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UV SPECTROPHOTOMETRIC METHOD DEVELOPMENT AND VALIDATION FOR ESTIMATION OF LENVATINIB

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ABSTRACT

The main objective of the present research is a novel, rapid, precise and UV-Spectrophotometer method validation for lenvatinib. The analytical method was developed using orthophosphoric acid buffer and acetonitrile in the ratio 50:50 v/v. The absorbance was measured over a range 200-400nm and wave length was found to be 212nm. The developed method obeyed beer's lamberts law showing goodlinearity over a range of 4-12 µg/ml. The developed method was found to be accurate, precise. This shows a good recovery value having % RSD 1.297250 with in the acceptance criteria. And LOD was 1.65 µg/ml LOQ was 5.0 µg/ml. Thus, the evaluated method can be used routinely for quality control analysis of Lenvatinib drug. Additionally, the development of precise analytical methods for the quantification of lenvatinib in various media is crucial for ensuring its therapeutic efficacy and safety. Advances in UV-visible spectrophotometry provide an effective, economical, and robust approach for the analysis of lenvatinib, supporting its application in pharmaceutical formulations and enhancing quality control measures. These analytical techniques are essential for routine laboratory testing, contributing to improved patient outcomes and optimized drug development processes.

Keywords: Lenvatinib, validation, Beer's lamberts law, anti-neoplastic agent, multi-kinase inhibitor

INTRODUCTION

Lenvatinib is chemically 4-(3-chloro-4[(cyclopropyl carbomyl) amino] phenoxy)-7-methoxy quinoline-6-carboxylic acid. It is a class of medication called multi-kinase inhibitors. It works by blocking the action of an abnormal protein that can trigger the cancer cells to multiply. It is also known to be anti-neoplastic agent used in the treatment of advanced, metastatic Medullary thyroid cancer and refractory renal cell carcinoma **[1-3]**.

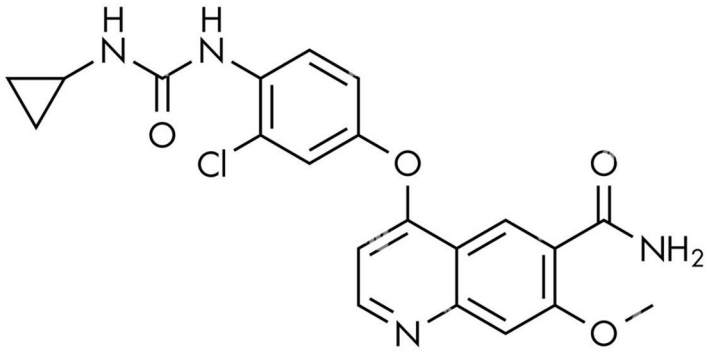

Figure 1: Chemical structure of lenvatinib

To develop suitable mobile phase, optimize chromatographic condition and selection of suitable detection wavelength for the preparation of standard calibration curve of selected drugs. To develop novel, rapid, precise, and UV-Spectrophotometry method by using a Lab India double beam UV-visible spectrophotometer. The method can be developed and validated for estimation of lenvatinib drug bulk in pharmaceutical formulation **[3, 4]**.

MATERIALS AND METHODS

Lenvatinib was purchased from Aarti Pharmaceutical (Zaint Health Care, Hyderabad, Telangana). Methanol and HCl was purchased from Pallav Pharmaceuticals.

Preformulation studies [5, 6]

Preformulation study is defined as the study of the physical and chemical properties of the drug molecular prior to the compounding process. It is the most important study in the development of any new dosage form of a drug. The main objective of the preformulation studies are as follows:

- ✓ To establish the physicochemical parameter of new drug activity.
- ✓ To establish its compatibility with common excipients.
- ✓ Physical characterization of Lenvatinib

The physical characterization of procured drug sample of lenvatinib was determined on the basis of following parameters.

Melting point

The melting point of lenvatinib was determined using capillary melting point method. Small quantity of drug was filled in a thin-walled capillary tube, sealed from one end. This capillary was then put in the melting point apparatus. The temperature at which the drug started melting and temperature at which it completely melts was recorded.

