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Validated spectrophotometric estimation of esomeprazole using hydrotrophic solubilisation technique

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ABSTRACT

A Simple, accurate and reproducible spectrophotometric method by Hydrotrophic Solubilisation was developed for the estimation of Esomeprazole. In the present investigation, hydrotropic solution of urea (10M) was employed as a solubilising agent to solubilise the poorly water soluble drug, esomeprazole in the tablet form and determined with the help of spectrophotometric determination in ultraviolet region. Esomeprazole showed maximum absorption at 301 nm and obeyed Beer's law in concentration range of 10-50µg/ml. Statistical analysis of the result has been carried out revealing high accuracy and good precision.

Key words: Esomeprazole, hydrotropy, spectrophotometry, urea.

INTRODUCTION

The term "hydrotropy" has been used to designate the increase in solubility of various substances due to the presence of large amount of additives. Various hydrotropic agents have been used to enhance the aqueous solubility of a large number of drugs.In solubility determination, it was found that there was more than 50-fold enhancement in solubility of Esomeprazole in 10 M Urea solution.

Esomeprazole is a proton pump inhibitor drug used for short term treatment of erosion and ulceration of the esophagus caused by gastro-esophageal reflux disease. Chemically it is known as 6-methoxy-2-[(4-methoxy-3, 5-dimethyl-2-pyridinyl) methyl] sulfinyl] -1H-benzimidazole. Esomeprazole is (S-isomer of omeprazole), the first single optical isomer proton pump inhibitor which generally provides better acid control than racemic proton pump inhibitors. Its molecular weight is 713.13. It is listed in Martindale, The complete drug reference. The literature study indicates that Esomeprazole has been determined by spectrophotometry[4-7], HPLC[8,9,11] and HPTLC[10]. No single UV method for Esomeprazole is reported till date using hydrotrophic solubilisation technique. Hence an attempt has been made to develop new UV method for its estimation by hydrotrophic solubilisation in bulk andPharmaceutical formulations with good accuracy, simplicity, precision and economy.

EXPERIMENTAL

Materials and Methods

An ELICO (SL 164) double beam UV-Visible spectrophotometer with a pair of 1 cm matched quartz cells was used to measure absorbance of the resulting solutions. All the chemicals used were of AR grade procured from Qualigens, Mumbai.

Solubility of Esomeprazole was determined in distilled water and 10M urea solution at 28± 1º C. There was more than 50- fold enhancement in the solubility of drug in 10 M urea solution, as compared to the solubility in the distilled water.

Drug (100 mg) was shaken with 20 ml of 10 M urea solution in a 100 ml volumetric flask, then drug was solubilised by shaking and the volume was made up to the mark by addition of distilled water, to get various standard dilutions containing 10, 20,30,40 and 50 µg/ml of drug. Absorbances of these dilutions were noted at 301 nm against respective reagent blank.

Twenty tablets were powdered and an amount equivalent to 20 mg of the drug was shaken with 20 ml of 10 M urea by continuous shaking for about 10 min and volume made up to 100 ml with distilled water. The resulting solution was filtered through whatman filter paper no.41 and appropriate aliquots were prepared by diluting with distilled water. Absorbances of different prepared aliquots were observed at 301 nm against reagent blanks.

RESULTS AND DISCUSSION

Validation of method

The optical characteristics such as Beer's law limits, molar absorptivity and sandell's sensitivity were given in Table-1. The precision of the method was found by measuring the absorbance of 6 separate samples containing known amounts of drug and the results obtained are incorporated in

Table 1: Optical and regression characteristics of the proposed method for ESO

Parameters	
λmax, nm	301
Beer's law limits mcg/ml	10-50µg/ml
Molar absorptivity, L/mol.cm	1.63×10^5
Sandell's sensitivity, mcg/cm2/0.001 absorbance unit	0.01
Regression equation Y = a +bc	
Slope(b)	0.0566
Intercept(a)	0.0346
Correlation coefficient(r)	0.9989

Table 2: Analysis of tablet formulation

Label claim	% Amount found ± S.D [n=5]	% R.S.D	% Recovery [n=5]
20mg	99.89±0.140	0.674	99.86

Table-1. Regression analysis using the method of least squares was made to evaluate the slope(b), intercept (a) and correlation coefficient (r).

The accuracy of the method was ascertained by comparing the results by proposed and reference methods. The comparison shows that there is no significant difference between the results of studied methods and those of reference. The similarity of the results is obvious evidence that during the application of these methods the excipients present in formulation do not interfere in the assay of proposed method. As an additional check of accuracy of the proposed method recovery studies were carried out. The recovery of the added amounts of standard drug was studied at 3 different levels. Each level was repeated 6 times. From the amount of drug found, the percentage recovery was calculated.

CONCLUSIONS

The developed method is new, simple, cost-effective, environment-friendly, safe, accurate, and reproducible. Decided advantage is that the organic solvent is precluded, but not at the expense of accuracy. The method doesnot involve any critical reaction conditions. The proposed method can serve as an alternative method for the routine analysis of Esomeprazole in pure drugs and in pharmaceutical formulations.

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