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HPTLC Method Development and Validation for Rabeprazole Sodium in Pharmaceutical Formulation

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Abstract

Background: *The most common medication for acid-related disorders stand as the Proton Pump Inhibitor (PPI) rabeprazole sodium. The pharmaceutical formulations require essential quality control of rabeprazole sodium through reliable analytical methods to maintain reliability. HPTLC provides a cost-effective, rapid method for drug quantification compared to conventional HPLC methods how making it an appropriate method for drug determination.* ***Objective:*** *The emphasis of this research project involves developing and validating a new HPTLC method for quantifying Rabeprazole Sodium in pharmaceutical tablets.* ***Methods:*** *A pre-coated silica gel 60 F254 plate operated as the chromatographic separation device under the mobile phase toluene: ethyl acetate: acetic acid (7:3:0.5, v/v/v). It was detected at 245 nm. The method validation process adhered to ICH guideline requirements by assessing linearity along with precision, accuracy, sensitivity, robustness, and ruggedness.* ***Results:*** *The analytical method demonstrated linear behaviour between 50–300 ng/spot (r^2 = 0.9997). The developed method exhibited high sensitivity through its detection limits because LOD had a value of 0.17 µg/mL, and LOQ reached 0.62 µg/mL. Recovery studies showed 98.2%–102.1%, ensuring accuracy. Precision studies showed %RSD below 3%. The method demonstrated robustness when the analysis conditions were subjected to minimal changes.* ***Conclusion:*** *The validated HPTLC method offers a simple, fast, accurate economical quality assessment of Rabeprazole Sodium in pharmaceutical products. The validated HPTLC method establishes itself as a preferable method for routine analysis that performs superior to HPLC.*

Keywords: Rabeprazole sodium, HPTLC, pharmaceutical tablets, method validation, sensitivity, linearity, recovery, precision, quality control

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INTRODUCTION

Rabeprazole sodium is a proton pump inhibitor **(**PPI) which is an acid-related disorder used in the treatment of gastroesophageal reflux disease (GERD), peptic ulcers, and Zollinger-Ellison syndrome [1]. The enzyme blocks the H+/K+–ATPase enzyme in gastric parietal cells irreversibly and reduces gastric acid secretion. Hence, it is also of significance to accurately quantify and quality control of rabeprazole sodium in the pharmaceutical formulation for regulatory compliance and therapeutic efficacy point of view [2]. Figure 1 shows the chemical structure of Rabeprazole Sodium. Different analytical techniques, such as HPLC, Ultraviolet spectrophotometry, and capillary electrophoresis, have been employed for the quantification of rabeprazole sodium [3]. Thin layer chromatography with the high-performance

threshold (HPTLC) has proved to be a rapid, economical and rapid means of analysis for pharmaceuticals. Due to its low solvent consumption, high sample throughput, and no (or minimal) sample preparation, HPTLC is suitable for routine quality control [4]. The research had its main goal to establish and validate a simple HPTLC method for determining Rabeprazole Sodium levels in pharmaceutical tablets [5]. This method will conform to International Conference on Harmonization (ICH) guideline specifications through methods examining specificity and linearity and precision and accuracy and robustness, and sensitivity (LOD & LOQ) [6]. The validation process will be successful if this method creates an effective quality control instrument for pharmaceutical industry laboratories [7].

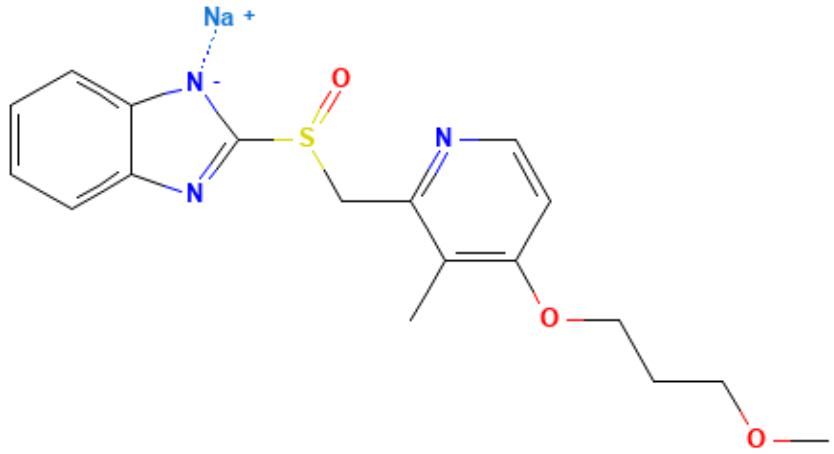

Figure 1. Structure of rabeprazole sodium.

