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Stability Indicating UV - Spectrophotometric Method for the Determination of Rifabutin in Bulk and Tablet Dosage Form

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ABSTRACT

A simple, and accurate and economic, precise, and reproducible UV Spectroscopy method has been developed for the estimation of Rifabutin capsule dosage form and validated by ICH guidelines. The standard (10µg/ml) was scanned between 200-400 nm and maximum absorption was recorded at 275 nm. The assay results are found to be 99.89±0.352. The linearity range of 3-24 µg/ml proved that it obeyed Beer's Law and the correlation coefficient (r^2) was found to be 0.9992 at 280 nm. The force degradation studies of Rifabutin formulation was done on Stress degradation by hydrolysis under alkaline condition by using 0.1N NaOH was found to be 16.07% for 60min, 21.55% for 90min. Stress degradation by hydrolysis under acidic condition by using 1N HCl and product degradation was found to be 14.75% for 60min and 19.79% for 90 min. Dry heat-induced degradation was done by using 55^0c temperature was found to be 0.33 % for 2 hrs. Oxidative degradation was done by using hydrogen peroxide and product degradation was found to be 12.65%for 60 min. Photolytic degradation was found to be 11.53% for 3hrs and 19.36% for 6hrs.

INTRODUCTION

Rifabutin (RFB) is a semi-synthetic derivative of Rifamycin S, a bactericidal antibiotic that is primarily used in the treatment of tuberculosis. It is effective against Gram-positive and some Gram-negative bacteria by blocking the *DNA-dependant RNA-polymerase* of the bacteria, it is also effective against the high resistance Mycobacteria. Rifabutin is official in the United States Pharmacopoeia [1]. Objective is to develop simple, accurate, and economic, precise, and reproducible stability indicating UV -Spectrophotometric method for the determination of Rifabutin in bulk and tablet dosage form and validate as per ICH guidelines[2,3].

MATERIALS AND METHODS

The standard stock solution of Rifabutin was prepared by dissolving 10mg of Rifabutin in methanol (100 ug/ml). Different aliquots were taken from the stock, diluted to 10 ml mark with distilled water to obtain a series of concentrations3-24 ug/ml. The solutions were scanned on a spectrophotometer in the UV range 200 - 400 nm. Rifabutin showed absorbance maxima at 275 nm. For analysis of commercial formulation, twenty capsules were weighed, average weight determined, and content was removed and crushed into a fine powder. An accurately weighed quantity of powder equivalent to 100 mg of RFB was transferred into a 100 ml volumetric flask and diluted with 100 ml of methanol. Shaken manually for 10 min., volume was adjusted to mark with the same solvent and filtered through Whatman filter paper no. 41. An appropriate aliquot was transferred to a 10 ml volumetric flask, volume was adjusted to the mark, and absorbance was recorded at 275 nm.

Method validation

The method was validated for different parameters like Linearity, Accuracy, Precision, Specificity, Robustness, Ruggedness, Limit of Detection (LOD) and Limit of Quantification (LOQ). The %RSD values found to be less than 2 indicate that method is accurate and precise.

A) Accuracy

The accuracy of the method is assessed by recovery studies. To the pre-analyzed 15 µg/mL a known amount of standard drug solutions of RFB was spiked with 80 %, 100 %, and 120 % levels i.e.12, 15, and 18 µg/mL.

B) Precision

Intra-day precision was determined by analyzing the 9, 12, and 15 µg/mL of RFB for three times in the same day. Inter-day precision was determined by analyzing 9, 12, and 15µg/mL of RFB solutions daily for three consecutive days over a week, results are reported.

C) Robustness

Robustness of the method was determined by carrying out the analysis at two different temperatures i.e. at room temperature and 18ºC.

D) Ruggedness

The ruggedness of the method was determined by carrying out the analysis by two different analysts and the respective absorbance was noted.

E) LOD and LOQ

The limit of quantitation (LOQ) is the concentration that can be quantitated reliably with a specified level of accuracy and precision. The LOQ was calculated using the formula involving the standard deviation of the response and slope of the calibration curve.

