Determination of Valsartan by Visible Spectrophotometry

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Abstract **- A simple and reproducible spectrophotometric method has been developed for the determination of Valsartan in bulk and pharmaceutical dosage forms. The method is based on the extraction of the drug into organic layer of the dye TPooo in presence of 0.1 N hydrochloric acid and the absorbances were measured at 483 nm. The method was optimized using eight parameters. The linearity range of Valsartan with TPooo was found to be 0.5 – 3.0 ml; 400 µg/ml. The developed method was found to be precise and accurate from the statistical validation of the analytical data. The proposed method has been successfully applied for analysis of dosage formulations.**

Index Terms **- Valsartan, TPooo, and Spectrophotometric method.**

INTRODUCTION

Valsartan chemically is N-[p-(o-1H-Tetrazol-5-ylphenyl) benzyl]-N-valeryl-L-valine1(Figure 1).It is an angiotensin II receptor antagonist, effective in the treatment of hypertension. It is also effective when used alone or in combination with other drugs for the treatment of high blood pressure. It is not official in any of the pharmacopoeia. The pharmacokinetic properties of valsartan have been investigated in healthy volunteers after oral administration of the sample. UV method is commonly employed method for routine analysis since it is economical and easy to perform. Literature reports reveal that olmesartan medoxomil can be estimated by RPLC-HPLC, RP-HPLC, LC-MS and HPLC methods individually or in combination with other drugs .Parambi and coworkers developed a UV spectrophotometric method for the estimation of Valsartan in pharmaceutical dosage form.

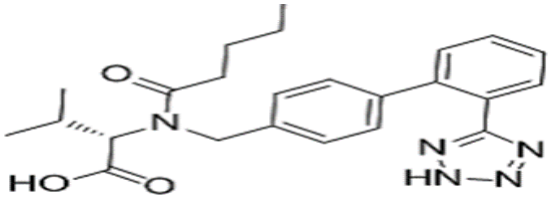

Fig. 1: Structure of valsartan

The authors proposed a simple and reproducible spectrophotometric method for the determination of antiviral drugs.

EXPERIMENTAL

A Systronics UV-Visible double beam spectrophotometer 2203 with 1 cm matched quartz cells was used for all spectral and absorbance measurements. A Systronics digital pH meter 361 was used for pH measurements. All the chemicals used were of AR grade. Solutions of 0.2 % TPooo and 0.1 N hydrochloric acid were prepared using distilled water. AR grade chloroform was used.

Preparation of Standard solution:
The stock solution (1mg/ml) of VLS was prepared by dissolving 100mg of it in 100ml of methanol. A portion of this stock solution was diluted stepwise with the methanol to obtain the working standard VLS solution of concentrations 400 µg/ml.

Preparation of sample solution:
An accurately weighed portion of the powdered tablets equivalent to 100 mg of drug was dissolved in 20 ml of methanol (MeOH), shaken well and filtered. The filtrate was diluted to 100ml with MeOH to get 1 mg/ml solution of drug in formulations.

Preparation of the reagents:
Tpooo (0.2%): Prepared by dissolving 200 mg of Tropaeolin ooo in 100 ml of distilled water and washed with chloroform to remove chloroform soluble impurities.
HCl solution: prepared by dissolving 8.6 ml of con HCl to 1000 ml of distilled water and Standardized.

Method:
Into a series of 125 ml separating funnels containing aliquots of standard VLS solution (0.5 – 3.0 ml; 400 µg/ml), 6.0 ml of 0.1M HCl and 2.0 ml of dye solution (TPooo) were added. The total volume of aqueous phase in each separating funnel was adjusted to 15 ml

with distilled water and then10 ml of $CHCl_3$ was added. The contents were shaken for 2 minutes. The two phases were allowed to separate and the absorbance of the separated organic layer was measured at λ_{max} 483 nm against a similar reagent blank. The colored species was stable for 1 hour. The amount of sample solution was calculated by using Beers-Lambert's plot.

RESULTS AND DISCUSSION

The optical characteristics such as Beer's law limits, Sandell's sensitivity, molarextinction coefficient, percent relative standard deviation and percent range of error were calculated for the method and the results are summarized in Table 1.The accuracy of the methods was ascertained by comparing the results of the proposed methods with that of reported method In order to justify the reliability and suitability of proposed methods, known amounts of pure drug was added to its various pre analyzed dosage forms and were analyzed by the proposed method. The results presented in Table 2, which indicates that the proposed method can be successfully applied for the analysis of Valsartan in dosage forms. Valsartan in dosage forms. The additives and excipients usually present in pharmaceutical preparations did not interfere. Thus the proposed method was simple, sensitive, accurate and reproducible and can be used for the routine analysis of Valsartan in bulk and in pharmaceutical dosage forms.

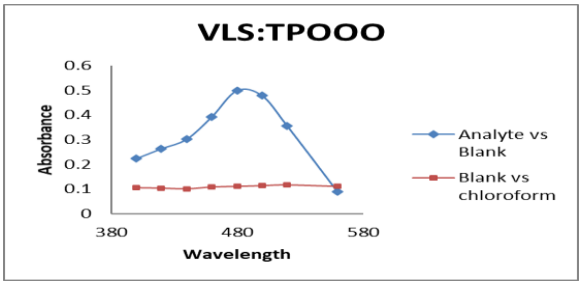

Fig.2: Absorption spectra of VLS: TPOOO

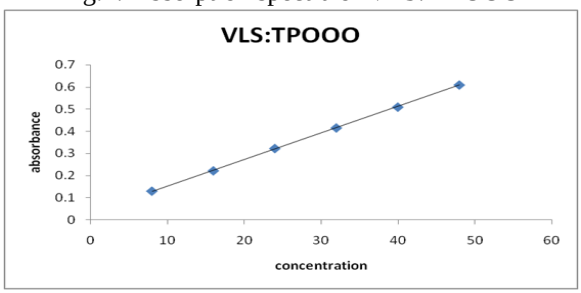

Fig 3.12 Beer's plot of VLS: TPOOO

Table 1. Optical Characteristics of the Proposed Method

Parameter	TPooo
λ_{max} (nm)	483
Beer's law limits (µg ml^{-1})	8-48
Detection limits (µg ml^{-1})	0.576
Molar absorptivity (1 mole cm^{-1})	1.388x 10^5
Sandell's sensitivity (µg cm^{-2} / 0.001 absorbance unit)	0.00784
Regressionequation (Y = a + bC) Slope (b)	0.012
Standard deviation of slope (S_b)	7.4x10^{-5}
Intercept (a)	0.032
Standard deviation of intercept (S_a)	2.305x10^{-3}
Standard error of estimation (S_e)	2.5x10^{-3}
Correlation coefficient (r^2)	0.999
Relative standard deviation (%)*	0.5283
% Range of error (Confidence limits)*0.05 level	0.5545
0.01 level	0.8696
Error in bulk samples **	0.392

*: Average of six determinations considered**: Average of three determinations

Table 2. Assay of in Pharmaceutical Formulations

Method	formulations	Labled amount (mg)	Amount Founded by proposed methods	t	f	Percentage Recovery by proposed method
TPooo	Tablet	80	79.382±0.472	1.84	3.24	99.540±0. 186

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