Asian Journal of Pharmaceutical and Health Sciences
www.ajphs.com

Simple Spectrophotometric Determination of Esomeprazole Magnesium in Pharmaceutical Formulations

Purushotham Reddy M.[1*], **Raveendra Reddy P.**[2], **N. Rami Reddy.**[3]

[*1]Department of Chemistry, Government College for Men Kurnool(Dt), Andhra Pradesh, India.
[2]Department of Chemistry, S. K. University, Anantapur- (Dt), Andhra Pradesh, India.
[3]Department of Chemistry, S.B.S.Y.M. Degree College, Kurnool(Dt), Andhra Pradesh, India.

ARTICLE HISTORY

Received: 25-Apr-2011
Accepted: 15-May-2011
Available online 10-Aug-2011

Keywords:

Spectrophotometry, Bromocresol green, Esomeprazole magnesium, Pharmaceutical dosage form

*Corresponding author:

E-mail: mpreddy50@gmail.com
Phone: 08518- 230094

ABSTRACT

A simple, fast and reliable spectrophotometric method was developed for determination of esomeprazole magnesium in pharmaceutical formulations. The method is based on the reaction of esomeprazole magnesium with bromocresol green, the formed ion pair complex extracted into chloroform at pH 3.5. The chloroform extractable layer is measured at 420 nm against reagent blank. Beer's law obeyed in concentration of 50-250 µg/ml of esomeprazole magnesium. The method is validated statistically.

INTRODUCTION

The chemical name of esomeprazole magnesium is bis (5methoxy-2-[(S)-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole-1yl) magnesium trihydrate. It is an proton pump inhibitor(PPI). It is used in the treatment of intravenous gastro-oesophageal reflux disease. Literature survey revealed that methods have been reported for the estimation of esomeprazole magnesium in pharmaceutical preparation which includes spectrophotometric method[1-3] RP-HPLC Method [4], and HPLC method[5]

The aim of the present investigation was to develop simple, rapid, sensitive and economical procedure that could be used to determine esomeprazole magnesium in bulk drug and pharmaceutical dosage forms by spectrophotometry.

MATERIALS AND METHODS

A Milton Roy spectrophotometer with 1 cm matched quartz cells were used for the estimation. All the reagents were of analytical grade. Glass double distilled water was used throughout the experiment. Buffer solution was prepared by diluting a mixture of 50 ml of 0.2M potassium acid phthalate and 8.4 ml of 0.2M HCl to 200 ml with distilled water and the pH is adjusted to 3.5 pH. Bromocresol green solution was prepared by dissolving 500 mg of bromocresol green (Loba) in 100 ml of distilled water. Chloroform AR grade was used in present investigation

Preparation of standard solution

An accurately weighed 50 mg of esomeprazole magnesium was dissolved in 10 ml of methanol in a 50 ml volumetric flask and the volume was adjusted up to the mark with methanol to obtain a stock solution of 1 mg/ml. The stock solution is further diluted to obtain the working concentration of 100µg/ml

Assay procedures

Different aliquots of the standard esomeprazole magnesium solution ranging from 0.5-2.5 ml were accurately measured and transferred into a series of separating funnel by means of micro burette. To each flask, 1.5 ml of bromocresol green solution, 2.0 ml of buffer solution and 5 ml of chloroform were added. Reaction mixture in each funnel is shaken gently for 5 min and allowed to stand for 5 min so as to separate aqueous and chloroform layers. The chloroform layer is separated out and absorbance is measured at 420 nm, against the reagent blank prepared in similar manner omitting drug solution. Calibration graph is obtained by plotting absorbance values against the concentration of esomeprazole magnesium solution. The calibration curve is found to be linear over a concentration range of 50 to 250 g/ml of esomeprazole magnesium. The amount of esomeprazole magnesium present in the sample is computed from the calibration graph.

Pharmaceutical formulation

Twenty capsules of esomeprazole magnesium were emptied and powder was weighed. Amount equivalent to 50 mg was transferred to 50 ml volumetric flask, dissolved in 20 ml of methanol and made up the volume with methanol, sonicated for 10 min and filtered through whatman Filter paper No.1. The filtrate was suitably diluted to get a final concentration of 100 µg/ml of esomeprazole magnesium. The absorbance of sample solution was measured as described in the calibration procedure

and amount of esomeprazole magnesium was determined by referring to the calibration curve.

Recovery Studies

To ensure the accuracy and reproducibility of the results obtained, known amounts of pure drug was added to the previously analysed formulated samples and these samples were reanalyzed by the proposed methods and also performed recovery experiments. The percentage recoveries thus obtained were given in Table No.2.

