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Research Paper

Method Development and Validation of Capmatinib in Solid Dosage Form by RP-HPLC Method

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ABSTRACT

The study focuses on the development and validation of a reverse-phase high-performance liquid chromatography (RP-HPLC) method for quantitative estimation of Capmatinib in bulk drug and marketed tablet formulation. The objective was to establish a rapid, precise, accurate, robust, and economical analytical method suitable for routine quality control. Chromatographic separation was achieved using a Phenomenex C18 column (250 × 4.6 mm, 5 µm). The mobile phase consisted of Methanol and 0.05% Orthophosphoric Acid in water (70:30, v/v), delivered at a flow rate of 1.0 mL/min. Detection was carried out at 233 nm using a UV detector. The retention time obtained for Capmatinib was approximately 3.15 minutes. The developed method was validated according to ICH Q2(R1) guidelines. Validation parameters included: System suitability Filter compatibility Solution stability Specificity Linearity Accuracy Precision LOD LOQ Robustness The developed analytical method demonstrated satisfactory performance in all validation studies and was found suitable for routine pharmaceutical quality control.

INTRODUCTION

Pharmaceutical Analysis

The thesis describes pharmaceutical analysis as the branch of analytical chemistry dealing with the qualitative and quantitative analysis of drug substances and pharmaceutical formulations. It highlights the growing importance of analytical techniques in ensuring drug quality, efficacy, and safety throughout product development and manufacturing.

Importance of Chromatography

The thesis explains chromatography as one of the most important separation techniques used in pharmaceutical industries. High-performance liquid chromatography (HPLC) has become the preferred analytical technique because of its:

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- High sensitivity
- High specificity
- Excellent precision
- Accuracy
- Rapid analysis
- Low detection limits

HPLC is extensively employed in routine quality control and stability testing of pharmaceutical formulations.

Capmatinib

Capmatinib belongs to the kinase inhibitor class.

It is approved for treating adult patients with metastatic non-small cell lung cancer (NSCLC) possessing MET exon 14 skipping mutations.

The thesis discusses:

- MET signalling pathway
- Mechanism of action
- Clinical importance
- Therapeutic application
- Role in targeted cancer therapy

Need of Study

The thesis indicates that although several analytical methods exist for Capmatinib, there remains a need for a method that is:

- Rapid
- Economical
- Highly accurate
- Precise
- Robust
- Suitable for routine industrial quality control

This forms the rationale for the study.

5. Aim

To develop and validate a simple, rapid, precise, accurate, and robust RP-HPLC method for estimation of Capmatinib in tablet dosage form according to ICH guidelines.

6. Objectives

The thesis supports the following objectives:

- Develop RP-HPLC analytical method.
- Optimize chromatographic conditions.
- Establish system suitability.
- Validate according to ICH Q2(R1).
- Apply method to marketed tablet assay.

7. Materials

The thesis includes:

Drug

Capmatinib

Chemicals

- Methanol
- Orthophosphoric Acid
- Water
- Analytical reagents

Instruments

- HPLC system
- UV detector
- OpenLab EZChrome software
- Phenomenex C18 column

8. Experimental Methodology

The thesis contains detailed procedures for:

- Standard preparation
- Sample preparation
- Placebo preparation
- Assay procedure
- Filter study
- Stability study
- Validation studies

9. Optimized Chromatographic Conditions

Parameter	Condition
Column	Phenomenex C18 (250 × 4.6 mm, 5 µm)
Mobile Phase	Methanol : 0.05% OPA (70:30 v/v)
Flow Rate	1.0 mL/min
Detection	UV
Wavelength	233 nm
Retention Time	3.15 min

LINEARITY AND RANGE:

Preparation of linearity solution The linearity of an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample. 5 levels of Linearity was performed from 50% to 150% of working concentration Linearity Capmatinib stock solution: Weighed 29.41 mg of Capmatinib HCl anhydrous (Equivalent to 25 mg of Capmatinib) and dissolved in 50 mL with methanol. Further diluted 5.0 ml of stock solution to 50 mL with methanol. (100 PPM)

Table: Linearity level preparation for HPLC

Level (%)	mL of stock solution	Diluted to with mobile phase (mL)	Capmatinib Concentration (µg/mL)
50	2	20	10
75	3	20	15
100	4	20	20
125	5	20	25
150	6	20	30

Determination:

Each level injected in triplicate and mean area calculated. Calibration curve was plotted graphically as a function of analyte concentration in µg/mL on X-axis Vs mean area on y-Axis as given in results.

Acceptance criteria:

Correlation Coefficient: NLT 0.98

Intercept: To be report

Slope: To be report

Limit of Detection (LOD) and Limit of Quantitation (LOQ):

Detection limit:

The detection limit of an individual analytical procedure is the lowest amount of analyte in a sample which can be detected but not necessarily quantitated as an exact value.

Quantitation limit:

The quantitation limit of an individual analytical procedure is the lowest amount of analyte in a

sample which can be quantitatively determined with suitable precision and accuracy. As per ICH Q2R1 guidelines LOD and LOQ was determined by using the approach Based on the Calibration Curve in which residual standard deviation of a regression line was calculated and determined the LOD and LOQ by using following formula:

Accuracy levels details:

Refer Following table for each sample:

Table : Accuracy of sample preparation

Level (%)	apmatinib HCl hydrous Std (mg)	acebo (mg)	Diluted to (mL)	ume ken mL)	Diluted to (mL)	Capmatinib oncentration (µg/mL)
50	29.6	186.7	100	1	25	10.06
	29.4	187.3	100	1	25	10.00
	29.5	187.1	100	1	25	10.03
100	58.9	186.8	100	1	25	20.03
	59.2	187.4	100	1	25	20.13
	59.1	187.2	100	1	25	20.09
150	88.4	186.9	100	1	25	30.06
	88.3	186.6	100	1	25	30.02
	88.4	187.1	100	1	25	30.06

Precision (Repeatability) Sample details are as follows:

Table: Repeatability Precision sample preparation Acceptance criteria:

Sample No.	Test powder material (mg)	Diluted to (mL)	Volume taken (mL)	Diluted to (mL)
1	245.6	100	1	25
2	245.8	100	1	25
3	246.1	100	1	25
4	246.3	100	1	25
5	246.2	100	1	25
6	245.3	100	1	25

% Assay: 90-110% for each sample and mean assay value

% RSD for % assay of 6 samples: NMT 2%

II. Intermediate precision

It is performed by doing analysis on another day to check reproducibility of results. Samples prepared

in same manner as that of Repeatability parameter (6 Samples prepared).

