International Journal of Research in Pharmaceutical sciences and Technology

Development and validation of a UV-spectrophotometric method for quantitative estimation of ranolazine in tablet dosage form

T. Vimalakkannan*[1], M. Arun Kumar[2], N. Kirithiga[2], S. Marimuthu[2], S. Mathumitha[2], V. Vigneshwaran[2]

[1]Department of Pharmaceutical Chemistry & Analysis, Dr. Kalam College of Pharmacy, Avanam, Thanjavur, Tamil Nadu, India.
[2]IV[th] B. Pharmacy, UG Students, Dr. Kalam College of Pharmacy, Avanam, Thanjavur, TamilNadu, India.

ABSTRACT

A simple, rapid, accurate, and cost-effective UV spectrophotometric method was developed and validated for the quantitative estimation of Ranolazine in pharmaceutical tablet formulations. Ranolazine, an antianginal drug used in the treatment of chronic stable angina, was analyzed using a hydrotropic solubilizing agent (0.2 M urea) as the solvent. The absorption maximum (λmax) of Ranolazine was found to be 271 nm. The method showed good linearity in the concentration range of 40–120 µg/mL with a correlation coefficient (R^2) of 0.9986. The developed method was validated according to ICH guidelines for parameters such as precision, accuracy, linearity, limit of detection (LOD), limit of quantification (LOQ), robustness, and ruggedness. The LOD and LOQ values were found to be 3.35 µg/mL and 10.16 µg/mL respectively. The percentage recovery ranged between 100–102%, confirming the accuracy of the method. The developed method was successfully applied for the assay of Ranolazine tablets with satisfactory results. The results demonstrated that the proposed method is reliable and suitable for routine quality control analysis of Ranolazine in pharmaceutical formulations.

Keywords: Ranolazine; UV spectrophotometry; Method validation; Hydrotropic solubilization; Pharmaceutical analysis.

ISSN: 2582-0672
Review Article

Corresponding Author
Name: T. Vimalakkannan
Email: vml05kannan@gmail.com

Article Info
Received on: 15-03-2026
Revised on: 22-03-2026
Accepted on: 02-04-2026
DOI: https://doi.org/10.33974/d7b91z64

INTRODUCTION

Analytical method development and validation are integral components of pharmaceutical drug development and Chemistry, Manufacturing, and Controls (CMC). These processes ensure that analytical procedures used for the evaluation of drug substances and drug products are reliable, reproducible, and suitable for their intended purpose. The primary objective of method development and validation is to establish procedures capable of accurately determining the identity, purity, potency, and stability of pharmaceutical compounds, thereby ensuring product quality, safety, and efficacy [1,2].

Analytical chemistry plays a significant role in pharmaceutical sciences as well as in various interdisciplinary fields such as medicine, forensic science, and environmental analysis. Analytical methods are broadly classified into qualitative and quantitative techniques. Qualitative methods provide information regarding the identity of chemical species or functional groups present in a sample, whereas quantitative methods determine the concentration or amount of analytes. Various physicochemical properties, including absorption and emission of electromagnetic radiation, are commonly utilized for analytical estimations. Among these, spectrophotometric techniques are widely employed due to their simplicity, sensitivity, and cost-effectiveness [3].

In pharmaceutical analysis, analytical methods are essential for the determination of active pharmaceutical ingredients (APIs), impurities, degradation products, and metabolites in biological and formulation matrices. These methods also play a critical role in quality control and regulatory compliance. When the quality of a drug product is questioned, analytical testing serves as a key tool to investigate and confirm product integrity [4].

Analytical method development involves the systematic selection and optimization of analytical procedures to achieve desired performance characteristics such as accuracy, precision, specificity, and robustness. The analytical procedure includes all steps necessary to perform the analysis, including sample preparation, use of reagents and reference standards, instrumentation, calibration, and data analysis [5].

Analytical methods are categorized into classical (non-instrumental) and instrumental techniques. Instrumental methods further include spectral, separative, and electroanalytical techniques. Spectral methods, such as UV-Visible spectroscopy, are based on the interaction of electromagnetic radiation with matter, while electroanalytical methods measure electrical parameters such as potential, current, and conductivity [3,6].

