



Trade Science Inc.

December 2009

Volume 8 Issue 4

Analytical CHEMISTRY

An Indian Journal

Full Paper

ACAJ, 8(4) 2009 [572-574]

Colorimetric determination of ranolazine in bulk and synthetic mixture

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Received: 7th August, 2009 ; Accepted: 17th August, 2009

ABSTRACT

A simple, rapid, economical and sensitive colorimetric method has been developed for the quantitative estimation of Ranolazine (RZL) in bulk and synthetic mixture. The method were based on the oxidation of RZL with Folincioalceu (FC) reagent producing blue coloured chromogen in presence of sodium carbonate which was measured at 731nm, Beer's law was obeyed in the concentration range of 5-25µg/ml. This method has been validated statistically and by recovery studies.

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KEYWORDS

Ranolazine;
Folincioalceu;
Colorimetric;
Synthetic mixture;
Antianginal.

INTRODUCTION

RZL^[1] is chemically known as N-(2, 6-dimethyl phenyl)-2-[4-[2-hydroxy-3-(2-methoxy phenoxy) propyl] piperazin-1-yl] acetamide used as an Anti-anginal drug and listed in the merck index^[1]. A few analytical methods such as LC-MS methods^[1-4] have been reported. In view of the above fact, some simple analytical methods are in need for RZL quantitative estimation. In the present work a simple, rapid economical and sensitive colorimetric method has been developed for the quantitative estimation of RZL.

MATERIALS AND METHODS

Apparatus

A Perkin elmer double beam spectrophotometer (model lamda 25) with 1 cm matched quartz cell used for all spectral measurements.

Reagents

All the chemicals used were of analytical reagent grade, double distilled water, FC reagent 1N (commercially available 2N solution was diluted with distilled water to get 1N concentration of reagent), 20% w/v sodium carbonate solution, lactose, starch, magnesium stearate, talc and methanol.

The pharmaceutical grade RZL was supplied by Madras pharmaceuticals, Chennai.

Preparation of stock solution

Stock solution of RZL 1mg/ml was prepared in methanol.

Preparation of calibration graph

5ml of stock solution was diluted with distilled water to 100ml. (stock solution II). Increasing volume of stock solution II were quantitatively transferred to a set of 25ml flasks so as to contain drug solution in the concentration range of 5- 25 µg/ml. 2ml of 20% w/v sodium carbonate solution followed by 1ml of FC reagent

(1N) were added to the flasks. The solutions were stored at 10min at ambient temperature then each flask was made up to the volume with distilled water. The absorbance was measured at 731nm against a reagent blank. The calibration curve was constructed by plotting absorbance against final concentration of the drug and corresponding regression equations were derived.

Preparation of synthetic mixture

Since the pharmaceutical formulation of ranolazine were not available in the local market a synthetic mixture containing commonly used excipients along with RZL was prepared. The synthetic mixture was prepared by mixing 100mg of Ranolazine with 26mg of lactose, 20mg of starch, 14mg of talc and 0.3mg of magnesium stearate.

Analysis of synthetic mixture

A powder equivalent to 100mg of RZL from the synthetic mixture was taken in a 100ml flask, dissolved in 50 ml of methanol and sonicated for 10min and the volume was made up to 100ml with methanol, mixed and filtered, further dilutions were made as necessary with distilled water to get a concentration of 15 μ g/ml.

Recovery studies

The recovery studies were carried out to ensure the reliability of the method. A known amount of standard drug was added to the sample and the total amount recovered was determined by the proposed method.

RESULTS AND DISCUSSION

This method is based on formation of blue coloured chromogen, following the reduction of phosphor molybdo tungstic mixed acid of FC reagent by RZL in presence of sodium carbonate, which was measured at 731nm. The mixed acids in the FC reagent are the final chromogen. The influence of FC reagent concentration on the colour development was investigated. It was found that 1ml of 1N FC reagent and 2ml of 20% w/v sodium carbonate solution gave maximum color intensity.

Linearity

The results showed that there were excellent cor-

relation between the absorbance and the concentration of the drug. The regression equation was found to be $y=0.0195x+0.0036$ ($r=0.9994$) and found to be linear over beers range of 5-25 μ g/ml. The correlation coefficient, slope and intercept, Limit of Detection (LOD) and Limit of Quantification (LOQ) was listed in TABLE 1.

TABLE 1 : Optical characteristics and other parameters

Parameters	Observations
Wavelength measured	731nm
Bee's lamberts law range(μ g/ml)	5 – 25
Correlation coefficient	0.9994
Regression equation $y = mx + c$	
a) Slope (m)	0.0195
b) Intercept (c)	0.0036
Limit of Detection (μ g/ml)	0.01382
Limit of Quantification(μ g/ml)	0.04190

Assay

The results for the assay of RZL were presented in TABLE 2, and the assay results of the method were found to be good with low standard deviation of 0.30.

Concentration of sample (μ g/ml)	Amount found (μ g/ml)	% Purity
15	14.99	99.93
15	14.92	99.46
15	15.02	100.01

Recovery

The results of recovery were shown in TABLE 3, the percentage recovery was close to 100%, and it proves the recovery of the method.

Accuracy Level (%)	Amount Added (μ g/ml)	Amount Present (μ g/ml)	Amount Recovered (μ g/ml)	% Recovery	Average Recovery
80	6	6	12.03	100.51	
100	6	9	14.97	99.54	99.66
120	6	12	17.93	98.92	

ACKNOWLEDGEMENTS

We are thankful to Madras pharmaceuticals for providing gift of RZL and SRM College of Pharmacy, SRM

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University for providing excellent facilities to carry out our work.

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