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Original Article

Analytical Method Development and Validation of Abacavir in Pure and Pharmaceutical Dosage Forms by Using UV- Spectrophotometric Method

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ABSTRACT

A novel, simple, accurate and precise Zero order derivative spectroscopic method was developed and validated for the estimation of Abacavir in bulk and pharmaceutical dosage forms and has an absorption maximum at 296 nm in 0.1 N HCl. The Linearity was found to be in the concentration range of 2-16µg/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 = 0.045 X + 0.006. The % recovery values were found to be within 99.61-99.92 % showed that the method was accurate. The LOD and LOQ were found to be 0.1281 and 0.3843 mcg/ ml, respectively. The % RSD values were less than 2. The present methods were accomplishing the validation parameters according to ICH guidelines like accuracy, precision, linearity, range, ruggedness, limit of detection and limit of quantization etc. Proposed method was successfully applied for the quantitative estimation of Abacavir in bulk and pharmaceutical dosage forms.

Key words: Abacavir, zero order derivative Spectroscopy, 0.1N HCl, Linearity, Precision, Reproducibility and Accuracy.

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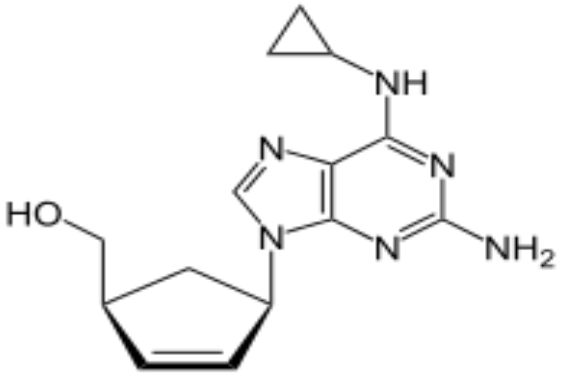
INTRODUCTION

Abacavir (ABC) is a medication used to prevent and treat HIV/AIDS. Similar to other nucleoside reverse transcriptase inhibitors (NRTIs), Abacavir is used together with other HIV medications, and is not recommended by itself. It is taken by mouth as a tablet or solution and may be used in children over the age of three months. Abacavir is a carbocyclic nucleoside[1].



Chemical structure of Abacavir

Abacavir is chemically {(1*S*,4*R*)-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl] cyclopent-2-en-1-yl}methanol. It has a molecular formula of $C_{14}H_{18}N_6O$ and molecular weight of 286.332 g/mol. It has the structural formula (Fig.1).Abacavir is a White to off-white solid. Which is freely soluble in distilled water, 0.1 N HCl, slightly soluble in Methnol & Ethanol. 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 Abacavir in its bulk and tablet dosage form.

MATERIALS AND METHODS

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

Chemicals: Abacavir pure form was obtained as gifted sample from pharma industry and its pharmaceutical dosage form Ziagen 30 Tablets labelled claim 300 mg were purchased from local pharmacy manufactured by STRIDES SHASUN LTD.

Solvent: 0.1N HCl (prepared by dissolving 8.5ml 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 296 nm was showing in Fig.1. And Zero order overlain spectra of Abacavir at 296 nm were shown in Fig.2.

Preparation of Standard stock solution: Accurately weigh 100mg of Abacavir was transferred into 100ml volumetric flask and diluted with 0.1N HCl up to the mark. From this pipette out 10ml into 100ml volumetric flask and diluted with 0.1N HCl up to the mark, from this solution pipette out 0.2,0.4,0.6,0.8,1.0,1.2,1.4 and1.6ml into 10ml individual volumetric flask and add 0.1N HCl up to the mark , this gives 2,4,6,8,10,12,14 and 16 μg/ml concentrations.