Fourier transform infrared spectroscopy (FTIR)

FTIR spectrum was used as an analytical technique for identification of pure drug sample. The spectra for the sample were recorded using a Bruker Vertex 70 FTIR spectrophotometer by KBr pellet method. The samples were analyzed by mixing with potassium bromide (1:10) individually and pressed to form a thin pellet by applying pressure using KBr press. The formed pellets were placed within the sample holder. Spectral scanning was taken in the wavelength region between 4000-400 cm^{-1}. FTIR scans of lenvatinib were recorded. The analysis of the drug was carried out by UV-Visible method which was validated on analytical parameters like linearity and range as per guidelines laid down by International Conference on Harmonization (ICH).

Determination of λmax by UV spectroscopy

Calibration curve of Lenvatinib was prepared with the help of UV spectroscopy. Calibration curve of lenvatinib was prepared in water, methanol, phosphate buffer 7.4 and 0.1N HCl.

Preparation of stock solution

Accurately weighed 100 mg of lenvatinib was transferred in 100 ml volumetric flask. The drug was dissolved and diluted up to the mark with water to give a solution with concentration of 1000 µg/ml. An aliquot of 10 ml from the above solution was withdrawn and diluted up to 100 ml with water to obtain a stock solution having concentration of 100µg/ml.

Preparation of solutions to obtain calibration curve

Appropriate aliquots from stock solution of lenvatinib (0.2, 0.4, 0.6, 0.8, 1 and 1.2 ml) were accurately withdrawn in 10 ml volumetric flask and diluted up to the mark with water to obtain the final concentration of solution in range of 2-12 µg/ml and scanned at λ_{max}. Absorbance of these solutions of lenvatinib were recorded at their λ_{max} using water as blank. Calibration curve of lenvatinib in phosphate buffer 6.8 as solvent.

Preparation of stock solution

Accurately weighed 100 mg of lenvatinib was transferred in 100 ml volumetric flask. The drug was dissolved and diluted up to the mark with phosphate buffer 6.8 to give a solution with concentration of 1000 µg/ml. An aliquot

of 10 ml from the above solution was withdrawn and diluted up to 100 ml with phosphate buffer 6.8 to obtain a stock solution having concentration of 100µg/ml.

Preparation of solutions to obtain calibration curve

Appropriate aliquots from stock solution of lenvatinib (0.2, 0.4, 0.6, 0.8, 1 and 1.2 ml) were accurately withdrawn in 10 ml volumetric flask and diluted up to the mark with phosphate buffer 6.8 to obtain the final concentration of solution in range of 2-12 µg/ml and scanned at λ_{max}. Absorbance of these solutions of lenvatinib were recorded at their λ_{max} using phosphate buffer 6.8 as blank. Calibration curve of lenvatinib in 0.1N HCl as solvent

Preparation of stock solution

Accurately weighed 100 mg of lenvatinib was transferred in 100 ml volumetric flask. The drug was dissolved and diluted up to the mark with 0.1N HCl to give a solution with concentration of 1000 µg/ml. An aliquot of 10 ml from the above solution was withdrawn and diluted up to 100 ml with 0.1N HCl to obtain a stock solution having concentration of 100µg/ml.

Preparation of solutions to obtain calibration curve

Appropriate aliquots from stock solution of lenvatinib (0.2, 0.4, 0.6, 0.8, 1 and 1.2 ml) were accurately withdrawn in 10 ml volumetric flask and diluted up to the mark with 0.1 N HCl to obtain the final concentration of solution in range of 2-12 µg/ml and scanned at λ_{max}. Absorbance of these solutions of lenvatinib were recorded at their λ_{max} using 0.1 N HCl as blank.

UV method validation [7-10]

The ultraviolet spectrophotometric method was validated for different parameters like solubility, linearity accuracy precision LOD and LOQ.

Solubility

Solubility was done by polar and non-polar solvents. So, the common solvent was found to bemethanol for analysis of lenvatinib drug mobile phase is used as a secondary solvent. Mobile phase consists of mixture of 0.1% orthophosphoric acid buffer and acetonitrile of ratio(200:300 v/v%). 25mg of lenvatinib raw material was weighed and transferred into 25ml volumetric flask separately and mobile phase was made up to the volume with water. The solution is further diluted with mobile phase, which contains 1000µgr/ml. Now, the lenvatinib stock solution was diluted with distilled water and the final solution contains 10micrograms/ml, was scanned between 200-400nm using mobile phase as blank from the spectra the 212 nm wavelength is selected because the absorbance of the drug is 0.062.

