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DETERMINATION OF λ-MAX AND LINEARITY FOR OMEPRAZOLE AND ASSAY METHOD FOR RABEPRAZOLE TABLETS I.P. USING UV-VIS SPECTROSCOPY

M. Mohanapriya*[1], A. Arun[2], G. Girish Kumar[3], V. Nandha Kumar[4], S. Savin[5] and Dr. R. Manivannan[6]

Department of Pharmaceutical Chemistry, Excel College of Pharmacy, Sankari West Post, Komarapalayam, Namakkal, Tamilnadu, India.

Affiliated by the Tamilnadu Dr. M.G.R. Medical University, Chennai.

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***Corresponding Author: M. Mohanapriya**
Department of Pharmaceutical Chemistry, Excel College of Pharmacy, Sankari West Post, Komarapalayam, Namakkal, Tamilnadu, India.
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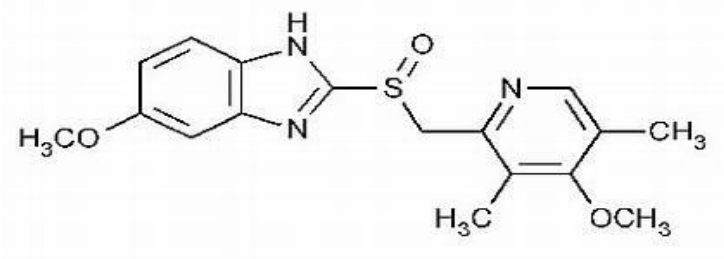
ABSTRACT

This study presents the development and validation of UV spectrophotometric methods for the analysis of Omeprazole and Rabeprazole in pharmaceutical formulations. The maximum absorption wavelength (λ-max) of Omeprazole was determined to be 269.4 nm, and the method exhibited excellent linearity across a concentration range of 5–25 µg/mL, with a correlation coefficient (*r*) of 0.9998. Similarly, the method for Rabeprazole tablet assay was precise and accurate, with a calculated percentage purity of 93.5% w/v, meeting pharmaceutical standards. Both methods demonstrated simplicity, stability, cost-effectiveness, and rapid analysis time, making them ideal for routine quality control. Adhering to ICH guidelines, these methods were validated for reliability, reproducibility, and compliance. The study highlights the suitability of UV spectrophotometry for determining drug concentration in various formulations due to its minimal sample requirements, ease of operation, and cost efficiency. The findings confirm the methods' applicability for routine pharmaceutical analysis and quality control of Omeprazole and Rabeprazole.

KEYWORDS: UV spectrophotometry, Omeprazole, Rabeprazole, λ-max, pharmaceutical analysis, linearity, quality control, ICH guidelines.

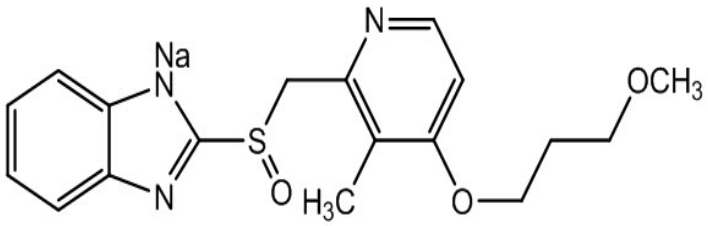
INTRODUCTION

Omeprazole is a widely used medication belonging to the class of proton pump inhibitors (PPIs). It works by reducing the production of gastric acid in the stomach, making it an effective treatment for conditions such as gastroesophageal reflux disease (GERD), heartburn, and excessive gastric acid secretion. Additionally, it is used to promote the healing of ulcers, manage tissue damage caused by stomach acid, and treat infections associated with Helicobacter pylori bacteria.Its chemical composition includes a molecular weight of 345.416 g/mol, with the chemical formula $C_{17}H_{19}N_3O_3S$. The IUPAC name for omeprazole is 6-methoxy-2-[(4-methoxy-3,5-dimethylpyridin-2-yl) methane sulfinyl]-1H-1,3-benzodiazole.



Chemical structure of omeprazole

Rabeprazole is a proton pump inhibitor (PPI) commonly used to treat various gastrointestinal conditions. It is effective in promoting the healing of gastric and duodenal ulcers, managing symptoms of gastroesophageal reflux disease (GERD), eradicating *Helicobacter pylori* infections, and treating hypersecretory disorders such as Zollinger-Ellison Syndrome. It works by inhibiting the H^+/K^+-ATPase enzyme system in the gastric lining, suppressing both basal and stimulated gastric acid secretion in a dose-dependent manner. Rabeprazole belongs to the antiulcer drug category and is chemically characterized by a molecular weight of 359.443 g/mol and the formula $C_{18}H_{21}N_3O_3S$. Its IUPAC name is 2-{[4-(3-methoxypropoxy)-3-methylpyridin-2-yl]methanesulfinyl}-1H-1,3-benzodiazole.



