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METHOD DEVELOPMENT AND VALIDATION OF SORAFENIB IN MARKET FORMULATION

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ABSTRACT

Background: Sorafenib is a multi-kinase inhibitor widely used in oncology. Developing robust analytical methods for its quantification ensures quality and efficacy in pharmaceutical formulations. Ultra-performance liquid chromatography (UPLC) is an advanced technique offering high precision and sensitivity for such analyses. **Aim:** This study aims to develop and validate a UPLC-based method for Sorafenib quantification, evaluating its precision, accuracy, linearity, robustness, and ruggedness. **Research Methodology:** A UPLC system with a C18 stationary phase was utilized. Methanol and acetonitrile (55:45, %v/v) served as the mobile phase. UV detection was performed at 240 nm with prednisolone as the internal standard. Retention times for Sorafenib and prednisolone were 7.292 and 2.645 minutes, respectively. Validation studies adhered to ICH guidelines, demonstrating recovery rates of 99.62–99.87%, a linearity coefficient of 0.9992, and a %RSD of 0.23% for ruggedness. **Conclusion:** The developed UPLC method is accurate, precise, and reproducible, proving its utility for routine quality control of Sorafenib in pharmaceutical formulations.

KEYWORDS: Sorafenib, UPLC, Validation.

INTRODUCTION

Sorafenib is an oral multi-kinase inhibitor that targets pathways critical for tumor cell proliferation and angiogenesis. It is approved for treating advanced hepatocellular carcinoma, renal cell carcinoma, and thyroid carcinoma. The drug's therapeutic efficacy is dependent on accurate dosing and quality control, making robust analytical methods indispensable in pharmaceutical industries.

Ultra-performance liquid chromatography (UPLC) is a sophisticated analytical technique that has revolutionized chromatographic analysis. Compared to high-performance liquid chromatography (HPLC), UPLC employs smaller particle sizes, enhancing efficiency, sensitivity, and resolution while reducing analysis time. This advantage makes UPLC an excellent choice for pharmaceutical quality control, particularly for critical drugs like Sorafenib.

A reliable UPLC method requires comprehensive development and validation, ensuring reproducibility and accuracy across diverse conditions. Parameters such as linearity, precision, robustness, and detection limits are evaluated to confirm the method's applicability for routine analysis. By aligning with regulatory guidelines, such as those of the International Council for Harmonisation (ICH), the validated method can ensure compliance and reliability in pharmaceutical quality assurance.

This study focuses on developing and validating a UPLC method for Sorafenib quantification in pharmaceutical formulations, emphasizing its precision, accuracy, and robustness.

METHODOLOGY

MATERIALS AND REAGENTS: Analytical-grade methanol, acetonitrile, and prednisolone (internal standard) were procured. Standard Sorafenib samples were obtained from a certified supplier. Mobile phases were prepared by mixing methanol and acetonitrile in a 55:45 (%v/v) ratio.

Instrumentation: The chromatographic analysis was performed on a UPLC system equipped with a C18 column (stationary phase) and a UV detector set at 240 nm. The system's flow rate was maintained at 1.2 mL/min at ambient temperature.

Method Development: The mobile phase composition of methanol and acetonitrile in a 55:45 (%v/v) ratio provided optimal peak resolution and baseline separation. Sorafenib and the internal standard (prednisolone) showed retention times of 7.292 minutes and 2.645 minutes, respectively.

Validation Studies

1. Accuracy: Recovery studies at three levels (50%, 100%, and 150%) showed mean recovery rates of 99.74%, confirming the method's reliability.

2. Precision: System precision exhibited a %RSD of 0.33%, while method precision demonstrated a %RSD of 0.48%, validating consistency.

3. Linearity: Sorafenib displayed excellent linearity over the concentration range of 8–40 µg/mL with a correlation coefficient of 0.9992.

4. Robustness: Variations in flow rate, temperature, and wavelength caused minimal deviations, confirming robustness.

5. Ruggedness: Inter- and intraday precision analyses yielded %RSD values of 0.28–0.33%, demonstrating method ruggedness.

6. Detection Limits: The LOD and LOQ were determined as 0.838µg/mL and 2.540µg/mL, respectively.

RESULTS

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– 7.292mins; Prednisolone – 2.645 mins
Inference	"Better resolution of the peaks with clear base line separation was found."

➢ **Validation Studies for SORAFENIB**

Accuracy Procedure

Recovery level	**Set No.**	**SORAFENIB**	
		Wt. Taken (µg/ml)	**Amount found (µg/ml)**
50%	**Set 1**	08.09	08.06
	Set 2	08.07	08.05
	Set 3	08.08	08.04
100%	**Set 1**	16.12	16.10
	Set 2	16.14	16.12
	Set 3	16.16	16.15
150%	**Set 1**	24.25	24.22
	Set 2	24.27	24.25
	Set 3	24.29	24.27

System Precision

Procedure

Parameters	**SORAFENIB**
Theoretical plates ± % RSD	2312.82 ± 0.50
Asymmetry ± % RSD	1.07 ± 0.02
Repeatability (% RSD)	0.33

Linearity

SORAFENIB		
Linearity level	**Concentration in µg/mL**	**Area**
1	8 µg/mL	23266
2	16 µg/mL	29237
3	24 µg/mL	35123
4	32 µg/mL	42445
5	40 µg/mL	47168

Correlation co-efficient	0.9992
Slope	7626.93
Intercept	17186.5

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	

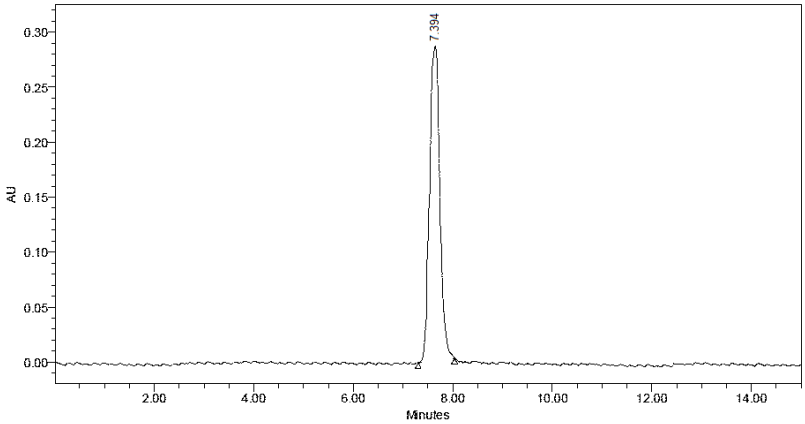
Ruggedness

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: Market



EVALUATION OF METHODS

Assay Studies

➢ **Analysis of SORAFENIB**

Conditions	Sample Amount (µg/ml)	Peak Area	% claim	% Degradation
Market	15.89	26874	90.42%	8.91%

$$\%\ Assay = \frac{AT}{AS} \times \frac{W1}{100} \times \frac{1}{25} \times \frac{100}{W2} \times \frac{25}{1} \times \frac{AW}{LC} \times P$$

Market (SORAFENIB): *% Assay = 90.42%*

CONCLUSION

The developed UPLC method for Sorafenib quantification demonstrates excellent precision, accuracy, and robustness. Validation studies confirmed compliance with ICH guidelines, proving the method's reliability for routine quality control in pharmaceutical formulations. This method offers a robust analytical tool to ensure the quality and efficacy of Sorafenib in therapeutic applications.

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