

New Spectrophotometric Determination of Esomeprazole in Bulk And Pharmaceutical Dosage Form Using Tropaeoline-OO

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Abstract: The new, selective and sensitive visible spectrophotometric method has been developed for the estimation of Esomeprazole in bulk and in pharmaceutical preparations. This method is based on the reaction with tropaeoline-OO dye under acidic condition with a λ_{max} 410nm. Beer's law is obeyed in the concentration range of 50-250 μ g/ml for both the methods. The method was extended to pharmaceutical formulations and there was no interference form in any common pharmaceutical excipients and diluents. The result of analysis has been validated statistically and by recovery studies.

Keywords: Spectrophotometric determination tropaeoline-OO dye, Esomeprazole.

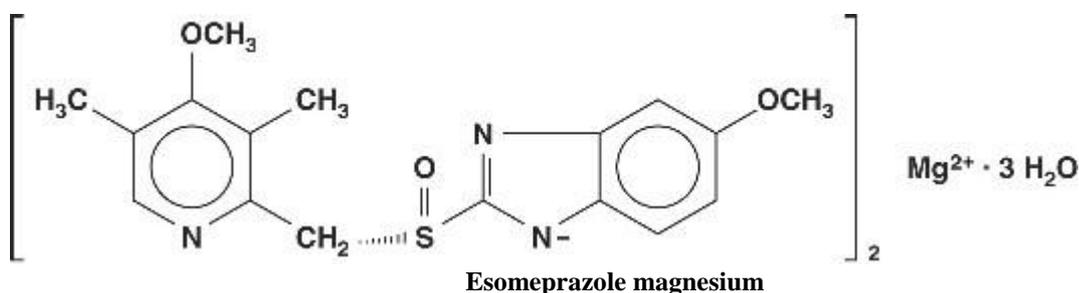
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I. Introduction:

Esomeprazole magnesium is a bis(5-methoxy-2-[(S)-[(4-methoxy-3,5-dimethyl-2-pyridinyl)methyl]sulfinyl]-1H-benzimidazole-1-yl) magnesium trihydrate. Esomeprazole is the S-isomer of omeprazole, which is a mixture of the S- and R- isomers. The magnesium salt is a white to slightly colored crystalline powder. It contains 3 moles of water of solvation and is slightly soluble in water. The stability of esomeprazole magnesium is a function of pH; it rapidly degrades in acidic media, but it has acceptable stability under alkaline conditions. At pH 6.8 (buffer), the half-life of the magnesium salt is about 19 hours at 25°C and about 8 hours at 37°C. Its molecular formula is (C₁₇H₁₈N₃O₃S)₂MgX.3H₂O with molecular weight of 767.2 as a trihydrate and 713.1 on an anhydrous basis. The methods is based on the reaction of esomeprazole magnesium drug as a secondary amine with Tropaeoline-OO, the formed complex extracted into chloroform at pH 1.5. The chloroform extractable layer is used to determine the esomeprazole magnesium spectrophotometrically.

The structure of esomeprazole magnesium is shown in below.



II. Experiment:

All spectral measurements were made on MAPADA double beam UV-Visible 1600 spectrophotometer & on an ELICO SL 171 MINI SPECS spectrophotometer. An ELICO LI-120 Digital pH meter was also used for pH measurements.

