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Development and Validation of UV Spectrophotometric Method for the Estimation of Ranolazine in Bulk Drug and Pharmaceutical Formulation

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Abstract: A simple, precise and economical UV spectrophotometric method has been developed for the estimation of Ranolazine in bulk and pharmaceutical formulations. In this method Ranolazine showed maximum absorption at 272 nm. It obeyed Beer's law in the concentration range of 10-100 µg / ml. The Regression equation was found to be Y = 0.0061X - 0.0018 with r^2=0.999. The values 0.192 and 0.436 represents % RSD for intra-day and Interday precision, respectively. The LOD and LOQ were found to be 0.27 µg / ml and 0.82 µg / ml, respectively. Recoveries of ranolazine in tablet formulations were observed in the range of 99.77 - 100.33 %. The proposed method is precise and accurate, and can be extended to the analysis of ranolazine in bulk and pharmaceutical formulations.

Key words: Ranolazine, UV Spectrophotometric Method, Ranolazine in Bulk Drug and Pharmaceutical Formulation.

Introduction

Ranolazine is a antianginal drug and chemically it is a piperazine derivative. Structurally it is N-(2,6-dimethylphenyl)-2-[4-[2-hydroxy-3-(2-methoxyphenoxy) propyl] piperazin-1-yl]acetamide. Ranolazine is believed to have its effects via altering the trans-cellular late sodium current. It is by altering the intracellular sodium level that ranolazine affects the sodium-dependent calcium channels during myocardial ischemia. Thus, ranolazine indirectly prevents the calcium overload that causes cardiac ischemia. Ranolazine is indicated for the treatment of chronic angina. Ranolazine may be used with beta-blockers, nitrates, calcium channel blockers, anti-platelet therapy, lipid-lowering therapy, ACE inhibitors, and angiotensin receptor blockers.

A survey of literature has not revealed any spectophotometric method for the determination of the drug in pharmaceutical formulation whereas reports are available for the estimation of the drug in pharmaceutical preparation and biological fluids by LC. The developed method was simple, precise, specific and accurate and the statistical analysis proved that method is selective for the analysis of ranolazine in bulk drug and tablet formulations [1-3].

Materials and Methods [4-14]

Instruments and reagents

An analytically pure sample of ranolazine was procured as gift sample from Sun pharmaceutical Ltd., Vapi, India. Analytical grade methanol was used as solvent for dilution. A double beam UV spectrophotometer (Shimadzu UV-1800) was used with 1 cm matched quartz cell. Tablet formulation [RANOZEX (Brand I), Sun pharmaceutical Ltd., Vapi, India and [RENZ-500 (Brand II), Intas pharmaceuticals Ltd., Ahmadabad] were procured

from a local pharmacy with labeled amount 500mg per tablet.

Preparation of working standard drug solution

Standard Ranolazine 100 mg was weighed and transferred to a 100 ml volumetric flask and dissolved in methanol. The flask was shaken and volume was made up to the mark with methanol to give a solution containing 1000 µg / ml. From this stock solution, pipette out 50 ml and placed into 100 ml volumetric flask. The volume was made up to mark with methanol to give a working stock solution containing 500 µg / ml.

Analysis of marketed formulations

For the estimation of ranolazine in tablets formulation by this method, 20 tablets of each brand were weighed and triturate to fine powder. Tablet powder equivalent to 100 mg of ranolazine weighed and transfer into 100 ml volumetric flask than dissolved with methanol and further diluted with methanol. It was kept for ultrasonication for 30 min; this was filtered through Whatman filter paper No. 41 to get the solution of 1000 µg / ml. The above solution was centrifuged at 2000 rpm for 10 minutes and carefully filtered through Whatmann filter paper (No. 41). From this solution, 50 ml was taken and diluted to 100 ml with methanol to give a solution of 500 µg / ml and used for the estimation of ranolazine. Various dilutions of the tablet solution were prepared and analyzed.

Calibration curve

Appropriate volume of aliquots from standard ranolazine stock solutions were transferred to different volumetric flasks of 10 ml capacity. The volume was adjusted to the mark with methanol to obtain concentrations of 10, 20, 30, 40, 50, 60, 70, 80, 90 and 100 µg / ml. Absorbance spectra of each solution against methanol as blank were measured at 272 nm and the graphs of absorbance against concentration was plotted. Similarly absorbance of sample solution was measured and amount of ranolazine was determined from standard calibration curve.

