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A NEW UV-METHOD FOR DETERMINATION OF BORTEZOMIB IN BULK AND PHARMACEUTICAL DOSAGE FORM

CHANDRA K SEKHAR*[1], P.SUDHAKAR[1], G.RAMESH REDDY[2], P.VIJAYA BABU[3], N.LINGA SWAMY[4]

*Quality Control, Bio-Leo Analytical Labs India Pvt Ltd, IDA, Prasanthi Nagar, Kukatpally, Hyderabad, India

*Corresponding Author Email: kudupudichandra@gmail.com

ABSTRACT

A new simple easy UV-spectrophotometric method was developed for the estimation of Bortezomib in bulk and dosage form. The maximum absorption was found to be at 270 nm. Methanol was used as a diluent. The Calibration curve was linear over the concentration range of 3.5-21.0 µg/ml. The propose method was validated as per the ICH guidelines parameters like Linearity, precision, accuracy, robustness and ruggedness. The method was accurate, precise, specific and rapid found to be suitable for the quantitative analysis of the drug and dosage form.

KEY WORDS

Method development and validation, Bortezomib, UV, Spectrophotometric.

1. INTORDUCTION

[(1*R*)3methyl1({(2*S*)3phenyl2[(pyrazin2ylcarbonyl)amino]propanoyl}amino)butyl]boronic acid. There is no official UV-method for the Bortezomib. As per literature survey a few methods have been reported the estimation of Bortezomib individually [1-5]. With this present proposed method Bortezomib estimates easy, simple and economical by UV-method in bulk and pharmaceutical formulation.

2. MATERIAL AND METHODS

2.1 Spectrophotometric Conditions

Shimadzu UV-Vis double beam spectrophotometer provided with matched 10mm quartz cuvettes equipped with UV-probe software from shimadzu corporation, Japan was employed in the study. AR grade methanol and Class-A glassware purchased from E.Merck Co; Mumbai, India were used in the study.

2.2 Drug Samples

The reference samples were obtained from M/s. Bio-Leo Analytical Labs India Pvt Ltd, Hyderabad, India, the formulation samples were purchased from local market.

2.3 Preparation of stock and working standard solution of Bortezomib

About 3.5mg of Bortezomib was weighed accurately on Sartorius semi micro balance model-CPA225D and transfers in to 25ml volumetric flask the solution was sonicated and the resulting solution was diluted with the methanol to get a working standard solution of 140 µg/ml.

2.4 Sample Preparation

Weighed accurately equivalent to 3.5 mg of sample transferred to 25ml volumetric flask make up to the mark with methanol sonicated and filtered through 0.45µ membrane filter paper. Further dilute 10ml to100 ml with methanol.

2.5 Linearity and Construction of Calibration Curve

Linearity of the peak area response was determined by taking measurement at Six concentration prints (6 replicates at each point) working standard dilution of Bortezomib in the range of 3.5-21µg/ml. The drug monitored at 270 nm and the corresponding spectrums were obtained. Form these chromatograms the mean peak areas were calculated and a plot of concentration over the peak absorbance was constructed. This regression equation was later used to estimate the amount of Bortezomib in pharmaceutical dosage form. A representative spectrum presented in fig.1

RESULTS AND DISCUSSION

The present study was aimed at developing a simple economical precise and accurate UV method for the analysis of Bortezomib in bulk drug and in pharmaceutical dosage form. Methanol was used as a diluent. A good linear relationship (r^2 = 0.993) was observed for Bortezomib. The regression concentration and absorbances are given in **Table 1 & 2**. When test solutions were analyzed by the proposed method for finding out intra and inter-day variation, low co-efficient of variation was observed.

High recovery values obtained from the dosage form by the proposed method indicates the method is accurate. The drug content in tablets was quantified using the proposed analytical method are given in **Table 3**.

The deliberate changes in the method have not much affected the results. This indicated the robustness of the method. The lowest value of LOD and LOQ as obtained by the proposed method by calculated using 3.3xstdev/slope for LOD and 10xstdev/slope for LOQ. The standard solution of the drug was stable up to 24 hrs as the difference in percent assay during the above period is within limit system suitability parameters were studied with six replicates standard solution of the drug and the calculated parameters are within the acceptance criteria.

The system precision was established by six replicate of the standard solution containing analytes of interest. The values of relative standard deviation were found within the limit, indicating the repeatability of the method. The relative standard deviation was found within the limit, indicating the injection repeatability of the method. The results were presented in **Table 4**.

The diluted preparations of marketed tablets were injected in duplicate and the results were calculated and presented in **Table 5**.

Hence it can be concluded that the proposed UV method is simple economical sensitive and reproducible for the analysis of Bortezomib in bulk and in pharmaceutical dosage form.

Table 1: Optical characteristics of the proposed method

Parameter	Value
Absorption Maxima(nm)	270
Beer's law	0.993
Regression equation (Y=mX+c)	Y=0.025x+0.023
Slope(m)	0.025
Intercept(c)	0.023
LOD(µg/ml)	0.09939
LOQ(µg/ml)	0.3012

Table 2: Calibration data of the proposed method

Bortezomib	
Conc (mcg/ml)	Mean Area
3.500	0.123
7.000	0.201
10.500	0.307
14.000	0.381
17.500	0.456
21.000	0.535

Table 3 : Accuracy data (Triplicate values at 50,100 &150 percent levels)

	Amount taken (µg)	Amount found (µg)	Percent Recovery	Percentage of mean recovery
Bortezomib	7.0	7.10	101.42	101.42
	10.5	10.45	99.52	99.52
	17.5	17.42	99.54	99.54

