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METHOD DEVELOPMENT AND VALIDATION OF OMEPRAZOLE IN BULK AND MARKETED FORMULATION BY USING UV-SPECTROPHOTOMETRY

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ABSTRACT

Omeprazole was estimated using a straightforward, sensitive, and selective UV approach that was devised and verified. The technique was developed using UV spectrometry; the optimal concentration was 8µg/ml, the absorbance was 0.428, and the λmax was reached at 301.00 nm. The linearity range of the test technique, which had an R^2 value of 0.998, was 0.5 µg/ml to 16 µg/ml. It was discovered that the precision and accuracy percentage RSD ranged from 0.23 to 1.67. The results indicated that the intraday precision was 0.26 and the interday precision (%RSD) was 0.22. The accuracy (recovery percentage) was found to be within the acceptable range of 99.89–100.21%. The developed method's LOD and LOQ were 0.061µg/ml and 0.186 µg/ml, respectively. The robustness results were found to be 98%-102%.

KEYWORDS: UV-Spectrophotometry, Omeprazole, Method validation, LOD, LOQ.

INTRODUCTION

The chemical name for omeprazole (OMZ), 5-methoxy-2-[[(4-methoxy-3,5-dimethyl-pyridin-2- yl) methyl]sulfinyl]-1H-benzimidazole (Figure 1), is a proton pump inhibitor that is commonly used as an anti-ulcer medication to treat duodenal and stomach ulcers as well as GERD (gastric reflux disease) and ZERD (Zollinger Ellison syndrome).[1-3] It functions by blocking the proton pump. This chemical belongs to the antisecretory class and is a substituted benzimidazole.[2] Inhibition of the parietal cell H+/K+ adenosinetriphosphate pump, the final step of acid production.

When taken daily, the effects of omeprazole will level off on the fourth day.[1-3] Numerous other methods, including as high-performance liquid chromatography, ultra-performance liquid chromatography, thin layer chromatography, and high-performance thin layer chromatography, have been reported for determining OMZ in bulk and formulations.[3-24]

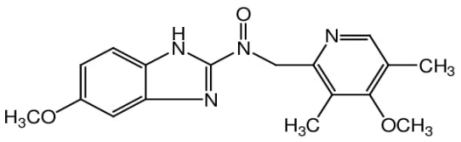

Figure 1: Omeprazole structure[4]

MATERIALS AND METHODS

The reagents and chemicals were all of analytical quality. After double distillation, the water was filtered through a membrane filter. ALSUCROSE Corporation, India, produces ethanol. We purchased Omeprazole, a pharmaceutical-grade standard medication, from MS Pharmaceuticals in Mumbai, Maharashtra, India.

Preparation of Standard solution

Weighed precisely, 40g of the Omeprazole working standard was deposited into a 50 ml calibrated, clean, and dry volumetric flask. We added roughly 50 ml of solvent (Ethanol: Water), shaken the flask thoroughly, and sonicated it (primary stock solution 800µg/ml) for improved solubility. Using a pipette, remove 0.1 ml of the primary stock solution from the aforementioned solution, then transfer it to a second 10 ml volumetric flask to create the secondary stock solution (8µg/ml).

Preparation of sample solution

Twenty tablets were precisely weighed, their average weight determined, and they were ground up using a clean motor and pestle. 207 mg of omeprazole tablet powder should be weighed. Then, 40 mg of the corresponding weight should be transferred into a 50 ml volumetric flask. After adding roughly 50 ml of the solvent (ethanol: water), sonicate it until it dissolves fully, then filter as necessary, then replenish the final volume (800µg/ml).Pipette out 0.1 ml of the primary stock solution (above) and pour it into a second 10 ml volumetric flask. Fill it up to the mark to create the secondary stock solution (8µg/ml).

Optimized parameters of method

The new method's optimal concentration was 8µg/ml and its absorbance was 0.427 and it was optimized at 301 nm using a solvent Water: Ethanol 5:5 (V/V).

Validation of analytical Method[25 & 26]

The suggested approach was verified for a number of criteria, including assay, linearity, precision, accuracy, specificity, robustness, stability studies, LOD, and LOQ.

Specificity and Selectivity

The response of the spectra to solvent (blank), standard, and sample solutions made using the suggested method was examined in order to investigate the specificity. No interference between the medication and the solvents or excipients was seen. Thus, it was demonstrated that the new approach was both selective and specific. (Figure 2).

