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SIMULTANEOUS SPECTROPHOTOMETRIC ESTIMATION OF ABACAVIR SULFATE AND LAMIVUDINE IN TABLET DOSAGE FORM BY Q-ANALYSIS METHOD

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KEYWORDS :

Simultaneous Spectrophotometric Estimation of Abacavir sulfate and Lamivudine in Tablet Dosage Form by Q-Analysis method or Absorbance ratio method Simple, accurate and economic method Q-Analysis has been described for the simultaneous estimation of Abacavir and Lamivudine in tablet dosage form. Abacavir shows absorption maximum at 284.0nm and Lamivudine shows absorption maximum at 270.0nm in distilled water. Beers law was obeyed in the concentration range of 5-30 µg/ml for Both Abacavir and Lamivudine. The coefficient correlations were found to be 0.9995 for LAM and 0.9992 for ABAC respectively.The method allows rapid analysis of binary pharmaceutical formulation with accuracy. Results of Tablet analysis by Q-Analysis or Absorbance ratio method was found to be 99.97% for ABAC and 99.99% for LAM respectively. Results of analysis of this method was validated statistically and by recovery studies and was found satisfactory.

Abacavir sulfate is {(1S, 4R)-4-[2-Amino-6-cyclopropyl amino) 9H-Purin-9yl) cyclopent-2-enyl) methanol sulfate. it works by preventing HIV from infecting new cells and taking them over. Abacavir is converted by cellular enzymes to the active metabolite, carbovir triphosphate (CBV-TP), CBV-TP inhibits the activity of HIV-1 reverse transcriptase (RT) by its incorporation into viral DNA.

Lamivudine Chemically it is (2R, 5S)-4-Amino1 [2-(Hydroxy methyl)-1, 3-oxathiolan-5yl]-2(1H)-Pyrimidinedione. It is used in HIV infection. Lamivudine is phosphorylated to its active 5'-triphosphate metabolite, lamivudine triphosphate (3TC-TP). The principal mode of action of 3TC-TP inhibition of RT via DNA chain termination after incorporation of the nucleotide analogue. Both Abacavir sulfate (ABAC) and Lamivudine (LAM) are official in IP [1]. Both the Drugs are marketed as combined dose tablet formulation and the Ratio is 300:600 mg LAM: ABAC. Literature survey revealed that a number of methods have been reported for estimation of Abacavir sulfate individually or in combination with other drugs and Lamivudine or in combination with other drugs[2-13]. Present work describes two simple, accurate, reproducible, rapid and economical methods for simultaneous estimation of ABAC and LAM in tablet formulation.

A Jasco UV-VIS spectrophotometer model UV V-630 spectrophotometer was employed (spectral bandwidth 2 nm) with a pair of 1 m quartz cell for the method of AUC and UV 1800 shimadzu (UV /Vis spectrophotometer) spectral bandwidth 2 nm with a pair of 1 m quartz cell employed for the method of Multicomponent mode. Standard gift sample of Abacavir sulfate and Lamivudine were provided by Aurobindo Ltd., Hyderabad. Distilled water used as a solvent. Stock solution (100µg/ml) of ABAC and LAM prepared by dissolving 10mg of drug in 100ml double distilled water. The maximum absorbance of ABAC and LAM obtained at 284.0nm and 270.0nm respectively. ABAC and LAM shows their respective linearity in the concentration range of 5-30µg/ml at their respective wavelength maxima.

For this method, same mixed standard in the linearity range for each drug from 5-30 µg/ml of ABAC and LAM were prepared by diluting appropriate volumes of standard stock solutions. The scanning of solution of ABAC and LAM was carried out in the range of 400nm-200nm.

In the simultaneous equation using Q-Analysis or Absorbance ratio method, However the Isobastic point was found to be at 265 nm. Thus the wavelength 284.0 nm with reference to 265.0 nm (Isobastic point) was feed to the instrument for analysis as sampling points.