Hence, the estimation of Lenvatinib can be done. The drug shows calculated and corrected absorbance of same solution at different time intervals. The drug in mobile phase was stable for more than 2 h at all selected wavelength.

Linearity

Different stock solution of lenvatinib was transferred into 100ml volumetric flask separately and madeup to volume with mobile phase. The absorbance of different concentration solution was measured at 212nm. The calibration curve is plotted at their respective wavelengths. Lenvatinib showed the linearity in the range of 4 to 12 µg/ml at 212nm.

Accuracy

The recovery experiment was done by adding known concentration of lenvatinib raw material to the pre-analyzed formulation. 25 mg equivalent of lenvatinib was weighed and transferred into 25ml volumetric flask and dissolved in mobile phase. The solution was subjected to ultrasonic vibrations for 30min and the solution was made up to the required volume and the solution was filtered through a Whatman filter paper 41. Then, the solutions of concentrations 4, 6, 8, 10, and 12 µg/ml of lenvatinib made up the required volume and measured the absorbance at their selected wavelengths of determination of lenvatinib. The recovery of the sample was found to be 99.13%.

Precision

The repeatability of the method was confirmed by the repetitive analysis of formulation for 5 times withthe same concentration.

Intermediate precision: The intermediate precision of Lenvatinib was determined by measuring the absorbance of 100% solutionon different days under identical conditions. The %RSD was found to be 1.297250 or 1.30.

LOD and LOQ

LOD and LOQ was calculated by using the average of slope and standard deviation of intercept.

RESULTS AND DISCUSSION

Physical characteristics of lenvatinib

The physical characteristics of lenvatinib are matching with those reported in the standard literature thus supporting its identity **(Table 1)**.

Melting point

The reported melting point of lenvatinib was in the range of 216-231 °C. The observed melting point was found at 226 °C. It confirms that the given powdered drug is pure in nature and it complies that powder is a lenvatinib.

FT-IR

In the infrared spectrum, various functional groups exhibit distinct peak positions. Alkane

halides show a peak at 653 cm^{-1} due to C–H bending. Benzene rings have a peak at 857 cm^{-1} indicating CH_3 bending. Amines display a peak at 1180 cm^{-1} associated with C=C stretching. Carboxylic acids have a peak at 1321 cm^{-1} due to C–O stretching, and alkanes exhibit C–H stretching at 1442 cm^{-1}.

A simple, rapid, precise and accurate UV-Spectrophotometric method was developed and validated for the estimation of Lenvatinib in bulk sad pharmaceutical dosage form. After many trials and errors, the mobile phase of 0.1% orthophosphoric acid: Acetonitrile (50:50 v/v) has shown the highest absorbance at max wavelength of 212 nm. It was finalized and proceeded for method validation. The method was shown to be linear in the concentration range of 4-12 µg/ml. The %RSD Was foundto be <2% and the recovery was found to be within the acceptance criteria. LOD and LOQ was found to be 1.65 µg/ml and 5.0 µg/ml respectively which proved the sensitivity of the method **(Figure 2-4)**.

Method validation (Table 2, 3)

Linearity

From the linearity graphs, it was confirmed that the method is exhibiting linearity over the range of 4-12µg/ml. The correlation coefficient is 0.9999 which is meeting. The validation criteria. The plotted graph and linearity data are provided in the table and spectrum of curve **(Table 6, Figure 5)**.