Chemical structure of Rabeprazole

METHODS AND MATERIALS

1. DETERMINATION OF λ-MAX AND VERIFICATION OF LINEARITY OF OMEPRAZOLE USING UV-VIS SPECTROSCOPY

Determination of λ-max of omeprazole solution

Selection of solvent

- Thoroughly weighed 2 grams of sodium hydroxide were then fed into a 500 mL measuring flask and then added and treated with distilled water up to 500 mL, then the mixture filtered with Whatman No 41 filter paper.

Preparation of standard stock solution of omeprazole

- The standard solution of omeprazole at 1000 µg / mL was prepared by carefully weighing 100 mg of pure omeprazole using an analytical scale, fed into a 100 mL measuring flask, then partially added 0.1 N NaOH, shaken until dissolved, then supplied with 0.1 N NaOH N to the limit.

Preparation of sample solution

- Each 1000 µg / mL omeprazole parent solution prepared with four various solvents (phosphate buffer pH 7.2, phthalate buffer pH 3.0, 0.1 N NaOH, and 0.1 N HCl) was diluted to a solution concentration of 100 µg / mL by measuring with a pipette of 1 mL of the solution, feed into a 10 mL measuring flask and dilute it with each solvent until the boundary marks, then homogenize. Then each solution of omeprazole 100 µg / mL with a variety of solvents, pipetted with 1 mL measuring pipette into a 10 mL measuring flask and then sufficient with each solvent to the limit, shake homogeneously to obtain a concentration of 10 µg / mL. Measure the absorbance in the wavelength range 200-400 nm with the UV-Vis spectrophotometer to obtain the maximum wavelength omeprazole.

Wavelength Vs Absorbance

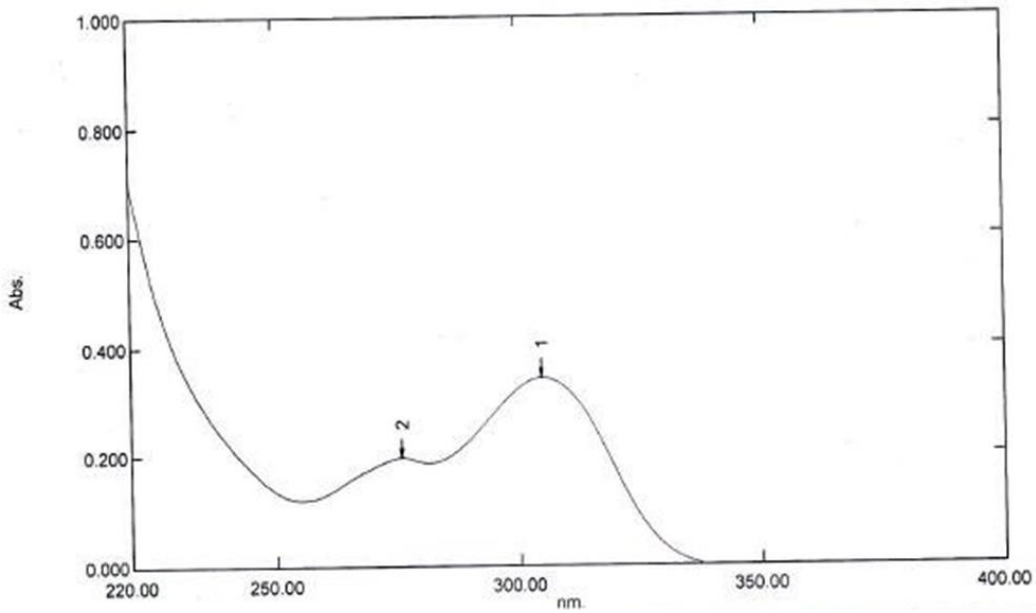


Fig. No. 1: Wavelength vs Absorbance curve.

Determination of λ Max of Omeprazole

- The standard solution of Omeprazole (10 µg/ml) was scanned in the wavelength region of 200-400 nm and the λmax was found to be 269.4 nm (λmax of Omeprazole), respectively. They are scanned in the wavelength range of 200-400 nm and the spectrum was obtained.

Determination of linearity

- Linearity is determined by processing the relationship data between concentration (x) with absorbance (y) and concentration (x) with the area under the curve (y) obtained from the calibration curve using linear regression equation, to obtain correlation coefficient value. The result of linearity measurement omeprazole with absorbance method obtained r value = 0.9998, whereas with method area under the curve obtained r value = 0.9970. The

correlation coefficient obtained from these two calibration curves shows a linear result, because it meets the acceptance criterion that is the correlation coefficient value of $0.9995 \leq r \leq 1$.

