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FORCE DEGRADATION METHOD DEVELOPMENT AND VALIDATION OF SORAFENIB IN BULK FORMULATION

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ABSTRACT

Background: Sorafenib is an essential therapeutic agent used in treating hepatocellular and renal cell carcinoma. The development of a precise, accurate, and robust UPLC method for its quantification ensures consistency in pharmaceutical formulations and enhances its therapeutic efficacy. **Aim:** To develop and validate a UPLC method for Sorafenib estimation, incorporating validation parameters such as accuracy, precision, linearity, robustness, ruggedness, and forced degradation studies. **Research Methodology:** The UPLC system with a C18 stationary phase was employed using methanol and acetonitrile (55:45% v/v) as the mobile phase, and prednisolone as the internal standard. Sorafenib's retention time was 7.289 minutes, with UV detection at 240 nm. Validation studies evaluated system precision, linearity, accuracy (mean recovery 99.74%), robustness, and ruggedness. Forced degradation under acidic, basic, oxidative, thermal, and photolytic conditions demonstrated the method's specificity. **Conclusion:** The developed UPLC method offers superior resolution, reliability, and sensitivity for Sorafenib quantification, meeting ICH guidelines. This robust analytical tool facilitates quality control in pharmaceutical formulations.

KEYWORDS: Sorafenib, UPLC, Validation.

INTRODUCTION

Sorafenib, a multikinase inhibitor, is widely used for treating advanced-stage hepatocellular carcinoma and renal cell carcinoma. Its role in oncology stems from its ability to inhibit tumor cell proliferation and angiogenesis. With its clinical significance, reliable and efficient analytical methods for its estimation in pharmaceutical formulations and biological matrices are crucial. High-performance liquid chromatography (HPLC) has long been a gold standard for such analyses, but Ultra-Performance Liquid Chromatography (UPLC) offers several advantages, including higher resolution, shorter run times, and lower solvent consumption.

The current study focuses on developing a UPLC-based analytical method to quantify Sorafenib accurately and validate it in line with ICH guidelines. This method not only ensures consistency and quality in pharmaceutical preparations but also addresses regulatory compliance, thereby fostering reliability in therapeutic applications.

METHODOLOGY

Method Development: A Waters UPLC system equipped with a C18 column was used to develop the method. The mobile phase consisted of methanol and acetonitrile in a 55:45% v/v ratio, ensuring optimal separation. The flow rate was set at 1.2 mL/min, and detection was carried out at 240 nm. Prednisolone served as the internal standard for calibration. The retention times for Sorafenib and prednisolone were 7.289 minutes and 2.639 minutes, respectively.

Validation Studies

1. **Accuracy**: Recovery studies demonstrated mean recoveries of 99.74% across 50%, 100%, and 150% levels, indicating high accuracy.
2. **Precision**: Method precision showed %RSD of 0.48%, confirming the method's reproducibility.
3. **Linearity**: Linearity was observed between 8–40 µg/mL with a correlation coefficient of 0.9985.
4. **Robustness**: Variations in flow rate, temperature, and wavelength had negligible effects, with %RSD remaining within acceptable limits.
5. **Ruggedness**: Inter- and intra-day precision studies revealed %RSD values below 0.33%.
6. **LOD and LOQ**: Limits of detection and quantification were calculated as 0.838µg/mL and 2.540µg/mL, respectively.

Forced Degradation Studies: Sorafenib was subjected to acidic, basic, oxidative, thermal, and photolytic stress conditions to assess the method's specificity. Minimal degradation was observed under all conditions, indicating the stability-indicating capability of the method.

RESULTS AND DISCUSSION: The developed UPLC method exhibited clear baseline separation with excellent resolution. Validation studies confirmed its robustness, precision, and accuracy, making it suitable for routine quality control. Forced degradation studies reinforced its specificity, demonstrating its capacity to distinguish Sorafenib from its degradation products under various stress conditions.

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

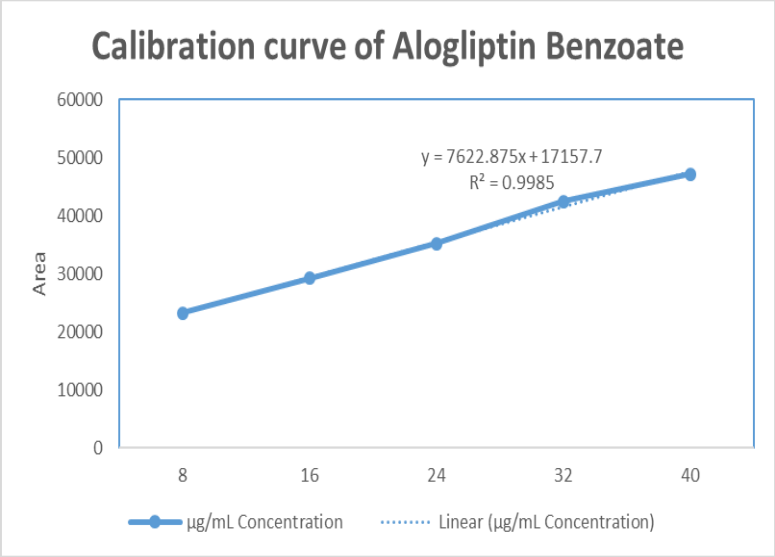
SORAFENIB						
Level %	**Amount added (µg/ml)**	**Amount found (µg/ml)**	**% Recovery**	**Mean recovery (%)**	**Std. Dev**	**% RSD**
50	08.09	08.06	99.62	99.74	0.12503	0.13%
100	16.18	16.16	99.87			
150	24.27	24.21	99.75			

