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[Research article]

DEVELOPMENT AND VALIDATION OF UV-SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF ABACAVIR SULFATE NANOPARTICLES.

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ABSTRACT

A simple, precise and accurate spectrophotometric method has been developed for the determination of Abacavir Sulfate nanoparticles. Standard Stock solution was prepared in pH 7.4 phosphate buffer and further dilution were carried out with the same. The λmax of Abacavir Sulfate nanoparticles was found to be 285 nm. The A (1%, 1cm) Value of Abacavir Sulfate nanoparticles was found to be 434. The correlation co efficient (r) was found to be 0.9999. The limit of detection (LOD) and limit of Quantification (LOQ) was found to be 0.1074 µg/ml and 0.3257 µg/ml respectively for Abacavir Sulfate nanoparticles. The result of estimation in Abacavir sulfate nanoparticles was found to be 99.62 ± 0.25%. The method was then validated statistically as per KH guidelines, which yielded good results concerning range, linearity, precision, accuracy specifically, Robustness and Ruggedness.

KEYWORDS: Abacavir Sulfate, Nanoparticles, Spectrophotometry estimation.

INTRODUCTION

Abacavir Sulfate is a nucleoside reverse transcriptase inhibitor (nrti) with activity against Human Immuno deficiency virus type 1 (HIV-1) and it is chemically {(S, 4R)-4-[2-amino-6-(Cyclopropylamino) 9H-purine-ayl] cyclopent-2-enyl} methanol Sulphate. There are number of analytical methods have been evoked for the estimation of Abacavir Sulfate either individually or combination with other antiviral agents in HPLC, literature survey didn't reveal any spectrophotometric method for estimation of Abacavir Sulfate nanoparticles, In this present investigation to develop a simple, rapid, precise and accurate, Robustness and Rugged of Abacavir sulfate nanoparticles.

Materials and Methods

Pure drug as obtained from Ranbaxy Chemical Guargon (India) as a gift sample pH 7.4 phosphate buffer are used entire the experiments. Shimadzu 1700, a double beam UV- spectrophotometer with 1cm matched Quartz cell were used for the measurement of absorbance. Shimadzu electronic balance was used for weighing the samples.

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Procedure

Preparation of standard solution (500 µg/ml) was prepared in ph 7.4 phosphate suffer. From the stock solution, working standard solution (10 ms/ml) was prepared by appropriate dilution with ph 7.4 phosphate buffer was determination of λmax and a (1% 1 cm) value. Working standard solution of Abacavir sulfate nanoparticles was scanned in the entire UV range of 200-400nm. The stability studies data were recovered at 1 hr 80 min. the λmax and (A1% 1cm) of Abacavir sulfate nanoparticles were found to be 285 nm and 434 respectively.

Preparation of calibration curve

Standard stock solution prepared in pH 7.4 phosphate buffer to obtained concentration ranging from 5-30 µg/ml. Absorbance of this solution were measured at 285 nm. Absorbance was plotted was plotted versus concentration to obtained calibration graph. From the calibration curve, the linearity range was found to out and LOD and LOQ values.

Analysis of the Nanoparticles formulations

Ten Capsules were weighted and average weight was determined. The average weight were found and remove the capsule shell and the powdered nanoparticles equivalent to among of Abacavir Sulfate into a 50ml volumetric flask, added 10ml of pH 7.4 phosphate buffer and sonicated for 15 min, then shaken vigorously for few min and produced to 50 ml with pH 7.4 phosphate buffer and filtered through Whatmann's filter paper No.41. from the filtrate, pipetted out 3 ml and transferred into 50 ml flask in some directions for six times.

Recovery studies

To the pre analyzed sample with excipients, a known quantity of standard solution was added. The content were mixed, finally made up to the volume with pH 7.4 phosphate buffer. Absorbance was measured at 274 nm and the amount present was calculated by using the slope and intercept.

Limit of Detection (LOD) and Limit of Quantification (LOQ)

Preparation of Calibration curve from the serial dilution of the standard was repeated for six times, the limit of detection and limit of Quantification was calculated by using the average values of slopes and standard deviations of intercept.

Repeatability

Repeatability is performed by inter day and intra day precision analysis. The assay and recovery procedures were repeated for three times on the some day and one time on three successive days.

Results and Discussion

The λmax of Abacavir Sulfate nanoparticles was found to be 234 nm from is spectrum. The A (1% 1cm) value was found to be 434 nm Abacavir Sulfate nanoparticles showed linear absorption from 5- 30 µg/ml. The correlation co efficient (r) was found to be 0.9999. The LOD and LOQ values were determined from the slope of linearity plot and standard derivation of y-intercept and found to be 0.1074µg/ml and 0.3257µg/ml respectively. The optical characteristics like correlation coefficient, slope, intercept, Sandell's sensitivity, LOD and LOQ were calculated.

Those are shown in Table. 1. The stability of solutions of formulations was determined by measuring the absorbance at 284nm at periodic intervals. There was no considerable change in the absorbance at this wave length up to 1hr 20 mins indicating that the solutions was stable for at least 1hr 20mins. The nanoparticles formulations were carried out and the mean assay values was found to be 99.62±0.25%. These are shown in Table 2.

The corresponding RSD values were found to be 0.76% indicating that the method has required precision. The accuracy of the Method was determined by recovery studies. The Mean recovery for Abacavir sulfate nanoparticles was found to be 100.38 ± 0.29% indicating that the method has required accuracy. The validation results are given in Table -3.

A new analytical method was developed and validated. The estimation of Abacavir Sulfate nanoparticles was achieved by U.V. method, after considering the solubility and stability, phosphate buffer pH 7.4 was selected as solvent and the 284nm was selected wave length for analysis.

Table 1: Optical characteristics of Abacavir sulfate by UV Spectroscopic method

S.NO	PARAMETERS	METHOD
1	λ max (nm)	285
2	Beers law limit (µg/ml)	4-24
3	Correlation coefficient (r)*	0.9999
4	Regression equation (y=mx+c)	0.04709+0.0002797
5	Slope (m)	0.04709
6	Intercept (c)	0.0002797
7	LOD (µg/ml)	0.1074
8	LOQ (µg/ml)	0.3257
9	Sandell's sensitivity (µg/cm^2/0.001 A.U)	0.021313
10	Standard Error of Mean	0.003886

*Average of six determinations

Table 2: Quantification of formulation - (Abacavir sulfate)

S.No	Labeled Amount (mg)	Amount Found (mg)	Percentage Obtained (%)	Percentage Found*	S.D. (+/-)	% R.S.D	S.E
1	50	49.93	99.87	99.62%	0.769225	0.77218	0.021367
2	50	50.25	100.51				
3	50	48.09	98.18				
4	50	49.83	99.66				
5	50	49.87	99.74				
6	50	49.87	99.74				

* Average of Six determinations

Table 3: Recovery studies for formulation - (Abacavir sulfate)

S.No	Amount Present (µg/ml)	Amount Added (µg/ml)	Amount Estimated (µg/ml)	Amount recovered (µg/ml)	Percentage recovered (%)	Average percentage recovery*
1	12.45	2	14.47	2.02	101	100.38%
2	12.45	4	16.39	3.94	98.50	
3	12.45	6	18.48	6.03	100.50	
4	12.45	8	20.52	8.07	100.80	
5	12.45	10	22.55	10.05	100.50	
6	12.45	12	24.58	12.13	101.08	

* Values are mean of Six observations

Conclusion

Thus, the development method is simple, accurate, precise and cost effective. Hence, it can be used for routine analysis of Abacavir sulfate nanoparticles in pharmaceutical preparation.

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