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NOTE

Spectrophotometric Estimation of Ranolazine in Tablet Dosage Form

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Two new, simple sensitive and reproducible spectrophotometric methods have been developed for the estimation of ranolazine in tablet dosage form, (**method A** and **method B**). **Method A** is based on the formation of a yellow coloured chromogen with ferric chloride and it obeys Beer's law in concentration ranging from 100-800 µg/mL and exhibiting maximum absorption at 379 nm. **Method B** is difference spectroscopic method which is based on shifting the λ_{max} by changing the pH of the solution by adding 1 M HCl and 1 M NaOH. At 215 nm the difference in absorbance is noted and it obeys Beer's law in concentration ranging from 10-60 µg/mL. The methods were extended to tablet formulation and there was no interference from excipients and diluents. These methods have been statistically validated and are found to be precise and accurate.

Key Words: Ranolazine, Spectrophotometric determination.

Ranolazine chemically is N-(2,6-dimethylphenyl)-2-(4-(2-hydroxy-3-(2-methoxy phenoxy)propyl)piperazin-1-yl) acetamide[1] 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[2]. All the measurements were made using Shimadzu UV-visible spectrophotometer with 1 mm matched quartz cells. All the solutions were freshly prepared with distilled water.

Preparation of standard stock solution: An accurately weighed amount of 100 mg of ranolazine 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 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[3,4]

Method A: Aliquots of the standard stock solution were transferred to a series of 25 mL volumetric flask. To each flask, 2 mL of 3 % ferric chloride were added and the volume made up with distilled water to give a varying concentrations ranging from 100-800 µg/mL and the solutions were scanned in the visible region between 350-450 nm using distilled water as blank. It was found that yellow coloured chromogen exhibited an intense maximum absorption at about 379 nm.

Method B: Aliquots of standard stock solution were transferred to a series of 100 mL volumetric flasks. To each flask sufficient 1 M HCl was added to make up to the volume and similar solutions were prepared by adding sufficient 1 M NaOH. These solutions were scanned between 200-400 nm using respective blanks to get the absorption spectra. The difference in absorbance at about 215 nm was calculated. The difference in absorbance at 215 nm was recorded and obeys Beer's law in the concentration range of 10-60 µg/mL. The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar absorptivity, % RSD, regression equation, correlation coefficient for the two methods were calculated and the results are summarized in Table-1.

TABLE-1
OPTICAL CHARACTERISTICS FOR RANOLAZINE

Parameters	Ranolazine	
	Colorimetry	Differential spectroscopy
λ_{max} (nm)	379	215
Beer's law limits (µg/mL)	100-800	10-60
Molar absorptivity (L mol^{-1} cm^{-1})	$3.367x10^2$	$1.65724x10^4$
Sandell's sensitivity (µg cm^{-2}/0.001 abs unit)	1.271983	0.025803
Slope (m)	0.000901	0.03971
Intercept(c)	-0.0402	-0.0227
Regression equation*		
Correlation coefficient (r)	0.99867	0.999907
Relative standard deviation (%)**	0.001021	0.0002232

*(Y = mx+c); ** Each average of 3 determinations.

To evaluate validity and reproducibility of the methods, known amount of pure drug was added to previously analyzed pharmaceutical preparations and the mixtures were analyzed. The proposed methods and the results are presented in Table-2. Interference studies revealed that the common 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-2
ASSAY AND RECOVERY OF RANOLAZINE AND ITS FORMULATIONS

Tablet	Label claim (mg)	Amount found by the proposed method*		% Recovery by the proposed method*	
		Colorimetry (%)	Differential spectroscopy (%)	Colorimetry (%)	Differential spectroscopy (%)
Ranolazine	500	100.28	99.91	99.18	99.52
		100.16	99.82	100.83	100.16
		100.08	100.04	99.84	99.91

*Each average of 3 determinations.

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