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DEVELOPMENT OF UV-SPECTROPHOTOMETRIC METHOD FOR LAPATINIB IN PURE AND DOSAGE FORM

SRIDEVI RANJITHA K, SAMBASIVA RAO AYVNSAD, DEDEEPYA G, PRIYANKA P, VARAPRASADA RAO K, RAJESH BABU KB*

Department of Pharmaceutical analysis, Vignan Institute of Pharmaceutical Technology, Visakhapatnam, Andhra Pradesh-530046, India

***Corresponding Author: Dr. Bhagavan Rajesh Babu Koppisetty: E Mail: koppisettybrbabu@gmail.com**

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ABSTRACT

This study primarily focuses on developing a novel UV method for the assay of Lapatinib in both pure form and pharmaceutical dosage forms. The process involves preparing standard and working solutions of Lapatinib, followed by the analysis of different concentrations of the working solution. The established method is then subjected to validation as per ICH guidelines. The results indicate that the developed method is sensitive and accurate, particularly within the concentration range of 10-60 µg/ml. The correlation coefficient (R2) was determined to be 0.998. Notably, there was no interference observed with the excipients present in the formulation. The proposed method holds potential for the analysis of Lapatinib in bulk and formulation, making it suitable for routine analysis.

Keywords: Ultraviolet Spectroscopy, validation, Lapatinib, method development, assay

INTRODUCTION:

Lapatinib (LPB) belongs to the category of organochlorine and organofluorine compounds, as well as being classified as a member of both quinazolines and furans. It functions as both an antineoplastic medication and inhibitor of tyrosine kinase. It shares

functional similarities with a monofluorobenzene compound. LPB **(Figure 1)** is an anticancer medication formulated specifically for addressing solid tumor types like lung and breast cancer. The mode of action of lapatinib involves inhibition of protein kinase **[1-3]**.

Through a comprehensive examination of existing literature, it has been observed that only a small amount of research has been recorded on this topic regarding the assessment of LPB using HPLC **[4-5]**. There are no UV spectrophotometric methods reported for analysis of LPB.

This investigation aimed to analyze LPB in both its pure form and pharmaceutical formulation, specifically tablets. Following the development of the UV method, all optimization parameters were taken into account. The validated method proved successful, affirming its appropriateness for determining the overall drug content in commercially accessible LPB formulations. Consequently, the development and validation processes adhered to ICH guidelines **[6-9]**.

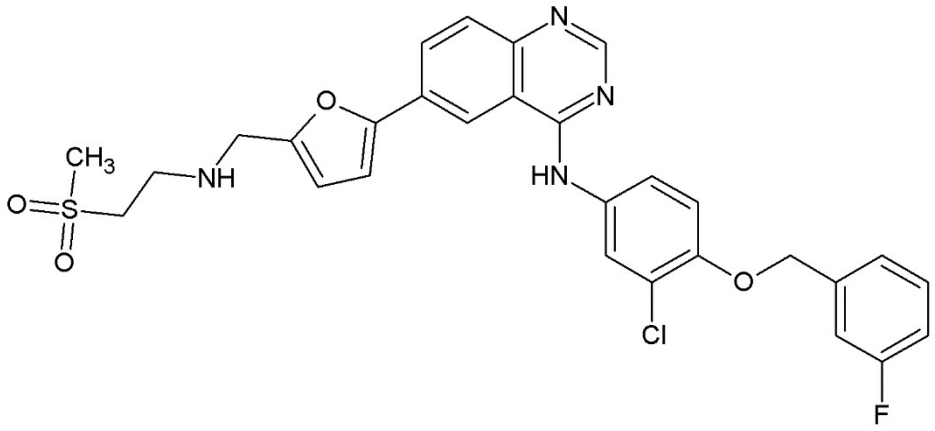

Figure 1: Chemical structure of LPB

MATERIALS AND METHODS:

Instruments and Reagents:

A complimentary sample of LPB with a purity level of 99.98% was obtained from a manufacturing facility located in Visakhapatnam. The instruments employed in the study included UV/Visible spectrophotometer, Lab india, model T60 and analytical balance, Shimadzu, Japan. The investigation utilized analytical-grade chemicals and reagents. COBINIB-branded LPB tablets, each containing 250 mg, were obtained for the formulation.

Standard stock solution (1000µg/ml):

A quantity of 100 mg of the drug was introduced into a 100 ml calibrated flask, where it was dissolved and topped up to the calibration mark with acetonitrile, resulting in

1000 µg/ml. This establishes the standard stock solution of LPB.

Working standard solution (100µg/ml):

A quantity of 2.5 ml was extracted from the standard stock solution mentioned earlier and transferred into a 25 ml calibrated flask. Acetonitrile was added to the flask to achieve a concentration of 100 µg/ml, and the solution was adjusted to the mark.

Calibration curve:

Following that, it was subjected to scanning using a UV Spectrophotometer covering the 200-400 nm range, with acetonitrile employed as the blank. The peak absorbance was pinpointed at a wavelength of 307 nm. To generate different concentrations spanning from 10 to 60 µg/ml, portions were formulated using distilled water as the solvent. These samples were then assessed at the specified wavelength of 307 nm to ascertain their respective absorbance values. The collected data was subsequently used to construct a calibration curve.

RESULTS AND DISCUSSION

Method Validation:

Linearity:

Various samples of LPB were created within the 10-60 µg/ml range using the working standard solution (40 µg/ml). These solutions underwent scanning on a UV-spectrophotometer spanning the 200-400 nm range, with acetonitrile serving as the reference. The spectrum was captured at 307 nm **(Figure 2)**. The data illustrated the relationship between concentration and absorbance, is depicted in **Table 1**. The results indicate a high degree of linearity in the established relationship.