Limit of detection (LOD) and Limit of Quantification (LOQ) (Table 7-9, Figure 6-8)

Standard deviation of intercept = Standard deviation error of intercept x√n

= 0.00151 x √5

= 0.00151 x 2.236

= 0.00337

Limit of detection (LOD) = 3.3 x S.D of intercept / Slope

The LOD value was analyzed by using formula

= 3.3 x 0.012/0.024

= 1.65µg/ml

Limit of Quantification (LOQ) = 10 x SD of intercept / slope

The LOQ value was analyzed by using the formula

= 10 x 0.012/0.024

= 5.0µg/ml

Table 1: Physical characteristics

Physical characteristics	Reported	Experimental
Colour	White	White
Odour	Odourless	Odourless
Taste	Tasteless	Tasteless
Appearance	Crystalline powder	Crystalline powder

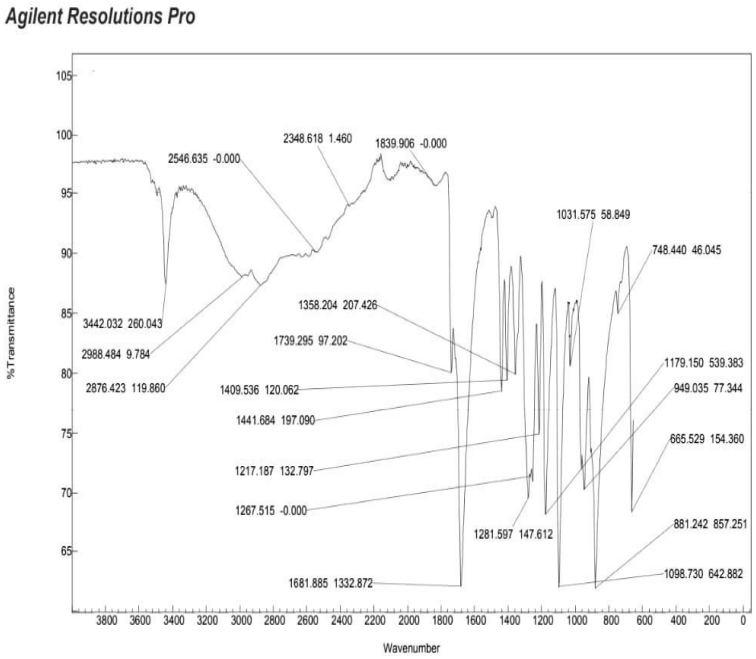

Figure 2: FT-IR of Lenvatinib

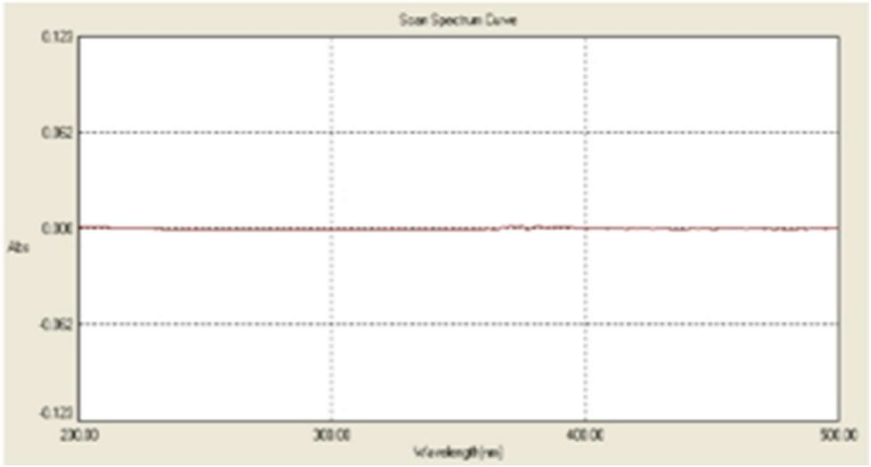

Figure 3: Standard spectrum of lenvatinib

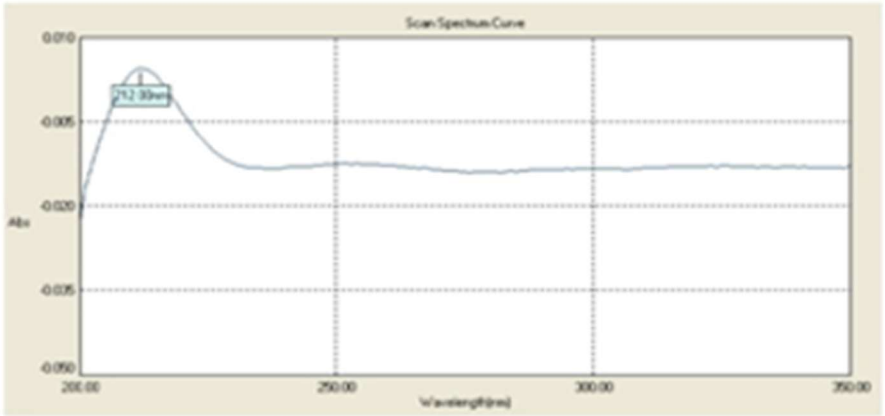

Figure 4: Absorbance maxima of lenvatinib

Table 2: Optical characteristics of lenvatinib by absorbance correction method

Parameters	At 212 nm
