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Novel Spectrophotometric method for estimation of Ranolazine in bulk and pharmaceutical dosage forms

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ABSTRACT

A simple and rapid UV-spectrophotometer estimation method for the evaluation of ranolazine is used in management of chronic angina has been developed and assessed. The proposed methods were successfully applied for the estimation of ranolazine in commercial pharmaceutical preparation and in bulk formulation with UV detection at 272 nm. A Shimadzu 1700 U.V visible spectrophotometer with 1cm matched quartz cells, and methanol: water solvent was employed in the method. Developed methods obeyed the Beer's law in the concentration range of 10-100 µg/ml. methods were validated statistically. The SD and RSD of that was found satisfactorily low. Percentage recovery of the drug for the proposed method ranged from 99.345-100.43% indicating no interference of the tablet excipients. The results of the tablet analysis were validated with respect to accuracy (recovery), linearity, limit of detection and limit of quantitation were found to be satisfactory.

Keywords: ranolazine, UV spectrophotometry, Absorbance maxima.

INTRODUCTION

Ranolazine is a BCS class II (Low soluble, highly permeable) drug with extensive and highly variable hepatic first pass metabolism following oral administration, with systemic bio-availability of between 76% and half life of 2.5 ± 0.5 hours.[1] To date there is no published methods for determination of ranolazine RAZINE® ER tablet. There are various methods for determination of ranolazine such as liquid chromatographic[3], high performance liquid chromatography with UV detection, capillary electrophoresis[6], Spectrofluorimetric Method, colorimetric[8], RP- HPLC[7].

Ranolazine is N-(2,6-dimethyl phenyl)-2-[4-[2-hydroxy-3-(2-methoxy phenoxy) propyl]-piperazine-acetamide[4,9]. Ranolazine is treating a human patient who is suffering from angina or other coronary disorder by using once or twice daily[9].

MATERIALS AND METHODS

2.1. Instrumentation

A double-beam Shimadzu UV–Visible spectrophotometer, model UV-1700 with 1-cm quartz cells attached with printer of ESPON LQ 1150 II.

2.2. Materials and reagents

Pharmaceutical grade of Ranolazine base from MACLEODS PHARMA LTD where methanol used of analytical grade from loba.chem and distilled water. TABLET from Ajanta Pharma Pvt. Limited.

2.3. Standard solutions and calibration

Stock standard solutions of Ranolazine were prepared by accurately weigh and dissolving 10 mg in 100 ml methanol: Distilled water (1:4) to get concentration of 100µg/ml.

The standard solutions were prepared by dilution of the stock standard solutions with methanol: distilled water (for spectrophotometric methods) to reach the concentration range of10 µg/ml to 100ug/ml. And calibration curve was taken at 272nm.

2.4. Analysis of the Tablet formulation: [6,7]

Twenty tablets were weighed and finely powdered weigh. A portion of the powder equivalent to about 10 mg of Ranolazine was weighed accurately, dissolved and diluted to 100 ml with methanol: distilled water. The sample solution was filtered. Further dilution was carried out with methanol: distilled water .The general procedures for described under calibration were followed and the concentrations of Ranolazine were calculated at 272nm.

Table No.1: Optical characteristics and Other Parameters

Sr. No.	Parameters	Absorbtion Maxima Method	Area Under Curve
1	λmax (nm) / wavelength range (nm)	272	272
2	Beer's-Lambert's range (µg/ml)	10-100	10-100
3	Coefficient of Correlation	0.99971	0.999
4	Slope	0.00588	0.0538
5	Y - Intercept	-0.005	0.0011
6	Sandell's Sensitivity (mg/cm2/0.001 absorbance unit)[12]	0.17016	0.018579
7	Molar absorbtivity	2512.59877	23011.5296
8	LOD (µg/ml)	2.806	0.067472
9	LOQ (µg/ml)	8.503	0.20446

Table No.2: Result of Analysis of Ranolazine in marketed tablet formulation

method	Lable Claim (mg)	Amount Found* (mg)	% Estimated*	S.D.* (±)	R.S.D.*
1	500	507.38	101.476	0.493384	0.48637
2	500	503.125	100.625	0.150947	0.005

*Where, * indicates mean of six determinations.*
1-Absorbtion Maxima Method.
2- Area Under Curve

3. Validation: [7, 8]

The methods were validated with respect to accuracy linearity, limit of detection (LOD) and limit of quantitation (LOQ).

Table No.3: Recovery study data.(Absorption Maxima Method)

Sr.No.	Level of Recovery (%)	Fixed amount added(mcg)	Amount Added (mcg)	Amount Estimated (mcg	Recovery* (%)	S.D.* (±)	R.S.D.*
1	80	30	24	54	100	0.04582	0.00085
2	100	30	30	59.99	99.99	0.1553	0.00259
3	120	30	36	66.94	101.43	0.03	0.00045

*Where, * indicates mean of six determinations*

Table No.4: Recovery study data (Area Under Curve)

Sr.No.	Level of Recovery (%)	Fixed amount added(mcg)	Amount Added (mcg)	Amount Estimated (mcg)	Recovery* (%)	S.D.* (±)	R.S.D.*
1	80	30	24	53.923	99.86	0.2177	0.00403
2	100	30	30	59.608	99.345	0.00173	0.000017
3	120	30	36	65.626	99.44	0.03213	0.00049

*Where, * indicates mean of six determinations.*

3.1. Accuracy (recovery test):

To ascertain the accuracy of proposed methods, recovery studies were carried out by standard addition method at three different levels (80%, 100% and 120%). Percent recovery for ranolazine, by all the methods, was found in the range of (Table no.3, 4)

3.2. Linearity:

The linearity of measurement was evaluated by analyzing different concentration of the standard solution of Ranolazine. Beer-Lambert's concentration range was found to be 10-100µg/ml.

3.3. Limit of detection (LOD) and limit of quantitation (LOQ):

The LOD and LOQ of Ranolazine were determined by using standard deviation of the response and slope approach as defined in International Conference on Harmonization (ICH) guidelines[5].The LOD and LOQ was found to be as in table no.1

RESULTS AND DISCUSSION

The methods discussed in the present work provide a convenient and accurate way for analysis of Ranolazine in its pharmaceutical dosage form. Absorbance maxima of Ranolazine at 272 nm were selected for the analysis. Linearity for detector response was observed in the concentration range of 10-100 µg/ml. Percent label claim for Ranolazine in tablet analysis, was found close to 100 %. Standard deviation for six determinations of tablet sample was found to be less than ± 2.0 indicating the precision of the methods. Accuracy of proposed methods was ascertained by recovery studies and the results are expressed as % recovery. Percent recovery for Ranolazine was found in the range of close to 100% and values of standard deviation were satisfactorily low indicating the accuracy of all the methods (Table no.3, 4).

CONCLUSION

The developed new method was found to be simple, sensitive, accurate, precise, reproducible, and can be used for routine quality control analysis of Ranolazine in bulk and pharmaceutical formulation.

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