RESULTS AND DISCUSSION

The proposed method was applied to the determination of esomeprazole magnesium in pharmaceutical tablets. The present method esomeprazole magnesium was treated with bromocresol green dye at 3.5 pH. The resultant solution is extracted with chloroform. The ion pair complex is formed in extractable chloroform layer is measured at 420 nm against the reagent blank prepared in a similar manner omitting drug solution. Beer's law is obeyed in the concentration range of 50-250 µg/ml of esomeprazole magnesium. Statistical analysis was carried out and the results were found to be satisfactory. Recovery studies were close to 100 % that indicates the accuracy and precision of the proposed methods. The optical characteristics such as absorption maxima, Beer/s law limits, molar absorptivity and Sandell´s sensitivity are presented in Table No.1. The regression analysis using method of least squares was made for the slope (b), intercept (a) and correlation (r) obtained from different concentrations and results were summarized. The percent relative standard deviation, standard deviation and student's't' test values calculated from the five measurements of esomeprazole magnesium are presented in Table No.2. Relative standard deviation values and standard deviation were low that indicates the reproducibility of the proposed methods. In the student's't' tests, no significant differences were found between the calculated and theoretical values of both the proposed methods at 95% confidence level. This indicated similar precision and accuracy in the analysis of esomeprazole magnesium in its tablets.

Table No 1: Optical characteristics of proposed method.

Statistical parameters	Proposed Method
λ_{max} nm	420
Beer's limits, mcg/ml	40-200
Sandell's , sensitivity, ($\mu g\, cm^{-2}$)	0.1189
Molar absorptivity, ($L\, mol^{-1}\, cm^{-1}$)	$1.18x10^2$
Regression equation, Y*	
Correlation coefficient, (r)	0.999
Intercept (a)	0.004
Slope (b)	0.006

*Y = a+bX, where Y is the absorbance and X concentration in µg / ml a= Intercept b= Slope.

Table No. 2: Assay of Esomeprazole Magnesium in Pharmaceutical Preparations

S.No	Sample (mg)	*Amount Found(mg) ±S.D*	% Recovery	*RSD	*t_{cal}
1	40	39.98±0.19	99.95	0.4809	0.2325
2	40	40.04±0.23	100.1	0.5749	0.0971
3	40	39.92±0.08	99.8	0.2079	2.156
4	40	40.03±0.38	100.07	0.9492	0.1765

*Average of five determinations based on label claim.

CONCLUSION

The proposed methods can be used for determination of esomeprazole magnesium in tablets. The methods are rapid, simple and have great sensitivity and accuracy. Proposed methods make use of simple reagents, which an ordinary analytical laboratory can afford. The proposed method is suitable for routine determination of esomeprazole magnesium in its formulations. The commonly used additives such as starch, lactose, titanium dioxide, and magnesium stearate do not interfere with the assay procedures.

The developed method is simple, sensitive, and reproducible, and can be used for the routine analysis of esomeprazole magnesium in bulk and tablet dosage form

REFERENCES

1. Rahman Nafisur, Bano Zehra, Syed Najmul Hejazmi, Spectrophotometric Determination of Esomeprazole Magnesium in Commercial Tablets Using 5-Sulfosalicylic Acid and N-Bromosuccinimide J Chin Chem Soc., 2008;55(3):557.

2. Vidya Gawande V. Spectroscopic estimation of esomeprazole magnesium in sold dosage form. International Journal of Pharmacy and Technology, 2010;2(3):617-622.

3. Putta Rajesh Kumar, Somashekar Shyale, Mallikarjuna Gouda M, Shanta Kumar, SM. Physico-chemical characterization, UV spectrophotometric method development and validation studies of Esomeprazole Magnesium Trihydrate. J. Chem. Pharm. Res., 2010;2(3):484-490.

4. Rathi1, Rakesh Kumar Singh, Pankaj Singh Patel, Rajan Kumar Singh, Brijesh Kumar1. RP- HPLC Method for the estimation of esomeprazole magnesium in bulk and its pharmaceutical dosage forms. International Journal of pharmaceutical Sciences and Reasearch. 2010;1(6): 75-81.

5. Arma ĞAn ÖNal, Aysel ÖZtun Ç. Development and Validation of High Performance LiquidChromatographic Method for The Determination of Esomeprazole in Tablets Journal of Food and Drug Analysis.. 2006;14(1):12-18.