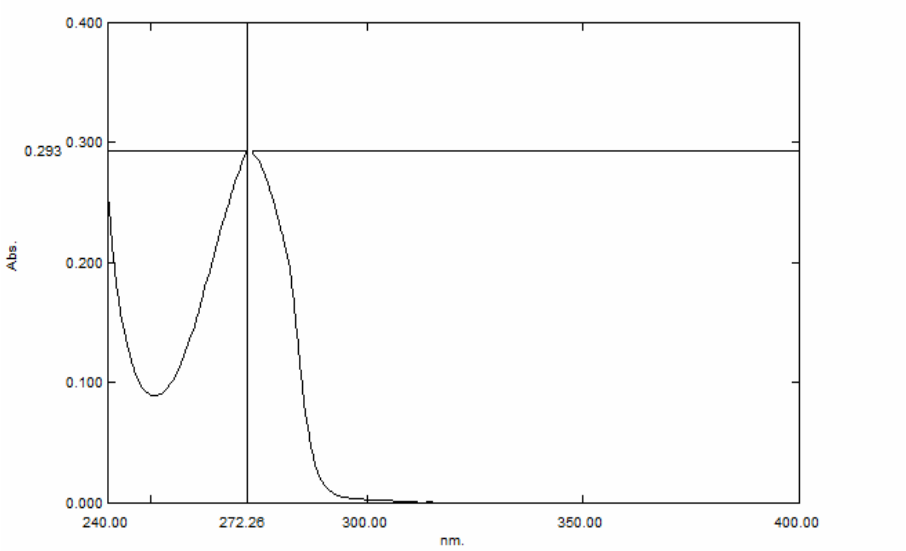

Figure 1: UV spectrum of Ranolazine

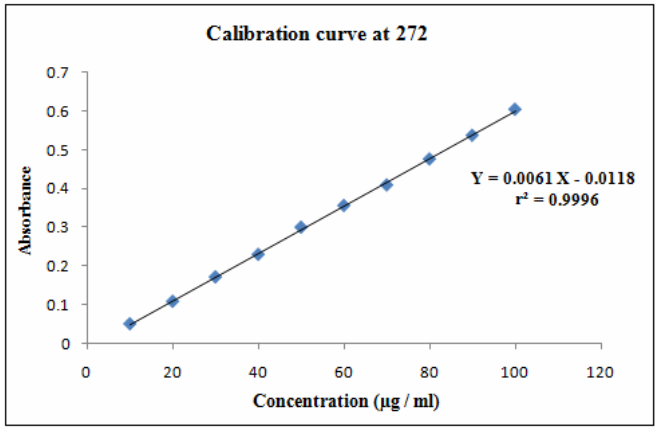

Figure 2: Calibration curve of ranolazine at 272 nm

Table 1: Calibration Parameters

Sr.No	Parameter	Results
1	Absorption Maxima (nm)	272
2	Beer's Law limits(µg / ml)	10-100
3	Regression equation (y)* Slope (b) Intercept (a)	0.9996 0.0061 - 0.0118
4	Limit of detection (µg / ml)	0.27
5	Limit of quantification (µg / ml)	0.82
6	Intraday precision (% RSD)	0.192
7	Interday precision (% RSD)	0.436

*y = mx+c; when x is the concentration in µg / ml and y is absorbance unit.

Table 2: Recovery study Data

Sample	Amount of sample (µg / ml)	Amount of drug added (µg / ml)	Amount recovered (µg / ml)	Recovery ± SD (%)	% RSD
BRAND I	10	8	17.95	99.77 ± 0.17	0.170
	10	10	19.97	99.85 ± 0.15	0.150
BRAND II	10	5	14.97	99.78 ± 0.18	0.180
	10	10	20.06	100.32 ± 0.17	0.170

Result and Discussion

The method was validated according to International Conference on Harmonization guidelines for validation of analytical procedures [15-17].

The proposed method shows absorption maxima at 272 nm and obeyed Beer's law in the concentration range of 10-100 µg / ml. The percentage recovery value indicates no interference from excipients used in formulation. The low value of percentage relative standard deviation shows that the developed method was precise.

All statistical data prove validity of proposed method, which can be applied in industries for routine analysis of this drug from tablet.

Conclusion

The proposed method is simple precise and accurate, and can be extended to the analysis of Ranolazine in bulk and tablet formulations.

Acknowledgement

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