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# FORCE DEGRADATION METHOD DEVELOPMENT AND VALIDATION OF SORAFENIB IN MARKET FORMULATION

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## ABSTRACT

**Background:** Sorafenib, a multi-kinase inhibitor, is widely used in oncology. A robust and validated analytical method is critical 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 in bulk and dosage forms under various 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 performed under acidic, basic, oxidative, wet heat, and photolytic conditions to assess method specificity. **Conclusion:** The developed UPLC method demonstrated excellent baseline separation with clear resolution for Sorafenib and its degradation products. The method proved to be precise, accurate, and robust, making it suitable for quality control and stability studies in pharmaceutical formulations.

**KEYWORDS:** Sorafenib, UPLC, Stability-indicating.

## INTRODUCTION

➢ Analytical chemistry is an essential tool in the pharmaceutical industry for quality control, drug stability, and ensuring patient safety. Sorafenib, a multi-kinase inhibitor, is utilized for treating advanced renal cell carcinoma and hepatocellular carcinoma. Its complex structure and sensitivity to environmental factors necessitate a stability-indicating analytical method for routine quality control and stability studies.

➢ The development of stability-indicating methods is mandated by regulatory authorities to ensure the detection of degradation products and to validate the method's specificity. Ultra-performance liquid chromatography (UPLC), an advanced chromatographic technique, offers superior resolution, speed, and sensitivity compared to traditional HPLC methods. UPLC methods require smaller sample volumes, making them eco-friendly and cost-effective for pharmaceutical analysis.

➢ This study focuses on the development and validation of a UPLC method for Sorafenib, ensuring its robustness and applicability under diverse stress conditions. Additionally, the study evaluates the method's ability to separate Sorafenib from its degradation products, emphasizing its specificity and precision.

## METHODOLOGY

The UPLC method for Sorafenib was developed using a Waters Acquity UPLC system equipped with a C18 column. Prednisolone served as the internal standard. A mobile phase comprising methanol and acetonitrile in a 55:45 ratio was used, with a flow rate of 1.2 mL/min. Detection was performed at 240 nm.

➢ **Method Validation**

- **Accuracy and Precision:** Recovery studies were conducted at 50%, 100%, and 150% levels, with recovery rates averaging 99.74%. Intraday and interday precision studies confirmed %RSD values within acceptable limits.
- **Linearity:** Calibration was performed over a range of 8–40 µg/mL, demonstrating a correlation coefficient of 0.9985.
- **Robustness and Ruggedness:** Minor variations in flow rate, temperature, and wavelength showed no significant impact on peak areas or retention times. %RSD values remained within permissible limits, confirming method robustness.

- **LOD and LOQ:** Calculated values were 0.838µg/mL and 2.540µg/mL, respectively, indicating the method's sensitivity.

➢ **Forced Degradation Studies:** Sorafenib was subjected to acidic, basic, oxidative, photolytic, and wet heat conditions to evaluate the method's specificity. Degradation products were effectively separated, and % assay values for degraded samples ranged between 96.27% and 97.89%.

## RESULTS AND DISCUSSION

The developed method exhibited exceptional performance in terms of peak resolution and baseline separation, with Sorafenib eluting at 7.289 minutes and Prednisolone at 2.639 minutes. Validation studies confirmed the method's precision (%RSD < 0.5%), accuracy (recovery ~99.74%), and robustness. Forced degradation studies revealed minimal degradation across all stress conditions, affirming the method's specificity. The degradation peaks were distinctly resolved, ensuring reliable quantification of Sorafenib in the presence of impurities or degradation products.

➢ The UPLC method meets all regulatory requirements for pharmaceutical analysis, making it a preferred choice for routine quality control and stability studies 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 | | | |

