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Spectrophotometric estimation of Valacyclovir in pharmaceutical preparations

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ABSTRACT

A simple and sensitive spectrophotometric method has been developed for the determination of valacyclovir in bulk and tablet dosage forms. The method was based on the charge transfer reactions of Valacyclovir with 2,5-dichloro-3,6-dihydroxy-1,4-benzoquinone. The absorbance of the highly intensive coloured solution was measured at 450 nm against reagent blank treated similarly. Beer's law is obeyed in the concentration range of 20-100 µg/ml. Statistical analysis proves that the proposed method is reproducible and selective for the routine analysis of pharmaceutical formulations of Valacyclovir.

Key words: Spctrophotometry, Valacyclovir, 2, 5-dichloro-3, 6-dihydroxy-1, 4-benzoquinone, Formulations.

INTRODUCTION

Valacyclovir Chemically, *L*-valine-2-[(2-amino-1, 6-dihydro-6-oxo-9-hipurin-9-yl) methoxy] ethyl ester is the *L*-valyl ester prodrug of the antiviral drug acyclovir that exhibits activity against herpes simplex virus types, 1 (HSV-1) and 2 (HSV-2) and vericellazoster virus [1]. The mechanism of action of acyclovir involves the highly selective inhibition of herpes virus DN Areplication, via enhanced uptake in herpes virus-infected cells and phosphorylation by viral thymidine kinase. The substrate specificity of acyclovir triphosphate for viral, rather than cellular, DNA polymerase contributes to the specificity of the drug. Valacyclovir is available as tablet dosage form in the market. Literature survey revealed the dissolution studies[1-2], pharmacological data [3-4], and few methods are reported in literature for the estimation of

Valacyclovir in pharmaceutical dosage forms which includes, spectrophotometric method[5-7], RP-HPLC Method[8].

UV-Visible spectrophotometry is the technique of choice in research laboratories, hospitals and pharmaceutical industries due to its low cost and inherent simplicity. The objectives of the work are to develop new spectrophotometric method for its estimation in bulk and tablet dosage form with good accuracy, simplicity, precision and economy. Hence the present work deals with the spectrophotometric estimation of Valacyclovir using 2, 5-dichloro-3, 6-dihydroxy-1, 4-benzoquinone.

EXPERIMENTAL SECTION

Instrumentation

All absorbance measurements were made on a Spectronic 1001 plus spectrophotometer (Milton Roy Company, USA) with 1 cm matched quartz cells. All the solutions were freshly prepared.

Chemical and reagents

All solvents and other chemicals used through this study were of analytical grade. 2,3-dichloro 5,6-dicyano-p-benzoquinone(DDQ; Merck, Schuchardt, Munich, Germany) solution(0.1%) solution was freshly prepared in methanol and it was prepared afresh daily.

Preparation of Standard Solution

50 mg of Valacyclovir was accurately weighed and dissolved in 50 ml of methanol to get a concentration of 1 mg/ml. The stock solution was suitably diluted to get a concentration of 100 mg/ml.

Assay procedure

Various aliquots of standard solution of Valacyclovir ranging from 0.2-1.0 ml were transferred into10 ml calibrated flasks. To each flask 1.0 ml of the DDQ solution was added, and the reaction was allowed to proceed at room temperature (25±5oC). The reaction was achieved instantaneously. The solutions were diluted to volume with methanol. The absorbance of the resulting solutions was measured at the wavelengths of maximum absorption 460 nm against reagent blanks treated similarly. The amount of drug present in sample is read from the calibration graph. Beer's law is obeyed in the concentration of 20-100µg/ml of Valacyclovir.

Twenty tablets of Valacyclovir was weighed accurately and ground into a fine powder. An amount of the powder equivalent to 50 mg of Valacyclovir was weighed and transferred into 50 ml volumetric flasks, 25 ml of methanol added and shaken thoroughly for about 20 min. Then, the volume was made up to the mark with methanol, mixed well and filtered using a quantitative filter paper and analyzed as given under the assay procedures for bulk samples. The results are represented in Table 2.

RESULTS AND DISCUSSION

The developed method based on the reaction of Valacyclovir as *n*-electron donor with acceptor, 2,5-dichloro-3,6-dihydroxy-1,4-benzoquinone. The absorption spectral analysis shows that the

maximum of absorbance of Valacyclovir was found to be 450 nm. The calibration curve was obtained for a series of concentration in the range of 20-100µg/ml (Fig. 1). It was found to be linear and hence, suitable for the estimation of the drug. Statistical analysis was carried out and the results were found to be satisfactory. The recovery technique was performed to study the accuracy and reproducibility of the proposed method. The results are shown in Table 2. The optical characteristics such as absorption maxima, Beer´s law limits, molar absorptivity and Sandell´s sensitivity are presented in Table 1. The regression analysis using method of least squares was made for the slope (b), intercept (a) and correlation (r) obtained from different concentrations and results are summarized.

Table 1: Optical characteristics of proposed method

parameters	Proposed method
λmax (nm)	590
Beer's law limit (µg/ml)	50-250
Molar absorptivity (l mole-1 cm-1)	$2.2x10^3$
Sandell's sensitivity (µg cm-2 / 0.001 absorbance unit)	0.2264
Regression equation (Y = a + bC)	Y=0.004x+0.03
Slope (b)	0.004
Intercept (a)	0.003
Correlation coefficient (r)	0.9992

**Y = a+bX, where Y is the absorbance and X concentration in µg / ml*

Table 2: Assay of Valacyclovir in tablets

Formulations	Labeled Amount (mg/tab)	*Amount Found(mg±S.D)	% Recovery	%RSD*	*t_{cal}
Tablet 1	500	500.14±0.27	100.36	0.0555	1.128
Tablet 2	500	499.97±0.25	100.04	0.0526	0.2617

**Average of five determination based on the label claim*

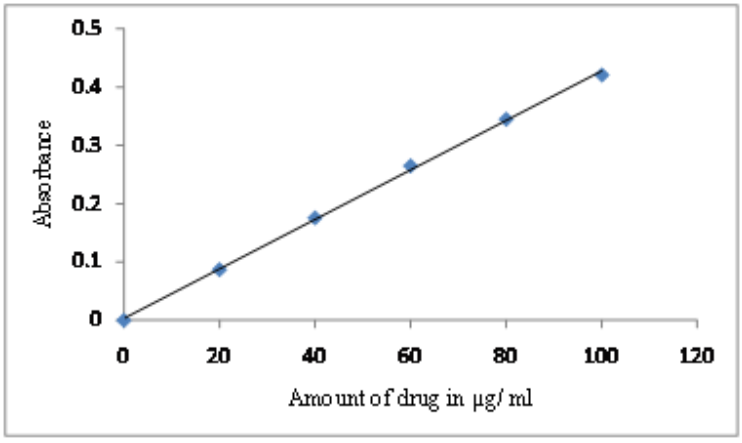

Fig. 2: calibration graph of Valacyclovir

The percent relative standard deviation, standard deviation and student's 't' test values calculated from the five measurements of Valacyclovir are presented in Table 2. Relative standard deviation values and standard deviation were low that indicates the reproducibility of the proposed method. In the student's 't' tests, no significant differences were found between the calculated and

theoretical values of both the proposed methods at 95% confidence level. This indicated similar precision and accuracy in the analysis of Valacyclovir in its tablets. Thus it can be concluded that the method developed in the present investigation is simple, rapid, accurate, economical and can be used for routine determination of Valacyclovir in bulk samples as well as tablet formulations.

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