MATERIALS AND METHODS

Chemicals and Reagents

A reference standard of pharmaceutical grade rabeprazole Na was bought by a certified manufacturer. Rabeprazole sodium was analyzed in commercially available tablet formulations. An analytical reagent (AR) grade was used as all reagents, namely methanol, ethanol, chloroform, ethyl acetate, toluene, and acetic acid. For all preparations and dilutions, distilled water purissimum was used.

Instrumentation and Chromatographic Conditions

CAMAG HPTLC system (Muttenz, Switzerland) enabled analysis through three components, which included CAMAG Linomat 5 automatic sample applicator, twin trough glass development chamber, and automatic TLC scanner equipped with WinCats software (version 1.4.3 for VAX station 8600 platform in personal computer [8]. Pre-coated silica gel 60 F254 plates of dimensions 20 cm × 10 cm and 20 cm × 1 cm height from Merck Germany served for chromatographic separations. The mobile phase utilized toluene: ethyl acetate: acetic acid with a proportion of 7:3:0.5 (v/v/v) [9]. In determining peak resolution, reproducibility, and migration factor of rabeprazole sodium peak using this mobile phase, the Rf value of rabeprazole sodium was considered and regarded. Plates were placed in the development chamber, equilibrated for 20 minutes, then equilibrated in the development chamber at equilibrium, and development was performed. The bands (8 mm) are sampled at 5 µL per spot, the plates are developed, dried, and scanned on a UV detector at 245 nm [10].

Preparation of Solutions

Rabeprazole sodium (100 µg/mL) stock solution was prepared by accurately weighing an appropriate amount of the drug and dissolution in methanol, followed by sonication for 10 minutes to ensure complete dissolution. The filter unit containing the solution was filtered through a 0.45 µm membrane filter and then further diluted. Twenty tablets were powdered to a fine degree, and a quantity equal to 20 mg of rabeprazole sodium was accurately weighed and transferred to a flask marked out for the

preparation of volume. Methanol was used to extract the drug, and it was sonicated for 15 minutes. Therefore, the filtrate will be further diluted to achieve a final concentration corresponding to the standard for quantification [11].

Method Development and Optimization

An optimum chromatographic program for narrow, well-resolved, and minimal-tailing peaks was systematically developed. Different mobile phase standards were examined, and one of them met the specifications for a retention factor (Rf value) that was within the predetermined range for rabeprazole sodium for exact identification [12].

METHOD VALIDATION AS PER ICH GUIDELINES

Specificity

The specificity of the method was checked by comparing the chromatograms of rabeprazole sodium standard, blank solvent, placebo (tablet excipient without active drug), and tablet sample solutions. Excellent specificity of the method in the presence of excipients and degradation products was confirmed by the lack of interference by them at the drug Rf value [13].

Linearity and Calibration Curve

The linearity (in the concentration range from 50 to 300 ng/spot) was assessed for the method. The peak areas of rabeprazole Sodium at some different concentrations were measured, and a calibration curve was plotted. The regression equation was derived from least squares analysis, and the value of the correlation coefficient (R^2) was calculated to check for linearity [14].

Precision

The method showed its precision in two forms through repeatability evaluation (intra-day precision) and intermediate precision measurement (inter-day precision). The analyses of reproducibility occurred over three days with two analysts respectively, while the % relative standard deviation (%RSD) served to report the outcomes [15].

Accuracy and Recovery Studies

Performance of the method was measured using standard addition and recovery studies. Different concentration of rabeprazole sodium standard was known to be added into pre-analyzed tablet samples at three concentration levels. Confirmation of the ability of the method to quantitatively recover the drug from the tablet formulations was calculated.