Preparation of Sample solution: Twenty tablets were weighed and powdered, the tablet powder equivalent to 100mg of Abacavir was transferred into100ml volumetric flask then it was diluted with 0.1NHCl 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 0.1N HCl. From this solution pipette out 0.6 ml into 10ml volumetric flask and make up the volume with 0.1N HCl, 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 HCl to obtain the range of 2-16μg/ml. a calibration curve for Abacavir was obtained by measuring the absorbance at the λmax of 296nm 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 2, 4, 6, 8, 10, 12, 14 and 16μg/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 Abacavir were found to be 0.1281µg/ml and 0.3843µg/ml.

CONCLUSION

Thus, The main advantage of the proposed method is its suitability for routine estimation of Abacavir 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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Table.1: Results of calibration curve at 296nm by zero order Spectroscopy.

Concentration in µg/ml.	**Absorbance± Standard deviation**
2	0.103±0.001214
4	0.193±0.000816
6	0.278±0.001247
8	0.278±0.00216
10	0.373±0.003859
12	0.562±0.004546
14	0.644±0.000816
16	0.735±0.000816

Table 2: Regression parameters for Abacavir by zero order spectroscopy

Regression Parameters	**Abacavir**
Range	2-16
λMax	296nm
Regression Equation	Y=0.045x+0.006
Slope (b)	0.045
Intercept(a)	0.006
Correlation coefficient (r2)	0.999
Sandell s Sensitivity	0.0194

Table.3: Determination of precision results for Abacavir at 296 nm by zero order derivative spectroscopy.

Concentration (µg/ml)	**Intra-day Absorbance ±SD****	**%RSD**	**Inter-day Absorbance ±SD****	**%RSD**
2	0.109±0.000816	0.740	0.103±0.000816	0.792
4	0.199±0.001247	0.626	0.217±0.002055	0.947
6	0.292±0.001633	0.559	0.312±0.001633	0.523
8	0.369±0.001247	0.337	0.412±0.00216	0.524
10	0.482±0.002055	0.426	0.517±0.001247	0.241
12	0.606±0.00555	0.917	0.626±0.0017	0.271
14	0.700±0.00262	0.375	0.719±0.001414	0.196
16	0.790±0.00758	0.960	0.812±0.001247	0.153

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

Spiked Levels	Amount of sample (µg/ml)	Amount of standard (µg/ml)	Amount Recovered	%Recovery ±SD**	%RSD
50	6	3	8.96	99.61±0.2843	0.2854
100	6	6	11.99	99.92±0.2405	0.2406
150	6	9	14.95	99.7±0.3741	0.3752

**Average of six determinations

Table.5: Ruggedness results at 296 nm by Zero order Spectroscopy

Analysts	Analyst-1	Analyst-2
Mean absorbance	0.790	0.812
Standard deviation	0.00758	0.001247
%RSD	0.960	0.153