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

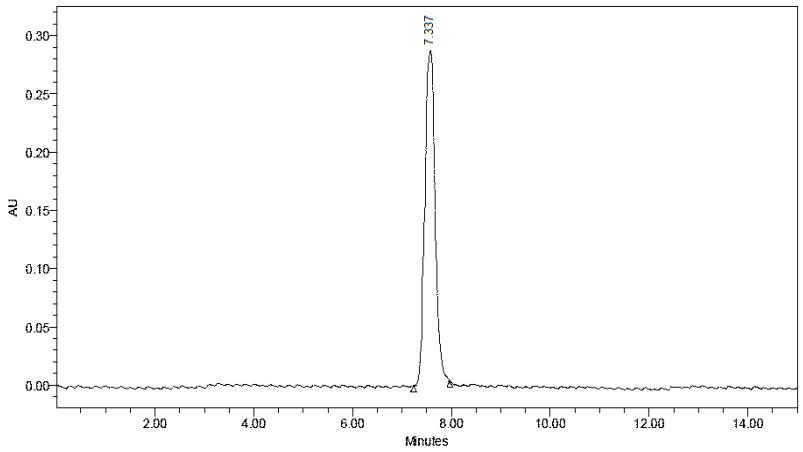
SORAFENIB			
Ruggedness			
Parameter	**Peak Area**	**% RSD**	**%LC**
Intraday precision	29326	0.33%	98.97%
	29453		99.54%
	29519		99.31%
Inter day precision	29371	0.28%	99.81%
	29434		99.60%
	29532		99.27%
Instrument:1 Acquity UPLC Waters,2695H	29548	0.02%	99.22%
	29554		99.20%
	29541		99.24%
Instrument:2 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)

