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Research Article

DETERMINATION OF ZIDOVUDINE IN TABLET DOSAGE FORM BY USING RP-HPLC

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ABSTRACT

A simple and cost effective, fast and precise reverse phase high performance liquid chromatographic method is described for the determination of Zidovudine in pure form and in pharmaceutical formulations. This method based on using a Luna 5µ C_{18} column, the size of coloum is 5 micron, 250 * 4.60 mm from phenomenex .The using a mobile phase is Acetonitrile: water (0.02M sodium dihydrogen orthophosphaste) the ratio of mobile phase is 70:30 v/v. the flow rate 1 m.l / min, and effluent was monitored at 270 nm. The elution time was 4.5 min. The linearity rang was 10-60 µ/ml for Zidovudine.

Key words: Zidovudine, RP- HPLC, C_{18}, Tablet.

INTRODUCTION

Zidovudine (Fig.1) is chemically as 3'-Azido-3'-deoxythymidine [1]. Antiretroviral drugs like nucleoside reverse transcriptase inhibitors, non nucleoside reverse transcriptase inhibitors, and protease inhibitors are essential in the management of HIV infection. The synthetic nucleoside reverse transcriptase inhibitor analogues abacavir, lamivudine and zidovudine form one of the fixed dosage combinations used in the effective management of HIV [2-3]. A literature survey reveals the report of a few analytical methods for the determination of these drugs individually in serum samples and in their dosage forms. Methods for the simultaneous determination of lamivudine and zidovudine in biological samples and in pharmaceutical preparations were also reported [4-7]. Reported methods involved complicated time-consuming multi-step liquid-liquid extraction techniques. To the best of our knowledge, there is no work in the literature reported about the estimation of Zidovudine from pharmaceutical formulation by using RP-HPLC. The purpose of this investigation was to development of a rapid, sensitive and validated HPLC method for quantification of Zidovudine from tablets forms.

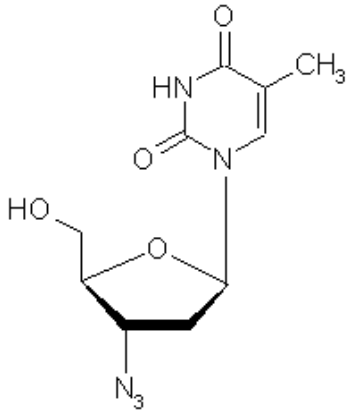

Fig.1 Chemical structures of Zidovudine

MATERIALS

Standard Efavirenz was obtained from Aurobindo Pharm, Hyderabad. Potassium dihydrogen phosphate AR, sodium dihydrogen orthophosphaste AR grade and methanol of HPLC grades were supplied by S.D Fine Chemicals, Mumbai. Water HPLC grade was obtained from a milli-QRO water purification system.

A gradient high-pressure liquid chromatography (Shimadzu HPLC Prominence UFLC Series) with LC-20AT Prominence Pumps, variable wavelength programmable UV/Vis SPD-20A Prominence Detector, SIL-20 AC HT/ Prominence UFLC auto Sampler (Shimadzu) and operating software LC Lab Solution. The method was carried on a Phenomenex Luna 5µ C_{18} (250 * 4.60 mm i.d, 5µ) column as a stationary phase. The mobile phase consisted of 0.02M potassium di hydrogen phosphate salt as aqueous phase and acetonitrile. The mobile phase was filtered through a 0.45 µ membrane filter and degassed before analysis. Acetonitrile and aqueous phase in the ratio of 70:30 v/v as the mobile phase flow rate of 1 ml/min. A SIL-20 AC HT/ Prominence UFLC auto Sampler used for the injection of sample. Detection was done at 270 nm and separation was carried out at the room temperature of about 20°.