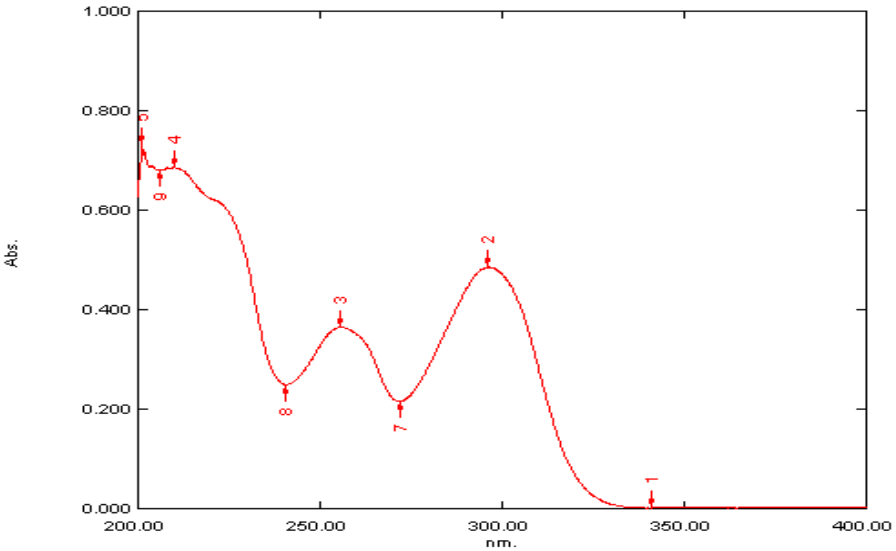

Fig.1: Zero order spectra of Abacavir showing absorbance at 296nm

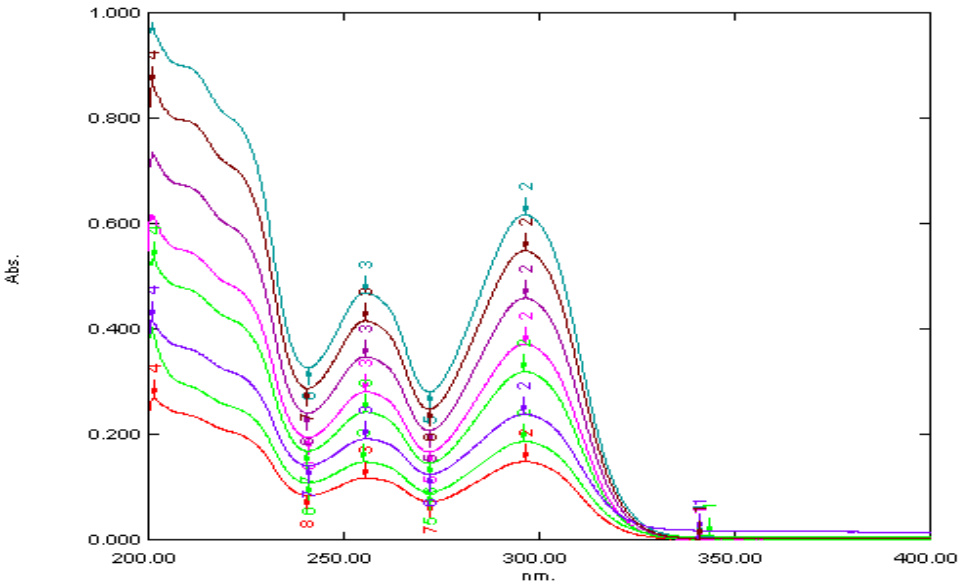

Fig.2: Zero order overlain spectra of Abacavir showing absorbance at 296nm

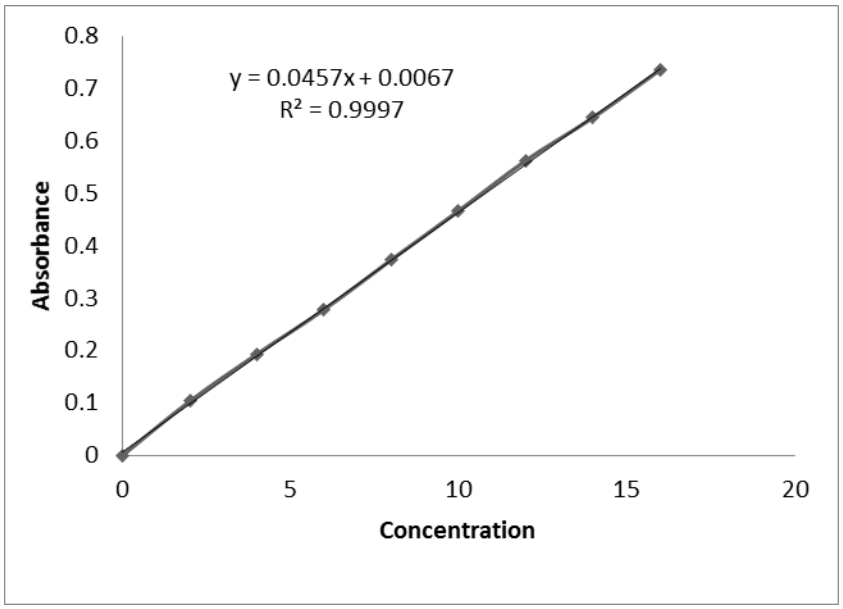

Fig.3: Linearity curves for Abacavir at 296nm by zero order Spectroscopy

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