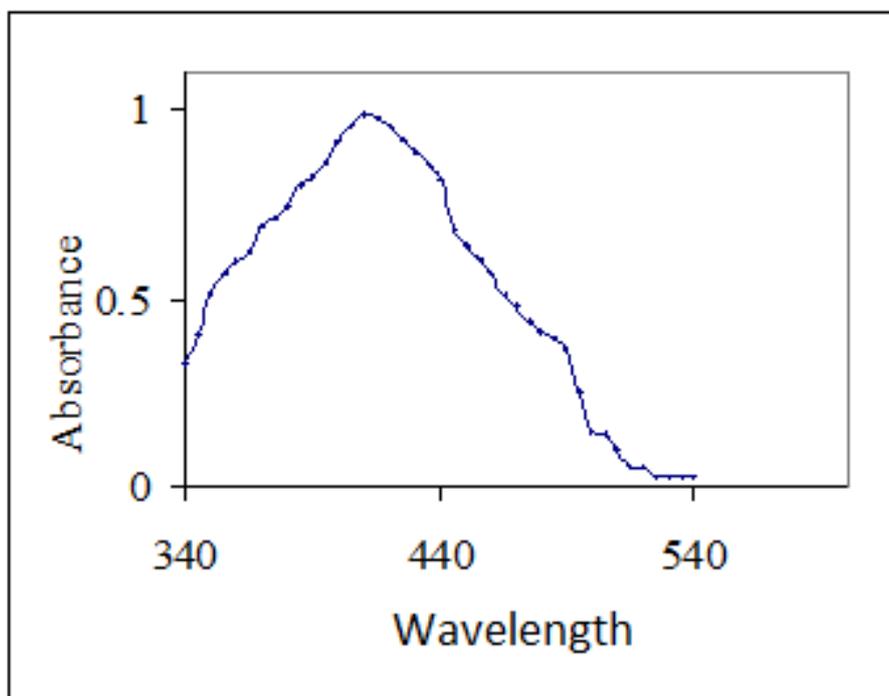
Method:

The method is based on the reaction of Esomeprazole having secondary amino (aliphatic) group with tropaeoline-OO, the formed complex extracted into chloroform in acidic medium. The chloroform extractable layer is used to determine the Esomeprazole spectrophotometrically. The amount of drug is computed from the calibration curve.

Spectrum of Esomeprazole treated with Tropaeoline-OO:

The wavelength of maximum absorbance of the Esomeprazole drug treated with tropaeoline-OOsolution is ascertained by the following procedure.

Into a 10 ml volumetric flasks, the standard drug solution (1.0 mg/ml) in chloroform were transferred and diluted with same so as to obtain 100 µg/ml of Esomeprazole. 1 ml of Esomeprazole solution is transferred into a separating funnel. To this solution 1.0 ml of tropaeoline-OO reagent 2.0 ml hydrochloric acid solution are added. Reaction mixture was shaken gently for 5 min and allowed to stand for 5 min so as to separate aqueous and chloroform layer. The chloroform layer is separated out and absorbance is measured in the wavelength range of 340-540 nm, against the reagent blank. The spectrum is given in below.

