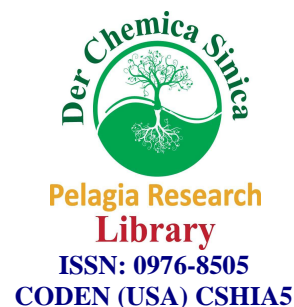




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Rapid RP-HPLC Method for Estimation of Zidovudine from Tablet Dosage Form

J.V. Manwar¹, B.V. Sonawane², S.V. Patil³ and S.P. Takle³

¹Department of Pharmaceutical Analysis, Institute of Pharmacy, Akola, India

²Department of Agricultural Biotechnology, Marathwada Agricultural University, Parabhani, India

³Department of Alcohol Technology, Vasantdada Sugar Institute, Manjari (Bk), Pune, India

ABSTRACT

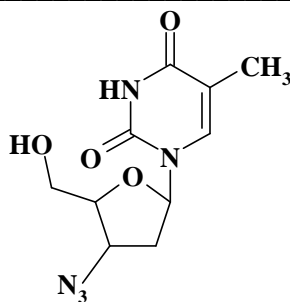
A new reverse phase HPLC method is developed for the rapid estimation of zidovudine, an antiviral agent from tablet dosage formulation. Standard solution of concentration 1 mg/mL was prepared in methanol. The analysis was carried out on a Nucleosil (4.6 mm I.D x 250 mm) C18 column using mobile phase Methanol. The flow rate was maintained at 1.0 ml/min. Detection was monitored at 267 nm. The retention time of drug was found to be 2.37 min. The validation of the proposed method was in terms of linearity and range, accuracy and precision. The drug showed the linear response over the concentration range from 400 to 1600 µg/mL. The percentage recovery obtained for drug from tablet formulation was 99.72 with relative standard deviation of less than 1%. Since the analysis is completed within 5 minute, the proposed method could be employed for routine analysis zidovudine from tablet formulation.

Key words: Zidovudine, RP-HPLC, Validation, Tablets

INTRODUCTION

Zidovudine (3'-Azido-3'-deoxythymidine) is the thymidine analogue, the prototype nucleoside reverse transcriptase inhibitors [1]. It is official in United States Pharmacopoeia, British Pharmacopoeia and European Pharmacopoeia [2-4]. It is used against human immunodeficiency virus (HIV-I and -II) and human T-cell lymphotropic virus (HTLV-I and -II) [5].

A literature survey shows that few analytical methods are available for the estimation of zidovudine and its major metabolites in biological fluids [6-9]. However, there are few methods for the determination of zidovudine in pharmaceutical dosage forms [10-12]. One reverse phase HPLC method is also reported for the estimation of zidovudine from tablet dosage form, which is more time consuming [13]. In present study, an attempt were made to develop alternative simple, rapid, accurate and precise Reverse phase HPLC method for the estimation of zidovudine from tablet dosage form.



Structure of Zidovudine

MATERIALS AND METHODS

Chemicals and reagent

Pure drug sample of Zidovudine was kindly supplied by the Cipla Pharmaceuticals Pvt. Ltd. India. HPLC grade methanol was purchased from Merck (Darmstadt, Germany). Drug product samples (tablet- Zidovir) were purchased from local pharmacy shop.

Standard Solution

An accurately weighed 100 mg of pure drug sample of zidovudine was dissolved in 100 mL of methanol with vigorous shaking. It was filtered through 0.45 μ membrane filter. Concentration of final solution is 1000 μ g/mL.

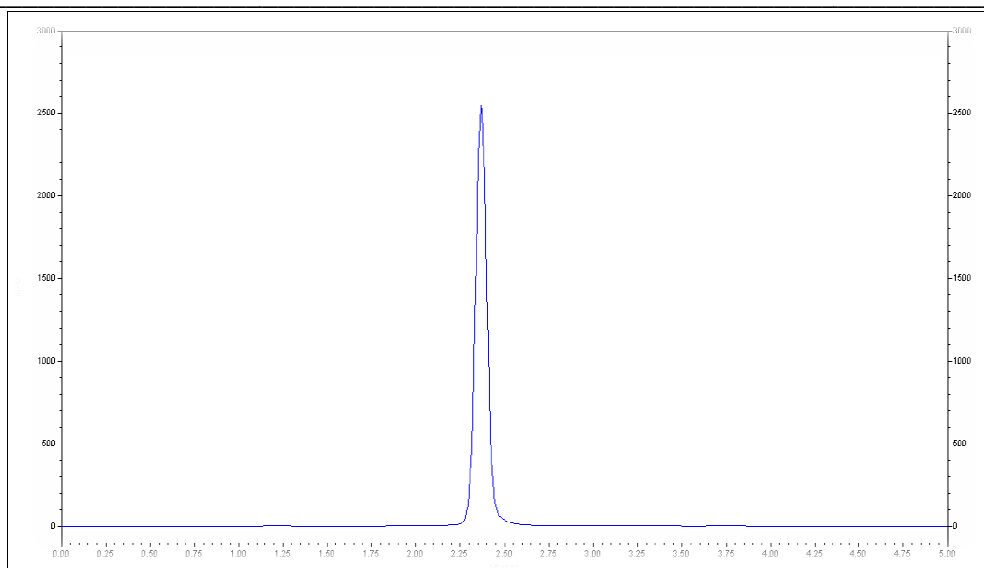
Chromatographic conditions:

The following Chromatographic conditions were maintained for analysis of drug throughout the experimental work.

