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METHOD DEVELOPMENT AND VALIDATION FOR QUANTITATIVE ANALYSIS OF RUPATADINE FUMARATE BY ULTRAVIOLET SPECTROPHOTOMETRY

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ABSTRACT

A simple and sensitive UV spectrophotometric method for the determination of rupatadine fumarate in tablet dosage form has been developed. Beer's law is obeyed in the concentration range of 2-20 µg/mL of rupatadine fumarate. Spectroscopic determination was carried out at an absorption maximum of 263 nm for rupatadine fumarate using methanol as a solvent. In UV spectroscopic method, the linearity over concentration range of rupatadine fumarate was 2-20 µg/mL with correlation coefficient 0.999. The mean assay and recovery percentage was found to be 99.4% and 99.25%, respectively. The results of the analysis for the method have been validated statistically and by recovery studies. The results obtained with the proposed methods are in given limits. This method is extended for analysis of drug in pharmaceutical formulation.

Key words: Rupatadine fumarate, UV spectrophotometer, Beer's law.

INTRODUCTION

Rupatadine fumarate is chemically 8-chloro-6,11-dihydro-11-[-1-[(5-methyl-3-pyridyl) methyl]-4-piperidylidine]-3H-benzo [5, 6] cyclohepta [1, 2-b]pyridine fumarate. Rupatadine fumarate is a non-sedating H1- antihistamine (second generation) and platelet activating factor receptor. It is potent and orally active that was developed as a therapeutic agent for the treatment of seasonal allergic rhinitis and chronic idiopathic urticaria[1].

A survey of literature revealed that very few analytical methods for this drug are available in human plasma and pharmaceutical formulations. These include HPLC[2] and LC-MS/MS[3] methods. But there is no evidence in the literature for estimation of this drug by UV-spectrophotometer method, which is essential for routine quality control analysis of

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pharmaceutical products containing rupatadine fumarate as a fast, selective and economical method and therefore, an attempt has been made to develop a simple, rapid and reproducible UV spectrophotometer method with greater precision, accuracy for analysis of rupatadine fumarate in bulk.

EXPERIMENTAL

All spectrum measurements were done on UV spectrophotometer Perkin Elmer with lambda 25 software using 1 cm quartz cell.

Reagents: Analytical grade reagents were used.

(i) Methanol (Merck)

(ii) Double distilled water

All weights are taken on electronic balance.

Working standard of drug solution

About 100 mg of rupatadine fumarate was accurately weighed and dissolved in 20 mL of methanol in a 100 mL volumetric flask and diluted up to the mark with methanol. The final concentration of rupatadine fumarate was brought to 100 µg/mL with double distilled water.

Sample preparation

One brand of commercial tablets from two batches was analyzed by proposed method. 15 Tablets of each containing 10 mg of rupatadine fumarate were accurately weighed and powdered. Weight of tablet powder equivalent to 100 mg of drug was taken in 40 mL of methanol and shaken for 15 minutes, filtered in to 100 mL volumetric flask through Whatmann filter paper and the remaining amount of methanol was added to tablet powder to make 100 mL. Final concentration was brought up to 100 µg/mL with double distilled water.

Assay

Aliquots of rupatadine fumarate ranging to 0.2, 0.4, 0.6, 0.8 mL (1 mL = 100 µg) were transferred in to series of volumetric flasks. The volumes are made up to the mark with double distilled water. The absorbance of the solution was measured at 263.0 nm against

solvent blank. The amount of rupatadine fumarate present in the sample was computed from calibration curve.

Table 1: Optical characteristics and precision

λ_{max}	**263 nm**
Beer's law limits (µg/mL) (c)	2 – 20
Molar absorptivity (L $mol^{-1}cm^{-1}$)	1.665×10^4
Regression equation (Y*)	
Slope (b)	0.0304
Intercept (a)	0.0091
Correlation coefficient (r)	0.9991
% RSD**	0.0103

Y*= bc + a, where is the concentration of rupatadine fumarate in µg/mL and
Y = absorbance at respective λ_{max}
** = for four measurements.

Table 2: Evaluation of rupatadine fumarate in tablet

Sample	Labelled amount (mg)	Amount found by proposed method (mg)	% Recovery
T1	10 mg	9.85	99.4%
T2	10 mg	9.87	99.1%

RESULTS AND DISCUSSION

The optical characteristics[4,5] such as absorption maxima, Beer's law limit, correlation coefficient (r), slope (m), intercept (c) and molar absorptivity have been calculated from 4 replicate readings. To test the accuracy and reproducibility of the proposed method, recovery experiments were carried out by adding known amounts of the drug. The results are shown in the Table 2. The reproducibility, repeatability and accuracy of this method were found to be good, which is evident by low standard deviation values (0.0148). The percentage

recovery obtained 99.25%, indicates that the accuracy of the method is good. The other active ingredients and excipients usually present in the pharmaceutical dosage forms did not interfere. Thus, the developed method is simple, sensitive, accurate, and precise and can be successfully applied for the routine estimation of rupatadine fumarate in pharmaceutical formulation.

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