F) Stress degradation study

The sample was subjected to different stress conditions such as acid, base, dry heat, and photo light. The graphs of samples degraded with acid, base, hydrogen peroxide, and light showed confirmed by the absorbance values calculated.

RESULT AND DISCUSSION

Stress degradation studies using UV spectroscopic method has been developed for RFB shows absorption maxima at **275 nm**. The linearity was found to be in the range of **3 - 24 µg/ml**. The respective absorbances were noted and the % R.S.D **0.56-1.14** indicates the robustness of the method. For ruggedness, the results for RFB were found to be **99.26%** and **99.83%** respectively. The LOD and LOQ were found to be **25.54µg and 77.41µg**, respectively. For accuracy % RSD of recovery study was found to be **0.88-1.13** which indicated that the method is accurate. The proposed method was applied for pharmaceutical formulation and % label claim was found to be **99.23±0.38%.** The summary of validation

parameters is as shown in **Table 1.** The sample was subjected to different stress conditions such as acid, base, dry heat, and photo light. The graphs of samples degraded with acid, base, hydrogen peroxide, and light showed confirmed by the absorbance values calculated. The force degradation studies of Rifabutin formulation was done on Stress degradation by hydrolysis under alkaline condition by using 0.1N NaOH was found to be 16.07% for 60min, 21.55% for 90min. Stress degradation by hydrolysis under acidic condition by using 1N HCl and product degradation was found to be 14.75% for 60min and 19.79% for 90 min. Dry heat-induced degradation was done by using 55^0c temperature was found to be 8.33 % for 2 hrs. Oxidative degradation was done by using hydrogen peroxide and product degradation was found to be 12.65%for 60 min. Photolytic degradation was found to be 11.53% for 3hrs and 19.36% for 6hrs **(Fig.1).**

Table No. 1: Summary of Validation Parameter

Parameter	**UV**
Linearity range	3-24 µg/mL
Regression equation [Y = mX + C]	Y = 0.00468X + 0.0031
Correlation coefficient	0.9992
Limit of detection	25.54 µg
Limit of quantitation	77.41 µg
% Recovery [n = 3]	99.67-100.05
Ruggedness [%]	
Analyst I [n = 3]	99.26
Analyst II [n = 3]	99. 83
Precision [% RSD]	
Repeatability [n = 6]	1.52
Inter-day [n = 3]	0.85-1.49
Intra-day [n = 3]	0.33-1.59
Robustness	Robust