Method validation is defined as the process of establishing documented evidence that an analytical method consistently produces reliable results within specified limits. According to guidelines provided by the International Council for Harmonisation (ICH) and pharmacopeial standards, validation parameters include accuracy, precision, specificity, linearity, range, limit of detection (LOD), limit of quantitation (LOQ), and robustness [1,7].

Accuracy refers to the closeness of agreement between the measured value and the true value, whereas precision indicates the reproducibility of results under specified conditions. Robustness evaluates the method's ability to remain unaffected by small variations in experimental parameters. Linearity and range establish the relationship between analyte concentration and response, while LOD and LOQ determine the sensitivity of the method [7,8].

Among various analytical techniques, UV-Visible spectrophotometry is widely used in pharmaceutical analysis due to its rapid analysis, simplicity, and applicability for a wide range of compounds. The technique is based on the absorption of ultraviolet or visible radiation by molecules, resulting in electronic transitions. The instrumentation typically consists of a light source, wavelength selector, sample holder (cuvette), and detector, which collectively enable accurate measurement of absorbance [6,9].

In conclusion, analytical method development and validation are essential for ensuring the reliability of analytical data and compliance with regulatory requirements. A well-developed and validated method significantly contributes to the success of pharmaceutical development and quality assurance processes.

MATERIALS

Ranolazine active pharmaceutical ingredient (API) was obtained as a gift sample from Yarrow Chem Products. Commercially available Ranolazine tablets (500 mg label claim) were procured from a local retail pharmacy. All chemicals and reagents used in the study were of analytical grade. A 0.2 M urea solution was prepared and used as the solvent throughout the analysis.

Instruments

The analysis was carried out using a double beam UV-Visible spectrophotometer (Model: GI-5700, Genius). Weighing of samples was performed using a calibrated electronic analytical balance (KAB Series). All glassware used was of standard quality and properly calibrated.

METHODOLOGY

Solvent Selection: Solvent selection was performed based on solubility studies of Ranolazine API. Various solvents were evaluated, including hydrochloric acid and hydrotropic agents such as urea, sodium salicylate, and sodium benzoate. Among these, Ranolazine exhibited good solubility in 0.2 M urea solution. Hence, 0.2 M urea was selected as the optimal solvent for further analysis.

Determination of Maximum Wavelength (λmax): A standard solution of Ranolazine (100 µg/mL) was prepared and scanned over the UV range of 200–400 nm using 0.2 M urea as blank. The maximum absorbance (λmax) was observed at **271 nm**, which was selected for further analysis.

Preparation of Standard Stock Solution: An accurately weighed quantity of 100 mg of Ranolazine API was transferred into a 100 mL volumetric flask and dissolved in 0.2 M urea solution. The volume was made up to the mark to obtain a stock solution. From this, 10 mL was further diluted to 100 mL with the same solvent to obtain a working stock solution of 100 µg/mL.

Preparation of Working Standard Solutions: Aliquots of the working stock solution were pipetted into 100 mL volumetric flasks to obtain concentrations of 40, 60, 80, 100, and 120 µg/mL. The volume was adjusted with 0.2 M urea solution.

Method Validation: The developed UV spectrophotometric method was validated as per ICH guidelines with respect to the following parameters:

Linearity and Range: Linearity was evaluated by analyzing solutions in the concentration range of 40–120 µg/mL at 271 nm. A calibration curve was plotted

between concentration and absorbance, and correlation coefficient (R^2) was determined.

Precision: Precision was evaluated in terms of intraday and interday variations.

- **Intraday precision:** Standard solutions were analyzed three times within the same day.
- **Interday precision:** The same procedure was repeated on different days.

The results were expressed as percentage relative standard deviation (%RSD).

Limit of Detection (LOD) and Limit of Quantification (LOQ)

LOD and LOQ were determined based on the standard deviation of the response and slope of the calibration curve, indicating the sensitivity of the method.

Accuracy: Accuracy was assessed using the standard addition method at three levels (50%, 80%, and 100%). Known amounts of standard Ranolazine were added to pre-analyzed tablet samples, and percentage recovery was calculated.

