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UV SPECTROPHOTOMETRIC METHOD DEVELOPMENT AND VALIDATION OF IMATINIB IN BULK AND SOLID DOSAGE FORM

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ABSTRACT

Objective: A new, simple, sensitive, precise and reproducible UV spectroscopic method was developed for the estimation of Imatinib in bulk and solid dosage form. **Methods:** The UV spectrum of Imatinib showed λ max at 274nm. Beer's law is valid in the concentration range of 4-20µg/ml. This method was validated for linearity, accuracy, precision, ruggedness and robustness. **Results:** The method has demonstrated excellent linearity over the range of 4-20µg/ml with regression equation y = 0.504x + 0.0014and regression correlation coefficient r^2= 0.9993. Moreover, the method was found to be highly sensitive with LOD (0.68µg/ml) and LOQ (2.06µg/ml). **Conclusion:** Depending on results the given method can be successfully applied for assay of Imatinib in Veenat capsule.

KEYWORDS

Imatinib, Methanol, UV spectroscopy, Method development and Validation and Imatinib Capsule.

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INTRODUCTON

Imatinib is anticancer medicine. Malignancy is a group of sicknesses including irregular cell development with the possibility to attack or spread to different pieces of the body. Imatinib is a protein tyrosine kinase inhibitor that represses Bcr-Abltyrosine kinase. Imatinib restrains profiliration actuates apoptosis in Bcr-Ablpositive cell lines just as new leukemic cells from Philadelphia chromosome positive incessant myeloid leukemia. Unequivocally imatinib is used for unremitting myelogenous leukemia (CML) and extreme lymphocytic leukemia (ALL) that are Philadelphia chromosome-positive (Ph), specific sorts of

gastrointestinal stromal tumours (GIST), steady eosinophilic leukemia), constant eosinophilic leukemia (CEL), fundamental mastocytosis, and myelodysplastic disorder hypereosinophilic (HES).

The Chemical name of Imatinib is α-(4-methyl-1-piperazinyl)- 3'- ((4-(3-pyridyl)- 2-pyrimidinyl) amino)- p-toluidide. The sub-atomic recipe Imatinib C29H31N7O and sub-atomic weight is 589.71. Imatinib is white crystalline powder which in openly solvent in refined water, 0.1 N Hcl, methanol and sparingly dissolvable in dimethyl ether. The point of this examination is to give another, straightforward, touchy, exact and reproducible UV spectroscopic strategy was created for the estimation of Imatinib in definition.

MATERIAL AND METHODS

Materials

Imatinib was take as gift sample from, Microlab Pvt. Ltd. Bengluru. Methanol was taken of analytical grade.

Instruments

Analytical balance (Shimadzu AY220), Sonicator (Oscar ultrasonicator microclean 103), UV-Visible double beam spectrophotometer (Systronic 2201).

Experimental

Preparation of standard stock solution

Accurately weighed 10mg of Imatinib transferred to 100ml volumetric flask. It was dissolved and sonicated for 10minutes. The volume was made up to mark with same diluent to obtain final strength.

Procedure for plotting calibration curve

For calibration curve in a series of 10ml volumetric flasks, 0.4-2ml of standard solution was pipetted out separately. The volume was completed to the mark using methanol. The absorbance was measured at wavelength 274nm against blank solution.

Analysis of Imatinib in Capsule formulation

10mg equivalent Imatinib was weighed and transferred to the 100ml volumetric flask and dissolved in methanol as a solvent. After that sonicated for 10min and vortex for 5min. 1ml of above solution was pipetted out and transferred to the 10ml volumetric flask and make up the volume upto the mark with same solvents and analysed at 274nm. Calculate the % purity of imatinib.

RESULTS AND DISCUSSION

The absorption spectrum shows λ max of Imatinib at 274nm.

The proposed method was validated according to ICH Q28 R1 guidelines for validation of analytical procedure.

Linearity

Five different concentrations of Imatinib were prepared and analysed at wavelength 274nm. The regression coefficient was found to be 0.9993. The absorbance was found in limit i.e. 0-2. Hence the analyzed parameter was found to be validated (Table No.1).

Accuracy

The concentration 4, 8, 12µg/ml was taken as 50, 100, 150% and % recovery was found to be in range 99%-101%. Hence the parameter was found to be validated.

Range

Range is aninterval between highest and lowest concentration limit of the analyte i.e. 4-20µg/ml.

Precision

In precision intra-day and inter-day precision were performed at concentration 12(µg/ml). The obtained results were found within limit i.e. less than 2% RSD.

Limit of Detection (LOD)

The limit of detection was found to be 0.68µg/ml (Table No.6).

Limit of Quantification (LOQ)

The limit of quantification was found to be 2.06µg/ml (Table No.6).

Ruggedness

The change in analyst with same concentration and environmental condition didn't affect the results.

Robustness

The change in wavelength (274nm and 280nm) and concentration (10µg/ml) didn't affect the results.

Assay

The assay was performed by using Veenat 100mg at concentration 10µg/ml. The % purity was found to be 98.2%.