System	:	The Agilent 1260 Infinity Quaternary LC System. HPLC
Column	:	Nucleosil (4.6 mm I.D x 250 mm) C18
Detector	:	Variable wavelength detector
Mobile phase	:	Methanol
Detection wavelength	:	267 nm
Mode	:	Isocratic
Sample size	:	5 μ L
Flow rate	:	1.0 ml/min.
Type of Injector	:	Auto injector system
Temperature	:	30°C

Selection of mobile phase

For the selection of mobile phase, various solvents individually and in combinations were tried and a mobile phase methanol alone was selected for study, as the drug was eluted within a time period of 5 minutes with sharp peak.

**HPLC chromatogram of zidovudine in pure drug sample**

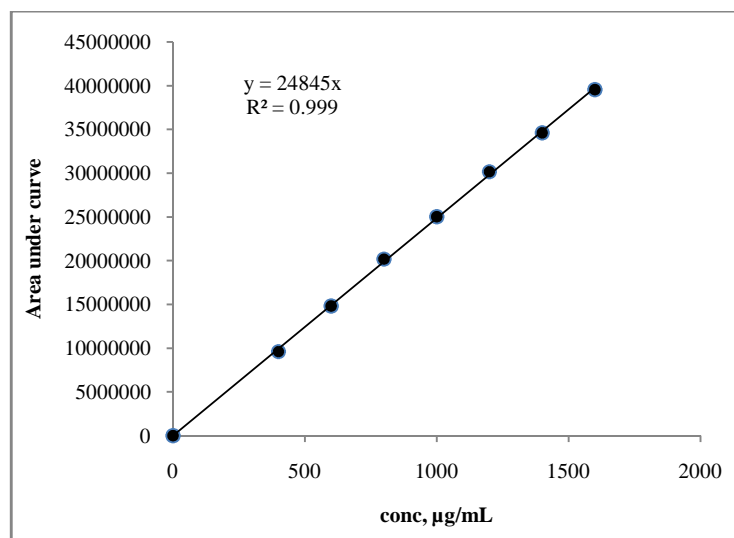
System suitability parameters

According to USP, system suitability tests were carried out on standard stock solution of zidovudine. About 5 μL of the solution was injected into the chromatographic conditions. Parameters studied to evaluate the suitability of system were retention time, area under curve, asymmetry, capacity factor and number of theoretical plates.

Table 1. Study of system suitability parameters

Sr. No.	Name	Mean*	RSD
1	Retention time	2.37	0.24
2	Area	24705920	0.02
3	Asymmetry (10%)	1.18	1.30
5	Capacity factor	46.39	0.21
6	Theoretical plates	6264	0.15

*Mean of three observations

**Linearity curve for zidovudine**

Linearity and Range

Linearity of the method was studied by injecting six concentrations of the drug prepared in the methanol in the range 400-1600 µg/ mL into the HPLC system by auto injector by keeping the injection volume constant (5 µL). The peak areas were plotted against the corresponding concentrations to obtain the calibration graphs. The results are given in **Table 2**.

Table 2. Linearity and range study

Sr. No.	Name	Result
1	Range	3-8 mg/mL
2	Coefficient of correlation	0.999

Assay of tablets

Ten tablets of zidovudine were weighed and crushed to fine powder. On the basis of labelled claim, powder equivalent to 50 mg of zidovudine was taken in 50 ml volumetric flask and was dissolved in about 20 ml methanol. The flask was shaken for 10 minutes and final volume was made up to 50 ml with methanol. The solution was then filtered through 0.45µ membrane filter and filtrate was used for analysis.

Method

The above mentioned chromatographic conditions were set and mobile phase was allowed to equilibrate with the stationary phase as indicated by steady base line. About 5 µL of each standard and sample solution were injected separately by auto injector and the chromatograms were recorded. The retention time for zidovudine was found is 2.37 min. From the corresponding areas obtained in standard and sample chromatograms, the amount of drug was calculated. The results of analysis of tablet formulations are given in **Table 3**.

Recovery

To study the accuracy and precision of the proposed method, recovery study was carried out by addition of standard drug solutions (30%) to preanalysed sample. Results of recovery studies are shown in **Table 3**.

Table 3. Analysis of Zidovudine tablet formulation

Sample	%Drug estimated		%Recovery	
	Mean	%RSD	Mean	%RSD
Zidovir	99.72	0.103	99.35	0.951

**Mean of four observations*

RESULTS AND DISCUSSION

The mobile phase methanol was selected because it was found to give sharp peaks of zidovudine with less retention time of 2.37 min. Wavelength was selected by scanning standard solution of drugs over 200 nm to 400 nm. The compound show good response at 267 nm. The low value of standard deviation indicates system suitability parameters are stable over the given chromatographic conditions. The value of coefficient of correlation reflects the method is linear over the concentration range of 400-1600 µg/mL. The percentage recovery of drug from formulation, close to 100%, and its low percent relative standard deviation values, indicates a high accuracy of the method.

CONCLUSION

The proposed RP-HPLC method is simple, sensitive, precise and accurate. Since the analysis is completed within 5 minutes, it clearly indicates that the method is rapid and thus it could be for routine analysis of zidovudine from bulk drug and its tablet dosage forms.

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