL

Preparation of Reagents:

1. Bromo Thymol blue Solution: 0.1 g BTB dye was dissolved in 100 ml of distilled water.
2. Saffranine Solution: 0.1g of SFN dye was dissolved in 100 ml of distilled water.
3. Phosphate Buffer pH 7.4 [I.P.]
4. Standard drug solution: About 100mg of Valsartan was accurately weighed and dissolved in 100ml methanol to obtain a stock solution of 1mg/ml strength. This solution was further diluted with distilled water to get a working standard solution containing100µg/ml of the drug.

Assay Procedures:

Method A: Aliquots of working standard solution of Valsartan ranging from 0.5-1.0ml (100 µg/ml) were transferred in to a series of 125ml separating funnels. To these 1ml of 0.1M HCl and 1ml of BTB dye were added. The total volume of aqueous phase was adjusted to 10ml with distilled water and 10 ml chloroform was added. The contents were shaken for 2 minutes. The two phases were allowed to separate and the absorbance of the yellow colored chromogen was measured at 440 nm against reagent blank and the amount of Valsartan present in the sample was computed from its calibration curve.

Method B: Aliquots of working standard solution of Valsartan ranging from 0.5-1.0ml (100 µg/ml) were transferred in to a series of 125ml separating funnels. To these 1ml of SFN dye and 1ml of Phosphate buffer solution (pH 7.4) were added. The total volume of aqueous phase was adjusted to 10ml with distilled water and 10 ml chloroform was added. The contents were shaken for 2 minutes. The two phases were allowed to separate and the absorbance of the red colored

chromogen was measured at 510 nm against reagent blank and the amount of Valsartan present in the sample was computed from its calibration curve.

3.RESULTS AND DISCUSSION

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar extinction coefficient, percentage relative standard deviation, percentage range of error (0.05-0.01) were calculated for the method and results are summarized in table 1. The values obtained for the determination of Valsartan in pharmaceutical formulation (tablets) by the proposed method is presented in table 2. Studies reveal that the common excipients and other additives usually present in the tablets did not interfere in the proposed methods.

4.CONCLUSION

The proposed methods are applicable for the assay of drug Valsartan and have an advantage of wider range under Beer's law limits. The proposed methods are simple, selective and reproducible and can be used in routine determination of Valsartan in pure form and formulation with reasonable precision and accuracy.

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Table-1: Optical characteristics, precision and accuracy of the proposed method

PARAMETERS	Method A	Method B
λ_{max} (nm)	440	510
Beer's law limit (µg/ml)	5-10	5-10
Sandell's sensitivity (µg/cm^2/0.001 abs. unit)	0.019685	0.0213675
Molar absorptivity (litre.mole^{-1}.cm^{-1})	9.7092 x 10^4	1.01268 x 10^4
Regression equation(Y*)		
Slope(b)	0.0015	0.0173
Intercept(a)	0.1777	0.1498
Correlation Coefficient®	0.9993	0.9994
%Relative standard deviation	1.63	0.67
% Range of error		
0.05 Significance level	1.362	0.560
0.01 Significance level	2.016	0.828

Y* = a + bx, where Y is absorbance and x is concentration of Valsartan in µg/ml.

Table 2: Estimation of Valsartan in Pharmaceutical Formulations

Formulations (tablets)	Labelled Amount (mg)	Amount found* by proposed method		% recovery** by proposed method	
		Method A	Method B	Method A	Method B
Tablets 1	160	158.8	159.2	98.3	99.13
Tablets 2	160	159.2	159.6	99.62	99.23
Tablets 3	160	159.4	158.7	98.26	98.8

*Average of 6 determinations

**Recovery of amount added to the pharmaceutical formulation

(Average of three determinations).

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