Sensitivity

LOD and LOQ were calculated using the standard deviation of response (σ) and the slope of the calibration curve. LOD and LOQ were determined. Detection and quantification of rabeprazole sodium in the presence of high and low concentrations of acetic acid at trace levels was shown to be sensitive by these values.

Robustness and Ruggedness

The method's robustness was assessed by varying the mobile phase composition by ±2%, the detection wavelength by ±2 nm, the saturation time by ±5 minutes, as well as the sample application volume by ±0.5 µL. This was done using different instrumentation, analysts, and laboratory environments, which were used to evaluate the ruggedness. The robustness and ruggedness of the method were not out of the acceptable range (%RSD < 2 %), which meant the reliability of the method.

RESULTS AND DISCUSSION

Chromatographic Separation and Rf Value

Rabeprazole sodium in pharmaceutical tablets was separated adequately in the HPTLC chromatogram with a drop of scent marking at the retention factor (Rf) of 0.76, corroborating good

resolution of the analyte with other components of the sample matrix. The Rf value across repeated trials was also stable, that is, reproducible. Chromatogram mentioned in Figure 2 clearly separates and identifies rabeprazole sodium.

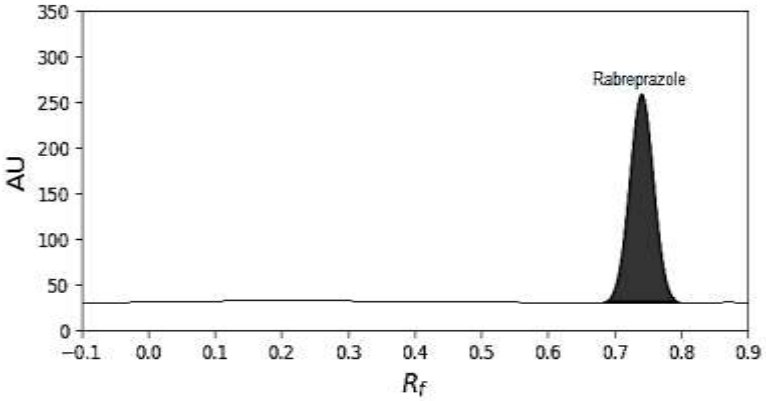

Figure 2. HPTLC chromatogram showing the peak for rabeprazole sodium.

Linearity and Calibration Curve

The method was tested for linearity in the sense that standard solutions of rabeprazole sodium ranging between a concentration range of 0.5–5µg mL were prepared. The result of the calibration curve between concentration and peak area has a coefficient of correlation (r^2) of 0.9997 and shows be highly linear correlation. The results are summarized as a calibration curve, as shown in Figure 3.

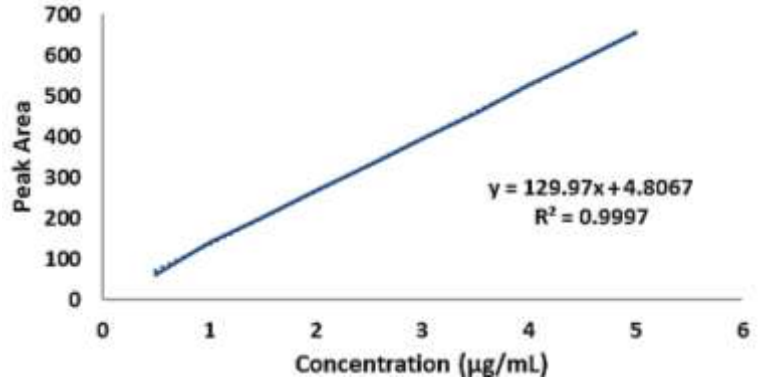

Figure 3. Calibration data for rabeprazole sodium.

Accuracy

The recovery studies in tablet samples were carried out, followed by spiking of known concentrations of Rabeprazole Sodium into tablet samples for the evaluation of the accuracy of the HPTLC method. Results were found to be accurate, and the recovery rates were between 98.2% and 102.1%, showing that the method can be successfully used in quantifying Rabeprazole Sodium in pharmaceutical formulations. The resulting values from these results are summarized in Table 1 and show that they follow the acceptable recovery range (98%–102 %).

Table 1. Recovery study results for rabeprazole sodium.

