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SPECTROPHOTOMETRIC ESTIMATION OF ZIDOVUDINE IN BULK SAMPLES AND ITS DOSAGE FORMS

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ABSTRACT

A simple, sensitive and economical spectrophotometric method has been developed for the determination of zidovudine in commercial dosage forms. The method was based on the the charge transfer reactions of zidovudine as *n*-electron donor with acceptor, 2,5-dichloro-3,6-dihydroxy-1,4-benzoquinone. The absorbance of the highly intensive coloured solution was measured at 460 nm against reagent blank treated similarly. Statistical analysis proves that the proposed methods are reproducible and selective for the estimation of zidovudine in bulk drug and in its tablet dosage form.

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

INTRODUCTION

Zidovudine (ZDV), chemically known as 31-azido-31-deoxy thymidine, was the first drug approved for the treatment of AIDS and HIV infection. Zidovudine is a thymidine analogue[1]. It is phosphorylated in the body to zidovudine triphosphate, which is the active form that inhibits HIV replication[2]. Zidovudine inhibits the key enzyme reverse transcriptase. The present study describes simple, sensitive, accurate, rapid and economical spectrophotometric method for the estimation of zidovudine in bulk and its tablet dosage forms. Literature survey reveals that, several spectrophotometric method[1,2] titrimetric and spectrophotometric method[3] and HPLC method[4] have been reported for the estimation of zidovudine in pharmaceutical formulations. Few analytical methods were reported in literature for the determination of zidovudine and lamivudine in combinations, which includes spectrophotometric method[5], HPLC[6] spectrophotometric, first derivative of the ratio-spectra and high-performance liquid chromatography–UV methods[7]

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Spectrophotometry is the technique of choice even today in the laboratories of research, hospitals and pharmaceutical industries due to its low cost and inherent simplicity. This paper describes a simple rapid, sensitive and economical spectrophotometeric method for the determination of zidovudine in commercial dosage forms. The proposed method is based on the charge transfer reactions of zidovudine as *n*-electron donor with acceptor, 2,5-dichloro-3,6-dihydroxy-1,4-benzoquinone. The molecular interactions between electron donors and electron acceptors are generally associated with the formation of intensely colored charge-transfer complexes, which absorb radiation in the visible region The charge-transfer reaction has not been reported yet for zidovudine and therefore, the aim of the present study was directed to investigate this reaction.

EXPERIMENTAL

Apparatus

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

Chemical and reagents

All the solutions were freshly prepared. All solvents and other chemicals used through this study were of analytical grade. 2,5-Dichloro-3,6-dihydroxy-1,4-benzoquinone solution (0.1%) was used. Solution was freshly prepared in methanol and it was prepared afresh daily.

Preparation of standard solution

A standard stock solution containing 1 mg/mL was prepared by dissolving 50 mg of zidovudine in 50 mL of distilled water. From this, a working standard solution containing 100 μg/mL was prepared for the estimation in proposed method.

Assay procedure

Various aliquots of standard solution of zidovudine ranging from 0.2-1.0 mL were transferred into 10 mL calibrated flasks. To each flask, 1.0 mL of the acceptor solution was added, and the reaction was allowed to proceed at room temperature (25 ± 5^{o}C). The reaction was achieved instantaneously. The solutions were diluted to desired volume with distilled water. 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 20-100 μg/mL of zidovudine.

Pharmaceutical preparations

A total number of twenty tablets of zidovudine accurately weighed and powdered by a mortar and pestle. Tablet powder equivalent to 50 mg of zidovudine was accurately weighed and transferred to 50 mL volumetric flask. Weighed tablet powder is dissolved in 25 mL distilled water and shaken for 15 minutes. Then the volume was diluted to 50 mL with distilled water and mixed well. The solution was filtered through Whatmann filter paper No. 42, suitably diluted with distilled water and analyzed as given under the assay procedure for bulk sample. The results are represented in Table 2.

Recovery studies

To ensure the accuracy and reproducibility of the results obtained, known amounts of pure drug was added to the previously analysed formulated samples and these samples were reanalyzed by the proposed method. The recovery experiments were also performed. The percentage recoveries thus obtained are given in Table 2.

RESULTS AND DISCUSSION

The optimum conditions were established by varying one parameter at a time and keeping the others fixed and observing the effect on absorbance of chromogen**.** In the present work, a method has been developed for the estimation of zidovudine from tablet formulations. The developed method is based on the reaction of zidovudine as *n*-electron donor with acceptor, 2,5-dichloro-3,6-dihydroxy-1,4-benzoquinone. Statistical analysis was carried out and the results were found to be satisfactory. Recovery studies were close to 100 % that indicates the accuracy and precision of the proposed method. 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 the results are summarized. The percent relative standard deviation, standard deviation and student's 't' test values calculated from the five measurements of zidovudine are presented in Table 3. Relative standard deviation values and standard deviation were low that indicates the reproducibility of the proposed method. In the student's 't' test, no significant differences were found between the calculated and theoretical values of the proposed method at 95% confidence level. This indicated similar precision and accuracy in the analysis of zidovudine in its tablets.

Table 1: Optical characteristics of proposed method

Statistical parameters	Proposed method
λ_{max} (nm)	460
Beer's limits (μg/mL)	20-100
Sandell's sensitivity, (μg cm^{-2})	0.163
Molar absorptivity (L mol^{-1} cm^{-1})	1.6 x 10^3
Regression equation Y^* = a + bX	
Correlation coefficient (r)	0.999
Intercept (a)	0.006
Slope (b)	0.002

*Y = a + bX, where Y is the absorbance and X concentration in μg/mL
a = Intercept; b = Slope

Table 2: Assay and recovery of zidovudine in tablet formulations

Tablets	Labeled amount (mg)	*Amount found (mg) ± S.D*	% Recovery	% RSD*	*t value
Tablet 1	100	100.26 ± 0.52	100.1	0.5258	1.103
Tablet 2	100	99.92 ± 0.48	100.3	0.4819	0.7414
Tablet 3	300	300.02 ± 0.5	99.99	0.1699	1.754
Tablet 4	300	300.06 ± 0.23	100.6	0.0795	0.7497

*Average of five determinations based on label claim

CONCLUSION

The proposed method is simple, rapid, accurate, economical and can be used for routine determination of zidovudine in bulk samples and its formulations. The commonly used additives such as starch, lactose, titanium dioxide, and magnesium stearate do not interfere with the assay procedures.

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