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Research Article

A SIMPLE UV SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF LANSOPRAZOLE IN BULK AND PHARMACEUTICAL DOSAGE FORMS

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ABSTRACT

Lansoprazole is a substituted benzimidazole, 2-[(3-methyl-4-(2, 2, 2-trifluoroethoxy) pyridin-2-yl) methylsulfinyl] -1*H*-benzoimidazole that inhibits gastric acid secretion and used for the treatment of erosive or ulcerative GERD, DU and hypersecretory syndromes including ZES. In present work, a simple, sensitive, accurate and economical spectroscopic method has been developed for the estimation of Lansoprazole in Bulk and its pharmaceutical dosage forms. An absorption maximum was found to be at 298 nm with the solvent system 0.01 M Phosphate Buffer of pH 6.8. The drug follows Beer law in the range of 5-30 µg/ml with correlation coefficient of 0.9996. The percentage recovery of Lansoprazole ranged from 99.8 to 100.2 % in pharmaceutical dosage form. Results of the analysis were validated for accuracy, precision, LOD, LOQ and were found to be satisfactory. The proposed method is simple, rapid and suitable for the routine quality control analysis.

Keywords: Lansoprazole, UV spectrophotometry, Estimation, Validation.

INTRODUCTION

Lansoprazole[1] is a substituted benzimidazole, 2-[(3-methyl-4-(2, 2, 2-trifluoroethoxy) pyridin-2-yl) methylsulfinyl] -1*H*-benzoimidazole. Molecular basis of lansoprazole[1] (LNZ) reveals that it is a proton pump inhibitor that suppress gastric acid secretion by specific inhibition of the enzyme system of Hydrogen/ potassium adenosine triphosphatase (H^+/ K^+ ATPase) at the secretory surface of the gastric parietal cell and is used in the treatment of various gastric disorders such as gastric and duodenal ulcers, gastro esophageal reflux disease and in pathological hypersecretory conditions[2-4]. For the estimation by UV method is because of the presence of trifluoroethoxy, Benzimidazole, pyridine[5]. A survey of literature also states that there was no specified reported data on UV method for the estimation of lansoprazole[6]. An absorbance was found to be 298 nm from the spectrum obtained by scanning of drug dissolved in 0.01 M Phosphate Buffer of pH 6.8. The method is validated according to ICH guidelines[7].

MATERIALS AND METHODS

Instrumentation

Spectrophotometer used was Double beam UV- Visible spectrophotometer with 10mm matched quartz cell Model- UV-1700 PHARMASPEC**.** Make – shimadzu, Japan and Analytical balance: shimadzu, Japan AX 200.

Chemicals and reagents

All the reagents and chemicals used were AR grade. Lansoprazole Capsules, LANCUS

(15mg), PROTOGUT (30mg), LANZAP (15mg, 30 mg), LANZOL (15mg, 30 mg), were purchased from Cadila pharma, Novartis, Dr .Reddys, cipla pharmaceuticals Ltd. Respectively.

METHOD DEVELOPMENT

Preparation of 0.01 M Phosphate Buffer

Preparation of 0.01M phosphate buffer: 7g of Potassium dihydrogen orthophosphaste was weighed accurately and dissolved in about 500 ml of distilled water and diluted with distilled water upto 1000 ml, and the pH was adjusted upto 6.8 with the sodium hydroxide solution and filtered through 0.45µ Whatmann filter paper .This buffer solution was used as diluent.

Preparation of standard stock solution and calibration curve

Standard stock solution of LNZ (100 µg /ml) was prepared by using 0.01 M Phosphate Buffer of pH 6.8 and aliquots of in the range of 2-40 µg /ml were prepared with the same solvent and scanned under spectrum mode for 200-400 nm wavelength range and a sharp peak was obtained at 298 nm (Fig-1). A calibration curve was plotted taking an absorbance on Y-axis against concentration of standard solution on X-axis (Fig-2). The method was applied for known sample solution and was found to be satisfactory for the analysis of Capsule dosage forms.