Robustness: Robustness was evaluated by making small deliberate variations in analytical conditions such as wavelength (±1 nm). The effect of these changes on absorbance and %RSD was studied.

Ruggedness: Ruggedness was determined by performing the analysis under different conditions such as different analysts and similar laboratory environments to evaluate reproducibility.

Assay of Marketed Formulation: Twenty tablets of Ranolazine (500 mg) were weighed and the average weight was calculated. The tablets were powdered, and an accurately weighed portion equivalent to 100 mg of Ranolazine was transferred into a 100 mL volumetric flask. The solution was prepared using 0.2 M urea, filtered, and suitably diluted to obtain concentrations within the linearity range (80–120 µg/mL). The absorbance was measured at 271 nm, and the amount of drug present was calculated using the calibration curve.

RESULTS AND DISCUSSION

Selection of Solvent: Solubility studies were performed using different solvents, including hydrochloric acid and hydrotropic agents such as urea, sodium salicylate, and sodium benzoate. Among these, Ranolazine exhibited maximum solubility and stability in **0.2 M urea solution**. The solvent showed negligible interference at the analytical wavelength, making it suitable for UV spectrophotometric analysis.

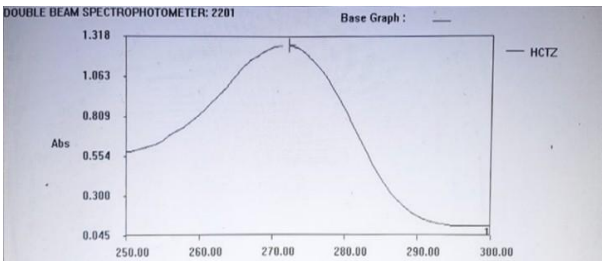

Figure 1: UV-Spectrum of ranolazine

Determination of λmax: The standard solution of Ranolazine (100 µg/mL) was scanned in the UV range of 200–400 nm using 0.2 M urea as blank. The drug showed maximum absorbance (λmax) at **271 nm**, which was selected for further analysis. The spectrum confirmed the suitability of the method for quantitative estimation.

Linearity and Range: Ranolazine obeyed Beer–Lambert's law in the concentration range of **40–120 µg/mL**. The calibration curve plotted between concentration and absorbance showed good linearity with a correlation coefficient (R^2) of **0.9986**, indicating a strong linear relationship.

- Slope: 0.00385
- Intercept: ~0.0044

This confirms that the method is suitable for quantitative analysis within the specified range.

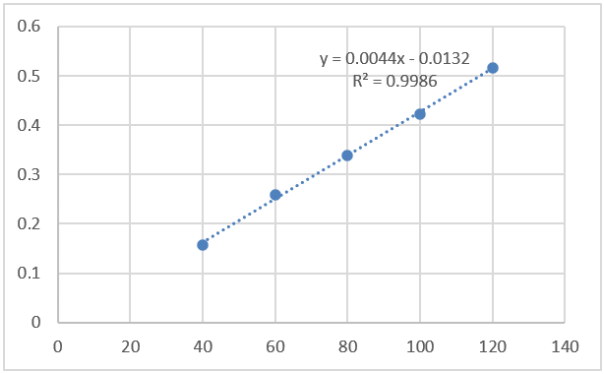

Figure 2: calibration curve of Ranolazine

Precision: Precision of the method was evaluated in terms of intraday and interday studies.

- **Intraday precision:** %RSD values were found to be **1.5246%, 0.8224%, and 0.4362%** for concentrations of 80, 100, and 120 µg/mL respectively.
- **Interday precision:** %RSD values were found to be **1.365%, 0.672%, and 1.142%** for the same concentration levels.

All %RSD values were less than 2%, indicating that the method is precise and reproducible.