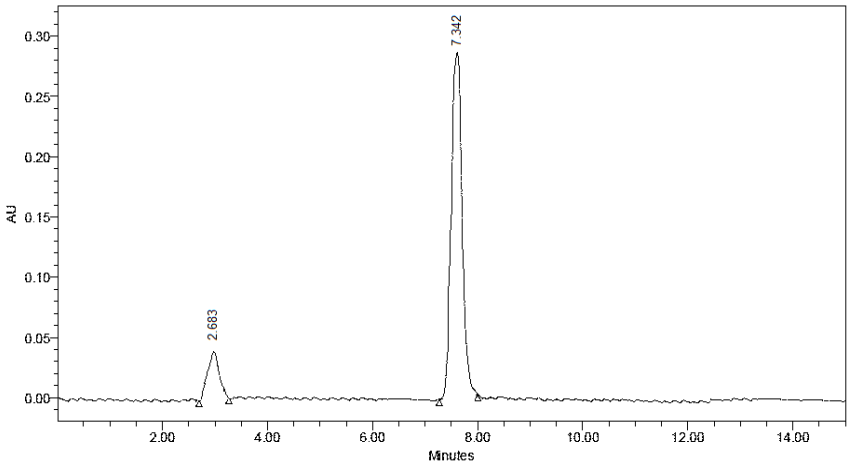
Assay Studies
Sample Control



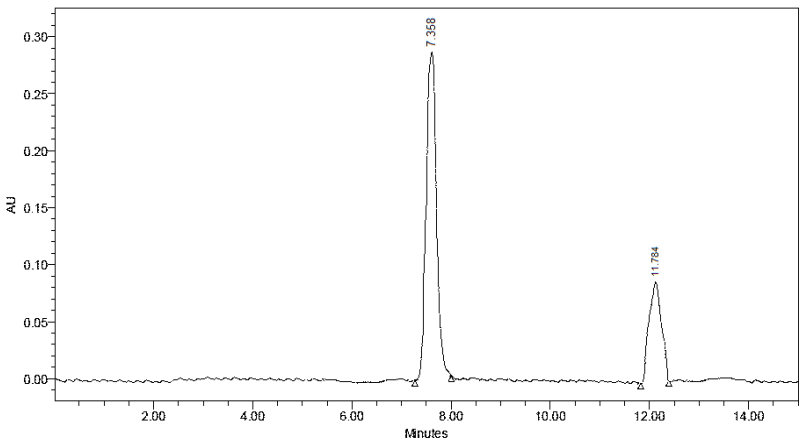
EVALUATION OF METHODS

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

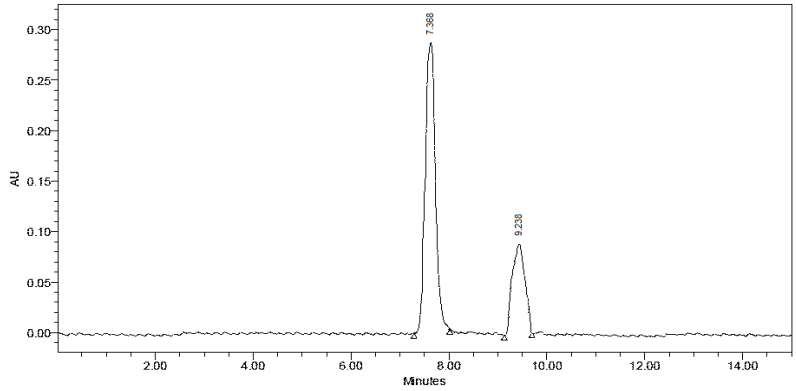
Forced degradation Study



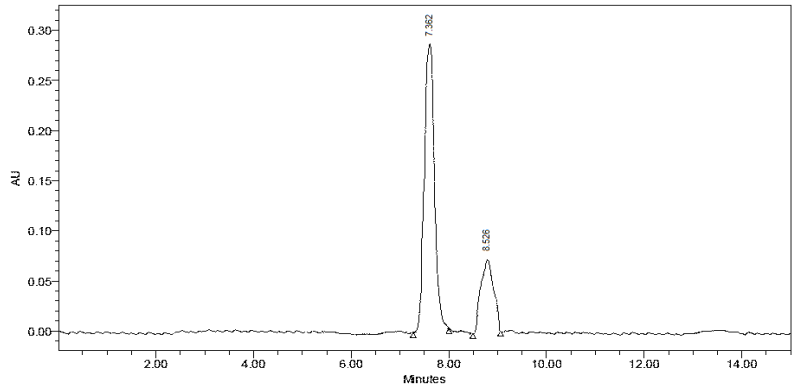
Acidic Degradation



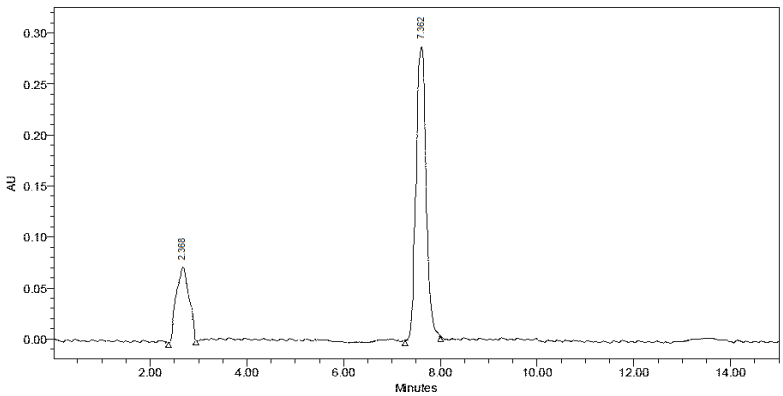
Basic Degradation



Oxidative Degradation



Wet Heat Degradation



Photolytic Degradation

Acidic Degradation

$$\% \ Assay = \frac{357338}{365461} \times \frac{04.05}{100} \times \frac{1}{25} \times \frac{100}{04.06} \times \frac{25}{1} \times \textbf{Error!} \times 98.60 = 96.26\%$$

Basic Degradation

$$\% \ Assay = \frac{362849}{365461} \times \frac{04.05}{100} \times \frac{1}{25} \times \frac{100}{04.06} \times \frac{25}{1} \times \textbf{Error!} \times 98.60 = 97.75\%$$

Oxidative Degradation

$$\% \ Assay = \frac{359276}{365461} \times \frac{04.05}{100} \times \frac{1}{25} \times \frac{100}{04.06} \times \frac{25}{1} \times \textbf{Error!} \times 98.60 = 96.78\%$$

Wet Heat

$$\% \ Assay = \frac{362765}{365461} \times \frac{04.05}{100} \times \frac{1}{25} \times \frac{100}{04.06} \times \frac{25}{1} \times \textbf{Error!} \times 98.60 = 97.72\%$$

Photolytic Control

$$\% \ Assay = \frac{363393}{365461} \times \frac{04.05}{100} \times \frac{1}{25} \times \frac{100}{04.06} \times \frac{25}{1} \times \textbf{Error!} \times 98.60 = 97.89\%$$

CONCLUSION

The developed and validated UPLC method for Sorafenib quantification is robust, precise, and efficient, aligning with ICH guidelines. Its reliability in routine

pharmaceutical analysis ensures consistent drug quality, facilitating its therapeutic application.

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