Optical characteristics

The optical characteristics such as beer's law limit, molar extinction coefficient, % RSD were calculated. Regression characteristics like slope, intercept, correlation coefficient, LOD, LOQ, standard deviation were calculated (Table-1).

ASSAY OF LANSOPRAZOLE CAPSULES

For the analysis of the dosage form 20 capsules of LNZ were weighed. Powder equivalent to 10mg of LNZ was taken in to a 100ml volumetric flask. The formulation first dissolved in 0.01 M Phosphate Buffer of pH 6.8 (25 ml) and sonicated for about 10-15 min. finally made up the volume with the same solvent. The solution was filtered and final concentration of the sample 10µg/ml was prepared and measured the absorbance against blank at 298nm. The amount of Lansoprazole was computed by using the equation referring to the calibration curve (Table-2).

METHOD VALIDATION

The method was validated for different parameters like Linearity, Accuracy and Precision.

Linearity

Fresh aliquots were prepared from the stock solution (100 µg/ml) ranging from 2-40 µg/ml. The samples were scanned in UV-Visible spectrophotometer using 0.01 M Phosphate Buffer of pH 6.8 as blank. It was found that the selected drug shows linearity between the 5-30 µg/ml (Table -3).

Accuracy

Accuracy of the method confirmed by studying recovery at 3 different concentrations for 80, 100, and 120% of these expected, in accordance with ICH guidelines, by replicate analysis. Standard drug solution was added to a pre analyzed sample solution and percentage drug content was measured. The results from study of accuracy were reported in table no.3. %Recovery = [(ct –cu)/ ca] × 100. Where ct is the total conc. of the analyte found; cu is the conc. of the analyte present in formulation; and ca is the conc. of the pure analyte added to the formulation (Table-3).

Precision

Precision (intra-day precision) of the method was evaluated by carrying out the five independent test samples of Lansoprazole. The intermediate precision (inter-day precision) of the method was also evaluated using two different analyst, and different days in the same laboratory. The percent relative standard deviation (%RSD) and assay values obtained by two analysts were found to be Good (Table- 4).

RESULTS AND DISCUSSIONS

From the optical characteristics (Table-1) of the proposed method, Lansoprazole was shown its λ max at 298 nm in the solvent 0.01 M Phosphate Buffer of pH 6.8 with a good correlation coefficient 0.9996. The percentage purity and relative standard deviation from the Assay of the tablet dosage forms (Table-2) were found to be within the limits. The accuracy data of the drug (Table-3) was shown good percentage recovery and %RSD with the range of 99.4 -101.3 and 0.2-0.4 respectively. The Inter-day and Intra-day(Table-4) precision values were found to be 0.57 and 0.79 respectively.

Table 1: Optical characteristics and precision of the proposed method

Parameter	Value
Absorption maxima (nm)	298 nm
Beer's law limit (µg/ml)	5-30 µg/ ml
Correlation coefficient (r)	0.9996
Regression equation (Y= mX+c)	Y= 5.34x + 0.267
Slope (m)	5.34
Intercept (c)	0.267
Standard Deviation	0.0075
LOD (µg / ml)	1.53
LOQ (µg / ml)	4.63

Table 2: Assay of Lansoprazole capsules

Dosage form	Label claim (mg/cap)	Amount found * ± SD	% Purity of the tablet ± %RSD
LANCUS	15	15.04 ± 0.07211	100.2 ± 0.36
PROTOGUT	30		99.85 ± 0.28
LANZAP	15	14.97 ± 0.0529	99.952 ± 0.35
LANZOL	30	30.09 ± 0.17776	100.02± 0.59