Limit of Detection (LOD) and Limit of Quantification (LOQ): The sensitivity of the method was determined by calculating LOD and LOQ:

Table 1: Intraday precision for ranolazine

Concentration µg/ml	Absorbance(nm) 1	2	3	Mean	SD	RSD%
80	0.227	0.23	0.234	0.230	0.0035	1.5246
100	0.353	0.348	0.348	0.174	0.0028	0.8224
120	0.396	0.396	0.399	0.397	0.00173	0.4362

Table 2: Interday Precision of Ranolazine

Concentration µg/ml	Absorbance(nm) 1	2	3	Mean	SD	RSD%
80	0.234	0.239	0.233	0.235	0.0032	**1.365**
100	0.372	0.374	0.377	0.374	0.0025	**0.672**
120	0.390	0.395	0.399	0.394	0.004	**1.142**

Table 3: Assay of Ranolazine 500mg

S.no	Concentration (µg/ml)	Label claim	% Purity	Amount present
1	80	500mg	**102**	**0.285**
2	100	500mg	**100**	**0.348**
3	120	500mg	**101**	**0.4277**

Table 4: Accuracy of Ranolazine 500mg

S.no	Level	Concentration Range	Working Conc.	% Recovery
1	50%	50µg/ml	100µg/ml	**102%**
2	80%	80µg/ml	100µg/ml	**101%**
3	100%	100 µg/ml	100µg/ml	**100%**

Table 5: Robustness data for Ranolazine

	Drug concentration (µg/ml)	Wavelength (nm) 270	272	%RSD
Wavelength of ranolazine (271nm)	80	0.345	0.346	**0.205**
	100	0.357	0.359	**0.395**
	120	0.367	0.371	**0.767**

- **LOD:** 3.3531 µg/mL
- **LOQ:** 10.1610 µg/mL

These values indicate that the developed method is sufficiently sensitive for the detection and quantification of Ranolazine at low concentrations.

Accuracy: Accuracy was evaluated using the standard addition method at three levels:

- 50% level: 102% recovery
- 80% level: 101% recovery
- 100% level: 100% recovery

The percentage recovery values were within the acceptable limit of **98–102%**, confirming the accuracy of the method.

Assay of Marketed Formulation: The assay of Ranolazine tablets (500 mg) showed percentage purity in the range of **100–102%**, indicating that the marketed formulation complies with the labeled claim. The results confirm that the developed method is suitable for routine quality control analysis.

Robustness: Robustness was evaluated by introducing small deliberate variations in wavelength (±1 nm). The %RSD values obtained were within acceptable limits (<2%), indicating that the method is robust and not significantly affected by minor changes in analytical conditions.

Ruggedness: Ruggedness studies were carried out by different analysts under similar experimental conditions. The results showed consistent absorbance values with low %RSD, demonstrating that the method is reproducible under varied conditions.

DISCUSSION

The developed UV spectrophotometric method for the estimation of Ranolazine using 0.2 M urea as a hydrotropic solvent was found to be simple, rapid, and cost-effective. The method showed good linearity within the selected concentration range and complied with ICH validation parameters.

The low %RSD values in precision studies indicate excellent repeatability and reproducibility. Accuracy results demonstrated that the method is reliable for quantitative analysis, while robustness and ruggedness studies confirmed its stability under slight variations in experimental conditions.

The use of hydrotropic solubilization (0.2 M urea) eliminates the need for organic solvents, making the

method environmentally friendly and economical. Overall, the method is suitable for routine analysis of Ranolazine in bulk and pharmaceutical dosage forms.

CONCLUSION

A simple, rapid, and cost-effective UV spectrophotometric method was successfully developed and validated for the quantitative estimation of Ranolazine in bulk and pharmaceutical dosage forms using 0.2 M urea as a hydrotropic solvent. The developed method exhibited maximum absorbance at 271 nm and showed good linearity in the concentration range of 40–120 µg/mL with a high correlation coefficient.

The method was validated as per ICH guidelines and demonstrated satisfactory results for all validation parameters, including accuracy, precision, linearity, robustness, and sensitivity. The percentage recovery values were within acceptable limits, confirming the accuracy of the method, while low %RSD values indicated excellent precision and reproducibility. The calculated LOD and LOQ values further established the sensitivity of the method.

The use of hydrotropic solubilization with urea eliminates the requirement for organic solvents, making the method environmentally friendly and economical. Additionally, the method was successfully applied to the assay of marketed tablet formulations, confirming its suitability for routine quality control analysis.