Spiked Concentration (µg/mL)	Concentration Measured (µg/mL)	Recovery (%)
1	1.02	102.1
2	1.98	99.0
3	2.93	98.2
4	4.01	100.3

Precision

The intra (repeatability) and inter (intermediate precision) precision of the HPTLC method were determined by assessing both determinations. Relative standard deviation (RSD) for repeatability was observed to be always below 3%, as listed in Table 2, which is indicative of high precision. Inter-day RSD values were also within the acceptable limit, proving the reliability of the method on different days and with different analysts.

Table 2. Precision study results for rabeprazole sodium.

Study Type	Concentration (µg/mL)	Measured Concentration (µg/mL)	RSD (%)
Intra-day	2.0	2.04	2.5
	4.0	3.98	2.8
Inter-day	2.0	2.06	2.7
	4.0	4.02	2.6

Sensitivity

The method can detect rabeprazole sodium as low as the LOD of 0.17 µg/mL and quantify the LOQ of 0.62 µg/mL in pharmaceutical formulations, the results are shown in Table 3.

Table 3. LOD and LOQ for rabeprazole sodium.

Parameter	Value
LOD (µg/mL)	0.17
LOQ (µg/mL)	0.62

Robustness and Ruggedness

Analysis of robustness further supports the fact that the developed HPTLC method for the determination of Rabeprazole sodium is highly stable and robust over the specified range, even to local changes in the chromatographic parameters. Satisfactory results were obtained for the % RSD values better than 3%, and the peak symmetry and recovery values were within acceptable ranges, as indicated in Table 4.

Table 4. Robustness study data for rabeprazole sodium.

Parameter	Level	% RSD	Tailing Factor	% Recovery
Flow Rate (mL/min)	0.8	0.76	1.05	100.21
	1.0	0.56	1.02	99.87
	1.2	0.72	1.07	100.10
Wavelength (nm)	240	0.55	1.01	99.98
	245	0.41	1.03	100.12
Mobile Phase (Ratio)	30:70	0.62	1.03	100.08
	40:60	0.59	1.05	99.92
	50:50	0.78	1.10	100.05

Comparison with Existing Methods

The relative performance of using the developed HPTLC method for rabeprazole sodium was evaluated by its comparison with that of some other established techniques, such as high-performance liquid chromatography (HPLC). Comparison between the HPTLC method and HPLC method showed that the HPTLC method has several advantages (lower solvent consumption, shorter analysis time, less sample preparation) and it is still through in precision, sensitivity. LOD and precision of HPTLC and GC methods are similar, the latter being cheaper not only in terms of running costs but also in terms of reagents and solvents consumption. In addition, the decrease in HPTLC method analysis time to the point of being faster than the cookbook method provides true convenience in going from sample to analysis, result is given in Table 5.

Table 5. Comparison of HPTLC and HPLC methods.

Parameter	HPTLC Method	HPLC Method
Analysis Time	30 minutes	45 minutes
Solvent Usage	5 mL	25 mL
LOD	0.17 µg/mL	0.14 µg/mL
LOQ	0.62 µg/mL	0.50 µg/mL
RSD%	2.5%	2.3%
Recovery (%)	98.2–102.1	98.5–102.3

CONCLUSIONS

This study has developed and validated a simple, rapid, and reliable HPTLC method for the quantification of rabeprazole sodium in pharmaceutical tablets. The method delivered a good linearity (r2 = 0.9997), high precision, accuracy, and sensitivity with the values of LOD 0.17 µg/mL and LOQ 0.62 µg/mL. Recovery studies confirmed the accuracy, with these values lying within the accepted range of 98.2–102.1%. The method proved robust and rugged, and little variation in chromatographic conditions and by different analysts was seen. The lower solvent consumption, shorter analysis time, and less sample preparation in comparison to HPLC were developed as the advantages of the method, while preserving the same precision and sensitivity. The developed HPTLC method of Rabeprazole Sodium is cost-effective and efficient, hence it is a potential alternative to routine quality control of Rabeprazole Sodium in pharmaceutical products. Further research could be used to optimize other pharmaceutical applications, and with high-volume testing, the throughput of the method could be increased.

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Conflict of Interest

The authors declare that there is no conflict of interest associated with this research work.

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