Beer's law limit (µg/ml)	4-12
Molar absorptivity (L mol Cm)	14883.9471
Sandell's sensitivity (µg/cm^2/0.01A.u)	0.025136
Correlation coefficient (r^2)	0.0999
Regression equation (y = mx + c)	y=0.012x+0.024
Slope (m)	0.012
Intercept (c)	0.024
LOD	1.65µg/ml
LOQ	5µg/ml
Standard deviation	0.0337

Table 3: Accuracy

Spiking level	Amount of absorbance (µg/ml)	Amount added (µg/ml)	Amount found (µg/ml)	% Recovery	Mean
80%	0.119	8	7.9	98.9%	99.2%
	0.119	8	7.9	98.9%	
	0.120	8	8	100%	
100%	0.143	10	9.8	98.3%	98.6%
	0.144	10	10	100%	
	0.143	10	9.8	98.3%	
120%	0.167	12	9.9	99.3%	99.6%
	0.168	12	10	100%	
	0.167	12	9.9	99.3%	

Table 4: Intraday analysis of lenvatinib by absorbance correction method

Concentration	
S. No.	Absorbance
1.	0.118
2.	0.119
3.	0.119
4.	0.119
5.	0.120
Mean	0.119
Standard Deviation	0.000707
% RSD	0.5941176

Table 5: Interday analysis of lenvatinib by absorbance correction method

Concentration	
S. No.	Absorbance
1.	0.115
2.	0.116
3	0.116
4.	0.116
5.	0.119
Mean	0.1164
Standard deviation	0.00151
% RSD	1.297250