Overall, the proposed analytical method is reliable, reproducible, and suitable for regular laboratory use in pharmaceutical industries and research laboratories for the estimation of Ranolazine.

Author Contributions: All authors contributed equally in this research work.

Funding: This research received no specific grant from any funding agency in the public commercial, or not-for-profit sectors.

Conflict of Interest: The authors declare that there are no conflicts of interest related to this work.

ACKNOWLEDGEMENT

All authors thank the management of our esteemed institution to support them to conduct this research work.

REFERENCES

1. ICH Q2(R1). Validation of Analytical Procedures: Text and Methodology. International Council for Harmonisation; 2005.
2. ICH Q14. Analytical Procedure Development. International Council for Harmonisation; 2023.
3. United States Pharmacopeia (USP 34–NF 29). Rockville, MD: USP Convention; 2011.
4. British Pharmacopoeia Commission. British Pharmacopoeia. London: The Stationery Office; 2019.
5. Indian Pharmacopoeia Commission. Indian Pharmacopoeia. Ghaziabad: IPC; 2018.
6. Skoog DA, Holler FJ, Crouch SR. *Principles of Instrumental Analysis*. 6th ed. Belmont: Thomson Brooks/Cole; 2007.
7. Willard HH, Merritt LL, Dean JA, Settle FA. *Instrumental Methods of Analysis*. 7th ed. New Delhi: CBS Publishers; 1986.
8. Chatwal GR, Anand SK. *Instrumental Methods of Chemical Analysis*. 5th ed. Mumbai: Himalaya Publishing House; 2007.
9. Beckett AH, Stenlake JB. *Practical Pharmaceutical Chemistry*. 4th ed. New Delhi: CBS Publishers; 2002.
10. Snyder LR, Kirkland JJ, Dolan JW. *Introduction to Modern Liquid Chromatography*. 3rd ed. Hoboken: Wiley; 2010.
11. Ermer J, Miller JH. *Method Validation in Pharmaceutical Analysis*. Weinheim: Wiley-VCH; 2005.
12. Ahuja S, Scypinski S. *Handbook of Modern Pharmaceutical Analysis*. San Diego: Academic Press; 2001.
13. Christian GD. *Analytical Chemistry*. 6th ed. New York: Wiley; 2004.
14. Mendham J, Denney RC, Barnes JD, Thomas MJK. *Vogel's Textbook of Quantitative Chemical Analysis*. 6th ed. Pearson; 2000.
15. Harris DC. *Quantitative Chemical Analysis*. 8th ed. New York: W.H. Freeman; 2010.
16. Swartz ME, Krull IS. *Analytical Method Development and Validation*. New York: Marcel Dekker; 1997.
17. Blessy M, Patel RD, Prajapati PN, Agrawal YK. Development of forced degradation and stability indicating studies of drugs—A review. *J Pharm Anal*. 2014;4(3):159–165. https://doi.org/10.1016/j.jpha.2013.09.003
18. Shah VP, Midha KK, Dighe S, et al. Analytical methods validation: bioavailability, bioequivalence and pharmacokinetic studies. *J Pharm Sci*. 1992;81(3):309–312. DOI: https://doi.org/10.1002/jps.2600810317
19. Lister AS. Validation of analytical methods. In: Ahuja S, editor. *Handbook of Pharmaceutical Analysis*. Academic Press; 2005.
20. Miller JC, Miller JN. *Statistics for Analytical Chemistry*. 6th ed. Pearson; 2010.
21. ISO/IEC 17025. General requirements for the competence of testing and calibration laboratories. ISO; 2017.
22. FDA. Guidance for Industry: Analytical Procedures and Methods Validation. US Food and Drug Administration; 2015.
23. Ribani M, Bottoli CBG, Collins CH, Jardim ICSF, Melo LFC. Validation for chromatographic and electrophoretic methods. *Quim Nova*.

