NOTES

UV-Spectrophotometric Determination of Imatinib Mesylate

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A simple and sensitive UV spectrophotometric method has been developed for the determination of imatinib mesylate in pure as well as in pharmaceutical formulations. The drug exhibits maximum absorption at 255 nm and the method obeys Beer's law at the concentration range of 0.25–1.25 µg/mL. This method was extended to pharmaceutical preparations and there is no interference from any common pharmaceutical additives.

Key Words: UV-Spectrophotometric, Imatinib Mesylate.

Imatinib mesylate (M)[1,2] is an anti-cancer drug and chemically it is benzamide 4-[(4-methyl-1-piperazinyl)methyl]-N-[4-methyl-3-[[4-(3-pyridinyl)-2-pyrimidinyl]amino]phenyl]-benzamide methane sulphonate. IM is used to treat chronic myeloid leukemia (CML) in chronic phase. Literature survey reveals that only one LC-MS[3] method was reported. The present investigation has been undertaken to develop a simple UV spectrophotometric method for the determination of imatinib mesylate.

All the chemicals used were of analytical grade. Spectral and absorbance measurements were made on Systronics UV-Visible spectrophotometer-117 with 10 mm matched quartz cells.

Preparation of Standard and Sample Solutions

Accurately weighed 100 mg of drug was dissolved and diluted with distilled water stepwise so as to obtain a concentration of 5 µg/mL IM.

Tablet powder equivalent to 100 mg of IM 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 (5 µg/mL) ranging from 0.5–2.5 mL were added and the volume was made up to 10 mL with distilled water. The absorbances were measured at 255 nm against the solvent blank. The amount of imatinib mesylate present in the sample solution was computed from the calibration curve.

The optical characteristics such as Beer's law limits, Sandell's sensitivity (µg cm^{-2}/0.001 absorbance unit), molar extinction coefficient (L mol^{-1} cm^{-1}), per cent relative standard deviation (calculated from the eight measurements containing 3/4th of the amount of the upper Beer's law limit), regression equation, correlation coefficient, % range of error (0.05 and 0.01 confidence limits) were calculated

and are presented in Table-1. To evaluate validity and reproducibility of the method, known amounts of pure drug were added to previously pharmaceutical preparations and the mixtures were analyzed by the proposed method and the results are presented in Table-2.

TABLE-1
OPTICAL CHARACTERISTICS AND PRECISION OF THE PROPOSED METHOD

Parameter	IM
λ_{max} (nm)	255
Beer's law limit (μg/mL)	0.025–1.25
Molar absorptivity (L mol^{-1} cm^{-1})	30.07×10^4
Sandell's sensitivity	
(μg cm^{-2}/0.001 absorbance unit)	0.00196
Regression equation (Y = a + bC)	
Slope (b)	0.5049
Intercept (a)	0.00209
Correlation coefficient (r)	0.9997
Relative standard deviation (%)*	0.18069
% Range of error (confidence limits)*	
0.05 level	0.1510
0.01 level	0.2235

*Average of eight determinations.

TABLE-2

Sample	Labelled amount (mg)	Amount obtained (mg)	% Recovery obtained*
1	100	99.95	99.95
2	100	99.90	99.90

*Recovery amount is the average of three determinations.

Since the pharmaceutical preparations containing imatinib mesylate are not available in the market, model preparations (tablets) were prepared and 1 mg/mL solution of standard IM and its dosage forms (tablets) were prepared in distilled water. The stock solutions were further diluted with distilled water to get working standard solution of 5 μg/mL. Interference studies revealed that the common excipients and other additives did not interfere.

Hence the method is most economic, simple, sensitive and accurate and can be used for the routine determination of IM in bulk as well as in pharmaceutical preparations.

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