

Analytical Method Validation Report for Assay of Lapatinib by UPLC

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ABSTRACT

Objective: A new, simple, rugged, rapid, robust and precise ultra-performance liquid chromatographic (UPLC) method for estimation of Lapatinib in a bulk and tablet dosage form has been developed and validated according to ICH Guidelines. **Methods:** The chromatographic separation was achieved using BHEL UPLC Column. The mobile phase used was a mixture of 0.1% OPA buffer 300 ml (30%) and 700ml Acetonitrile (70%) at isocratic mode and eluents were monitored at 309 nm using PDA detector. **Results:** By the method Lapatinib was eluted with retention time of 0.516 mins. The method was continued and validated accordance with ICH guidelines. Validation revealed the method is rapid, specific, accurate, precise, reliable and reproducible. Calibration curve plots were linear over the concentration ranges 10-50 µg/mL for Lapatinib. Limit of detection (LOD) were 0.06 µg/ml

and limit of quantification (LOQ) were 0.18µg/mL for Lapatinib. **Conclusion:** The statistical analysis was proves the method is suitable for the estimation of Lapatinib as a bulk and tablet dosage form without any interference from the excipients.

Key words: Lapatinib, UPLC, Method Development, Method Validation, ICH Guidelines.

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INTRODUCTION

Lapatinib is an anti-cancer drug developed by GlaxoSmithKline (GSK) as a treatment for solid tumours such as breast and lung cancer. It was approved by the FDA on March 13, 2007, for use in patients with advanced metastatic breast cancer¹⁻³ in conjunction with the chemotherapy drug Capecitabine. It binds to the intracellular phosphorylations domain to prevent receptor auto phosphorylations upon ligand binding. Indicated in combination with capecitabine for the treatment of patients with advanced or metastatic breast cancer whose tumors over express the human epidermal receptor type 2 (HER2) proteins and who have received prior therapy including an anthracycline, a taxane and trastuzuma. An additive effect was demonstrated in an *in vitro* study when lapatinib and 5-florouracil (the active metabolite of capecitabine) were used in combination in the 4 tumor cell lines tested. The growth inhibitory effects of lapatinib were evaluated in trastuzumab-conditioned cell lines. Lapatinib⁴⁻⁶ retained significant activity against breast cancer cell lines selected for long-term growth in trastuzumab-containing medium *in vitro*. These *in vitro* findings suggest non-cross-resistance between these two agents.

Lapatinib is chemically N-{3-chloro-4-[(3-fluorophenyl) methoxy] phenyl}-6-(5-[(2-methane sulfonyl ethyl) amino] methyl) furan-2-yl) quinazolin-4-amine and its molecular formula C₂₉H₂₆ClFN₄O₄S (Figure 1)^{7,8} The Chemical Structure of Lapatinib is shown in Figure 1.

In the scientific Literature survey⁹ reveals that various analytical methods^{10,11} have been reported for the assay of Lapatinib in pure form and in tablet dosage forms. Many methods have been reported in the literature,^{12,13} for the estimation of Lapatinib individually^{14,15} and in other combination.^{15,10} The present investigation was aimed at developing a fully validated UPLC method for the estimation of Lapatinib in bulk and tablet dosage form^{11,12} that is more economical, simple, new, precise, robust, rugged and accurate than the previous methods.

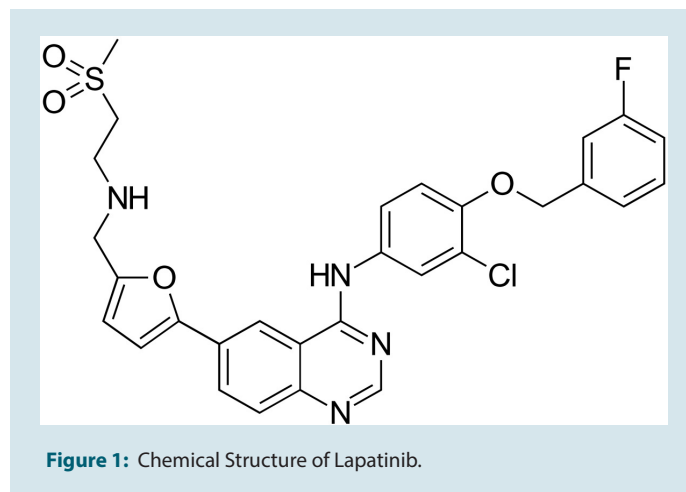


Figure 1: Chemical Structure of Lapatinib.

