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VALIDATED SPECTROPHOTOMETRIC ESTIMATION OF DIDANOSINE IN BULK AND TABLET DOSAGE FORM

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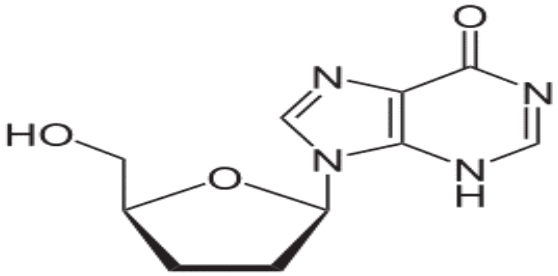
ABSTRACT
A novel, simple, accurate and precise Zero order derivative spectroscopic method was developed and validated for the estimation of Didanosine in bulk and Pharmaceutical dosage forms and has an absorption maximum at 243 nm in 0.1 N H_2SO_4. The Linearity was found to be in the concentration range of 5-30µg/ml and the correlation coefficient was found to be 0.999 and it has showed good linearity, reproducibility, precision in this concentration range. The regression equation was found to be Y = 0.019 X + 0.002. The % recovery values were found to be within 99.89-100.45 % showed that the method was accurate. The LOD and LOQ were found to be 0.2032 and 0.6096 µg/ ml, respectively. The % RSD values were less than 2. The present methods were accomplish the validation parameters according to ICH guidelines like accuracy, precision, linearity, range, ruggedness, limit of detection and limit of quantization. The developed method was successfully applied for the quantitative estimation of Didanosine in bulk and pharmaceutical dosage forms.

KEYWORDS: Didanosine, Zero Order Derivative Spectroscopy, 0.1N H_2SO_4, Linearity, Precision, Reproducibility and Accuracy.

INTRODUCTION
Didanosine is used for the treatment of infection with the human immunodeficiency virus (HIV). It is in class of drug called "reverse transcriptase inhibitor.[1] It works by decreasing the amount of HIV in the blood. It is used in combinations with other medication as part of higly active antiretroviral therapy.[2]



Chemical structure of Didanosine.

DDI is chemically9-[(2R,5S)-5-(hydroxymethyl) oxolan-2-yl]-6, 9-dihydro-3H-purin-6-one. It has a molecular formula of $C_{10}H_{12}N_4O_3$ and molecular weight of 236.22728 g/mol. It has the structural formula (Fig.1). DDI is a white crystalline powder which Sparingly soluble in water; slightly soluble in methanol and ethanol,Soluble in dimethylsulfoxide.

Literature Survey revealed that the drug has been estimated by UV spectrophotometric, HPLC, and HPTLC method has been reported so far.

The aim of present work was to develop and validate a novel, rapid, simple, precise, and specific Zero order derivative UV-Spectrophotometric method for estimation of Didanosine in its bulk and tablet dosage form.

MATERIALS AND METHOD
Instrument: UV-Visible double beam spectrophotometer, SHIMADZU (model UV-1800) with UV probe software. All weights were taken on analytical balance.

Chemicals: Didanosine pure form was obtained as gifted sample from pharma industry and its pharmaceutical dosage form videx 30 Tablets labelled claim 400 mg were purchased from local pharmacy manufactured by CIPILA LTD.

Solvent: 0.1N H_2SO_4, (prepared by dissolving 2.75ml in 1000ml of distilled water).

Selection of analytical wavelength: Appropriate dilutions were prepared for drug from the standard stock solution and the solution was scanned in the wavelength

range of 200-400 nm. The absorption spectra thus obtained were derivatized from Zero order method. It shows maximum absorbance at 243 nm was showing in Fig.1. And Zero order overlain spectra of Didanosine at 243 nm were shown in Fig.2.

Preparation of Standard stock solution: Accurately weigh 100mg of Didanosine was transferred into 100ml volumetric flask and diluted with 0.1N H_2SO_4 up to the mark. From this pipette out 10ml into 100ml volumetric flask and diluted with0.1N H_2SO_4 up to the mark, from this solution pipette out 0.5,1.0,1.5,2.0,2.5, and 3.0ml into 10ml individual volumetric flask and add 0.1N H_2SO_4 up to the mark , this gives 5,10,15,20,25, and 30µg/ml concentrations.

Preparation of Sample solution: Twenty tablets were weighed and powdered, the tablet powder equivalent to 100mg of Didanosine was transferred into100ml volumetric flask then it was diluted with 0.1NH_2SO_4 and made up to mark and the solution was filtered through Whatmans filter paper no.41. From this pipette out 10 ml in a 100ml volumetric flask and make up the volume up to the mark with 0.1NH_2SO_4. From this solution pipette out 0.6 ml into 10ml volumetric flask and make up the volume with 0.1NH_2SO_4, this gives 6µg/ml concentrations.

Method validation: The method is validated according to the ICH guidelines.

RESULTS AND DISCUSSION

Method: Zero order derivative spectroscopy.

Linearity: The working standard solution were diluted serially with 0.1N H_2SO_4 to obtain the range of 5-30µg/ml. a calibration curve for Didanosine was obtained by measuring the absorbance at the λmax of 243nm and absorbance values are shown in Table.1 and Calibration graph were presented in Fig.3. Statistical parameters like slope, intercept, coefficient of correlation, and Sandel sensitivity were determined and presented in Table.2.

Precision: Precision of the method was studied as intra-day and inter-day precision. Intra-day precision was determined by analyzing the 5, 10, 15, 20, 25 and 30µg/ml concentration for three times in same day. Inter-day precision was determined by analyzing the same concentration of solution daily for three days. Precision results are shown in Table. 3.