Intermediate Precision Sample details are as follows:

Table: Intermediate Precision sample preparation

Sample No.	Test powder material (mg)	Diluted to (mL)	Volume taken (mL)	Diluted to (mL)
1	245.4	100	1	25
2	245.9	100	1	25
3	245.2	100	1	25
4	246.3	100	1	25
5	245.7	100	1	25
6	246.1	100	1	25

Procedure for preparation of Accuracy sample solution:

Take clean and dried 9 volumetric flasks of 100 mL. Weighed approx. 186.98 mg of placebo and transferred in each 100 mL volumetric flask. Weighed Capmatinib HCl anhydrous API as per accuracy level and transferred in same 100 ml volumetric flask. Add 70-75 ml of Methanol sonicated it for 10 minutes with intermittent shaking. Allowed to cool the solution at room temperature and made the volume up to the mark with Methanol. Filter the solution through suitable 0.45 µ syringe filter discarding5 mL of filtrate. Further dilute 1.0 ml of filtrate to 25 ml with mobile phase**.** **Selection of analytical wavelength**

1) Blank Methanol:

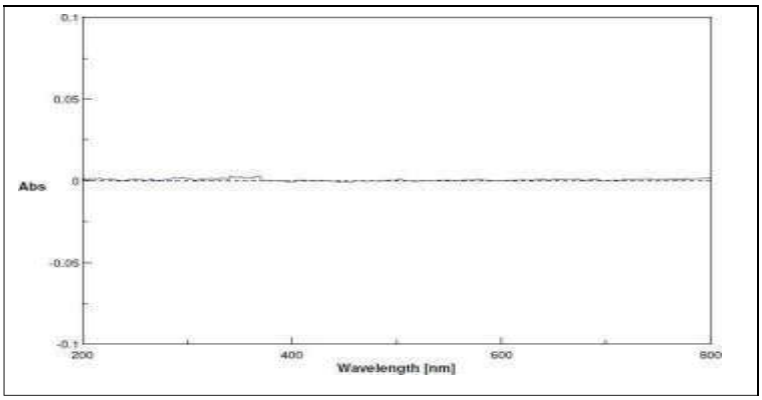


Fig. UV spectrum of Methanol as a blank

2) Capmatinib STD solution: (20 PPM)

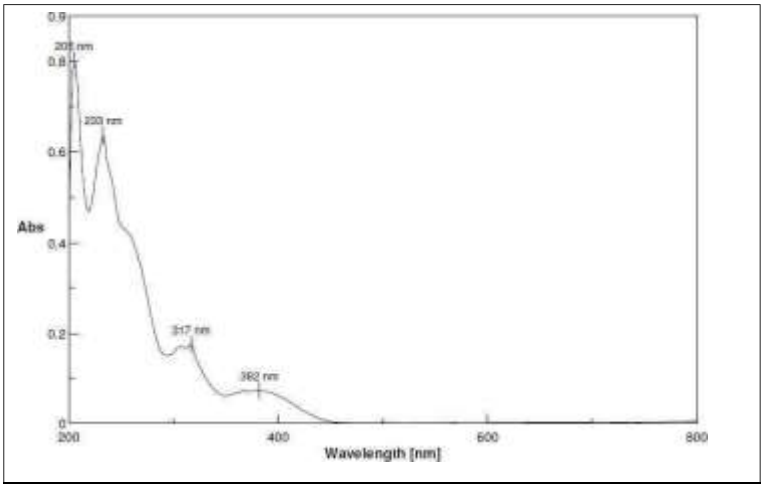


Fig. UV spectrum of Capmatinib

Observation: The standard solution was scanned between 200 nm to 800 nm. Wavelength of maximum absorption was determined for drug. Capmatinib showed maximum absorbance at 233 nm. It is shown in Figure No.2. Therefore 233 nm considered as an analytical wavelength for further determination.

Method Development by RP – HPLC

Optimization of HPLC method

Trial 1:
Chromatogram:

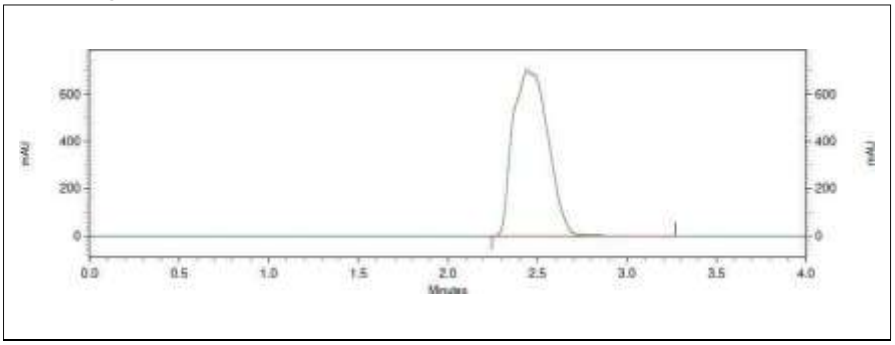


Fig. Typical chromatogram of Trial 1

Observation: Capmatinib eluted with unacceptable chromatography. (Asymmetry: 2.41 & Theoretical plate: 720) Conclusion: Method rejected.

Trial 2:
Chromatogram:

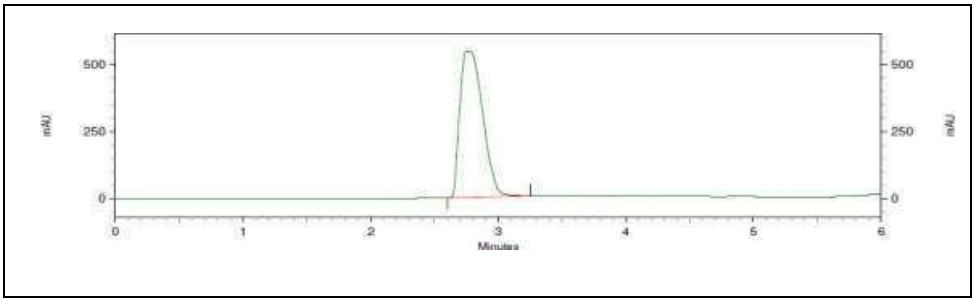


Fig. Typical chromatogram of Trial 2

Observation: Capmatinib eluted with unacceptable chromatography. Peak shape is not sharp. (Asymmetry: 2.29 & Theoretical plate: 813)

Conclusion: Method rejected Trial 3:

Chromatogram:

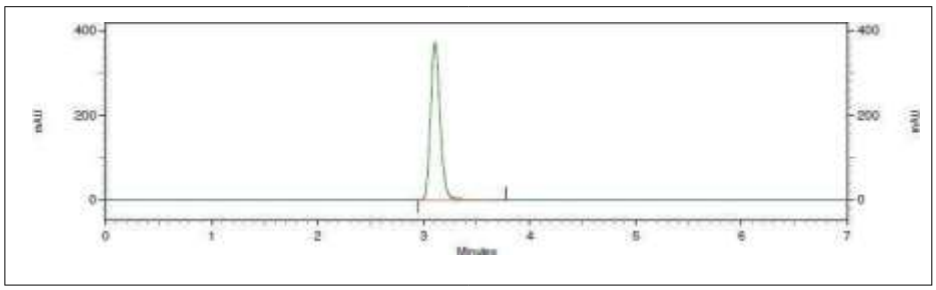


Fig. Typical chromatogram of Trial 3

Observation: Capmatinib eluted at R.T. 3.13 min, with good chromatograph. (Asymmetry: 1.23 & Theoretical plate: 8957) Conclusion: Method Accepted.