MATERIALS AND METHODS

Chemicals and Reagents

Pharmaceutical grade working standards Lapatinib was a gift sample obtained from Syncorp Clinicare Pvt. Laboratories, Hyderabad, India. The tablets of Lapatinib were obtained from Local Market. All chemicals and reagents were required for the method development and validation and Stability Studies were purchased from S D Fine-Chem Limited and Loba Chemie Pvt. Ltd, Mumbai, India.

Instrumentation Conditions

The analysis was performed using Ultra performance liquid chromatography (UPLC) equipped with Auto Sampler and PDA detector and analytical balance 0.1mg Sensitivity (SHIMADZU), pH meter (Labindia), Ultra Sonicator. The column used is BHEL UPLC Column with the flow rate 0.25ml/min (isocratic) Detection was carried out at 309nm and peak purity of Lapatinib was also determined. The method which is developed was validated according to ICH guidelines.

Preparation of 0.1% OPA buffer pH 3

To prepare 0.1% OPA buffer solution, by adding 1ml of ortho phosphoric acid in 1000ml water. Adjust this solution to pH 3 by using sodium hydroxide.

Preparation of mobile phase

Mix a mixture of 0.1% OPA buffer 300 ml (30%) and 700 ml Acetonitrile (70%) and degas in ultrasonic water bath for 5 min. Filter through 4.5 µ filter under vacuum filtration.

Diluents Preparation

0.1% OPA buffer: Acetonitrile (30:70) ratio.

Study of Spectra and Selection of Wavelength

UV spectrum of 10µg/ml Lapatinib in diluents (mobile phase composition) was recorded by scanning in the range of 200nm to 400nm. From the UV spectrum wavelength selected as 309 nm. At this wavelength⁷ both the drugs show good absorbance. UV spectrum and typical standard chromatogram of Lapatinib are shown in Figure 2.

Preparation of Standard Solution

Accurately weigh and transfer 10 mg of Lapatinib is taken into a 10ml clean dry volumetric flask add Diluent and sonicate to dissolve it completely and make volume up to the mark with the diluent. (Stock solution)

Further pipette 0.3 ml of Lapatinib of the above stock solution into a 10ml volumetric flask and dilute up to the mark with diluent.

Sample Solution Preparation

Accurately weigh and transfer equivalent to 10 mg of Lapatinib sample is taken into a 10ml clean dry volumetric flask add diluents and sonicate to dissolve it completely and make volume up to the mark with the diluent. (Stock solution)

Further pipette 0.3 ml of Lapatinib of the above stock solution into a 10ml volumetric flask and dilute up to the mark with Diluent.

Optimization of UPLC Method

The selected and optimized mobile phase was 0.1% OPA Buffer: Acetonitrile (30:70v/v) and conditions optimized were: flow rate (0.25 ml/min), wavelength (309 nm, PDA-detector), run time was 3 mins and injection volume was 5 µl.

Method Validation

The developed method for the estimation of Lapatinib was validated according the guidelines ICH^{17,18} for the method validation parameters

such as system suitability, specificity, accuracy, precision linearity, ruggedness and robustness, detection limit (LOD) and quantification limit (LOQ).

Linearity and range

Aliquots of 0.1, 0.2, 0.3, 0.4 and 0.5ml of standard working solution of Lapatinib was pipetted out from the standard stock solution of 1000µg/ml of Lapatinib and transferred into a series of 10ml clean dry volumetric flask and make volume up to the mark with diluent to get the concentration of 10, 20, 30, 40 and 50µg/ml of Lapatinib.

Accuracy

The accuracy of the method was determined by calculating recovery of Lapatinib by the method of standard addition. Known amount of standard solution of Lapatinib at 50%, 100% and 150% was added to a pre quantified sample solution and injected into the UPLC system.

Precision

The precision of each method was ascertained separately from the peak areas obtained by actual determination of five replicates of a fixed amount of drug Lapatinib.

Limit of Detection and Quantification

Detection Limit (LOD) and Quantification Limit (LOQ) are measured as $3.3 \times SD/S$ and $10 \times SD/S$ respectively as per the Guidelines of ICH, Where SD is the standard deviation response (Y-intercept) and S is the slope of calibration curve. The LOD is the least amount of concentration of the analyte that gives a measurable response (signal to noise ratio of 3). The LOQ is the concentration of the analyte which gives a response that can be precisely quantified (signal to noise ratio of 10). Signal to noise ratio between 10:1 has been considered for this method.

Robustness

Robustness is intentional smallest changes in the flow rate. Temperature ($\pm 2^\circ\text{C}$), flow rate (± 0.1 ml/min) organic phase (± 2) and wavelength (± 2 nm) were made to assess the influence on the developed method.