*An average of three samples for each concentration

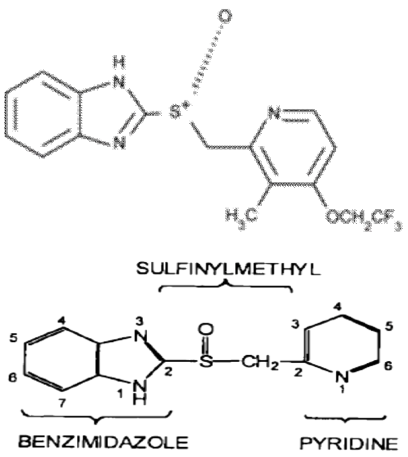
Table 3: Accuracy data of the drug

Sample ID	Concentration µg /ml		(%)Recovery* ± S.D	(%)RSD
	Formulation			
80%	24	15	101.3±0.308	0.305
100%	30	30	99.4±0.397	0.40
120%	36	15	99.9±0.222	0.223

* An average of three samples of each concentration

Table 4: Precision of the Lansoprazole working standards

Assay of Lansoprazole as percent of labeled amount		
Sample no	Analyst –I (Intra-day precision)	Analyst –II (Inter-day precision)
1	100.62	99.58
2	101.54	101.52
3	99.66	100.46
4	100.24	101.44
5	99.68	99.77
Mean	100.32	100.54
%RSD	0.57	0.79



Structure of Lansoprazole

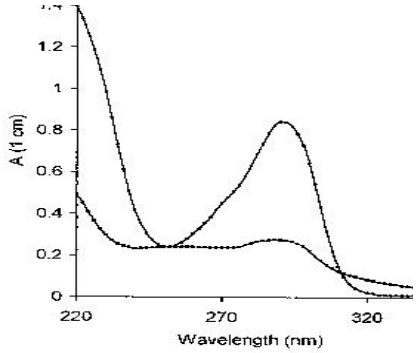


Fig. 1: Spectrum of Lansoprazole in 0.01 M Phosphate Buffer of pH 6.8

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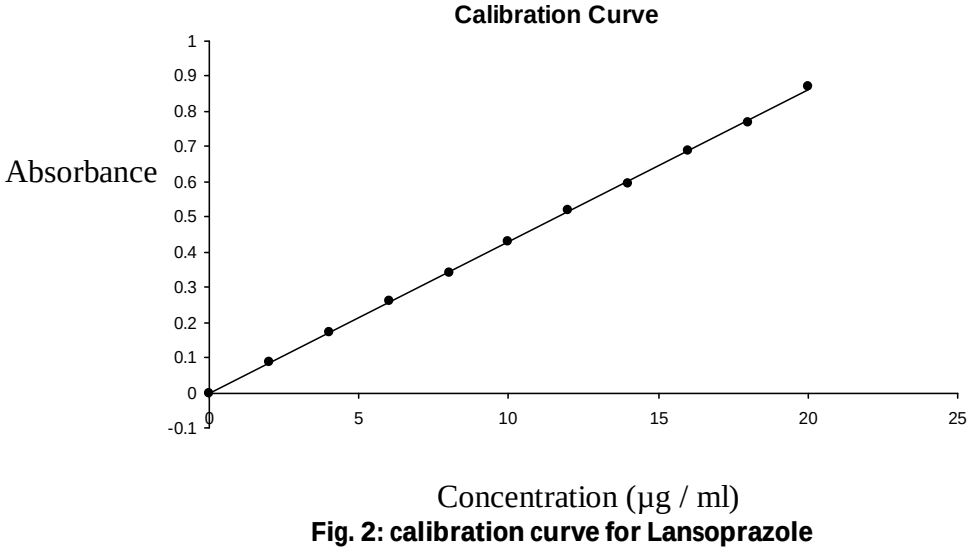

Fig. 2: calibration curve for Lansoprazole

CONCLUSION

The proposed method for the estimation of Lansoprazole was found to be simple, sensitive and reliable with good precision and accuracy. The method is specific while estimating the commercial formulations without interference of excipients and other additives. Hence this method can be used for the routine analysis of Lansoprazole in bulk and pharmaceutical formulations.

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