Conclusion: From the observations of trials first to three, it was concluded that chromatographic conditions in trial three gives better peak, good retention time and tailing factor therefore chromatographic conditions in trial three was subjected for method validation

Table: Optimized Chromatographic Conditions

Parameter	Description
Mode	Isocratic
Column Name	Phenomenex C18, 250 mm X 4.6mm ID, 5 µm
Detector	UV Detector
Injection Volume	20 µl
Wavelength	233 nm
Column Oven temp	35ºC
Mobile Phase	Methanol :0.05% OPA in Water (70:30 % V/V)
Flow Rate	1.0 ml/min
Run time	07 Minutes

System suitability test

Results for System Suitability Test of Capmatinib

Table: Results for System Suitability Test of Capmatinib

No.	Standard solution	Area	Asymmetry	Theoretical plates
1	Standard_1	8861005	1.22	9416
2	Standard_2	8822250	1.23	9431
3	Standard_3	8850329	1.22	9409
4	Standard_4	8841307	1.22	9415
5	Standard_5	8823705	1.23	9123

Mean	**8839719**	**1.22**	**9359**
TD Dev	**16806.26220**		
RSD	**0.19**		

System Suitability Acceptance Criteria:

1. Relative standard deviation of the area of analyte peaks in standard chromatograms should not be more than 2.0 %.
2. Theoretical plates of analyte peak in standard chromatograms should not be less than 2000.
3. Tailing Factor (Asymmetry) of analyte peaks in Standard Chromatograms should be less than 2.0

Data interpretation: It was observed from the data tabulated above; the method complies with system suitability parameters. Hence, it can be concluded that the chromatographic method is adequate for intended analysis.

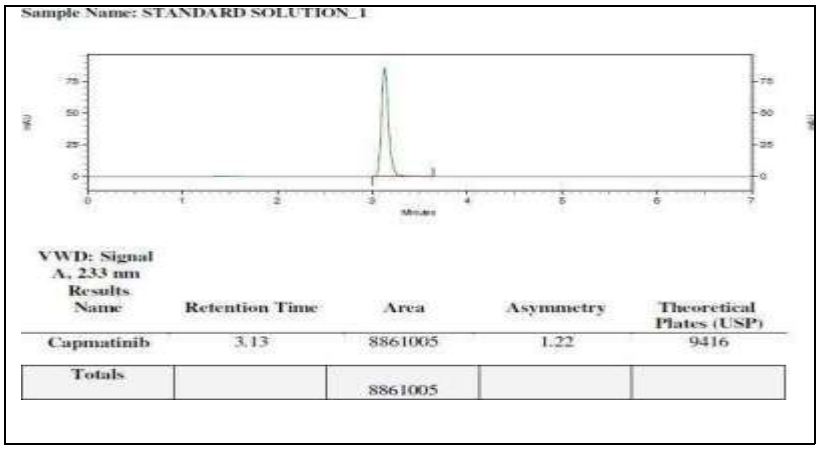


Fig. Typical chromatogram Standard solution 1 of system suitability solution.

Analysis of Marketed Test samples (Assay)

a) Rahika 200 mg Tablet:

Weight of 20 tablets = 19.6640 gm

Average weight of tablet = 19.6640 /20 = 0.9832 gm = 983.2 mg

Assay results of Rahika 200 mg Tablet

Sample	Area	% Assay	Mean Assay
Sample 1	8870252	100.38	**99.89**
Sample 2	8801796	99.40	

Table: Assay results of Capmatinib Tablet

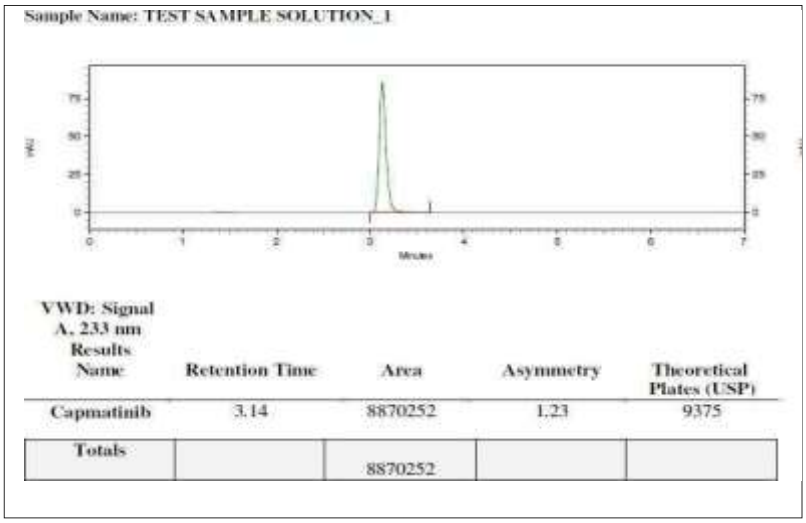


Fig. Typical chromatogram Rahika 200 mg Tablet sample.

Acceptance criteria:

1) % Assay found should be in the range of 90-110%.

Data interpretation:

From the above results, it can be concluded that the assay result is within the limit for selected marketed test sample and sample can be used for validation.

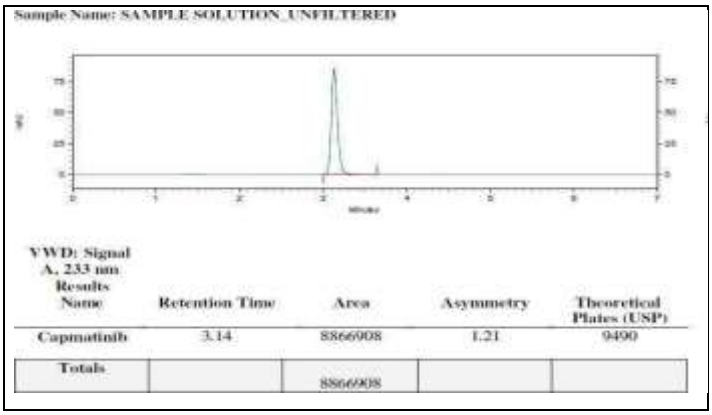
VALIDATION OF RP-HPLC METHOD 1) FILTRATION STUDY:

Filtration study of an analytical procedure checks the interference of extraneous components from filter, deposition on filter bed and compatibility of filter with sample. Performed on Tablet test sample.

