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Spectrophotometric Determination of Esomeprazole in Tablet Dosage forms

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ABSTRACT

A New, simple, sensitive spectrophotometric method in U.V region has been developed for the determination of Esomeprazole in bulk and in its dosage form. Esomeprazole shows maximum absorbance at 275 nm in Dimethyl formamide (DMF) solvent for first dilution and further dilution with 50:50 v/v of DMF:Water. Beers laws obeyed in the concentration range of 10-60mcg/ml.Results of analysis were validated statistically and by recovery studies.

Key Words: Esomeprazole, Spectrophotometric Determination.

INTRODUCTION

 $\label{eq:someprazole Chemically (S)-5-methoxy-2-[(4-methoxy-3,5-dimethylpyridin -2-yl) methylsulfinyl]-3H-benzoimidazole (M.F: C_{17}H_{19} N_3O_3S; M.W: 345.417) ^[4]. Esomeprazole is in a class of drugs called proton pump inhibitors (PPIs) ^[1] which blocks the production of acid by the stomach. Other drugs in the same class include Omeprazole, Lansoprazole, Rabeprazole and Pantoprazole ^[3]. Chemically, esomeprazole is very similar to Omeprazole.NEXIUM (esomeprazole magnesium trihydrate) delayed release tablets contain esomeprazole (the S-isomer of omeprazole) ^[2]. Esomeprazole is acid labile and therefore is administered orally as enteric-coated granules compressed into a tablet ^[5].$



Fig. 1: Structure of Esomeprazole

EXPERIMENTAL

Instrumentation:

An Elico UV – Visible spectrophotometer (model SL–164) with matching quartz cells were used for all absorbance measurements. The solvent DMF used to be analytical graded (S. d. Fine-Chem. Ltd.). The commercially available tablets in the local market of Esomeprazole were IZRA-40 (Unichem), ESOFAG (Micro labs) and ESCZ (Glenmark) were procured from local market and estimated.

Reagent used: Dimethyl formamide (A.R.GRADE) S.D.Fine-Chem. Ltd

Preparation of Stock Solutions:

25 mg of Esomeprazole was accurately weighed and dissolved in 25 ml of dimethyl formamide in 25ml of volumetric flask.

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Optimization:

Optimum Conditions Fixation in Procedures:

In order to ascertain the wavelength of maximum absorbance (λ_{max}) of the pharmacodynamic agents in each of the above methods, specified amount were taken and the absorption spectra were scanned in the wavelength region of 200 - 380nm against a corresponding reagent blank. The resulting spectra of the absorption curves show characteristic absorption maximum at 275nm.

The Optimum Conditions incorporated in the procedure of the proposed spectrophotometric method were ascertained by performing systematic investigation as given below.

The optimum conditions in all those methods were fixed basing on the study of the effects of various parameters such as organic solvents for Esomeprazole, temperature and stability of the species. The author performed controlled experiments by measuring the absorbances at respective λ_{max} of a series of solutions varying only one and fixing the other parameters such as effect of volume of reagent or solvent temperature, time, and nature of the solvents for final dilutions. The optimum conditions developed and actual conditions chosen for the procedures are recorded.

Preparation of Working Standard Solutions and Procedure for Calibration curve:

The above stock solution was further diluted with 50:50 DMF: distilled water to get working standard solutions of 100 μ g/ml. Aliquots of working standard solutions from 100 μ g/ml of Esomeprazole ranging from 1 to 6 ml were transferred separately into a series of 10 ml volumetric flasks and final volume was brought to 10 ml with 50:50 DMF:distilled water. The absorbances were measured at λ_{max} 275 nm against reagent blank.





Fig. 2: Calibration curve of Esomeprazole

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Table No. 1: Optical Characteristics and Precision

Parameters	Esomeprazole	
Maximum absorbance	275 nm	
Linearity range (µg/ml)	10-60	
Sandell's sensitivity (µg/cm ² /0.001 absorbance unit)	0.00162	
Molar extinction coefficient (1mole ⁻¹ . cm ⁻¹)	$2.2104 \ge 10^4$	
% Range of error	+0.6417	
0.05 confidence limits	+2 1024	
0.01 confidence limits		
Correlation coefficient	0.99977	
Regression equation (Y)*	0.01372	
Slope (a)	-0.002285	
Intercept (b)	-0.002203	

 $Y^* = ax+b$, where 'x' is concentration in $\mu g/ml$ and Y is absorbance unit

Preparation of Test Solutions:

20 tablets containing Esomeprazole of each marketed formulation were taken and powdered. The powder equivalent to 25 mg of Esomeprazole was dissolved in 15 ml of dimethyl formamide, sonicated for 2 mins and filtered. The residues were washed with dimethyl formamide, and the total volume was made to 25 ml with DMF the filtrate was further diluted with distilled water to get the required concentration within the linearity of range and the absorbance measured at 275nm against reagent blank. From this absorbance value and calibration curve the amount of esomeprazole present in solution was estimated.

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Formulations	Labeled amount (mg)	Amount obtained (mg) by proposed method	%RSD
IZRA-40(Unichem)	40	40.05 ± 0.08544	±0.21333
ESOFAG(Microlabs)	40	39.86 ± 0.08888	± 0.22298
ESCZ(Glenmark)	40	40.97 ± 0.14525	± 0.3544

Each v alue is aver age of three determinations \pm standard deviation.

 ${f T}$ he proposed method was simple, sensitive and reliable

CONCLUSION

with good precision and accuracy. The proposed method is specific

while estimating the commercial formulations without interference

of excipients and other additives. Hence, this method can be used for

the routine determination of Esomeprazole in bulk samples and

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