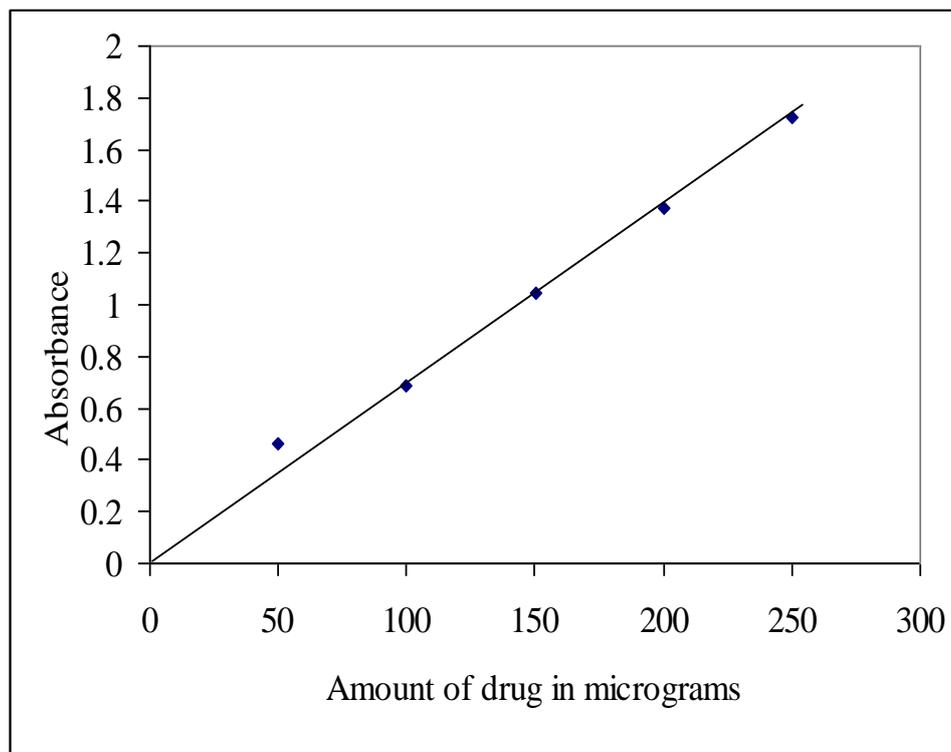


Spectrum of Esomeprazole magnesium

Assay Procedure:

To study the effect of drug concentration on the absorbance of the ion pair complex under optimal conditions now arrived is studied by the following method to know the suitability of the method for the assay of Esomeprazole.

Varioualiquots of the standard Esomeprazole solution ranging from 0.5-2.5 ml are transferred into a series of separating funnels. To each flask, 1.0 ml of tropaeoline-OOsolution, 1.5 ml of hydrochloric acid solution and 5 ml of chloroform are 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 layer. The chloroform layer is separated out and absorbance is measured at 410 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 solution. The calibration curve is found to be linear over a concentration range of 50-250µg/ml of Esomeprazole. The amount of Esomeprazole present in the sample is estimated from the calibration graph. The results are presented in fig.



Calibration curve of Esomeprazole magnesium

Pharmaceutical formulation of Esomeprazole:

For analysis of tablet formulation, twenty tablets of Esomeprazole are weighed accurately and finely powdered. An accurately weighed portion of powdered sample, equivalent to 50 mg of Esomeprazole was taken in a 50 ml volumetric flask containing 25 ml of chloroform, sonicated for 20 minutes.

The resultant solution is filtered through Whatmann filter paper No. 41 into another 50 ml volumetric flask. The filter paper was washed several times with chloroform. The washings were added to the filtrate and the final volume was made up to the mark with chloroform. 5 ml filtrate of the sample solution was diluted to 10 ml with chloroform and treated as per the procedure of the calibration curve. Amount of the drug present in sample was computed from respective calibration curve. The results are present in below table.

Table of Assay of esomeprazole magnesium

S.No	Sample (mg)	*Amount Found(mg) ±S.D*	% of Label claim	*C.V	*t _{cal}
1	20	20.02±0.25	100.1	1.292	0.1728
2	20	20.1±0.27	100.5	1.380	0.8064
3	40	39.96±0.28	99.9	0.7272	0.3105
4	40	39.9±0.22	99.75	0.5604	1.000

(*Average of five determinations)

III. Results and discussion:

In this method the Esomeprazole treated with tropaeoline-OO dye in acidic medium. The resultant solution is extracted with chloroform. The ion pair complex is formed in extractable chloroform layer.

The absorbance of the extractable ion pair complex is measured at 410 nm against the reagent blank (prepared in a similar manner devoid of drug solution). The calibration curve (concentration vs absorbance) is linear over the range of 50-250 µg/ml of Esomeprazole. The values of standard deviation values are low, indicates high accuracy and reproducibility of the method. The 't' calculated values are compares well with the theoretical value of 2.78 thereby indicating the precision of the method. There is no effect of additives and excipients such as starch, calcium lactose and glucose in the concentrations of those present in general

The proposed method is found to be simple, precise, accurate and time saving, reproducible and can be conveniently adopted for routine analysis of estimation of Esomeprazole in bulk drugs samples and

pharmaceutical formulations as seen from the agreement of the amount of Esomeprazole in the present method and the labeled amount of the pharmaceutical preparation.

IV. Conclusion:

The proposed method is found to be simple, precise, accurate and time saving reproducible and can be conveniently adopted for routine analysis of estimation of esomeprazole magnesium in bulk drug samples and pharmaceuticals formulations.

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