Results of Filter study

Table: Results of Filter study Chromatograms:

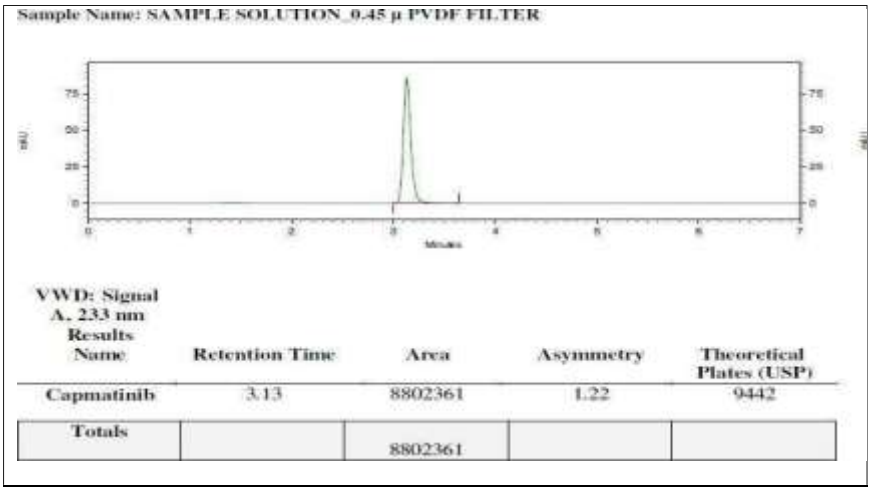
Sample description	Area	% Absolute difference
Unfiltered	8866908	NA
0.45 µ PVDF filter	8802361	0.73
0.45 µ Nylon filter	8829684	0.42



VWD: Signal A, 233 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical Plates (USP)
Capmatinib	3.14	8866908	1.21	9490
Totals		8866908		

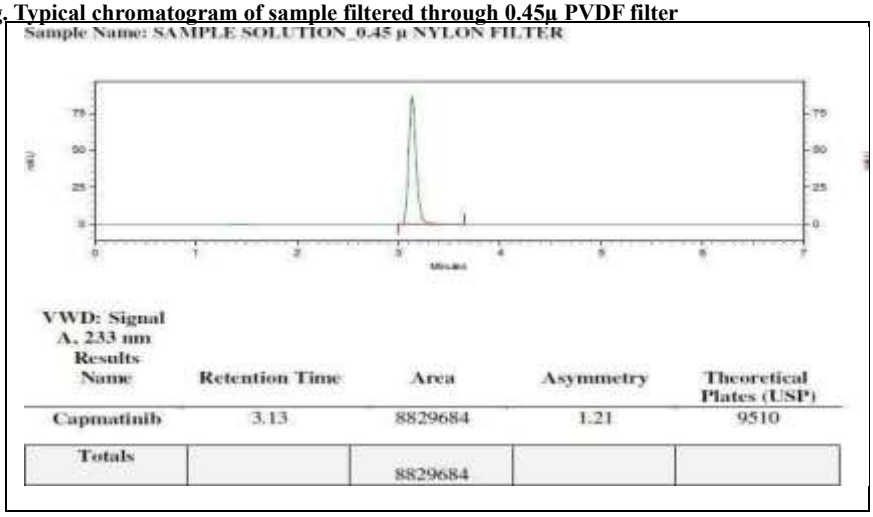
Fig. Typical chromatogram of unfiltered sample.



VWD: Signal A, 233 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical Plates (USP)
Capmatinib	3.13	8802361	1.22	9442
Totals		8802361		

Fig. Typical chromatogram of sample filtered through 0.45µ PVDF filter



VWD: Signal A, 233 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical Plates (USP)
Capmatinib	3.13	8829684	1.21	9510
Totals		8829684		

Fig. Typical chromatogram of sample filtered through 0.45µ Nylon filter.

SOLUTION STABILITY: Stability study was conducted for Standard as well as Test Sample. Stability study was performed at normal laboratory conditions. The solution was stored at normal illuminated laboratory conditions and analyzed at initial, after 12 hours and 24 hours.

Results of Solution stability.

Table: Results of Solution Stability

Sample solution			Standard solution		
Time point	**Area**	**% Absolute difference**	**Time point**	**Area**	**% Absolute difference**
Initial	8841223	NA	**Initial**	8869037	NA
12 Hours	8786410	0.62	**12 Hours**	8830200	0.44
24 Hours	8762315	0.89	**24 Hours**	8812891	0.63

Chromatograms:

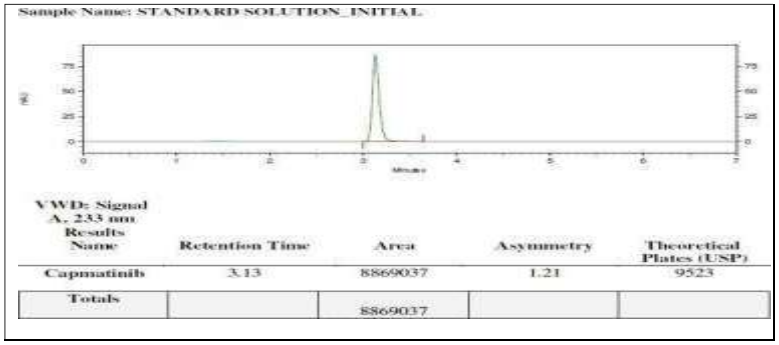


Fig. Typical chromatogram of Standard solution Initial.

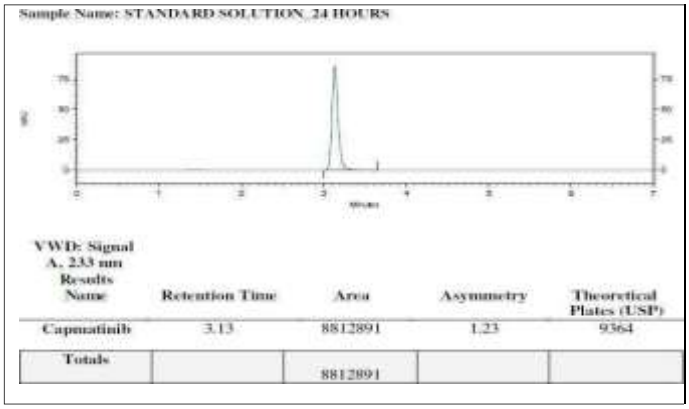


Fig. Typical chromatogram of Standard solution After 24 Hrs.

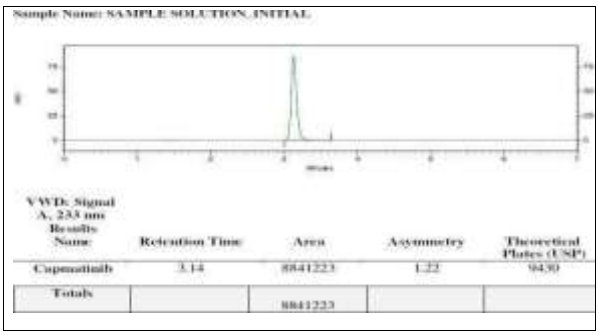
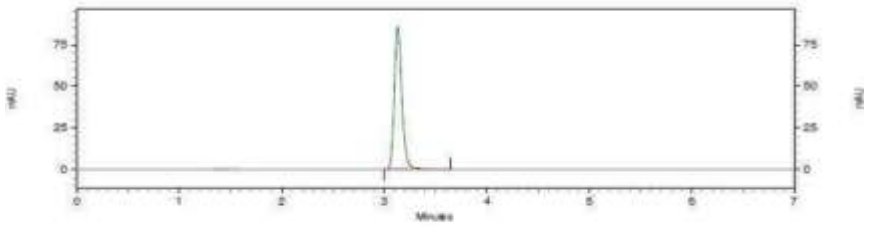


Fig. Typical chromatogram of Test solution Initial.