System suitability

The system suitability parameters with respect of tailing factor, theoretical plates, repeatability and resolution between Lapatinib peaks was defined.

Specificity

The influence of excipients and other excipients present in the dosage form of Lapatinib in the estimation under the optimum conditions are investigated. The specificity of the developed UPLC method was recognized by injecting the solution of blank into the UPLC system. The specificity method was also evaluated to ensure that there were no interference products resulting from forced degradation studies.

Forced degradation study

The API (Lapatinib) was subjected to keep in some stress conditions in various ways to observe the rate and extent of degradation that is likely to occur in the course of storage and/or after administration to body. The different types of forced degradation pathways/studies are studied here are acid hydrolysis, basic hydrolysis, thermal degradation and oxidative degradation. Degradation studies were done to find the loss of drug by acid, alkali, thermal, photo and oxidation were carried out. These studies find out the Lapatinib drug was found to be stable in oxidative stress studies.

Acid Degradation

An accurately weighed 10 mg of pure drug was transferred to a clean and dry round bottom flask. 30 ml of 0.1 N HCl was added to it and it was refluxed in a water bath at 60°C for 4 h. Allowed to cool to room temperature. The sample was then neutralized using dilute NaOH solution and

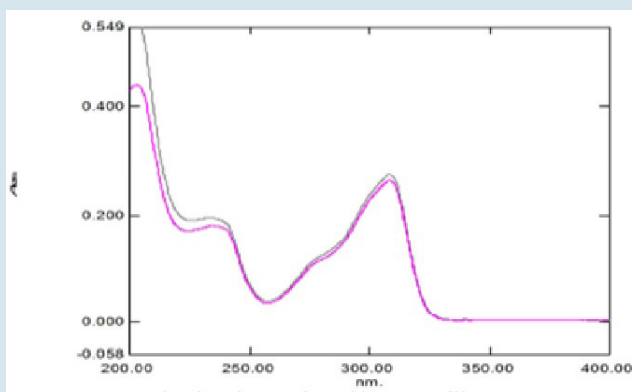


Figure 2: UV-Spectrum of Lapatinib at 309nm

final volume of the sample was made up to 100ml with water to prepare 100 µg/ml solution. It was injected into the UPLC system against a blank of mobile phase (after optimizing the mobile phase compositions). This experiment was repeated several times using same concentration of HCl (0.1N) and observed its degradation profile. The typical chromatogram shown below is the degradation profile of Lapatinib in 0.1N HCl.

Alkali Degradation

An accurately weighed 10 mg of pure drug was transferred to a clean and dry round bottom flask. 30 ml of 0.1N NaOH was added to it, and it was refluxed in a water bath at 60°C for 4 h. Allowed to cool to room temperature. The sample was then neutralized using 2N HCl solution and final volume of the sample was made up to 100ml to prepare 100 µg/ml solution. It was injected into the UPLC system against a blank of mobile phase after optimizing the mobile phase compositions. This experiment was repeated several times using same concentration of NaOH such as 0.1N to observe its degradation profile. The chromatogram shown below is the degradation profile of Lapatinib in 0.1N NaOH.

Oxidative Degradation

Accurately weighed 10 mg. of pure drug was taken in a clean and dry 100 ml volumetric flask. 30 ml of 3% H₂O₂ and a little methanol was added to it to make it soluble and then kept as such in dark for 24 h. Final volume was made up to 100 ml. using water to prepare 100 µg/ml solution. The above sample was injected into the UPLC system.

Photolytic Degradation

Approximately 10 mg of pure drug was taken in a clean and dry Petri dish. It was kept in a UV cabinet at 254 nm wavelength for 24 h without interruption. Accurately weighed 1 mg of the UV exposed drug was transferred to a clean and dry 10 ml volumetric flask. First the UV exposed drug was dissolved in methanol and made up to the mark with mobile phase to get 100 µg/ml solution. Finally this solution was injected into the UPLC system against a blank of mobile phase and chromatogram was obtained.

Thermal Degradation

Accurately weighed 10 mg of pure drug was transferred to a clean and dry round bottom flask. 30 ml of HPLC water was added to it. Then, it was refluxed in a water bath at 60° C for 6 h uninterruptedly. After the reflux was over, the drug became soluble and the mixture of drug and water was allowed to cool to room temperature. Final volume was made up to 100 ml with HPLC water to prepare 100 µg/ml solution. It was injected into the UPLC system against a blank of mobile phase.

Estimation of marketed formulation

The marketed formulation was assayed by above description. The peak areas were monitored at 309nm and determination of sample concentrations were using by multilevel calibration developed on the same UPLC system under the same conditions using linear regression.

