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IMPURITY PROFILING AND RELATED SUBSTANCES STUDY OF SORAFENIB

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ABSTRACT

Background: Sorafenib, a multi-kinase inhibitor, is widely utilized in oncology. Developing a validated analytical method is essential for ensuring its quality and stability in pharmaceutical formulations. **Aim:** To develop and validate a stability-indicating UPLC method for the quantitative analysis of Sorafenib and its related impurities in bulk and dosage forms under stress conditions. **Research Methodology:** The study employed a Waters UPLC system with a C18 stationary phase, methanol: acetonitrile (55:45 v/v) as the mobile phase, and UV detection at 240 nm. The method was validated for precision, accuracy, linearity, robustness, ruggedness, and specificity. Forced degradation studies were conducted under acidic, basic, oxidative, wet heat, and photolytic conditions to evaluate method specificity and impurity profiling. **Conclusion:** The developed UPLC method demonstrated excellent resolution, allowing for effective impurity profiling and stability analysis of Sorafenib. The method proved precise, accurate, and robust, making it ideal for quality control and regulatory compliance in pharmaceutical formulations.

KEYWORDS: Sorafenib, UPLC, Impurity profiling.

INTRODUCTION

Analytical chemistry is a crucial instrument in the pharmaceutical sector for quality assurance, medication stability assessment, and safeguarding patient safety. Sorafenib, a multi-kinase inhibitor, is used in the treatment of advanced renal cell carcinoma and hepatocellular carcinoma. The intricate structure and susceptibility to environmental influences need a stability-indicating analytical approach for regular quality control and stability assessments.

- Regulatory bodies demand the development of stability-indicating procedures to identify degradation products and evaluate the method's specificity. Ultra-performance liquid chromatography (UPLC) is a sophisticated chromatographic technology that provides enhanced resolution, velocity, and sensitivity relative to conventional HPLC procedures. UPLC procedures need reduced sample quantities, making them environmentally sustainable and economically advantageous for pharmaceutical analysis.
- This work emphasizes the development and validation of a UPLC technique for Sorafenib, confirming its resilience and applicability under various stress situations. The research also assesses the method's capacity to isolate Sorafenib from its breakdown products, highlighting its specificity and accuracy.

Approach

The UPLC technique for Sorafenib was established using a Waters Acquity UPLC machine fitted with a C18 column. Prednisolone functioned as the internal standard. A mobile phase consisting of methanol and acetonitrile in a 55:45 ratio was used, with a flow rate of 1.2 mL/min. Detection occurred at 240 nm.

- **Validation of Methodology**

- Accuracy and Precision: Recovery trials were performed at 50%, 100%, and 150% levels, with average recovery rates of 99.74%. Intraday and interday precision analyses validated %RSD results within permissible thresholds. Calibration exhibited linearity within the range of 8–40 µg/mL, with a correlation value of 0.9985.
- Stability and Durability: Minor fluctuations in flow rate, temperature, and wavelength had no substantial effect on peak areas or retention durations. The %RSD results stayed within acceptable bounds, validating the resilience of the technique.
- LOD and LOQ: The calculated values were 0.838µg/mL and 2.540µg/mL, respectively,

demonstrating the method's sensitivity. Sorafenib underwent forced degradation studies in acidic, basic, oxidative, photolytic, and moist heat conditions to assess the specificity of the approach. Degradation products were successfully isolated, with test results for deteriorated samples ranging from 96.27% to 97.89%.

Findings and Analysis

The new approach demonstrated outstanding performance for peak resolution and baseline separation, with Sorafenib eluting at 7.289 minutes and Prednisolone at 2.639 minutes. Validation studies affirmed the method's precision (%RSD < 0.5%), accuracy (recovery ~99.74%), and resilience. Forced degradation investigations demonstrated little deterioration under all stress levels, confirming the method's specificity. The degradation peaks were well delineated; enabling accurate measurement of Sorafenib among contaminants or degradation by products. The UPLC technique complies with all regulatory standards for pharmaceutical analysis, making it a favored option for regular quality control and stability assessments of Sorafenib.