Sample Name: SAMPLE SOLUTION_24 HOURS



VWD: Signal A, 233 nm Results Name	Retention Time	Area	Asymmetry	Theoretical Plates (USP)
Capmatinib	3.13	8762315	1.24	9309
Totals		8762315		

Fig. Typical chromatogram of Test solution After 24 Hrs. Results of Specificity.

Table: Results of Specificity

Description	Observation
Blank	No interference at R.T. of Capmatinib due to blank
Placebo	No interference at R.T. of Capmatinib due to placebo

Chromatograms:

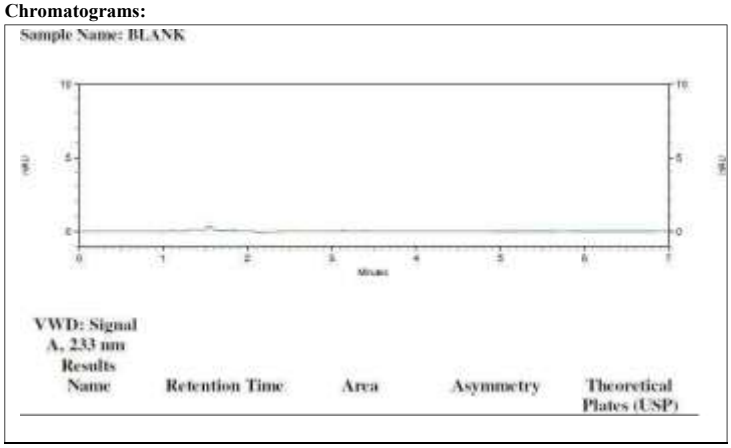


Fig. Typical chromatogram of Blank solution.

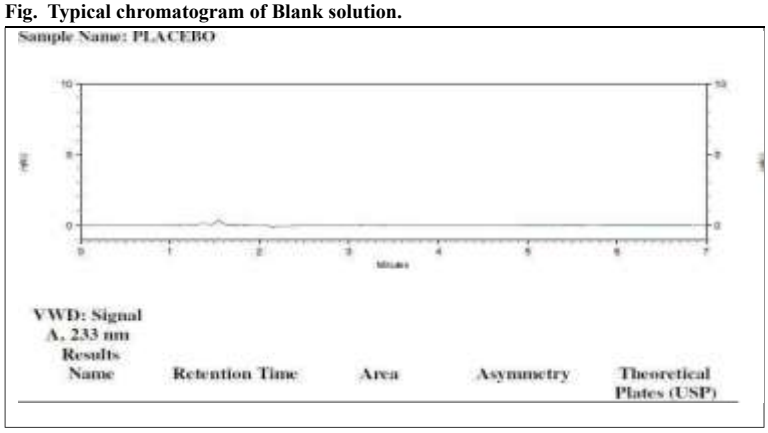


Fig. Typical chromatogram of Placebo solution.

Linearity and Range

Linearity of an analytical method is its ability to elicit test results that are proportional to the concentration of analyte in samples within a given range.

Linearity Data for Capmatinib:

Table: linearity Data for Capmatinib

	Level	Conc (µg/mL)	Area	Mean	% RSD
50%		10.00	4441053	4442701	0.128
			4449034		
			4438015		
75%		15.00	6659020	6664618	0.091
			6663791		
			6671042		
	100%	20.00	8873691	8862692	0.111
			8859707		
			8854679		

125%		25.00	11082691 11060783 11058704	11067393	0.120
150%		30.00	13386025	13375587	0.099

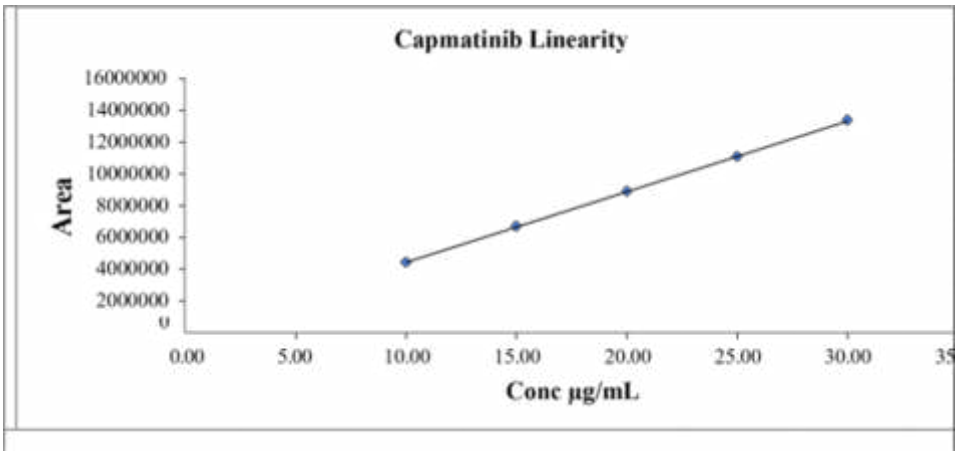


Fig. Calibration curve of Capmatinib

Data of linearity of Capmatinib:

Table: Linearity summary of Capmatinib

Sr no.	Parameter	Result value	Acceptance criteria
1	Beer's linearity range	10.0-30.0µg/mL	NA
2	Correlation coefficient (R^2)	0.99996	NLT 0.98
3	Intercept	-24820.600	To be report
4	Slope	445397.6639	To be report
5	% RSD for area at each level	NA	NMT 2.0

The respective linear equation for Capmatinib was

Y = M X + C

Y = 445397.6639 X + -24820.600

Where, X= concentration of Analyte in µg/ml Y = is area of peak.

M = Slope

C= Intercept

Chromatograms:

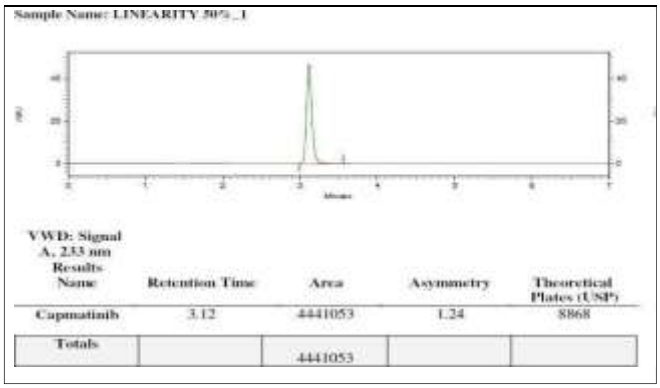


Fig. Typical chromatogram of Linearity 50%.

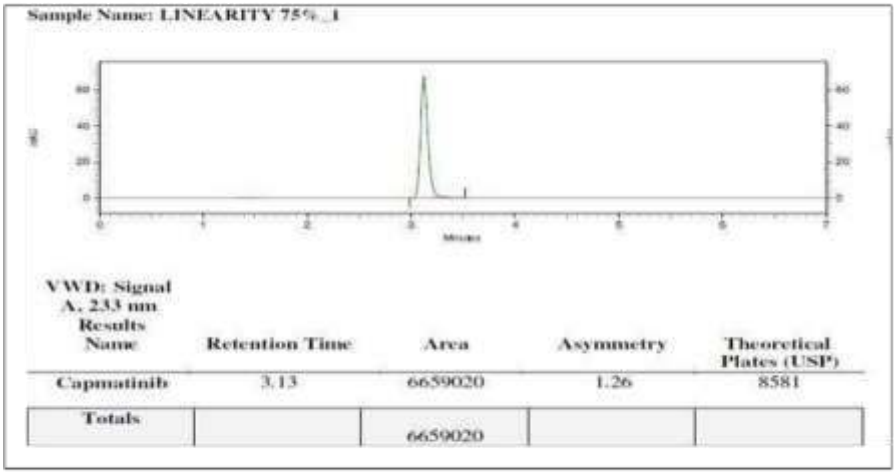


Fig. Typical chromatogram of Linearity 75%.