RESULTS AND DISCUSSION

Study of Spectra and Selection of Wavelength

The maximum absorbance of the Lapatinib was found to be 309nm.

Optimization of Chromatographic Method

To develop a new, precise, robust, linear, rugged, specific and suitable stability indicating UPLC method for analysis of Lapatinib, different chromatographic conditions were applied. The optimized conditions were mobile phase was 0.1% OPA Buffer: Acetonitrile and conditions optimized were: flow rate (0.25 ml/minute), wavelength (309 nm, PDA-detector), run time was 3 mins and injection volume was 5 µl. The proposed chromatographic conditions were found appropriate for the

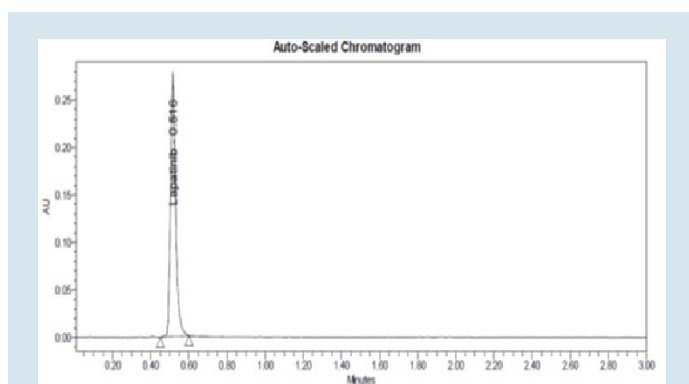


Figure 3: Chromatogram for Optimized Condition

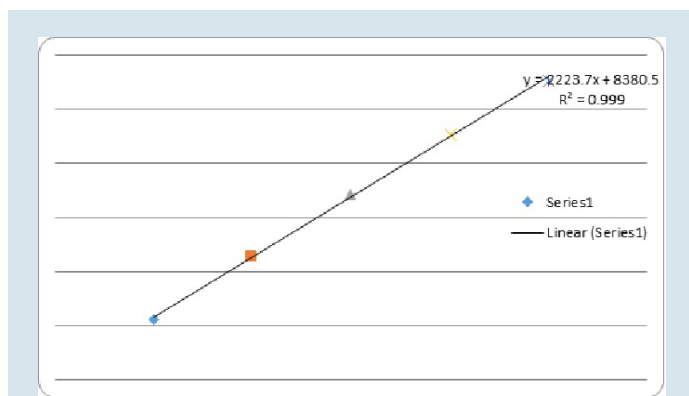


Figure 4: Calibration Curve for Lapatinib

quantitative determination of the drugs and also suitable for determination. The Optimized chromatogram shown in Figure 3.

Method Validation Results

Linearity and Range

The calibration standard solutions of Lapatinib were injected into the UPLC system and the chromatograms were recorded at 309nm and a calibration graph was obtained by plotting peak area versus concentration of Lapatinib. The linearity data is presented in Figure 4 and Table 2. Linearity range was found to be 10-50 µg/ml for Lapatinib. The correlation coefficient was found to be 0.999, the slope was found to be 2223 and intercept was found to be 8380 for Lapatinib. The results are shown in Table 1. The graph of area Vs concentration recorded for the drug and is shown in Figure 4.

Accuracy

The mean recovery was found to be 99.69% for Lapatinib. The limit for mean % recovery is 98-102% and the values are within the limit, hence it can be said that the proposed method was accurate. The results are shown in Table 6.

Precision

The percentage relative standard deviations were calculated for Lapatinib is presented in the Table 2.

LOD and LOQ

The LOD was found to be 0.06µg/ml and LOQ was found to be 0.18 µg/ml for Lapatinib which shows that the sensitivity of the proposed method is high.

Robustness

The obtained results make known that the method is robust. The gained results are summarized in Table 3.

System suitability

To establish the system suitability for the proposed method and the parameters such as retention time, peak asymmetry and theoretical plates and tailing factor were taken and obtained results were presented in Table 4.

Specificity

No peaks were found at the retention of Lapatinib. Specificity studies indicating that the excipients did not interfere with the analysis.

Forced degradation studies

The obtained results of the degradation (stress) studies indicated that the specificity of the developed method. The Lapatinib was stable in oxidative (degradation) stress condition. The obtained results of forced degradation studies are given in Table 5.

Estimation of Marketed Formulation

The amount of drugs in Tykerb tablet was found to be 249.86 (99.39±0.26%) mg/tab for Lapatinib. The results are shown in following.

