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VALIDATED SPECTROPHOTOMETRIC ESTIMATION OF IMATINIB MESYLATE IN PURE AND TABLET DOSAGE FORM

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ABSTRACT

A Simple and sensitive spectrophotometric method has been developed for the estimation of Imatinib mesylate in both pure and tablet dosage form. The proposed method is based on the measurement of light absorption in uv region in distilled water. The UV spectrum of Imatinib mesylate in distilled water showed λ_{max} at 256 nm. Beer's law is valid in the concentration range of 2-12 $\mu\text{g/ml}$. This method was validated for precision, accuracy, ruggedness and robustness. Statistical analysis proves that the method is reproducible and selective for the estimation of the said drug.

Key Words: Spectrophotometry, Imatinib mesylate

INTRODUCTION

Imatinib mesylate is a 2-phenylamino pyrimidine derivative that functions as a specific inhibitor of a number of tyrosine kinase enzymes. It occupies the TK active site, leading to a decrease in activity. Chemical name of imatinib is 4-4[(4-methyl-1- piperazinyl) methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl] amino] phenyl] – benzamide mono methane sulfonate. It has a molecular formula of $\text{C}_{29}\text{H}_{31}\text{N}_7\text{O} \cdot \text{CH}_4\text{O}_3\text{S}$ and a molecular weight of 589.71. It has the structural formula (Fig.1). Imatinib mesylate is a white crystalline powder which in freely soluble is distilled water, 0.1 N Hcl, methanol and sparingly

volumetric flask, distilled water was added and made up to volume. Then the solution was sonicated for 15 minutes. After sonication, the solution was filtered through whatmann filter paper no.41. From the solution, further dilution was made to bring a final concentration of 6µg/ml with distilled water and used for the analysis. In this method aliquots of Imatinib mesylate ranging from 0.2-1.2 ml of standard solution were transferred into 10 ml volumetric flask and made up to the mark with distilled water. The absorbance was measured at 256 nm against the reagent blank. The amount of the drug in the sample was calculated from the calibration graph.

RESULTS AND DISCUSSION

The absorption spectral analysis shows the λ max of Imatinib mesylate to be 226 nm. The calibration curve was obtained for a series of concentration in the range of 2-10 mcg/ml (Fig.2). It was found to be linear and hence suitable for the estimation of the drug. The slope, intercept, correlation coefficient and optical characteristics are summarized in table 1. Regression analysis of Beer's law plot revealed a good correlation. The effects of various excipients generally present in the tablet dosage form of Imatinib mesylate were investigated. The results indicated that they did not interfere in the assay. The proposed method was validated as per the ICH guidelines. The precision was measured in terms of repeatability, which was determined by sufficient number of aliquots of a homogeneous sample. The % RSD was found and lying within the range of ± 2.0 . This showed that the precision of the method is satisfactory. The recovery technique was performed to study the accuracy and reproducibility of the proposed method. For this, known quantities of the Imatinib mesylate solution were mixed with definite amounts of pre-analyzed formulations and the mixtures were analyzed. The total amount of Imatinib mesylate was determined by using the proposed method and the amount of added drug was calculated by difference. The % RSD was less than ± 2.0 . This showed that the recovery of Imatinib mesylate by the proposed method is satisfactory and the results are shown in table 2. Ruggedness and Robustness were determined and the % RSD values

calculated from precision study was less than ± 2.0 . Limit of detection (LOD) and Limit of quantitation (LOQ) were also determined for the proposed method. Thus it can be concluded that the methods developed in the present investigation are simple, sensitive, accurate, rapid and precise. Hence, the above said method can be successfully applied for the estimation of Imatinib mesylate in tablet dosage form.