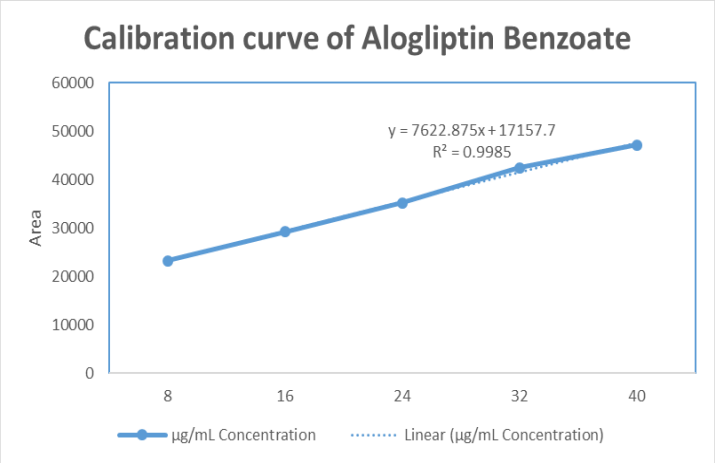
**Method Precision**

| ***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%** |

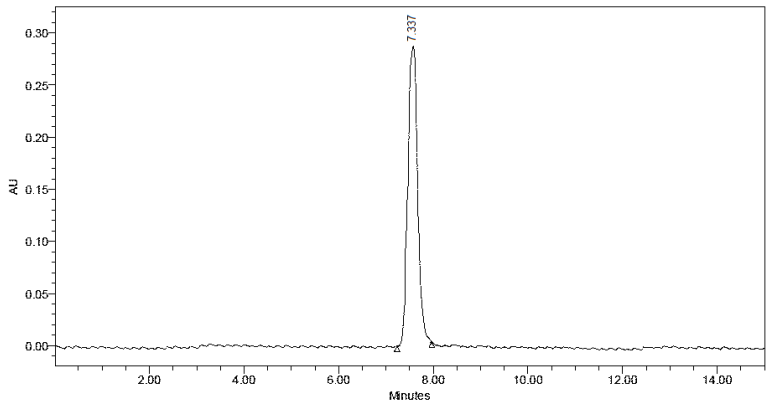
**LOD and LOQ**

**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**

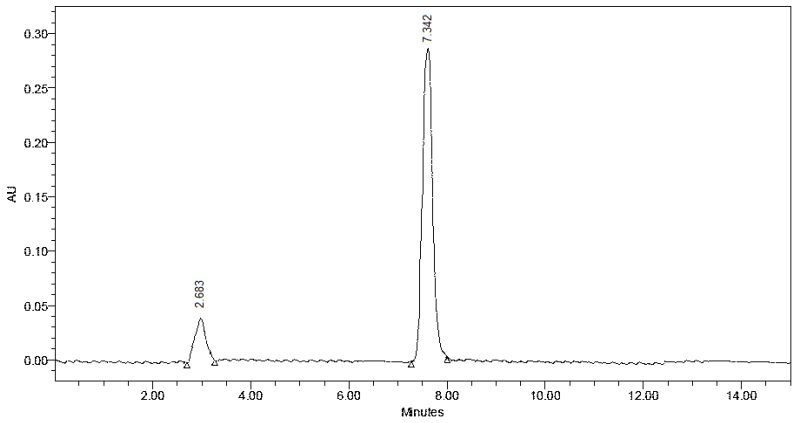
**Sample Control**



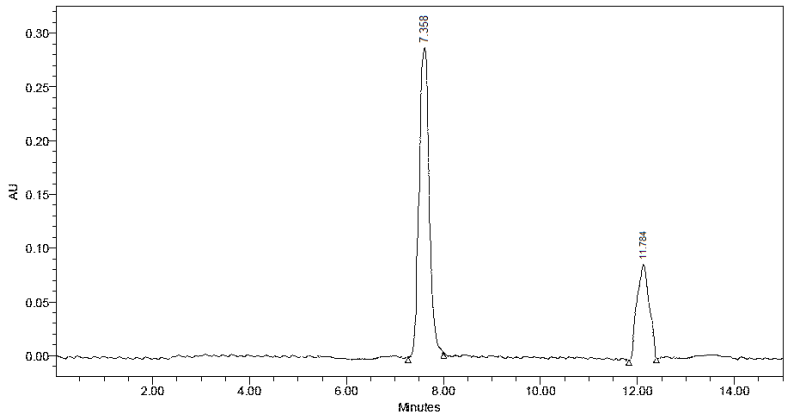

**EVALUATION OF METHODS**

| 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 |

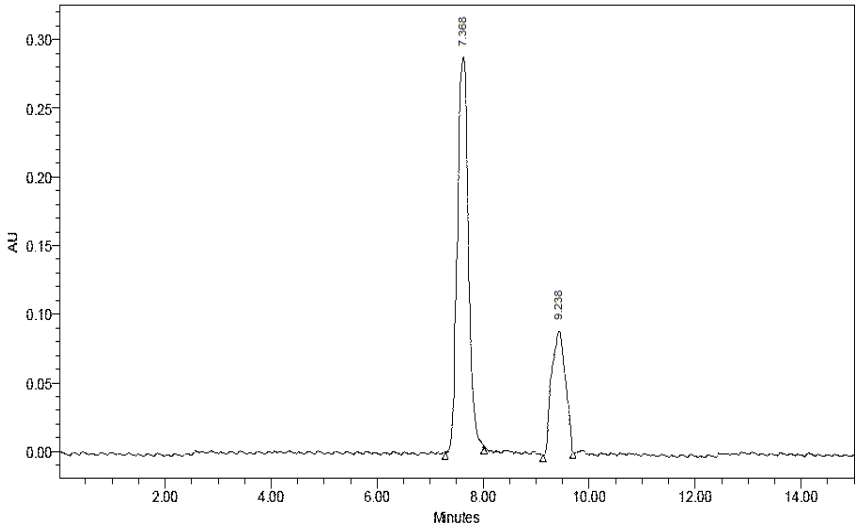
**Forced degradation Study**



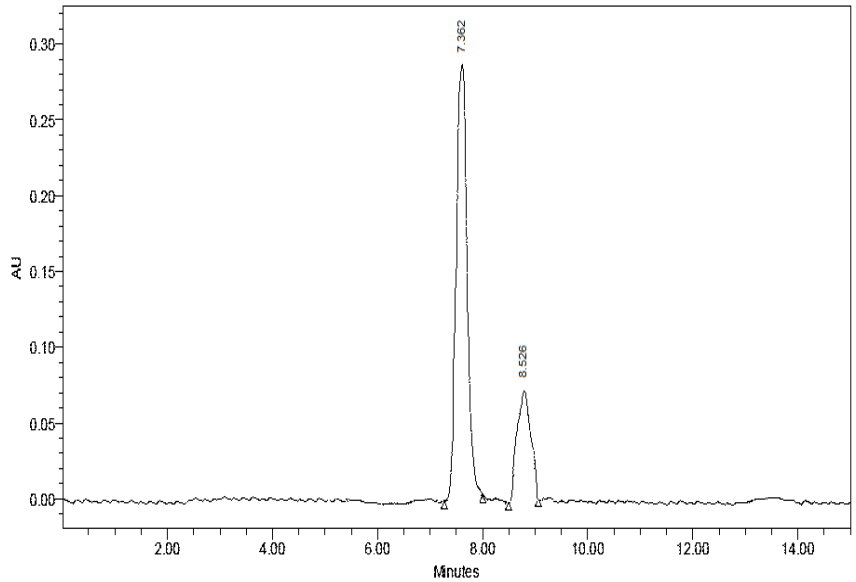

**Acidic Degradation**



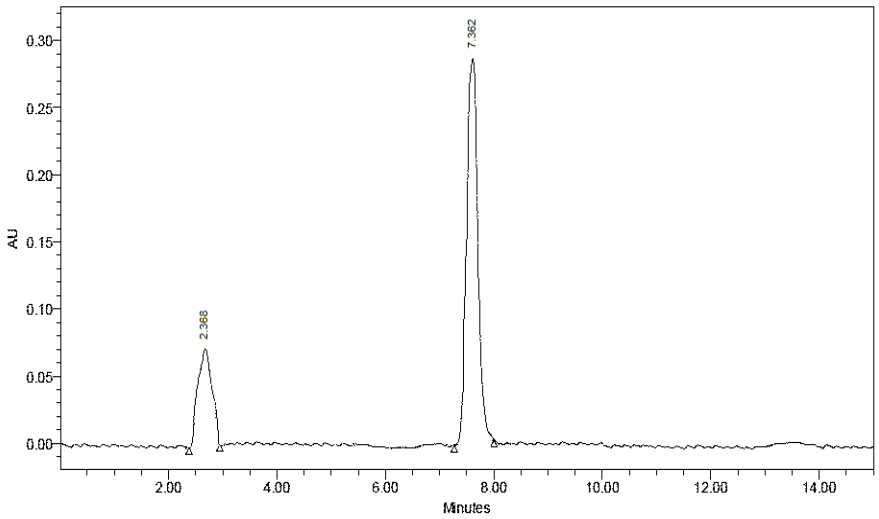
**Basic Degradation**




**Oxidative Degradation**




**Wet Heat Degradation**



**Photolytic Degradation**

**Acidic Degradation**

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

**Basic Degradation**

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

**Oxidative Degradation**

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

**Wet Heat**

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

**Photolytic Control**

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

## 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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