SORAFENIB	
Method development by UPLC	
System	UPLC
Stationary Phase	C18
"Mobile Phase"	"Methanol and Acetonitrile in the ratio of 55:45 %v/v"
Internal Standard	Prednisolone
Injection volume	20µl
Temperature	Ambient
Flow rate	1.2 mL/min
UV detection	240 nm
Retention Time	SORAFENIB– 7.289mins; Prednisolone – 2.639 mins
Inference	"Better resolution of the peaks with clear base line separation was found."

➢ **Validation Studies for SORAFENIB**

Accuracy Procedure

SORAFENIB						
Level %	**Amount added (µg/ml)**	**Amount found (µg/ml)**	**% Recovery**	**Mean recovery (%)**	**Std. Dev**	**% RSD**
50	08.09	08.06	99.62	99.74	0.12503	0.13%
100	16.18	16.16	99.87			
150	24.27	24.21	99.75			

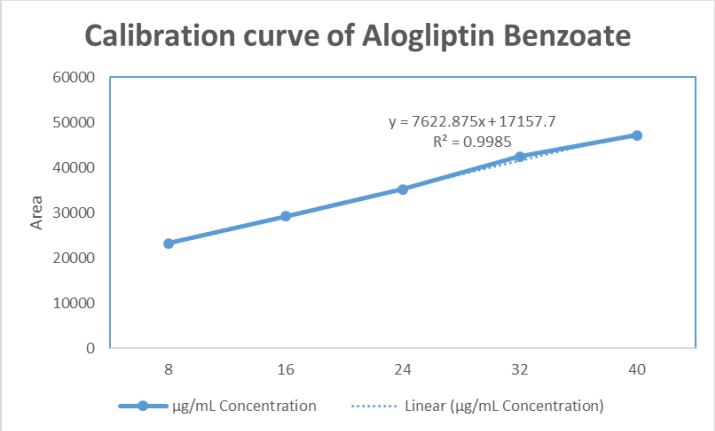
Method Precision

Replicate		***SORAFENIB***	
S. No.	**Concentration Taken (µg/ml)**	**Area**	**% LC**
1	16.18	29234	99.98%
2		29318	99.70%
3		29421	99.35%
4		29521	99.01%
5		29556	99.90%
6		29581	98.81%
Average			99.45%
Std. Dev			0.4813
% RSD			0.48%
Standard weight			16.18mcg
Standard potency			99.80%

Linearity

SORAFENIB		
Linearity level	**Concentration in µg/mL**	**Area**
1	8 µg/mL	23261
2	16 µg/mL	29231
3	24 µg/mL	35187
4	32 µg/mL	42432
5	40 µg/mL	47152

Correlation co-efficient	0.9985
Slope	7622.875
Intercept	17157.7



Robustness

Robustness Studies			
Parameter	**Value**	**Peak Area**	**% RSD**
Flow Rate	**Low**	29541	0.02%
	Actual	29546	
	Plus	29551	
Temperature	**Low**	29392	0.05%
	Actual	29406	
	Plus	28420	
Wavelength	**Low**	29604	0.01%
	Actual	29609	
	Plus	29612	