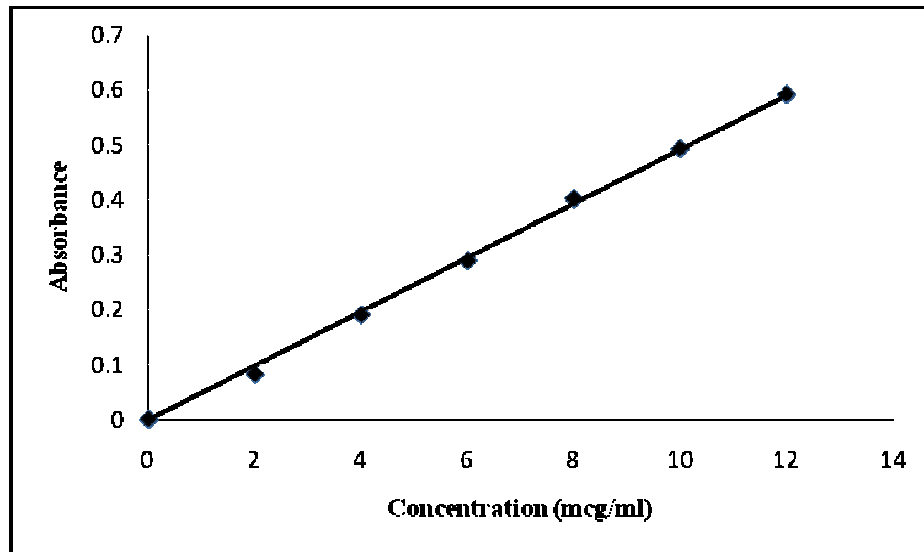


Fig.2: Calibration curve of Imatinib mesylate by the proposed method

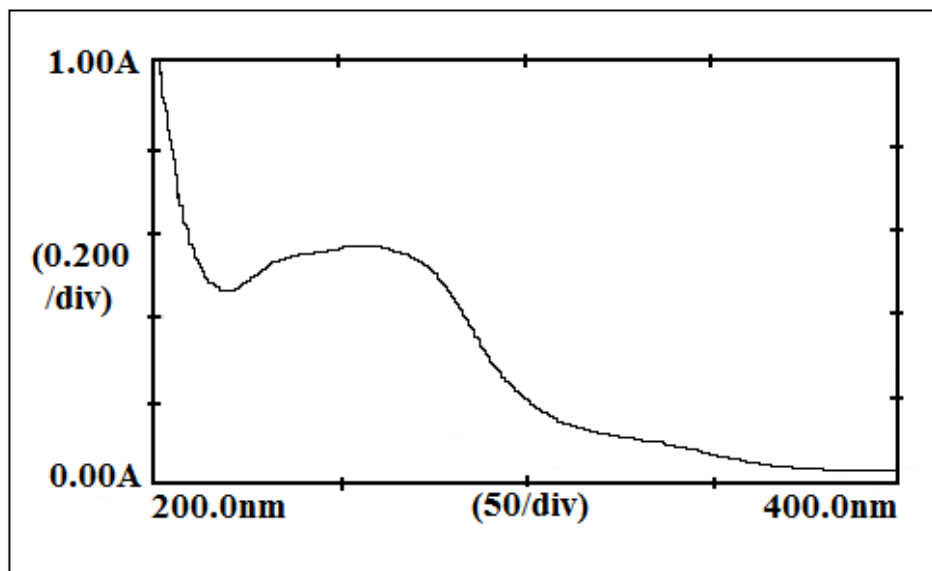


Fig.3: UV-Spectrum of Imatinib mesylate

Table 1: Regression analysis of the calibration curve for the proposed method

Parameters	Method Values
λ_{\max} (nm)	256
Beer's law limit($\mu\text{g/ml}$)	2-12
Sandell's sensitivity ($\mu\text{g/cm}^2/0.001 \text{ AU}$)	0.021855
Molar absorbtivity($\text{L mol}^{-1} \text{ cm}^{-1}$)	1.2810×10^2
Correlation Co-efficient (r)	0.99967
Regression equation ($Y=mx+c$)	$Y=0.04619x+0.005637$
Slope(m)	0.04619
Intercept(c)	0.005637
LOD($\mu\text{g/ml}$)	0.33930
LOQ($\mu\text{g/ml}$)	1.02820
Standard error of mean of regression line	0.001484

Table 2: Summary of validation parameters

Parameters	Values
Label Claim (tablet-mg)	100
Amount found \pm SEM*	100.2 ± 0.22
Precision (% RSD)	1.056
% Recovery \pm SEM*	100.6 ± 0.63
Recovery (% RSD)	0.68

*Mean of six determinations, SEM indicates standard error mean, RSD indicates relative standard deviation

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