Table 1: Linearity Results: (for Lapatinib)

S.No.	Linearity Level	Concentration	Area
1	I	10	223566
2	II	20	451574
3	III	30	686062
4	IV	40	910009
5	V	50	1106177
Correlation Coefficient			0.999

Table 2: Repeatability Results of Lapatinib

Injection	Area
Injection-1	517409
Injection-2	510348
Injection-3	513414
Injection-4	512149
Injection-5	519131
Injection-6	518382
Average	514490.2
Standard Deviation	3669.3
%RSD	0.7

Table 3: Robustness results for Lapatinib

S.No.	Change in Organic Composition in the Mobile Phase	System Suitability Results	
		USP Plate Count	USP Tailing
1	10% less	3456	1.50
2	*Actual	3559.77	1.34
3	10% more	3658.61	1.20

Table 4: System suitability results for Lapatinib

S.No.	Flow Rate (ml/mm)	System Suitability Results	
		USP Plate Count	USP Tailing
1	0.225	3912.96	1.33
2	0.25	3559.77	1.34
3	0.275	3777.23	1.37

Table 5: Forced Degradation Studies of Lapatinib

Sample Name	Lapatinib	
	Area	% Degraded
Standard	515334	3.11
Acid	499327	3.94
Base	495047	3.11
Peroxide	499327	4.87
Thermal	490258	3.66
Photo	496473	3.11

Table 6: Accuracy Results for Lapatinib

Concentration (at specification Level)	Area	Amount Added (mg)	Amount Found (mg)	% Recovery	Mean Recovery
50%	259165	5	5.02	100.38	99.69
100%	512988	10	9.93	99.35	
150%	769433.0	15	14.90	99.34	

$$\frac{513204}{515334.3} \times \frac{10}{10} \times \frac{3}{10} \times \frac{10}{45} \times \frac{10}{3} \times \frac{45}{10} \times \frac{99.8}{100} \times 100 = 99.39\%$$

CONCLUSION

The result shows the developed method is yet another new suitable method for assay and stability studies which can help in the analysis of Lapatinib in bulk and tablet dosage form. Based on peak purity results, obtained from the analysis of forced degradation samples using described method, it can be concluded that the absence of co-eluting peak along with the main peak of Lapatinib indicated that the developed method is specific for the estimation of Lapatinib in presence of degradation products. Further the proposed UPLC method has excellent sensitivity, precision and reproducibility.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

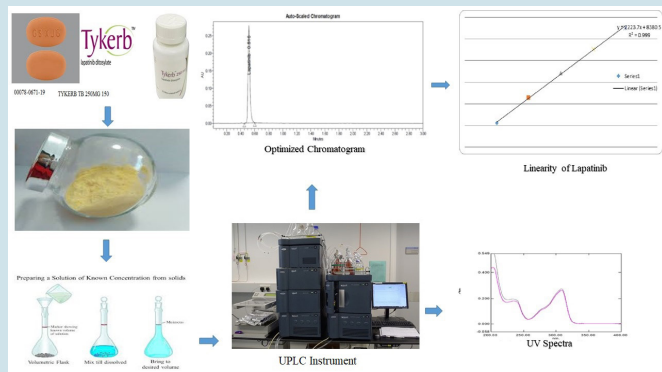
ABBREVIATIONS

UPLC: Ultra Performance Liquid Chromatography; **OPA:** Ortho-Phosphoric acid; **ICH:** International Council for Harmonization; **LOD:** Limit of Detection; **LOQ:** Limit of Quantitation; **RSD:** Relative Standard Deviation.

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PICTORIAL ABSTRACT



SUMMARY

- The Present Research work was designed to validate a UPLC method for estimation of Lapatinib in a bulk and tablet dosage form. The chromatographic separation was achieved using BHEL UPLC Column. The mobile phase used was a mixture of 0.1% OPA buffer 300 ml (30%) and 700 ml Acetonitrile (70%) at isocratic mode and eluents were monitored at 309 nm using PDA detector. The developed method was validated as per ICH guidelines.
- The result (%RSD) of the each validated parameters were within the limit.
- Force degradation studies show various degradation patterns of Lapatinib.
- The developed method was applied successfully for the determination of Lapatinib in tablet dosage form.

ABOUT AUTHORS



Mr. Sabyasachi Biswal: Research Scientist in a Pharma Industry and pursuing PhD under the guidance of Dr. Sumanta Mondal at GITAM Institute of Pharmacy, GITAM (Deemed to be University), Andhra Pradesh, India. He has 6 yrs good research knowledge on the polymorphism and chromatographic technique.



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