Ruggedness

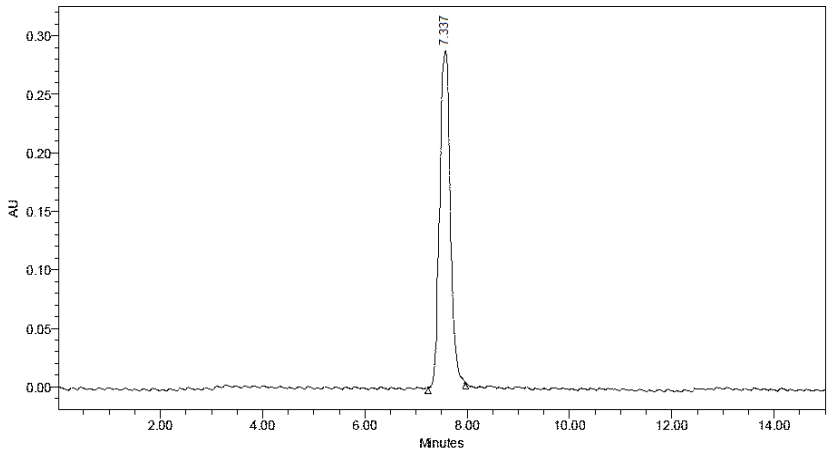
SORAFENIB			
Ruggedness			
Parameter	**Peak Area**	**% RSD**	**% LC**
Intraday precision	29326	0.33%	98.97%
	29453		99.54%
	29519		99.31%
Inter day precision	29371	0.28%	99.81%
	29434		99.60%
	29532		99.27%
Instrument:1 Acquity UPLC Waters,2695H	29548	0.02%	99.22%
	29554		99.20%
	29541		99.24%
Instrument:2 Agilent Technologies,1290	29546	0.01%	99.22%
	29552		99.20%
	29547		99.22%
Average			**99.31**
Std. Dev			**0.225**
% RSD			**0.23%**

LOD and LOQ

LOD: LOD= 3.3*(1936.58/ 7622.875), LOD= 3.3*(0.2540485), LOD= 0.83836(µg/ml)

LOQ: LOQ=10*(SD/S), LOQ= 10*(1936.58/ 7622.875), LOQ= 2.54048(µg/ml).

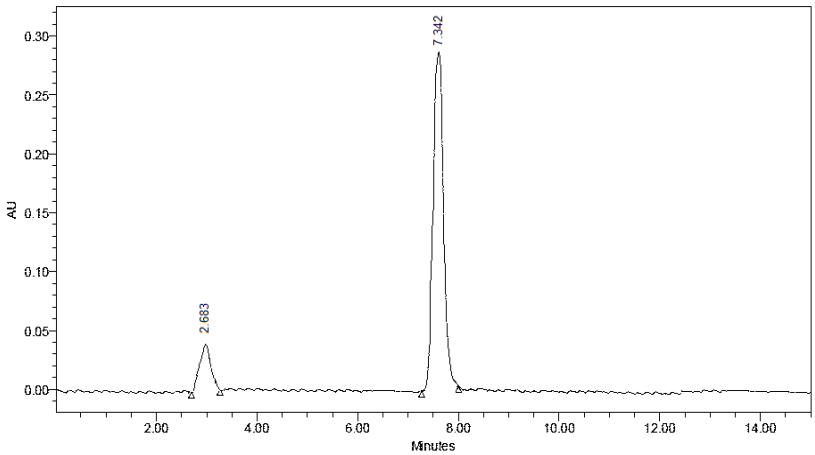
Assay Studies
Sample Control



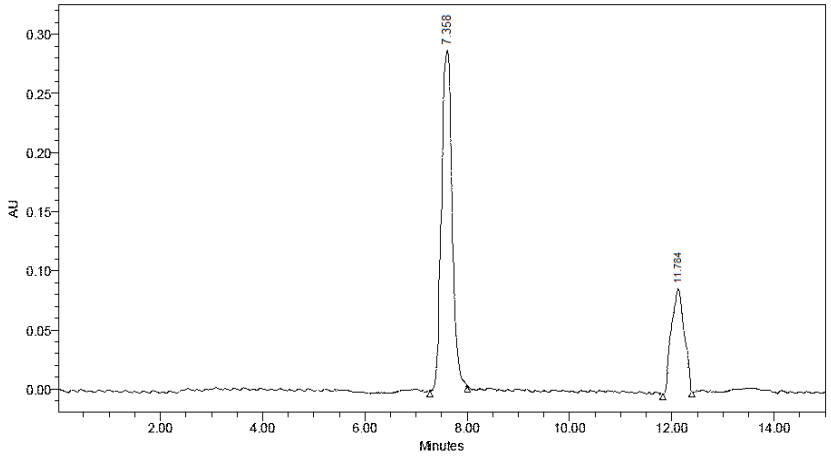
EVALUATION OF METHODS

Nature of Stress	Degradation condition	Time (h)	Number of degradation products
Acidic	60°C	6	1
Basic	60°C	12	1
Oxidative	RT	24	1
Wet Heat	105°C	48	1
Photolytic	AT	72	1