TABLE:

CONCENTRATION(µg/mL)	ABSORBANCE AT 269 nm
5	0.188
10	0.394
15	0.613
18	0.686
22	0.814
25	0.997

Linearity of Omeprazole

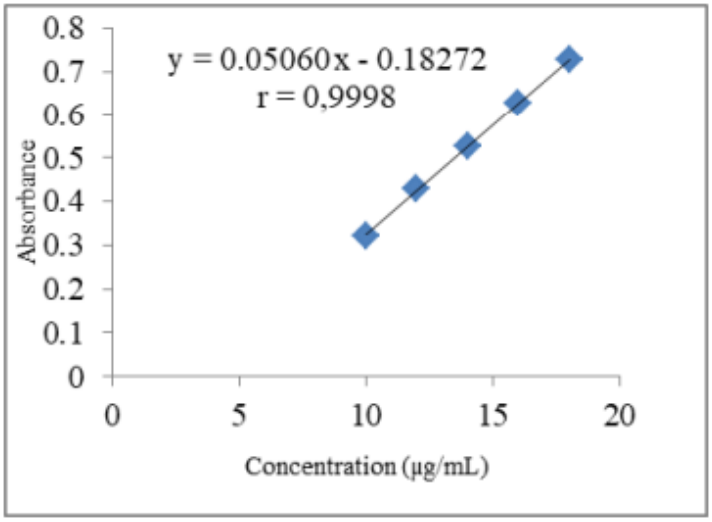


Fig No 2: Omeprazole calibration curve.

2. ASSAY OF RABEPRAZOLE TABLETS I.P USING UV SPECTROSCOPY

PROCEDURE

- Weigh 20 tablets correctly and calculate their average weight.
- To calculate weight to be taken of sample by using average weight, label claim and required weight.

SOLUTION A

- Weigh accurately 0.15g and transfer to 250ml standard flask and add 50ml of 0.1M sodium hydroxide.
- Dilute with 100ml of water to produce 250ml filter it.

SOLUTION B

- Dilute 10ml of filtrate to 100ml of 0.1M sodium hydroxide dilute to 100ml with water.
- Measure the absorbance of solution B at 284nm calculate the content of Rabeprazole taking as the value & E1%1cm = 284nm.

CALCULATION

Weight of 20 tablet = 0.2734 gm

Average weight = 0.01367 gm

Label claim =0.01gm

Required weight = 0.004 gm

Weight to be taken = Average weight / Label claim × Required weight

= (0.01367 / 0.01) × 0.004

=0.005468.

AMOUNT PRESENT

Amount present = (absorbance of sample / absorbance of standard) × (standard wt / sample wt) dilution factor × average weight

= (0.49 / 0.55) × (0.01 / 0.013) × (100/100) × (100/10) × (10/100) × 0.01367

= 0.00935gm.

PERCENTAGE PURITY OF SAMPLE

Percentage purity = Amount present / Label claim × 100

= (0.00935/0.01) x 100

= 0.935 × 100

= 93.5% w/v.

RESULTS AND DISCUSSION

The UV spectrophotometric method developed in this study provides a simple, stable, rapid, and accurate approach for the analysis of Omeprazole. With an absorption maximum (λ-max) identified at **269.4 nm**, the method exhibited excellent linearity across a concentration range of 5–25 µg/mL, with a correlation coefficient of **0.9998**. These results confirm the method's reliability and suitability for routine analysis of Omeprazole in pharmaceutical formulations.

Additionally, the UV spectrophotometric method for the assay of Rabeprazole tablets was successfully established. The method involved straightforward preparation and demonstrated precision and accuracy in quantification. The percentage purity of Rabeprazole tablets was determined to be **93.5% w/v**, aligning with acceptable pharmaceutical standards.

Both methods adhered to ICH guidelines, ensuring reliability and compliance for use in quality control settings. The cost-effectiveness, minimal sample requirements, and rapid analysis time make these methods ideal for routine pharmaceutical quality control and analysis of Omeprazole and Rabeprazole.

CONCLUSION

The UV spectrophotometric methods developed for the analysis of Omeprazole and Rabeprazole are simple, precise, and cost-effective, making them highly suitable for routine pharmaceutical quality control. The determination of λ-max for Omeprazole at **269.4 nm** and its demonstrated linearity across a concentration range of 5–25 µg/mL confirm the method's reliability for quantitative analysis. Similarly, the assay of Rabeprazole tablets, with a percentage purity of **93.5% w/v**, validates the method's accuracy and compliance with pharmaceutical standards.

Both methods adhere to ICH guidelines, ensuring robustness and reproducibility in quality control settings. Their straightforward protocols, minimal sample requirements, and rapid analysis times highlight their efficiency and practicality for the routine evaluation of pharmaceutical formulations.

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