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SPECTROPHOTOMETRIC ESTIMATION OF RANOLAZINE IN BULK DRUG AND TABLET FORMULATION

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ABSTRACT

Two simple, precise and economical spectrophotometric methods have been developed for the estimation of ranolazine in bulk and pharmaceutical preparations. Ranolazine shows zero crossing at 272 nm in the first order derivative spectrum with $\Delta\lambda$ 2 (Method A)[1, 2]. Method B[3] based on the calculation of Area Under Curve (AUC) in the wavelength range from 251 nm to 290 nm. The drug follows linearity in concentrations ranging from 10-400 µg/ mL for both the methods. Results of the analysis were validated statistically and were found to be satisfactory.

Key words : Ranolazine, Derivative spectroscopy, Area Under Curve

INTRODUCTION

Ranolazine is chemically N-(2, 6-dimethylphenyl)-2-(4-(2-hydroxy-3-(2-methoxy phenoxy) propyl) piperazin-1-yl) acetamide[4], which is used in the treatment of chronic stable angina. No method of estimation for ranolazine in bulk and formulation has been reported so far except LC-MS method of estimation of the drug in biological fluids[5].

EXPERIMENTAL

All the measurements were made using Shimadzu UV-Visible spectrophotometer with 1mm matched quartz cells. All the solutions were freshly prepared with distilled water.

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Preparation of Standard stock solution

An accurately weighed amount of 100 mg of ranolazine was taken in 100 mL volumetric flask and dissolved in 25 mL of ethanol and made up to the volume using the same solvent.

Preparation of sample solution

The average weight of 20 tablets of ranolazine was determined and and these were finely powdered. The powder equivalent to 100 mg of ranolazine was taken in 100 mL volumetric flask and dissolved in 25 mL of ethanol and made up to the volume with the same solvent. The solution was then filtered, first few mL of the filtrate was discarded and remaining solution was used for the analysis.

Assay procedure

Method A: Aliquots of the standard stock solution were transferred to a series of 100 mL volumetric flask and suitably diluted to give a varying concentration ranging from10-400µg/ mL and the solutions were scanned in the spectrum mode from 400 nm–200 nm using distilled water as blank and the first derivative spectra were obtained using derivative mode. The amplitudes of the derivative spectra between 272 nm to 275 nm were noted.

Method B: Area under the curve method involves the calculation of integrated value of absorbance with respect to the wavelength between two selected wavelengths λ_1 and λ_2. The area under curve between λ_1 and λ_2 were calculated by inbuilt software.

Aliquots of stock solutions were suitably diluted with distilled water to give varying concentrations ranging from 10-400 µg/mL. The solutions were scanned in the spectrum mode in the wavelength range of 400 nm – 200 nm. The AUC calculations were done and calibration curve was plotted as concentration against area.

RESULTS AND DISCUSSION

The optical characteristics such as % R. S. D., regression equation, correlation coefficient, slope and intercept for the two methods were calculated and the results are summarized in Table 1.

To evaluate validity and reproducibility of the methods, known amount of pure

drug was added to previously analysed tablet powder sample and analysed. The results are presented in Table 2. Interference studies revealed that the excipients and additives did not interfere. Hence, these methods are most economic, simple, sensitive and accurate and can be used for the routine determination of ranolazine in pharmaceutical preparations.

Table 1 : Optical characteristics for ranolazine

Parameters	Derivative spectroscopy	Area under the curve
λ_{max} (nm)	272-275 nm	251-290 nm
Linearity	10-400 µg/mL	10-400 µg/mL
Slope (m)	0.164	0.09896
Intercept(c)	-0.4	-0.0706
Regression equation*	y = 0.164x - 0.4	y = 0.09896x - 0.0706
Correlation coefficient	0.9997	0.9999
Relative standard deviation (%)**	0.0239	0.1095

*(y = mx+c)

** Each average of 3 determinations

Table 2 : Assay and recovery of ranolazine and its formulations

Tablet	Label claim (mg)	Amount found by the proposed method*		% Recovery by the proposed method*	
		Derivative spectroscopy	Area under the curve	Derivative spectroscopy	Area under the curve
Ranolazine	500	499.95	500.45	99.96	99.99
		499.89	501.47	99.95	100.16
		500.12	500.61	99.97	99.72

*Each average of 3 determinations

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