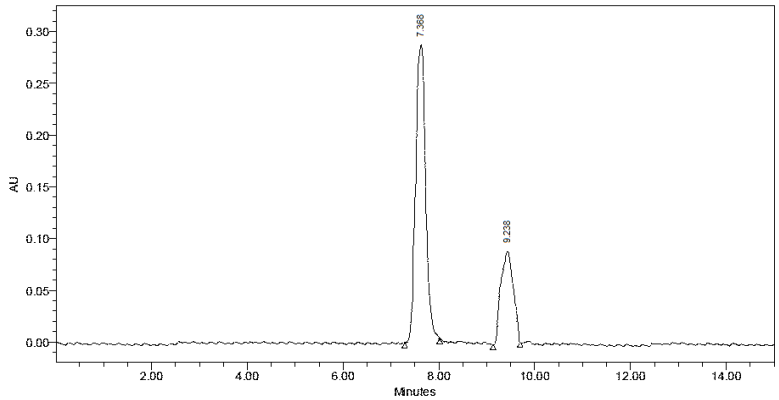
Forced degradation Study



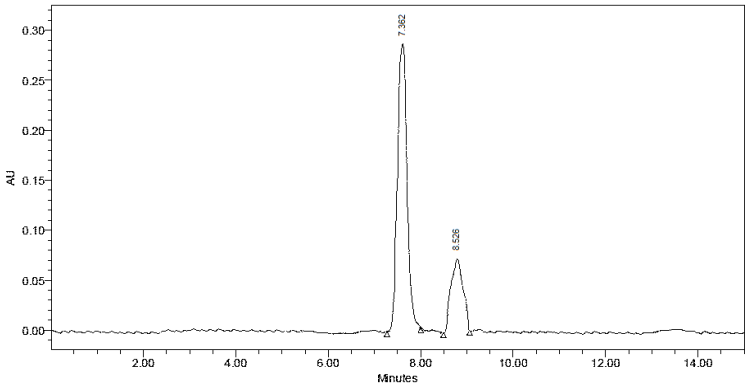
Acidic Degradation



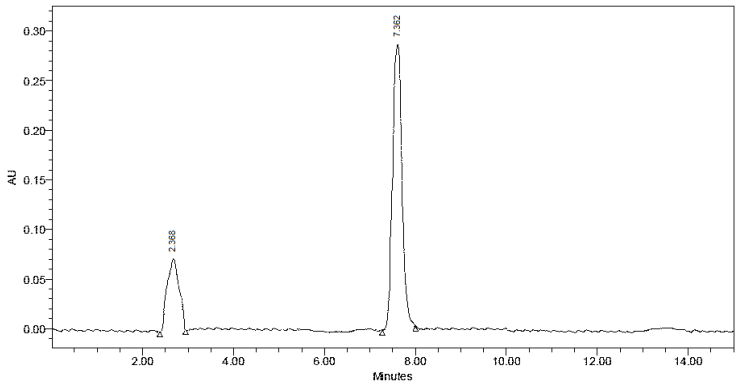
Basic Degradation



Oxidative Degradation



Wet Heat Degradation



Photolytic Degradation

Acidic Degradation

$$\% \ Assay = \frac{357338}{365461} \times \frac{04.05}{100} \times \frac{1}{25} \times \frac{100}{04.06} \times \frac{25}{1} \times \textbf{Error!} \times 98.60 = 96.27\%$$

Basic Degradation

$$\% \ Assay = \frac{362849}{365461} \times \frac{04.05}{100} \times \frac{1}{25} \times \frac{100}{04.06} \times \frac{25}{1} \times \textbf{Error!} \times 98.60 = 97.76\%$$