METHOD

Standard stock solution of the drug was prepared by dissolving 25 mg of Zidovudine in a mixture of methanol: water (1:1 v/v) and made up to with 25 ml with the same (1000 µg/ml). Working standard solution was prepared by diluting 1 ml of the stock solution to 10 ml with methanol: water (1:1 v/v) (100µg/ml). The gradient dilution were prepared by taking 1, 2, 3, 4, 5 and 6 ml of solution and made up to 10 ml with methanol: water (1:1 v/v) solution. Twenty micro liter of the solution from each flask to use for experiment. Calibration curve was constructed by plotting mean peak area against the corresponding drug concentration (fig.2). The detector response was found to be liner in the concentration range of 10-60 µ/ml (Table 1). The typical chromatogram of Zidovudine drug solution shows fig.3. Calibration curves could be represented by the following equation y=46135x-32099 (R^2=0.9972) this equation was used for the determination of Zidovudine from tablets.

Y=46135x-32099 (R^2=0.9972)

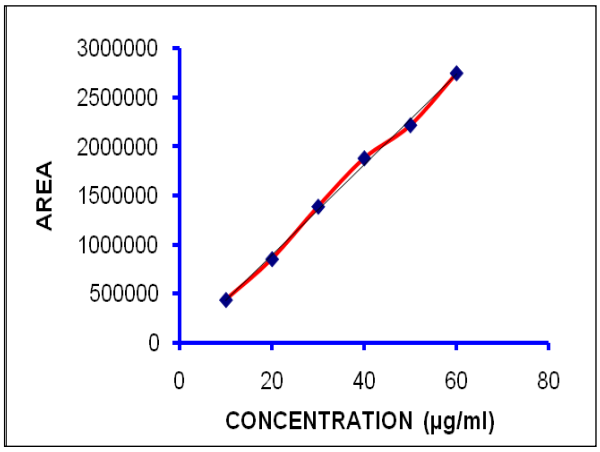

Fig. 2: Zidovudine Standard plot (Concentration vs Area)

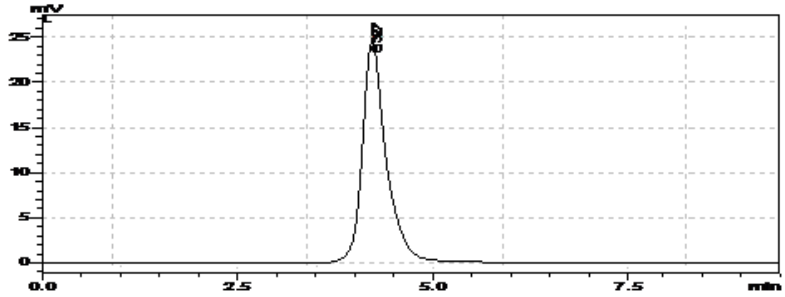

Fig. 3: Chromatogram of Zidovudine drug solution

Table 1: detector response (concentration vs area)

Concentration(µg/ml)	1	2	3	Average Area
10	431309	431937	432003	431750
20	851671	847982	844294	847982
30	1385188	1384692	1378806	1382895
40	1874268	1877546	1877565	1876460
50	2213812	2216498	2209889	2213400
60	2749339	2736797	2743524	2743220

For the estimation of drug from commercial formulation, 20 tablets of two brands- Zidovir Tablets 300 mg (Cipla Limited, Goa.) and Zidovudine Tablets 60mg (Aurobindo Pharm, Hyderabad) of Zidovudine, were powdered finely. A quantity equivalent to 25 mg was transferred in to 25 ml volumetric flask, dissolved and made up to acetonitrile: water (1:1 v/v) solution. The solution filtered through a 0.45 µ membrane filter. One milliliter of the resulting solution was then diluted to 10 ml with an about used solution. From this 0.5 and 1 ml sample was taken and their volume was made up to 10 ml each.