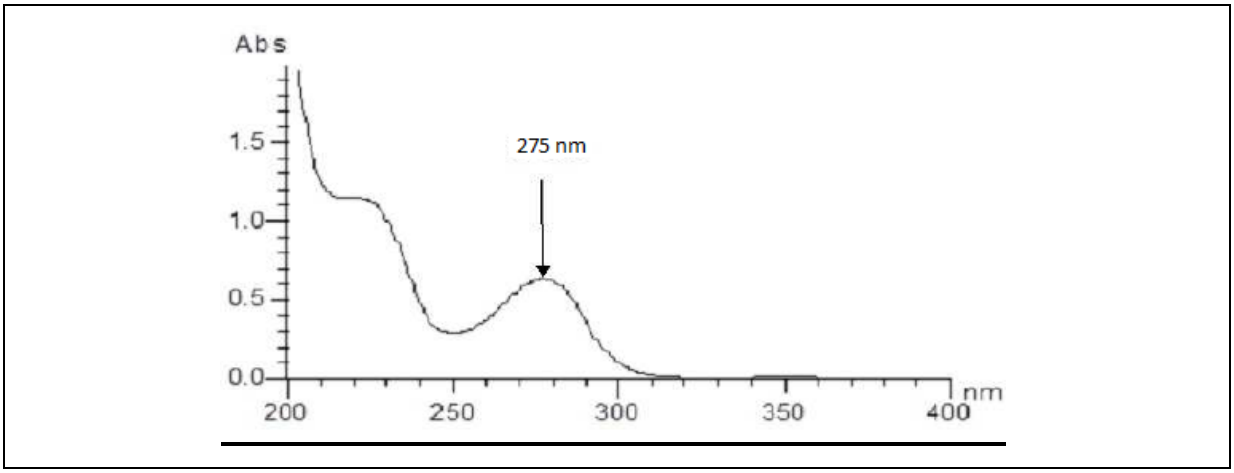

Figure No. 1: UV Absorbance graph

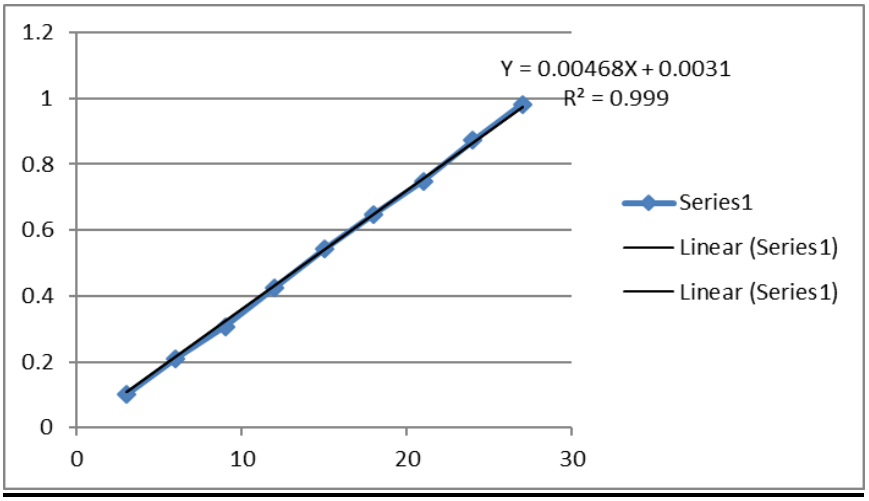

Figure No. 2: Linearity of RFB

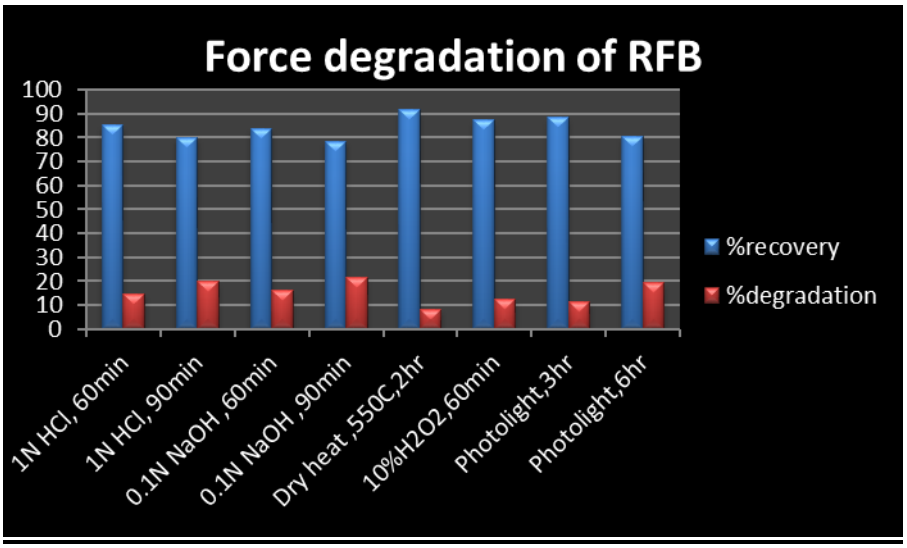

Figure No. 3: Force degradation of RFB

CONCLUSION

The results and the statistical parameters demonstrate that the proposed stability indicating UV Spectrophotometric method is simple, rapid, specific, accurate, and precise. Therefore, this method can be used for the determination of Rifabutin either in bulk or the dosage formulations without interference with commonly used excipients and related substances.

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