Table No.1: Results of Linearity

S.No	Concentration(µg/ml)	Absorbance
1	4	0.201
2	8	0.397
3	12	0.602
4	16	0.819
5	20	0.998

Table No.2: Optimization parameters of Imatinib

S.No	Parameters	Method values
1	Maximum Wavelength	274nm
2	Beer's Law	4-20µg/ml
3	Correlation Coefficient (r^2)	0.9993
4	Regression Equation	y = 0.0504x + 0.0014
5	Slope (m)	0.0504
6	Intercept (c)	0.0014

Table No.3: Results of Accuracy

S.No	Name of Drug	Recovery Level in %	Concentration	Amount Recovered	% recovery with SD
1	Imatinib	50	4µg/ml	4.05	100.05±0.25
		100	8µg/ml	8.03	99.03±0.7
		150	12µg/ml	12.04	100.06±0.04

Table No.4: Results of Intra-day Precision

S.No	Concentration	Absorbance
1	12(µg/ml)	0.602
2		0.601
3		0.602
4		0.603
5		0.601
6		0.604
7	SD	0.001169
8	%RSD	0.19414

Table No.5: Results of Inter-day precision

S.No	Concentration	Absorbance (Day1)	Absorbance (Day2)
1	12(µg/ml)	0.602	0.604
2		0.601	0.603
3		0.602	0.604
4		0.603	0.605
5		0.601	0.602
6		0.604	0.604
7	SD	0.001169	0.001033
8	%RSD	0.19414	0.171087

Table No.6: Results of LOD and LOQ

LOD	0.68µg/ml
LOQ	2.06µg/ml

Table No.7: Results of Ruggedness

S.No	Concentration	Absorbance (Analyst1)	Absorbance (Analyst2)
1	10µg/ml	0.485	0.486
		0.487	0.485
		0.484	0.487
		0.488	0.486
		0.485	0.485
		0.486	0.485
2	Average	0.485833	0.485667
3	SD	0.001472	0.000816

Table No.8: Results of Robustness

Wavelength	274nm	280nm
Concentration	10µg/ml	10µg/ml
Absorbance	0.485	0.484
	0.487	0.487
	0.484	0.483
	0.488	0.482
	0.485	0.487
	0.486	0.484
Average	0.485833	0.4845
SD	0.001472	0.002074

Table No.9: Results of Assay

S.No	Formulation	Labeled Amount	Amount obtained	% purity
1	Veenat Capsule	100mg	98.2	98.2%

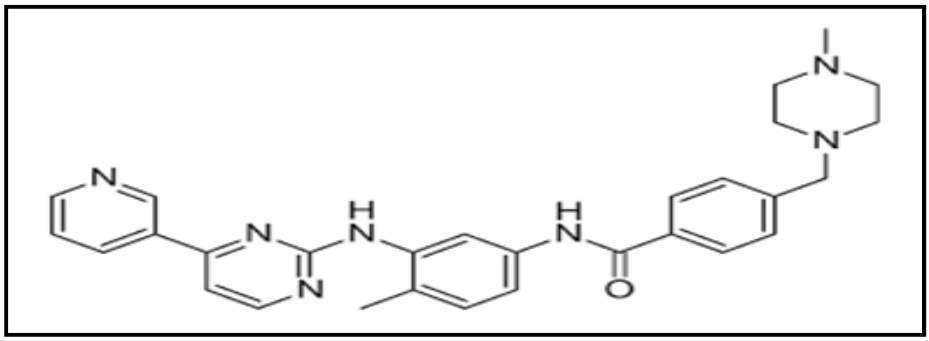

Figure No.1: Structure of Imatinib

Figure No.2: UV spectrum of Imatinib

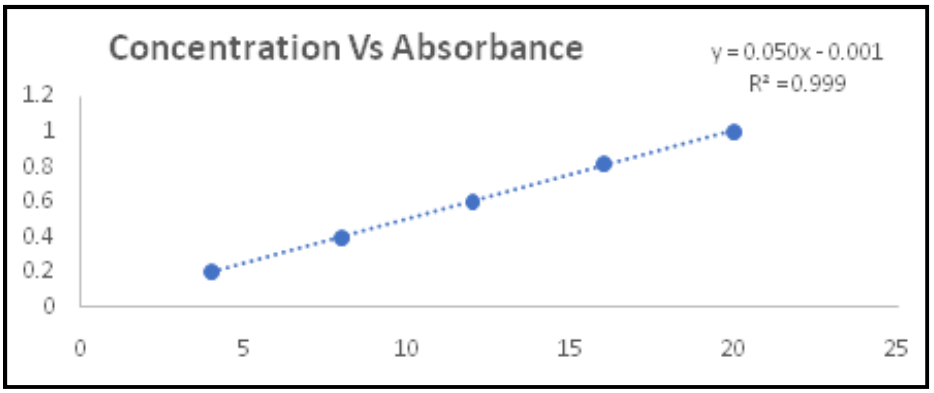

Figure No.3: Calibration curve for Imatinib (Concentration Vs Absorbance)

CONCLUSION

An analytical UV spectrophotometric method was developed and validated thoroughly for quantitative determination of Imatinib in bulk and solid dosage form. The presented method was found to be simple, precise, accurate, rugged, reproducible and gives an acceptable recovery of the analyte.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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