Table 6: Linearity

Concentration (µg/ml)	Absorbance
4	0.062
6	0.09
8	0.118
10	0.143
12	0.168

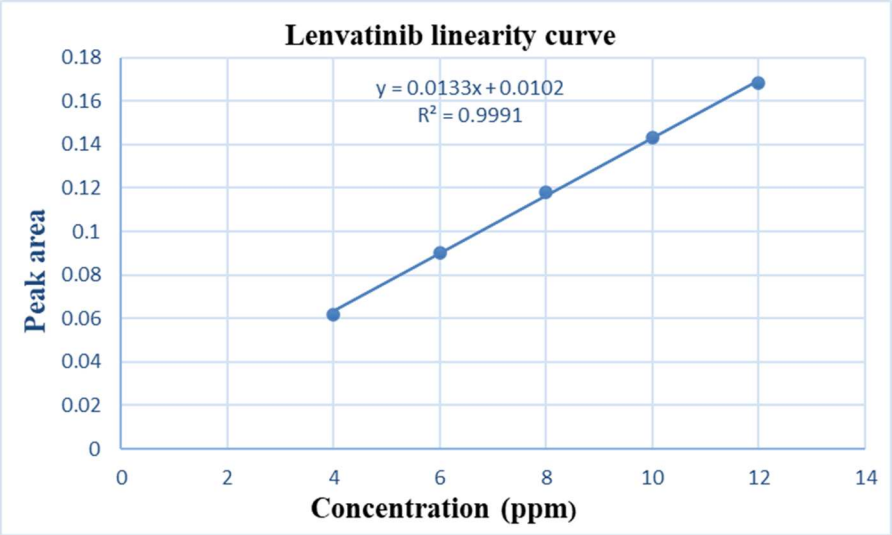

Figure 5: Linearity

Table 7: Calibration curve of lenvatinib in water as solvent

S. No.	Concentration	Absorption
1	0	0
2	1	0.1423
3	2	0.2792
4	3	0.3466
5	4	0.3870
6	5	0.4592

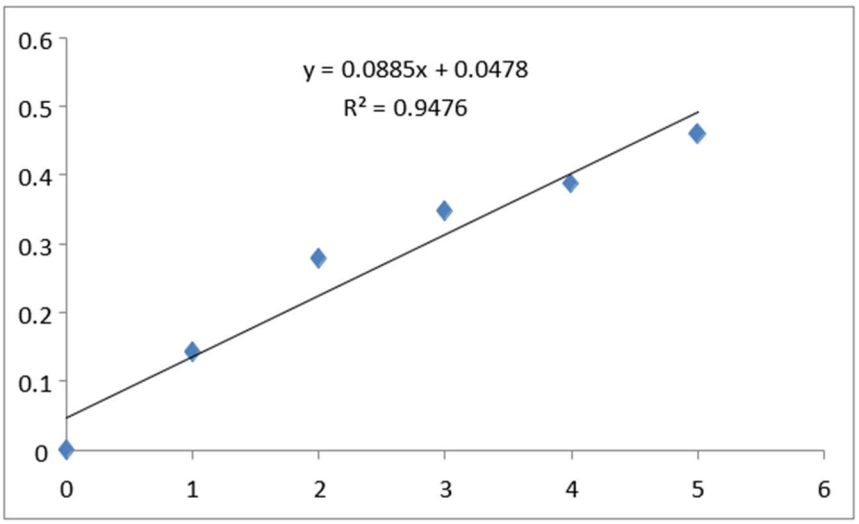

Figure 6: Calibration curve of lenvatinib in water as solvent

Table 8: Calibration curve of lenvatinib in phosphate buffer 6.8

S. No.	Concentration	Absorption
1	0	0
2	1	0.1227
3	2	0.2262
4	3	0.3591
5	4	0.4472
6	5	0.5397

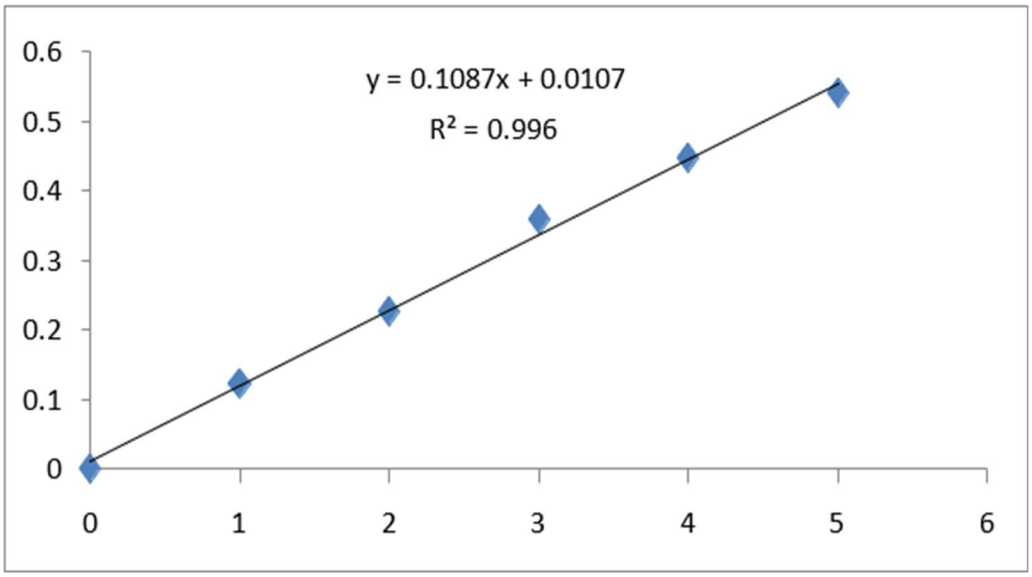

Figure 7: Calibration curve of lenvatinib in phosphate buffer 6.8

Table 9: Calibration curve of lenvatinib in 0.1N HCl

S. No.	Concentration	Absorption
1	0	0
2	1	0.1327
3	2	0.2762
4	3	0.3126
5	4	0.4509
6	5	0.5276

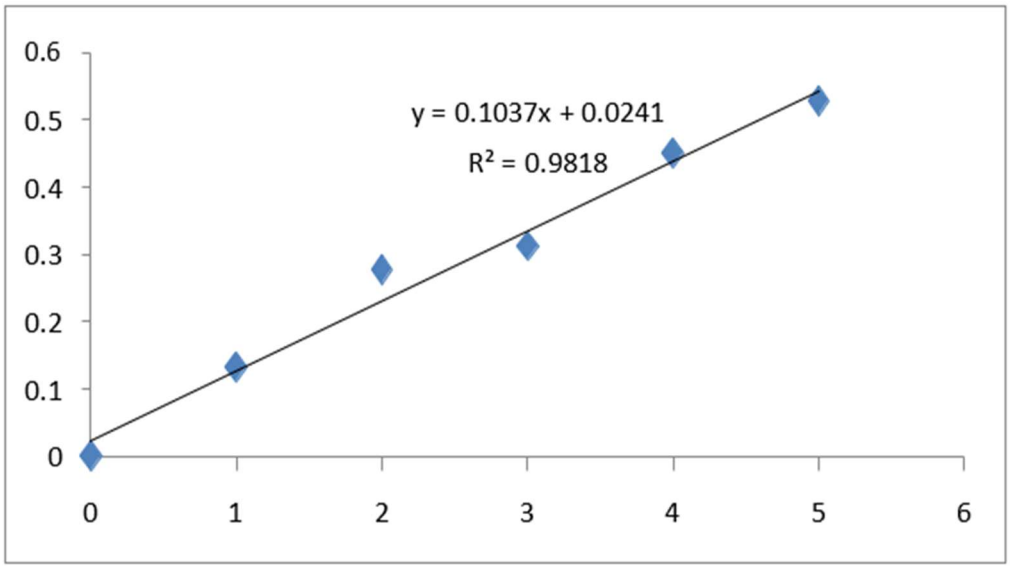

Figure 8: Calibration curve of lenvatinib in 0.1N HCl

Lenvatinib in different medium

Linearity: The linearity for Lenvatinib was determined by taking the concentration from 1-5 µg/ml for each solvent. The regression equation for water as solvent was found to be $y = 0.088x + 0.047$, $R^2 = 0.947$, for methanol as solvent was found to be $y = 0.100x + 0.029$, $R^2 = 0.955$, for phosphate buffer pH 6.8 as solvent the regression equation is y $y = 0.108x + 0.010$, $R^2 = 0.996$ and for 0.1 N HCl as solvent was found to be $y = 0.103x + 0.024$, $R^2 = 0.981$.

Range: The observed range of Lenvatinib in test solution was observed from 0.1423 nm to 0.4592 nm for water as solvent, 0.1627 nm to 0.4976 nm for methanol as solvent 0.1227 nm to 0.5397 for phosphate buffer pH 7.4 as solvent and 0.1327 nm to 0.527 for 0.1 N HCl as solvent.