Selection of standard to be used: after optimization the concentration of 15 mcg/ml of LAM and 30 mcg/ml of ABAC were found to give best results. The Q values and Molar Absorptivities for both drugs were calculated as follows:

$$Q_{LAM} = \frac{\text{Absorbance of Std.1 at 284nm}}{\text{Absorbance of Std.1 at 265nm}}$$

$$Q_{ABAC} = \frac{\text{Absorbance of Std.2 at 284 nm}}{\text{Absorbance of Std.2 at 265nm}}$$

$$A_{LAM} = \frac{\text{Absorbance of Std.1 at 265nm}}{\text{Concentration of Std.1 in gms/lit}}$$

$$A_{ABAC} = \frac{\text{Absorbance of Std.2 at 265 nm}}{\text{Concentration of Std.2 in gms/lit}}$$

Q – ANALYSIS METHOD EQUATIONS

$$C_{LAM} = \frac{Q^0 - Q_{ABAC}}{Q_{LAM} - Q_{ABAC}} \times \frac{A}{a_{LAM}} \quad \text{--------} \quad (1)$$

$$C_{ABAC} = \frac{Q^0 - Q_{LAM}}{Q_{ABAC} - Q_{LAM}} \times \frac{A}{a_{LAM}} \quad \text{---------} \quad (2)$$

$$Q^0 = \frac{\text{Absorbance of mixture at 284 nm}}{\text{Absorbance of mixture at 265 nm}}$$

$$A = \text{Absorbance of mixture at 265nm}$$

Now if a mixture of LAM and ABAC were to be analysed a solution of suitable dilution should be prepared in water. The absorbance of the solution at 284.0nm and 265.0nm were measured. The values were substituted in above equation (1) and (2) to get concentration of LAM and ABAC.

Twenty tablets of LAM and ABAC in combination were weighed; their average weight was determined and finally crushed to powder

sample. from the triturate, tablet powder equivalent to 300mg of LAM and 600 mg of ABAC was weighed and transferred to 100 ml volumetric flask and dissolve in 50 ml water and the content was kept in ultrasonicator for 30 min. finally the volume was made up to the mark with water. The solution was filtered through Whatman filter paper No.41.

This tablet solution was further diluted to obtained 15 mcg/ml of LAM and 30 mcg/ml of ABAC. The mixed sample solution were analysed to obtained spectra and absorbance value at 284.0 nm and 265.0 nm (Isobastic point) were noted. The concentration of LAM and ABAC were calculated from above equation.

The coefficient correlations were found to be 0.9995 for LAM and 0.9992 for ABAC. The results of tablet analysis and recovery studies obtained by proposed methods were validated by statistical evaluation. The percentage of coefficient of variation for both the drugs was found to be less than 2%. All the developed methods were found to be simple, rapid, precise, economical and accurate for routine simultaneous estimation of ABAC and LAM in tablet dosage form. The recovery was close to 100% indicating the reproducibility and accuracy of the methods. The Q-Analysis method is rapid and easy because it does not require manual calculations.

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TABLE 1: RESULTS OF TABLET ANALYSIS

Method	Tablet sample	Label claim (mg/tab)		Label claim(%)		S.D*		% mean recovery*	
		ABAC	LAM	ABAC	LAM	ABAC	LAM	ABAC	LAM
Q method	T1	600	300	100.09	100.26	0.028	0.033	99.99	100.03

T_1 is the brand of tablet formulation. * denotes n=6 , average of estimation. ABAC and LAM denotes Abacavir and Lamivudine respectively.

TABLE 2: RECOVERY STUDY DATA FOR TABLET FORMULATION

Method	Level of recovery	% mean recovery		S.D		C.V		S.E	
		ABAC	LAM	ABAC	LAM	ABAC	LAM	ABAC	LAM
Q Method	80%	99.93	99.73	0.082	0.031	0.082	0.031	0.033	0.12
	100%	100.04	100.1 1	0.097	0.049	0.0971	0.0495	0.03	0.10
	120%	99.97	99.83	0.034	0.150.	0.15	0.0341	0.13	0.03

* denotes n=6 , average of six estimation. ABAC and LAM denotes Abacavir and Lamivudine respectively.

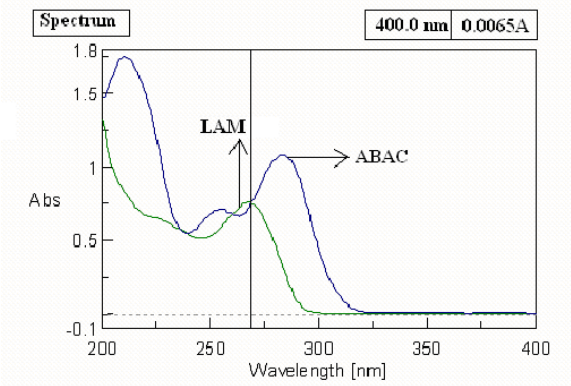

Fig 1. Overlain Spectra Of LAM And ABAC Showing Isobastic Point.

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