*Each value is a mean of three readings

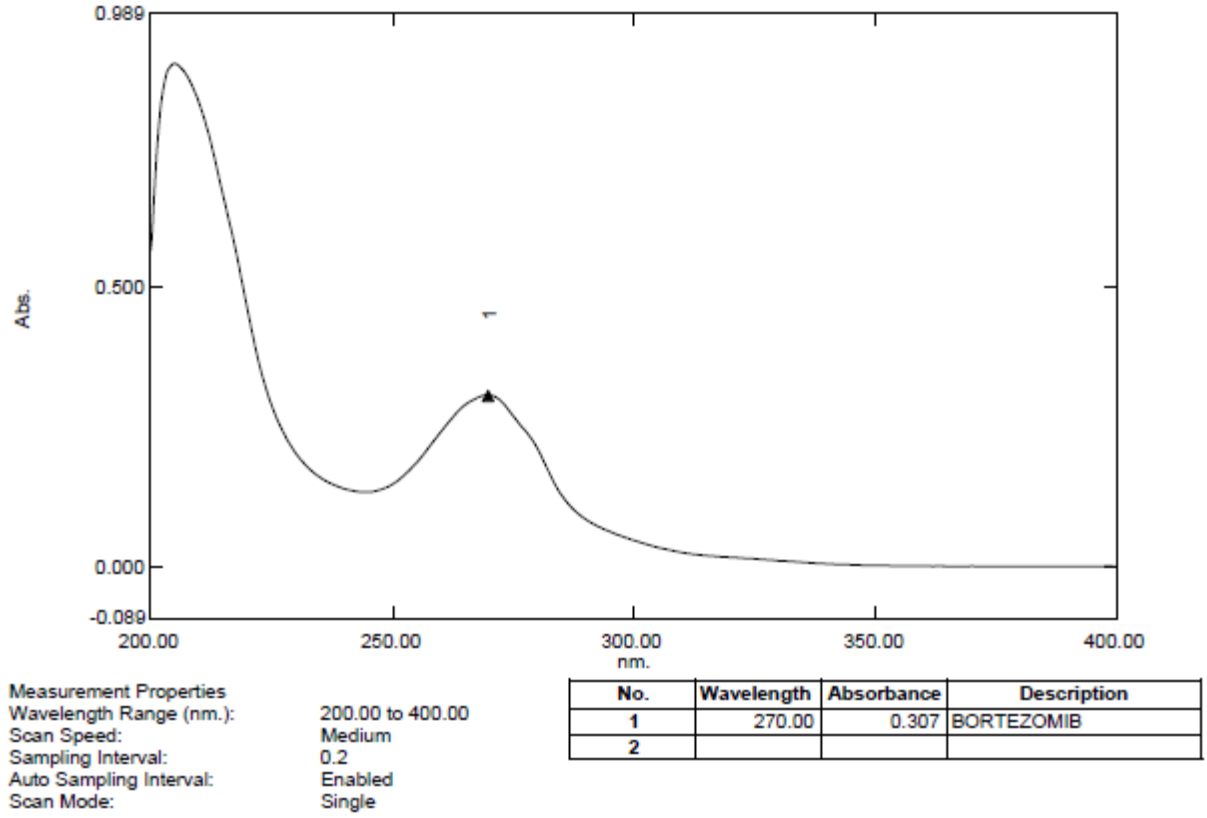
Table 4: Precision Study

S.No.	Abs
1	0.307
2	0.306
3	0.306
4	0.307
5	0.305
6	0.306
avg	0.306167
stdev	0.000753
%RSD	0.246

Table 5: Assay Results

Drug	Amount present/ml	% of Assay
Bortezomib	3.52 mg	100.57

Figure 1: UV-spectrum of Bortezomib (10.5mcg/ml).

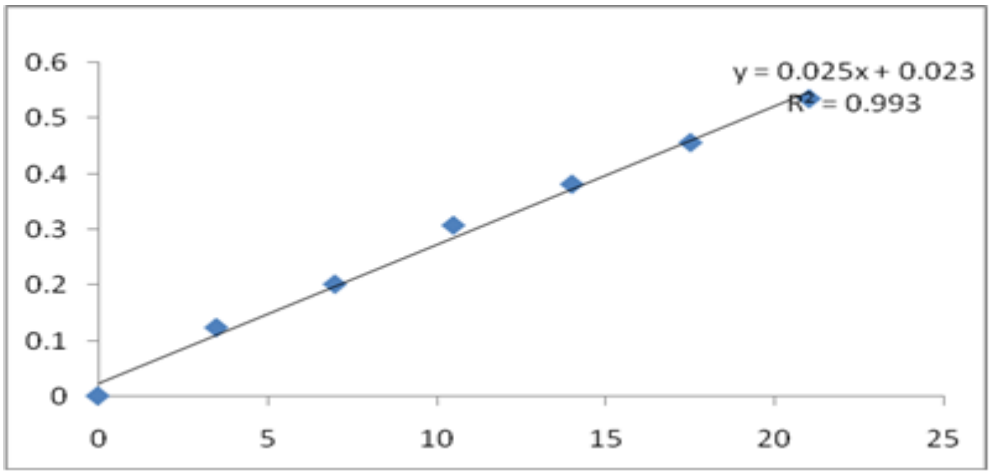


Measurement Properties

Wavelength Range (nm.):	200.00 to 400.00
Scan Speed:	Medium
Sampling Interval:	0.2
Auto Sampling Interval:	Enabled
Scan Mode:	Single

No.	Wavelength	Absorbance	Description
1	270.00	0.307	BORTEZOMIB
2			

Figure 2: Linearity of Bortezomib



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***Corresponding Author:**
CHANDRA K SEKHAR,
Bio –Leo Analytical Labs India Pvt Ltd,
IDA, Prasanthi Nagar, Kukatpally,
Hyderabad, India.
Email: kudupudichandra@gmail.com