METHOD DEVELOPMENT

DOSAGE FORM BY RP

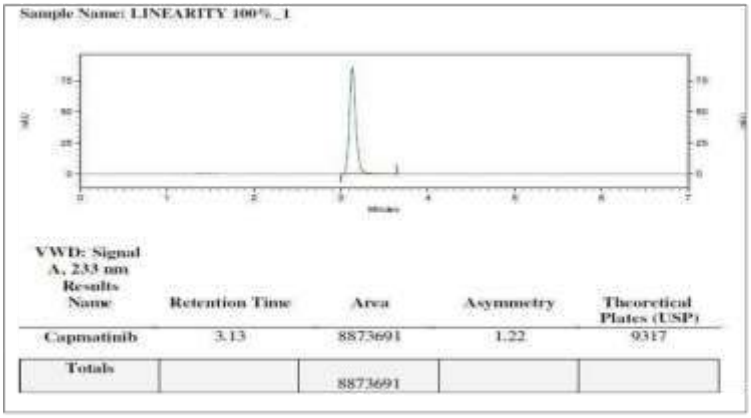


Fig. Typical chromatogram of Linearity 100%.

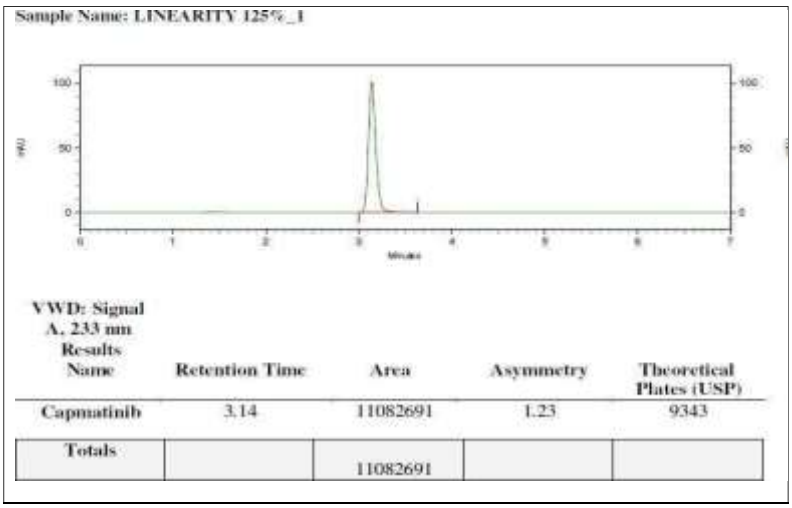


Fig. Typical chromatogram of Linearity 125%.

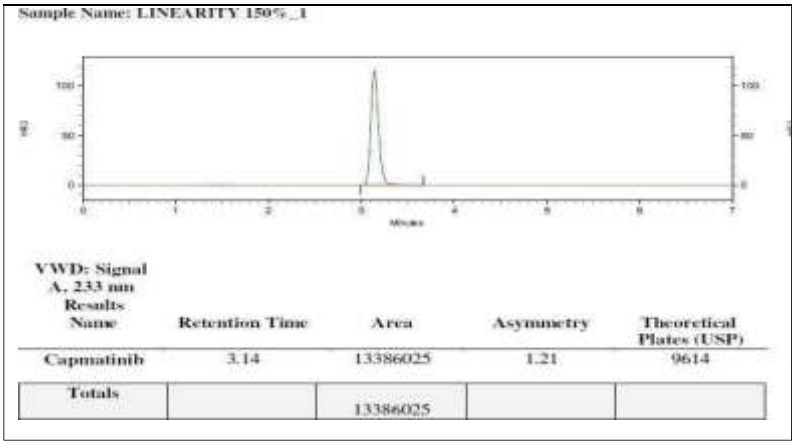


Fig. Typical chromatogram of Linearity 150%.

Results and statistical data of Accuracy of capmatinib:

Table: Result and statistical data of Accuracy of Capmatinib

Level (%)	Area	covered conc (µg/mL)	dded conc (µg/mL)	% Recovery	Mean ecovery	% RSD
50	4402507	9.96	10.06	99.01	99.84	1.113

	4469280	10.11	10.00	101.10		
	4404916	9.97	10.03	99.40		
	8870251	20.07	20.03	100.20		
100	8835893	19.99	20.13	99.30	99.47	0.669
	8780325	19.87	20.09	98.90		
	13129002	29.70	30.06	98.80	99.73	0.891
	13245890	29.97	30.02	99.83		
150	13363025	30.23	30.06	100.57		

Overall Recovery: 99.68%

% RSD for Overall Recovery: 0.805

Chromatograms:

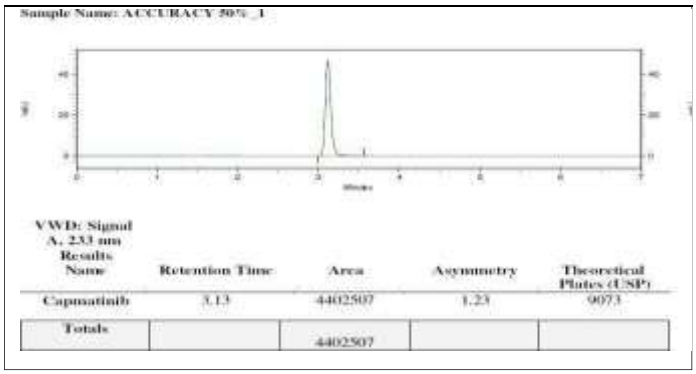


Fig. Typical chromatogram of Accuracy 50%.

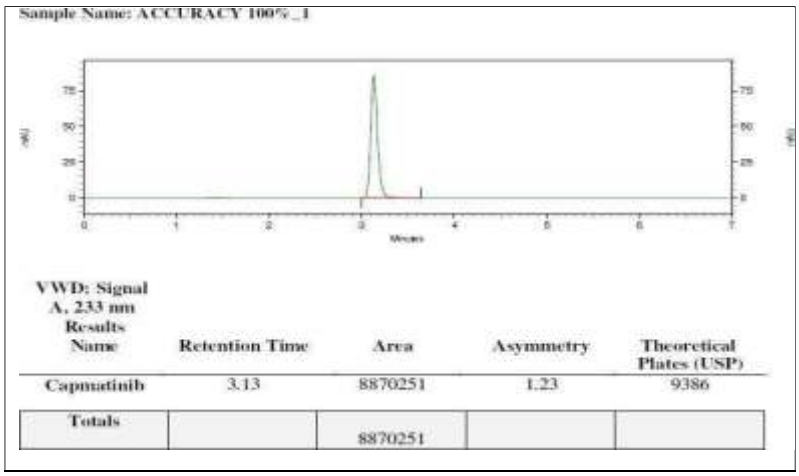


Fig. Typical chromatogram of Accuracy 100%.

