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NOTE

UV-Spectrophotometric Determination of Esomeprazole in Tablet Dosage Forms

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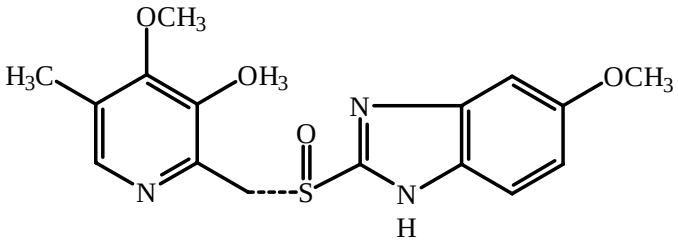
A new, simple ,sensitive UV-spectrophotometric method has been developed for the determination of esomeprazole in bulk and in its dosage form. Esomeprazole shows maximum absorbance at 275 nm in dimethyl formamide solvent for stock solution and further dilution with 50:50 (v/v) of DMF: distilled water. Beer's law obeyed in the concentration range of 10-50 mcg/mL. Results of analysis were validated statistically and by recovery studies.

Key Words: Esomerozole, Spectrophotometric determination.

Esomeprazole magnesium tri hydrate having the property of proton pump inhibitors[1] (PPI's) which blocks the production of acid by the stomach. Chemically, it is (S)-5-methoxy-2-[[[4-methoxy-3,5-dimethyl-2-pyridinyl]methyl]sulfiny]-1H-benzimidazole. Esomeprazole not having official method in I.P., B.P., U.S.P. The present study deals with the development of ultraviolet spectrophotometeric method for quantification of esomeprazole in tablets in different brands by using methanol as solvent[2-5]. Statistical validation was performed for the experimental data to as certain the precision, accuracy and reproducibility of the proposed method[6,7].



Chemical structure of esomeprazole

Spectral measurements were recorded in UV-Visible double beam spectrophotometer Elico-SL164. Esomeprazole (reference standard) was obtained as a gift sample from Unichem Laboratories Ltd., Mumbai. Three different brands of esomeprazole tablets were procured from market.

Preparation of standard solution: The standard drug solution was prepared by dissolving 25 mg of esomeprazole in 25 mL DMF taken in a 25 mL standard flask. This stock solution was suitably diluted with 50:50 v/v of DMF: Distilled water solvent to get a standard drug solution of 100 mcg/mL.

Aliquots of 1-5 mL standard drug solution were transferred to a series of 10 mL volumetric flasks. To each of these flasks were made up to the volume with 50:50 v/v of DMF: distilled water and the absorbance of the solutions were measured at 275 nm against reagent blank. A linear calibration graph was plotted using concentration *vs.* absorbance. The optical characteristics are given in Table-1

TABLE-1
OPTICAL CHARACTERISTICS OF ESOMERPRAZOLE

Parameter		Esomerprazole
Maximum absorbance (nm)		275
Beer's law limit (mcg/mL)		10-50
Sandell's sensitivity (mcg cm^{-2}/0.001 AU)		0.43478
Molar absorptivity (L mol^{-1} cm^{-1})		2.068×10^4
Regression equation (Y = a + bC)	Slope (b)	0.021
	Intercept (a)	0.0052
Correlation coefficient (r)		0.9984

Preparation of sample solution: The proposed method was applied to the analysis of commercially available esomeprazole tablets. A quantity of mixed contents of 20 tablets equivalent to 25 mg of esomeprazole was transferred into 25 mL of volumetric flask. A small quantity of DMF was added and shaken well to dissolve the drug. It was made up to volume with DMF and the solution is filtered. The filtrate was further diluted with 50:50 v/v DMF: distilled water to get required concentration and the absorbance measured at 275 nm against reagent blank.

Esomeprazole exhibits its maximum absorption at 275 nm and obeyed Beer's law in the concentration range of 10-50 mcg/mL. The optical characteristics such as Beer's law limits, Sandell's sensitivity, molar absorptivity, correlation coefficient, slope, intercept obtained are shown in Table-1. The results of analysis under recovery studies are presented in Table-2. The percentage recovery value indicates that there is no interference from the excipients present in the formulation. The developed method

was found to be sensitive, accurate, precise and reproducible and can be used for the routine quality control, analysis of esomeprazole in bulk drug and formulations.

TABLE-2
RESULTS OF ASSAY AND RECOVERY STUDIES

Pharmaceutical formulation	Labelled amount (mg)	Amount found		% Recovery*
		Mg	%	
IZRA-40 (UNICHEM)	40	39.48	98.70	98.68
ESOFAG (MICROLABS)	40	38.42	96.05	97.80
ESCZ (GLENMARK)	40	38.76	96.90	98.21

*Mean of five determinations.

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