Oxidative Degradation

$$\% \ Assay = \frac{359276}{365461} \times \frac{04.05}{100} \times \frac{1}{25} \times \frac{100}{04.06} \times \frac{25}{1} \times \textbf{Error!} \times 98.60 = 96.79\%$$

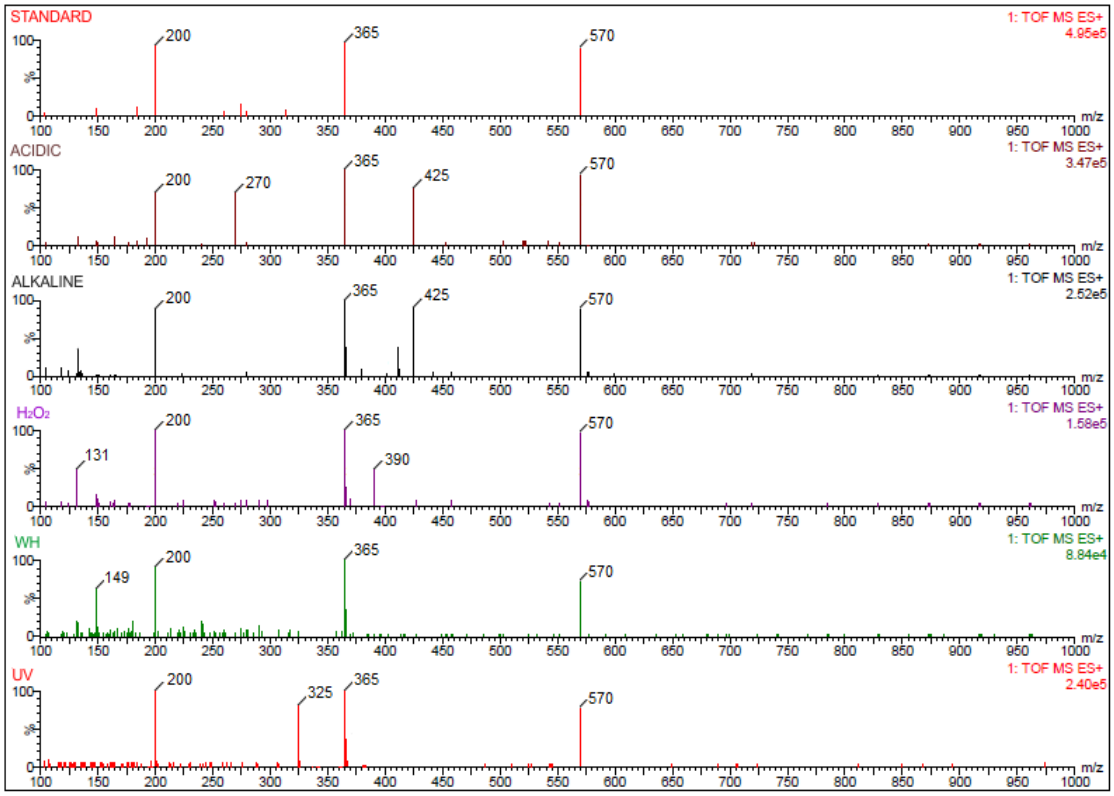
Wet Heat

$$\% \ Assay = \frac{362765}{365461} \times \frac{04.05}{100} \times \frac{1}{25} \times \frac{100}{04.06} \times \frac{25}{1} \times \textbf{Error!} \times 98.60 = 97.74\%$$

Photolytic Control

$$\% \ Assay = \frac{363393}{365461} \times \frac{04.05}{100} \times \frac{1}{25} \times \frac{100}{04.06} \times \frac{25}{1} \times \textbf{Error!} \times 98.60 = 97.87\%$$

LCMS



CONCLUSION

The developed UPLC method for Sorafenib is a robust, accurate, and precise analytical tool. Its ability to separate Sorafenib from its degradation products under various stress conditions underscores its suitability for stability-indicating studies. This method provides a reliable framework for quality control and regulatory compliance in the pharmaceutical industry.

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