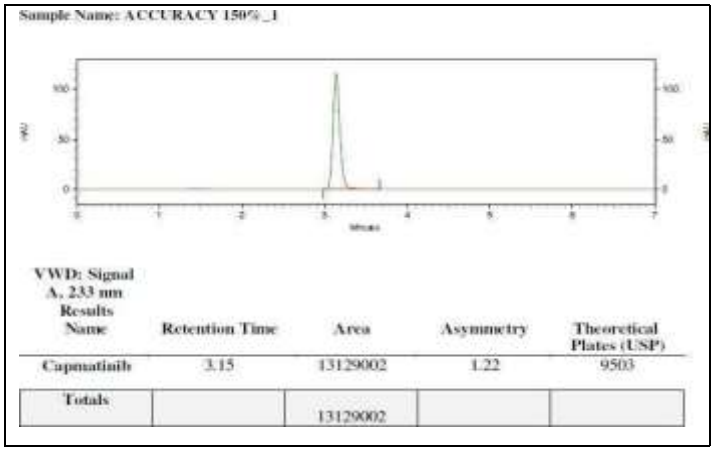


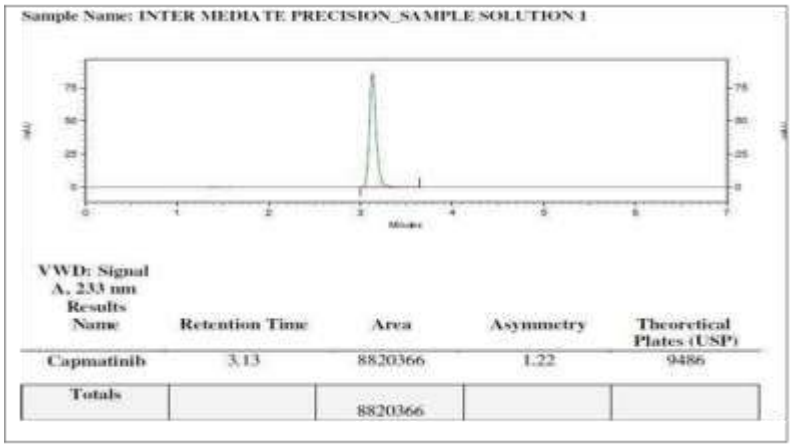
Fig. Typical chromatogram of Accuracy 150%.

Result of Intra- day and Inter- Day Precision for Capmatinib test sample assay:

	Sample	Test Sample (mg)	Area	% Assay
Repeatability	Sample 1	245.6	8760733	99.18
	Sample 2	245.8	8851407	100.13
	Sample 3	246.1	8731326	98.65
	Sample 4	246.3	8746971	98.74
	Sample 5	246.2	8801449	99.40
	Sample 6	245.3	8919300	101.10

	Mean			**99.53**
	STD DEV			**0.934102**
	% RSD			**0.939**
	Sample 1	245.4	8820366	99.94
	Sample 2	245.9	8661672	97.94
Intermediate precision (Inter-Day)	Sample 3	245.2	8884910	100.75
	Sample 4	246.3	8725043	98.50
	Sample 5	245.7	8769133	99.24
	Sample 6	246.1	8751644	98.88
	Mean			**99.21**
	STD DEV			**1.013043**
	% RSD			**1.021**
Repeatability Plus Inter-day	**Mean**			**99.371**
	STD DEV			**0.94440**
	% RSD			**0.950**

Table. Result of Intra- day and Inter- Day Precision for Capmatinib Chromatograms:



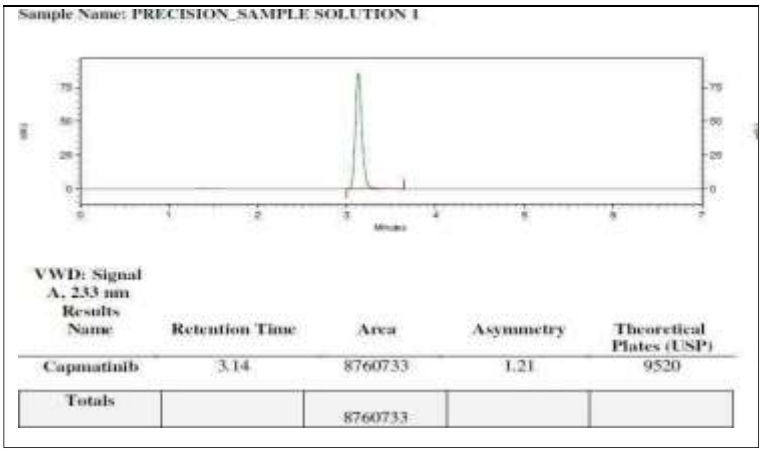


Fig. Typical chromatogram of Repeatability precision (Sample 1).

Fig. Typical chromatogram of Inter-day precision (Sample 1).

Result of Robustness study of Capmatinib

Acceptance criteria:

Chromatograms:

A. Change in Wavelength by +3 NM:

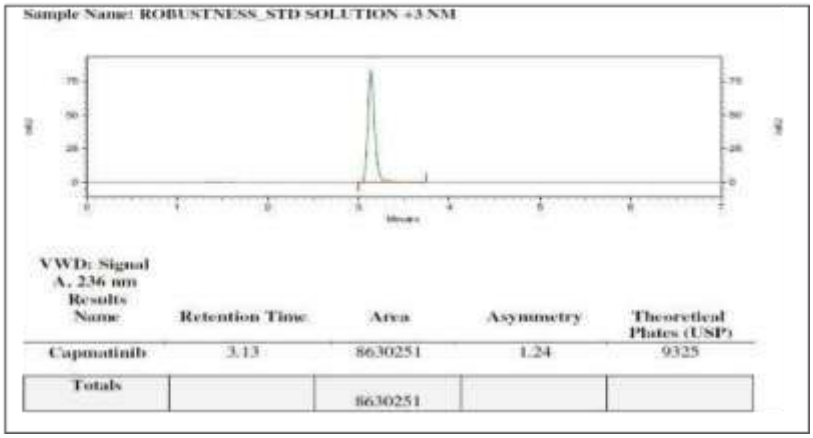


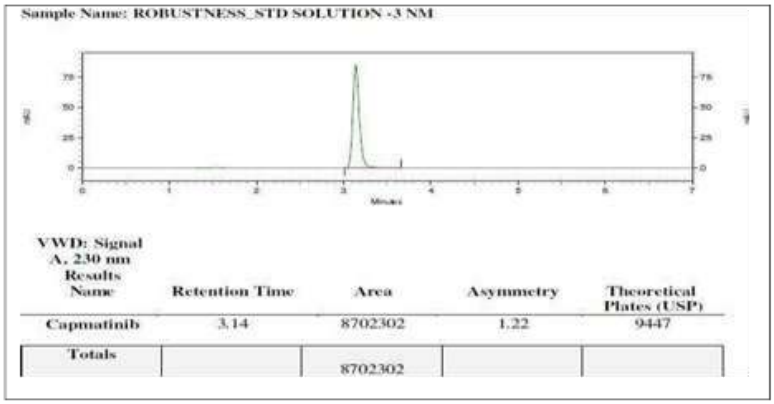
Table. Result of Robustness study

Change in Parameter	R.T.	Standard area	Asymmetry	Theoretical plates
Wavelength by +3 NM (236 NM)	3.13	8630251	1.24	9325
Wavelength by -3 NM (230 NM)	3.14	8702302	1.22	9447
Flow rate by +10% (1.1 mL/min)	2.88	8034177	1.23	9174
Flow rate by -10% (0.9 mL/min)	3.47	9547810	1.26	8176
Column oven temp by +2ºC (37 ºC)	3.14	8823601	1.24	8992
Column oven temp by -2ºC (33 ºC)	3.13	8812073	1.21	9193

