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NOTE

UV-Spectrophotometric Determination of Dasatinib in Pharmaceutical Dosage Forms

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UV spectrophotometric method has been developed for the quantitative estimation of dasatinib in pure form as well as in pharmaceutical formulations. The drug exhibits absorption maximum at 330 nm in 0.1N HCl and obeys Beer's law in the concentration range of 2-10 µg/mL. The method was extended to pharmaceutical preparations and there is no interference from any common pharmaceutical additives.

Key Words: UV-Spectrophotometric, Dasatinib.

Dasatinib (Fig. 1) is chemically N-(2-chloro-6-methylphenyl)-2-[[6-[4-(2-hydroxyethyl)-1-piperazinyl]-2-methyl-4-pyrimidinyl]amino]-5-thiazole carboxamide monohydrate. It is a tyrosine kinase inhibitor[1] and is used in patients with chronic myelogenus leukemia after imatinib treatment and Philadelphia chromosome positive acute lymphoblastic leukemia[2]. Literature survey reveals that, one chromatographic[3] (HPLC, HPTLC) method has been reported for the estimation of dasatinib. No UV method was reported in literature for analysis of dasatinib. Hence, an attempt has been made to develop a new UV spectrophotometric method for estimation of dasatinib in bulk drugs and pharmaceutical formulations.

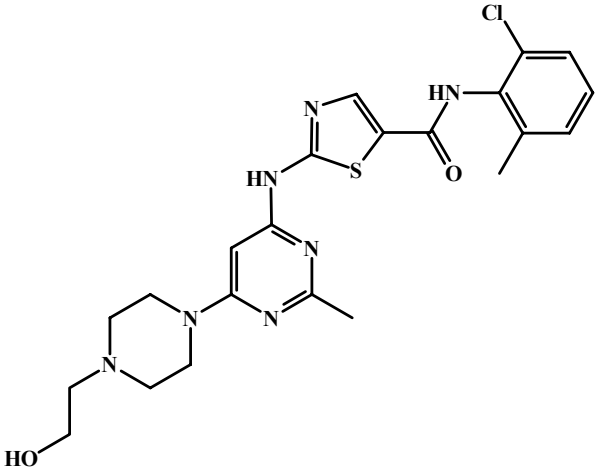

Fig. 1. Structure of dasatinib

All spectral and absorbance measurements were made on a Shimazdu model 1601 digital spectrophotometer with 10 mm matched quartz cells.

Preparation of standard and sample solutions: Accurately weighed 100 mg of drug was dissolved and diluted with 0.1 N HCl stepwise so as to obtain a concentration of 20 µg/mL.

Tablet powder equivalent to 100 mg of dasatinib was accurately weighed and sample solution prepared as per the standard solution.

Assay procedure: Into a series of 10 mL volumetric flasks aliquots of working standard solution (20 µg/mL) ranging from 1-5 mL were added and the volume was made up to 10 mL with 0.1 N HCl. The absorbance's were measured at 330 nm (Fig. 2) against solvent blank. The amount of dasatinib present in the sample solution was computed from the calibration curve.

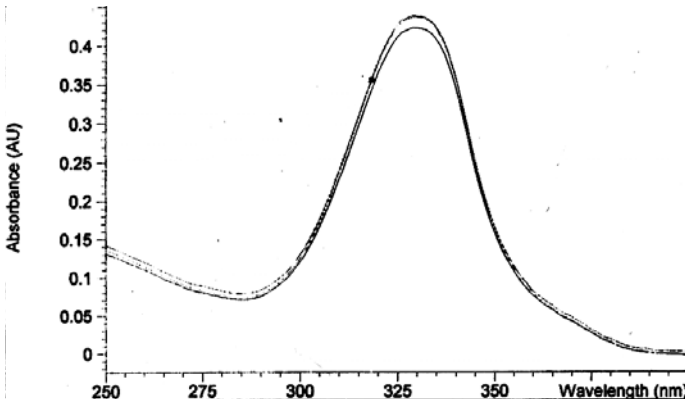

Fig. 2. Representative spectrum of dasatinib

The optical characteristics such as Beer's law limits, sandell's sensitivity, molar absorptivity, per cent relative standard deviation (calculated from eight replicate samples containing 3/4th of the amount of the upper beer's law limits) were calculated and the results are summarized in Table-1. Regression characteristics like slope, intercept and % range of error (0.05 and 0.01 confidence limits) were calculated and shown in Table-1.

Application of proposed method for the determination of dasatinib in its dosage forms was successfully made and the results are presented in Table-2. The excellent recoveries obtained indicated the absence of any interference from the excipients.

Conclusion

The proposed method was found to be simple, economical and sensitive. The statistical parameters and recovery study data clearly indicate the reproducibility and accuracy of the method. Analysis of authentic samples containing dasatinib showed no interference from common excipients. Hence this method could be considered for the determination of dasatinib in quality control laboratories.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION
OF THE PROPOSED METHOD FOR DASATINIB

Parameter	Dasatinib
λ_{max} (nm)	330
Beer's law limits (µg/mL)	2-10
Molar absorptivity (L mol^{-1} cm^{-1})	43.9×10^5
Sandell's sensitivity	0.00111
Regression equation (Y = a + bC)	
Slope (b)	0.1842
Intercept (a)	-0.0102
Correlation coefficient (r)	0.9995
Relative standard deviation (%)*	0.24817
% Range of error (confidence limits)*	
0.05 level	0.20751
0.01 level	0.3070

Average of eight determinations
In Y = a + bC, Y is absorbance and C is concentration

TABLE-2
RESULTS OF ANALYSIS OF TABLET FORMULATIONS CONTAINING DASATINIB

Formulation	Labeled amount (mg)	Amount obtaned (mg)	% Recovery obtaned*
Tablet-1	50	49.98	99.970
Tablet-2	50	49.97	99.940
Tablet-3	70	70.01	100.014
Tablet-4	70	69.99	99.980

*Average of three determinations.

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