RESULTS & DISCUSSION

A chromatogram of these solutions was obtained by injecting 20 µl of each sample in to the chromatographic system (fig. 4). There was no interference from diluents and lubricants. The retention time of the drug was 4.5 min. chromatographic parameters such as peak asymmetry (A) and capacity factor (k) were found to be 1.09 and 0.75 respectively. To study the accuracy, reproducibility, precision of the proposed method and l recovery experiments were carried out. A fixed amount of the pre analyzed sample was taken and standard were added at three different levels. Each level was repeated at five times. The summaries of recovery studies are reported in Table 2. The present study comprises a high performance liquid chromatography method to determine Zidovudine from tablet dosage form. Experiment was carried out to establish the method. The mobile phase, bearing acetonitrile: buffer in proportion of (70:30) was found to be idle. The retention time of Zidovudine were found 4.5 min. the value of percent recovery and standard deviation indicate that method is accurate, reproducible, and precise. The summaries of final result are illustrated in Table 3.

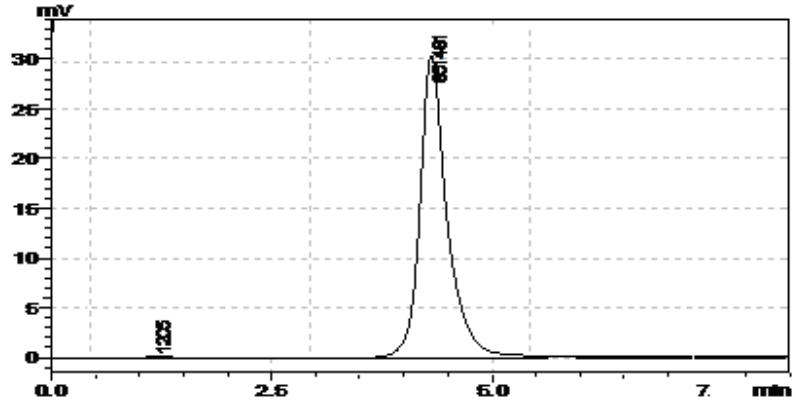

Fig. 4: Chromatogram of the sample tablet solution.

Table 2: Summary of recovery studies.

Drug Zidovudine	Label Claim tablet (mg)	Amount Found(mg)	Recovery studies		
			Amount added(mg/ml)	Amount recovery(mg/ml)	Percentage Recovery (%)
Tablet A	10	9.95±0.025	5	14.9±0.05	99.6
			10	20.5±0.11	101.5
Tablet B	10	9.98±0.025	5	15.1±0.11	100.6
			10	19.7.2±0.11	99.8

Tablet-A is Zidovir Tablets 300 mg (Cipla Limited, Goa.) and Tablet B is Zidovudine Tablets 60mg (Aurobindo Pharm, Hyderabad.)

Table 3: Summaries of final result

Brand Name	Amount Found (mg/Tablet)	% RSD	Percentage Assay
Zidovir Tablets 300 mg (Cipla, Goa.)	10.01±0.025	0.249	100.1
Zidovudine Tablets 60mg (Aurobindo Pharm, Hyderabad.)	9.92±0.025	0.231	99.2

ACKNOWLEDGEMENTS

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REFERENCES

1. Martindale, The complete drug reference. 36th edition, Pharmaceutical press, Lambeth High Street, London; 2009. p. 913-916.
2. Sweetman S C, Martindale, the Complete Drug Reference, 33rd Ed., London, Pharmaceutical Press, 2002.
3. Montvale, N J, Physician's Desk Reference, 56th Ed., Montvale, Medical Economics Company Inc, 2003.
4. Indian Pharmacopoiea 1996 (Addendum 2002), Govt. of India, Ministry of Health and Family Welfare. Delhi, Controller of Publications, 2002.
5. Uslu B and Ozkan S. Anal Chem Acta; 2002, 59,175-182.
6. Moore J D, Valette G, Darque A , Zhou X J and Sommadassi J P, J Am Soc Mass Spectrom; 2000, 11,1134.
7. Kenney K B, Wring S A, Carr R M, Well GN and Dunn J A. J Pharm Biomed Anal; 2000, 22, 967.