Fig. Typical chromatogram of Standard +3 NM.

B. Fig. Typical chromatogram of Standard -3 NM

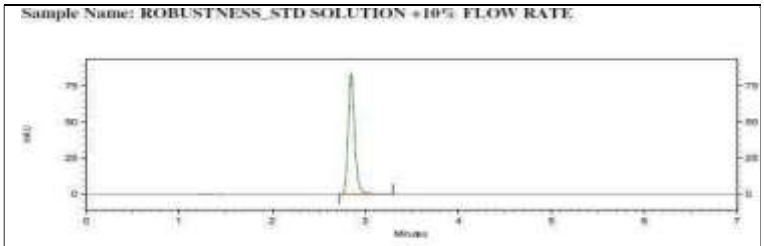
B. Change in Wavelength by -3 NM:



VWD: Signal A, 230 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical Plates (USP)
Capmatinib	3.14	8702302	1.22	9447
Totals		8702302		

C. Change in Flow rate by + 10% (1.1 mL/min)



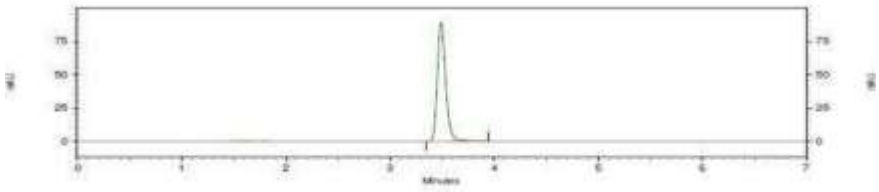
VWD: Signal A, 233 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical Plates (USP)
Capmatinib	2.88	8034177	1.23	9174
Totals		8034177		

Fig. Typical chromatogram of Standard +10 F.R.%.

D. Change in Flow rate by - 10% (0.9 mL/min)

Sample Name: ROBUSTNESS_STD SOLUTION -10% FLOW RATE



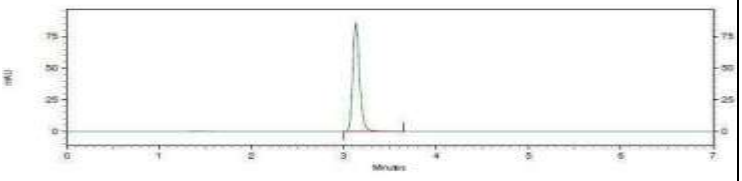
VWD: Signal A, 233 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical Plates (USP)
Capmatinib	3.47	9547810	1.26	8176
Totals		9547810		

Fig. Typical Chromatogram of standard -10 F.R.%

E. Change in Column Oven temperature by +2°C:

Sample Name: ROBUSTNESS_STD SOLUTION +2 COT



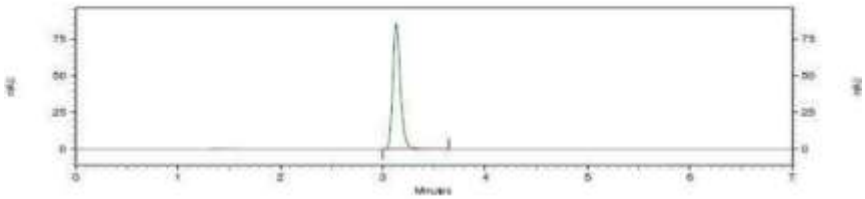
VWD: Signal A, 233 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical Plates (USP)
Capmatinib	3.14	8823601	1.24	8992
Totals		8823601		

Fig. Typical chromatogram of Standard +2°C C.O.T

Change in Column Oven temperature by -2°C:

Sample Name: ROBUSTNESS_STD SOLUTION -2 COT



VWD: Signal A, 233 nm Results

Name	Retention Time	Area	Asymmetry	Theoretical Plates (USP)
Capmatinib	3.13	8812073	1.21	9193
Totals		8812073		

Fig. Typical chromatogram of Standard -2°C C.O.T.

11. Validation Parameters

The thesis validates the method according to ICH Q2(R1), covering:

- System suitability
- Specificity
- Linearity
- Accuracy
- Precision (repeatability and intermediate precision)
- LOD
- LOQ
- Robustness
- Filter study
- Solution stability

Acceptance criteria are also provided.

DISCUSSION

The thesis supports discussion points such as:

- Successful optimization of chromatographic conditions.
- Symmetrical peak shape with a short retention time (~3.15 min).
- Validation parameters meeting ICH acceptance criteria.
- Suitability of the method for routine quality control.
- Comparison with previously reported RP-HPLC methods, highlighting reduced analysis time and satisfactory validation performance.

The quantitative values for each validation parameter should be taken directly from the Results chapter when drafting the manuscript.

CONCLUSION

- The present work involved the development of simple, accurate, precise and suitable RPHPLC method.
- Literature survey revealed that several methods have been reported for determination of Capmatinib in bulk drug or in pharmaceutical dosage forms. Hence, in the present study, a new, sensitive and suitable reversed-phase high performance liquid chromatography method was developed and validated for the determination of Capmatinib in bulk drug and pharmaceutical dosage form.
- In developed RP-HPLC method, the analyte were resolved by using isocratic program and mobile phase was used Methanol: 0.05% OPA in Water 70:30 at a Flow Rate: 1.0 ml/min, on HPLC system containing UV- visible detector with Open lab EZ-Chrome Software and Phenomenex C18, 250 mm X 4.6 mm, 5 µm. The detection was carried out at 233 nm.
- The results of analysis in the developed method were validated in terms of linearity, accuracy, precision, robustness, limit of detection and limit of quantification.
- The developed method has several advantages, including reproducibility of results, rapid analysis, simple sample preparation and improved selectivity as well as sensitivity.
- The regression coefficient R^2 for each analyte is not less than 0.999 which shows good linearity.
- The % recovery was in the acceptable range in tablet dosage form. The %RSD was also less than 2% showing high degree of precision of the proposed method.

Since the developed method is robust and reproducible and also less time consuming, it can be performed for routine analysis in pharmaceutical industry for bulk drug of Capmatinib and also in pharmaceutical dosage form.

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