Accuracy: To assess the accuracy of the proposed method, recovery studies were carried out at three different levels i.e, 50%, 100% and 150%. In which the formulation concentration was kept constant and varied pure drug concentration. Accuracy results were shown in Table.4.

Ruggedness: Ruggedness was determined between different analysts. The value of %RSD was found to be less than 2 were shown in Table.5.

Limit of Detection and Limit of Quantitation: The LOD and LOQ of the present method were calculated based on standard deviation of the Response and slope of linearity curve. LOD and LOQ values of Didanosine were found to be 0.2032µg/ml and 0.6096µg/ml.

Table. 1: Results of calibration curve at 243nm by zero order Spectroscopy.

Sl. No.	Concentration in µg/ml.	Absorbance± Standard deviation
1	5	0.106±0.00147
2	10	0.205±0.00274
3	15	0.287±0.00082
4	20	0.386±0.00266
5	25	0.496±0.00197
6	30	0.594±0.00216

Table. 2: Regression parameters for Didanosine by zero order spectroscopy.

Regression Parameters	Didanosine
Range	5-30
λMax	243nm
Regression Equation	Y=0.019x+0.002
Slope (b)	0.019
Intercept(a)	0.002
Correlation coefficient (r^2)	0.999
Sandell s Sensitivity	0.0504

Table. 3: Determination of precision results for Didanosine at 243 nm by zero order derivative spectroscopy.

Concentration (µg/ml)	Intra-day Absorbance ±SD**	%RSD	Inter-day Absorbance ±SD**	%RSD
5	0.106±0.00115	1.084	0.110±0.002	1.818
10	0.203±0.00208	1.024	0.208±0.00306	1.471
15	0.286±0.00058	0.202	0.288±0.00115	0.399
20	0.386±0.00208	0.538	0.388±0.0052	1.340
25	0.496±0.00231	0.465	0.492±0.00173	0.351
30	0.595±0.00208	0.349	0.593±0.001	0.168

Table. 4: Determination of accuracy results for Didanosine by Zero order derivative spectroscopy.

Spiked Levels	Amount of sample (µg/ml)	Amount of Standard (µg/ml)	Amount Recovered	%Recovery ±SD**	%RSD
50	10	5	15.00	100.047±0.891	0.8906
100	10	10	19.97	99.89±0.1.034	1.03513
150	10	15	25.11	100.45±0.992	0.9875

**Average of six determinations

Table. 5: Ruggedness results at 243 nm by Zero order Spectroscopy.

Analysts	Analyst-1	Analyst-2
Mean absorbance	0.385	0.388
Standard deviation	0.00234	0.00248
%RSD	0.6077	0.6391

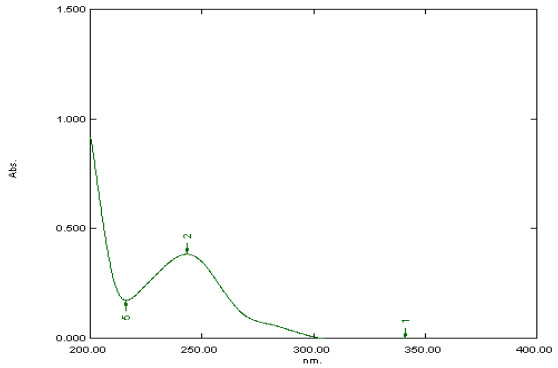


Fig. 1: Zero order spectra of Didanosine showing absorbance at 243nm

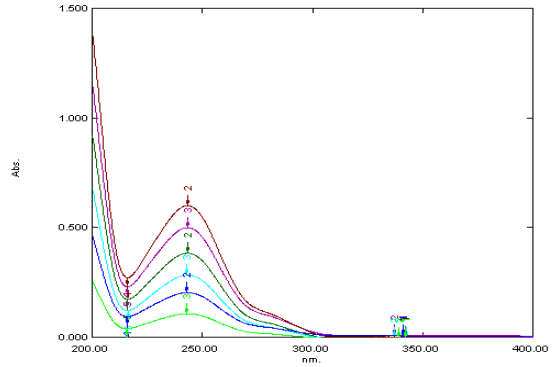


Fig. 2: Zero order overlain spectra of Didanosine showing absorbance at 243nm.

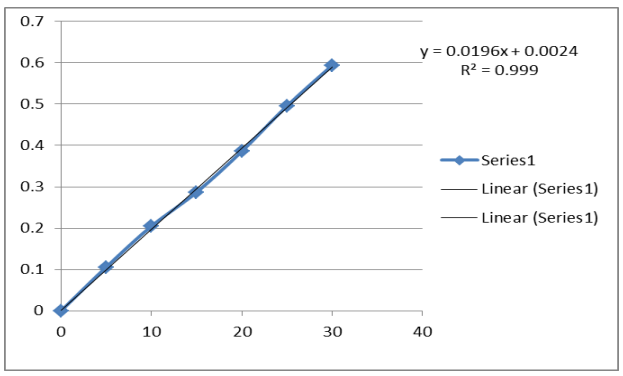


Fig. 3: Linearity curves for Didanosine at 243nm by zero order Spectroscopy.

CONCLUSION

Thus,The main advantage of the proposed method is its suitability for routine estimation of Didanosine in bulk and pharmaceutical dosage form, the developed spectrophotometric method was found to be easy, simple, accurate, precise, selective, economical and shows the good linearity.

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