CONCLUSION

A simple, rapid, precise and accurate UV-Spectrophotometric method was developed and validated for estimation of lenvatinib in bulk and pharmaceutical dosage forms. All the validation parameters were found to be within the acceptance criteria. This, the present developed method can be applied for the routine quality control analysis. Lenvatinib represents a significant advancement in the treatment of hepatocellular carcinoma (HCC) and other malignancies. As a multi-targeted tyrosine kinase inhibitor, it effectively impedes tumor growth by inhibiting receptors crucial for angiogenesis and proliferation. This pharmacological profile not only addresses the limitations of prior treatments like sorafenib but also offers potential synergy with immune checkpoint inhibitors, expanding therapeutic options. The therapeutic use of lenvatinib is further improved by the creation of an exact UV-visible spectrophotometric approach that guarantees precise dose and monitoring. Because of its affordability and ease of use, this approach is a vital tool for pharmaceutical analysis, enabling regular quality control and promoting the best possible patient results. Lenvatinib's function in targeted therapy highlights the significance of ongoing research and innovation in medication development as the field of cancer treatment changes. Its multi-pathway targeting makes it a vital component in the battle against many types of cancer, underscoring the continuous necessity for all-encompassing strategies that combine cutting-edge treatments with tried-and-true therapeutic methods.

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