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SPECTROSCOPIC ESTIMATION OF ESOMEPRAZOLE MAGNESIUM IN SOLID DOSAGE FORM

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ABSTRACT

A simple and sensitive spectrophotometric method had been developed for the quantitative estimation of esomeprazole magnesium in bulk and its tablets. Esomeprazole magnesium showed maximum absorbance at about 279 nm and obeys beer's law in the concentration range of 4-40 µg/ml. The results of assay and recovery studies were found to be satisfactory. The method was validated in terms of different parameters. The method was found to be simple, precise and accurate and can be applied for the routine estimation of Esomeprazole Magnesium in solid dosage form.

Keywords: Absorbance, Esomeprazole Magnesium, Estimation

INTRODUCTION

Esomeprazole Magnesium (ESO) is 5- methoxy 2- {(s)-[(4-methoxy-3, 5 dimethyl 2-pyridyl) methyl] sulfinyl} benzimidazole magnesium (2:1) trihydrate. It is proton pump inhibitor and used alone and with Domperidone for the treatment of peptic ulcer as well as Gastroesophageal Reflux Disease.

Literature survey revealed that Esomeprazole Magnesium is reported to be estimated by RPHPLC alone and in combination with other drugs by RPHPLC, HPTLC and spectroscopic methods.

So, far no method for estimation of Esomeprazole Magnesium was reported by spectroscopy. So an attempt has been made to develop a simple, precise, reliable, accurate and economic method for estimation of Esomeprazole Magnesium in solid dosage form using methanol AR grade as a solvent.

MATERIALS AND METHOD

Methanol AR grade was obtained as LOBA chemicals. Esomeprazole Magnesium was obtained from gift samples from Bluecross Labs, Nasik. Marketed formulation (Raciper D) was obtained from local drug stores.

All spectral absorbance measurements were made on Thermo Double beam spectrophotometer with 10mm matched quartz cells.

Standard solution:

Standard stock solution was prepared by dissolving about 40 mg drug in 100 ml methanol (0.4 mg/ml). Different aliquots were taken from stock solution and diluted with the same solvent to prepare a series of concentrations and calibration curve was plotted.

Beer's law was obeyed in the range 4-40µg/ml. The solutions were scanned on spectrophotometer in the UV range and their absorbances were measured at about 279 nm using methanol AR grade as blank. The calibration curve was found to be linear in the range of 4-40µg/ml.

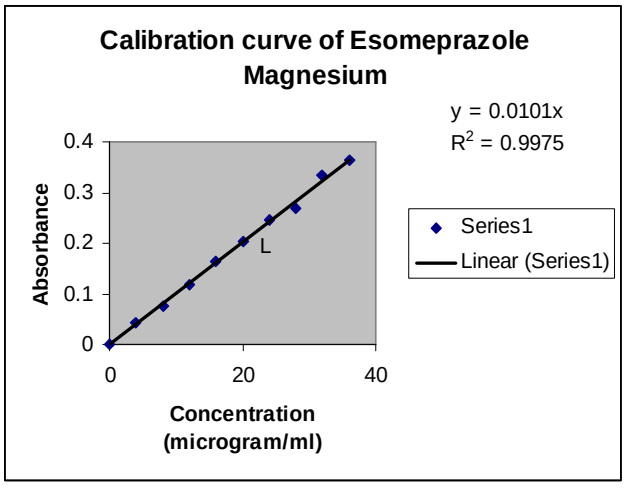

Fig. 1Calibration Curve of Esomeprazole Magnesium

Assay

Twenty tablets of single batch were weighed and powdered. A quantity of the powder equivalent to about 40 mg of Esomeprazole Magnesium was weighed accurately and transferred into 100 ml volumetric flask. It was dissolved and diluted to volume with methanol and filtered through a whatmann filter No. 41. Filterate was further diluted with same solvent to obtain required concentration. The absorbances of these solutions measured at about 279 nm using methanol as blank.

Validation of method

The proposed method had been validated in terms of different parameters accuracy, precision, linearity and range, limit of detection, limit of quantitation, ruggedness, robustness. Accuracy was determined by recovery studies, intraday and interday studies and different analysts studies were carried out by taking absorbance of samples made on different days, made on same day at two hours interval and by different analysts. Results were found to be satisfactory.

Recovery studies

It is obvious that the tablets contain excipients, binders used to manufacture a formulation. These substances may cause some interferences using estimation of active drug constituent. No interference was observed at the time of recovery studies found to be quite satisfactory. The proposed method can be utilized for the routine analysis of Esomeprazole Magnesium in quality control laboratories.

RESULTS AND DISCUSSION

The values of percent recovery and low values of standard deviation indicate the accuracy, precision and reproducibility of the proposed method. Ruggedness was carried out using different analysts, intraday and interday studies.

Table No. 1: The slope, correlation coefficient and optical characteristics:

Parameters	**Value**
Absorption maxima	279 nm
Beer's law	4-40 µg/ml
Correlation coefficient	0.9975
Regression equation	Y= 0.0101x
Slope	0.0101

Table No.2: Results of assay

Sr. No.	**Name of formulation with label claim**	**Amount estimated (mg)**	**% label claim**
1	Raciper D tablets	39.69	99.22
2	Esomeprazole Magnesium	40.56	101.40
3	40 mg	39.69	99.22
4		39.70	99.25
5		39.71	99.27

Table No.3: Recovery studies

Sr. No.	**Weight of sample taken(mg)**	**Amount of ESO added to preanalysed sample(mg)**	**Amount recovered(mg)**	**% recovery**
1	139.4	32	71.39	99.15
2	139.9	40	80.68	100.85
3	139.9	48	88.78	100.89

Table No.4: Validation of Method

SR. No.	Parameter	ESO
1	Accuracy: Recovery studies(mean)	99.67 %
2	Precision(n=5), RSD	0.00969
3	Linearity and Range	4-40 µg/ml
4	Limit of detection(µg/ml)	3.67 µg/ml
5	Limit of quantitation	13.28 µg/ml
6	Intraday precision (n=3), RSD	0.002661
7	Interday precision (n=3), RSD	0.001324
8	Different Analysts (n=3), RSD	0.001152

CONCLUSION

The proposed spectroscopic method is simple, precise, accurate, reliable, economic, reproducible, specific and can be used for routine analysis of Esomeprazole magnesium in solid dosage form by quality control laboratories.

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