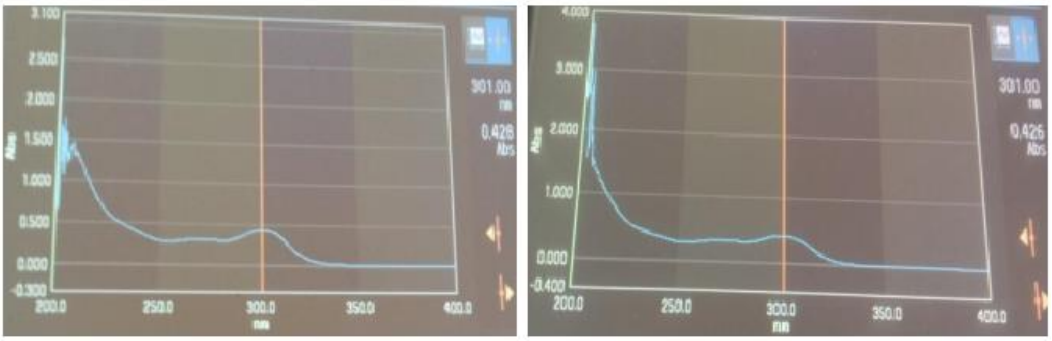

Figure 2: Standard and Sample spectrums of Omeprazole.

Linearity

The concentration and absorbance response were plotted on a graph (Figure-3), the regression coefficient (R^2) was determined to be 0.998. The Omeprazole calibration curve was linear throughout the concentration range. The standard solution concentration was determined to have a linearity range of 0.5 µg/mL to 16 µg/mL. The figure 3 displayed the linearity graph.

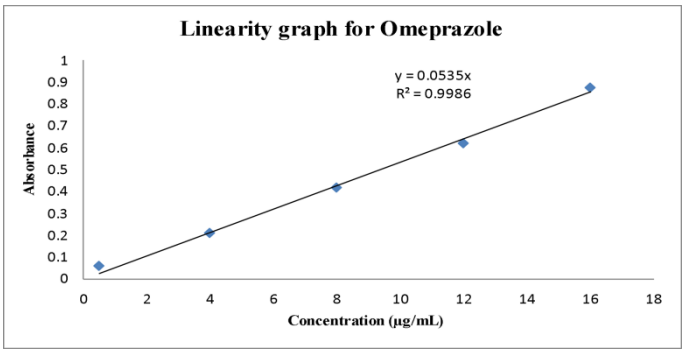

Figure 3: Linearity graph of Omeprazole.

Precision

Each level of precision, including intraday and intermediate precision, was evaluated using six repeated Omeprazole sample solutions.

Intraday Precision

The intraday precision test was conducted three times a day at 9:00 am, 1:00 pm, and 5:00 pm using a sample solution containing 8 µg/mL. Six duplicate measurements were taken at each level. For every interval, the % RSD was determined to be between 0.24 and 0.32.

Interday Precision

Using a solution concentration of 8 µg/mL, the interday precision was carried out on days 1, 2, and 3. Six repeated injections' spectrums were recorded at each level, and the average percentage RSD was determined to be between 0.17 and 0.28.

Accuracy

The accuracy of the process was examined by spiking the standard solution with the analyzed sample solution at three concentration levels: 80%, 100%, and 120%. The recovery experiments were conducted under optimal conditions in

duplicate. The range of accuracy should be 98% to 102%.The RSD percentage value shouldn't be more than 2.0. The results were reported in table 1.

Table 1: Results of Accuracy.

Spiked level	Sample weight (mg)	Absorbance	µg/ml added	µg/ml found	% Mean recovery
80%	165.6	0.340	6.36	6.36	100.21
100%	207	0.426	7.95	7.95	100
120%	248.4	0.511	9.54	9.55	99.89

Detection limit and quantification limit

The linearity curve of slope and the response of the standard deviation (precision) were used to establish the detection limit and quantification limit. Omeprazole's LOD and LOQ were found to be 0.061µg/mL and 0.186µg/mL, respectively.

Robustness

The robustness was tested at a concentration of 8µg/mL with only slight modifications to the method's flow rate and mobile phase composition. The organic phase composition was altered by ±0.3 mL, and the wavelength was altered by ± 2 nm. captured six replicate samples' spectrums. (Table-2).

Table 2: Results of Robustness.

Sr. No	Parameter	Condition	Absorbance	% Assay
1	Wavelength (±2 nm)	299	0.424	99.06
2		301	0.428	100.00
3		303	0.425	99.29
4	Changed Organic Solvent ratio (±0.3mL)	5.3:4.7	0.429	100.94
5		5:5	0.426	99.53
6		4.7:5.3	0.423	98.83

CONCLUSION

The development and validation of various UV-Spectrophotometric techniques for the measurement of omeprazole in pharmaceutical dosage forms and bulk was attempted. It was discovered that the suggested spectrophotometric approach was straightforward, accurate, and precise. The technique was created using a 5:5 V/V ratio of ethanol to water. Excipients did not interfere with the active moiety. The technique demonstrated good linearity, durability, accuracy, and precision. Omeprazole in bulk and its prescription dose forms were routinely analyzed using the suggested method.

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