Precision:

The method's precision was showcased through assessments of intra-day and inter-day variations. In the intra-day analysis, six separate solutions with 40 µg/ml were created and assessed twice daily. For the inter-day study, solutions of 40 µg/ml were formulated and was tested six times over two successive days, and the absorbance was noted (refer to **Table 2**). The calculated percentage of relative standard deviations was found to be below 2%.

Accuracy:

The method's accuracy was assessed using the standard addition method, wherein the percent recovery of LPB was computed. Pre-quantified sample solutions of LPB were supplemented with known quantities of standard solutions at 80%, 100%, and 120% levels. These solutions were prepared in triplicate, and the accuracy, as indicated by the %recovery, was calculated and presented in **Table 3**. The %recovery was determined to be satisfactory.

Robustness:

The method's reliability was evaluated through the examination of a sample with a concentration of 40 µg/ml at three distinct wavelengths, including one at λ max, and recording the corresponding absorbance values. The outcomes presented in **Table 4** suggest that the method demonstrated robustness.

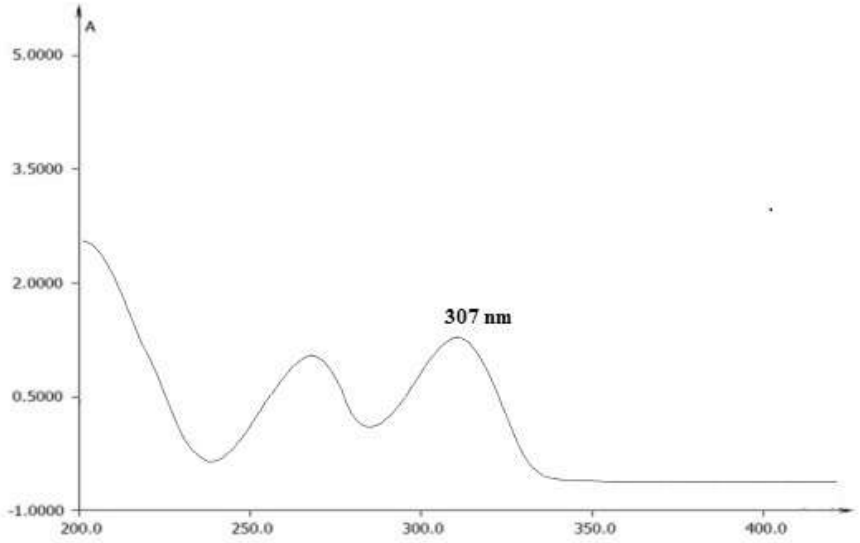

Figure 2: Spectrum obtained for pure drug

Table 1: Linearity

Concentration (µg/ml)	Absorbance
10	0.2154
20	0.3272
30	0.4314
40	0.5341
50	0.6497
60	0.7824
Regression equation	Y = 0.0112x + 0.0995
Correlation coefficient(R^2)	0.9981

Table 2: Intermediate Precision

Conc. [µg/ml]	Absorbance	
	Examiner-1/Day-1	Examiner-2/Day-2
40	0.5341	0.5398
40	0.5301	0.5347
40	0.5367	0.5323
40	0.5398	0.5304
40	0.5324	0.5365
40	0.5366	0.5355
Mean	0.5349	0.5348
S.D	0.0034	0.0032
%RSD	0.64	0.61

Table 3: Accuracy of method

Addition Level	Amount of formulation	Quantity added	Hypothetical quantity.	Experimental amount	% recovery
80%	40	32	36	35.87	99.63
100%	40	16	40	39.74	99.35
120%	40	48	44	43.91	99.79

Table 4: Robustness Study

Conc. (µg/ml)	Absorbance		
	306nm	307nm	308nm
40	0.5247	0.5341	0.5421
40	0.5298	0.5301	0.5485
40	0.5274	0.5367	0.5402
40	0.5215	0.5398	0.5391
40	0.5238	0.5324	0.5455
40	0.5267	0.5366	0.5486
AVG	0.5256	0.5349	0.5440
SD	0.0029	0.0034	0.0041
%RSD	0.55	0.64	0.76

Ruggedness:

To assess the ruggedness of the method, the sample was analyzed by two different analysts using the identical apparatus, and by the same examiner using two different cuvettes, with the respective absorbance values recorded. The results from the first analyst revealed a %RSD of 0.34, while the second analyst showed a %RSD of 0.47. These results indicate that the utilized methodology was robust, as no notable distinction is evident among various operators.

Sensitivity:

The drug's LOD and LOQ were determined from the standard curve and found to be 2.83 µg/ml and 8.59 µg/ml, respectively.

Assay of formulation*:*

The analysis of the obtained formulation involved assaying an equivalent weight of 25 mg of LPB formulation in a 25 ml calibrated flask, utilizing acetonitrile as the diluent. The final concentration was adjusted to 40 µg/ml using distilled water. The assessment was conducted at a UV wavelength of 307 nm, revealing an assay result of 99.64%.

CONCLUSION:

The proposed method proved to be simple, exhibiting accuracy, precision, and robustness while being easily implementable. The calibration plot covered a broad range, and the recoveries of samples were consistent. The equipment and reagents utilized are likely to be accessible, even in basic laboratory setups. Therefore, the established method is recommended for regular use in quality control analysis of LPB. Additionally, it is deemed suitable for analyzing samples in accelerated stability studies, routine

formulation analyses, and the assessment of drug substance.

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