2004;27(5):771–780.
DOI: https://doi.org/10.1590/S0100-40422004000500017

24. Shrivastava A, Gupta VB. Methods for determination of limit of detection and limit of quantitation. *Chron Young Sci*. 2011;2(1):21–25. DOI: https://doi.org/10.4103/2229-5186.79345
25. Sethi PD. *High Performance Liquid Chromatography: Quantitative Analysis of Pharmaceutical Formulations*. New Delhi: CBS Publishers; 2001.
26. Patil SU, Gandhi SV, Sengar MR, Rajmane VS. UV spectrophotometric method development and validation: A review. *Int J Pharm Sci Rev Res*. 2014;28(2):118–122.
27. Kulkarni AP, Sathe SR. Hydrotropic solubilization: A novel approach for solubility enhancement. *Int J Pharm Sci*. 2012;4(4):1–7.
28. Maheshwari RK. Mixed hydrotropy: Novel science of solubility enhancement. *Indian J Pharm Sci*. 2010;72(5):547–553. DOI: https://doi.org/10.4103/0250-474X.78524
29. Ravisankar P, Navya CN, Pravallika D, Sri DN. A review on analytical method validation. *IOSR J Pharm*. 2015;5(10):7–19. DOI: https://doi.org/10.9790/3013-0510010719
30. Snyder LR. Classification of the solvent properties of common liquids. *J Chromatogr A*. 1974;92:223–230. DOI: https://doi.org/10.1016/S0021-9673(00)85732-5
31. Cheu R. A step-by-step guide to analytical method development and validation. 2023 Mar 7.
32. Emery Pharma. Instrumentation of UV spectrophotometer.
33. Available from: https://emerypharma.com/blog/a-stepby-step-guide-to-analytical-method-development-and-validation/
34. Ugale JB, Mulgund SV. Development and validation of UV spectrophotometric area under curve method for quantitative estimation of ranolazine in API and tablet formulation. World J Pharm Res. 2015;4(5):2665–2672.
35. Kamil NAA, Shantier SW, Gadkariem EA. Derivative spectrophotometric methods for the analysis and stability studies of ranolazine in bulk and dosage forms. Hacettepe Univ J Fac Pharm. 2022;42(1):13–21. https://doi.org/10.52794/hujpharm.1039776
36. Reddy AR, Sabu S, Rao TR. Analytical method development and validation of ranolazine in bulk and tablet formulation by UV spectrophotometry. Int J Pharm Sci. 2024;2(11):757–763.
37. Doppa DRS, Konidala SK, Khanabhi S. Development and validation of UV spectroscopic method for determination of ranolazine in bulk and formulation. Res J Pharm Technol. 2019;12(10):4750–4754. https://doi.org/10.5958/0974-360X.2019.00822.6
38. Ramesh J, Rajasekhar K, Gandhi RK, Kumar NS. Method development and validation for estimation of ranolazine in bulk and pharmaceutical dosage form by UV spectrophotometry. Ann Pharma Res. 2013;1(1):4–7.
39. Kumar GS, Harish KH, Dinesh M, Joshi H. Spectrophotometric method for estimation of ranolazine in bulk and pharmaceutical formulation. URJC. 2014;2(1):5–7.
40. Bidada JP, Gonjari ID, Raut CS, Bhutada CJ. Novel spectrophotometric method for estimation of ranolazine in bulk and pharmaceutical dosage forms. Der Pharma Chemica. 2011;3(2):1–4.
41. Mahatara RB, Maharjan S, Thapa R, Budhathoki U. Analytical method validation of ranolazine tablets by RP-HPLC. Asian J Pharm Anal. 2025;15(1).
42. Patel J, Patel P, Mashru R. Novel UV spectrophotometric and RP-HPLC method development and validation for simultaneous estimation of ranolazine: A statistical approach. Pharma Innov J. 2020;9(7):50–57.
43. Gunjkar PM, Patharkar P. Development and validation of analytical method for estimation of ranolazine in tablet dosage form by RP-HPLC. Der Pharma Chemica. 2011;3(2):1657–1673.
44. Rathod V, Kadam A, Bembade A, Bhusnure OG. Development and validation of stability-indicating instrumental method for estimation of ranolazine in bulk and tablet dosage form. JETIR. 2023;10(4).