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Development and validation of RP-HPLC method for the estimation of Lansoprazole in tablet dosage form

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ABSTRACT

A simple Reverse phase liquid chromatographic method has been developed and subsequently validated for estimation of lansoprazole in tablet dosage form. The separation was carried out using a mobile phase consisting of disodium hydrogen phosphate buffer of pH 3.0, and Acetonitrile in the ratio of 30: 70. The column used was Phenomenex Luna C8, (5μ, 250 mm × 4.6 mm id) with flow rate of 1.0 ml / min using UV detection at 285 nm. The described method was linear over a concentration range of 40-60 μg/ml for the assay of Lansoprazole. The retention time of Lansoprazole was found to be 8.82 min. Results of analysis were validated statistically. The results of the study showed that the proposed RP-HPLC method is simple, rapid, precise and accurate, which is useful for the routine determination of Lansoprazole in tablet dosage form and in its pharmaceutical dosage forms.

Keywords: Lansoprazole, RP-HPLC.

INTRODUCTION

Lansoprazole, chemically known as 2-[[3-methyl- 4-(2,2,2-trifluoroethoxy) pyridin-2-yl] methylsulfinyl] -1H-benzimidazole. (Mol.Formula: $C_{16}H_{14}F_3N_3O_2S$, Mol.wt: 369.36, CAS no 103577-45-3). Lansoprazole, a member of the proton-pump-inhibitor class of gastric acid

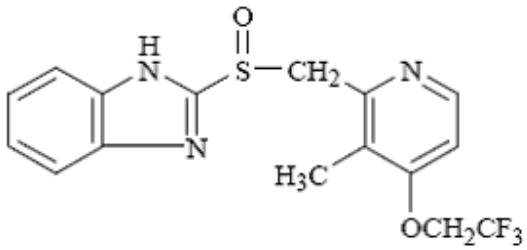
inhibitory agent, effectively raises intragastric pH and is indicated for the short-term treatment of active erosive reflux esophagitis, gastric ulcer, duodenal ulcer, and nonerosive gastroesophageal reflux disease. Lansoprazole is also indicated as a long-term maintenance therapy in patients with healed reflux esophagitis and healed duodenal ulcer and in the treatment of pathological hypersecretory conditions, such as Zollinger-Ellison syndrome.

As a proton-pump inhibitor, lansoprazole is also a necessary component of dual- and triple-therapy regimens for the eradication of Helicobacter pylori infection. The latest FDA-approved labeling for lansoprazole includes the indication of healing and risk reduction in nonsteroidal anti-inflammatory drug-associated gastric ulcers [1-3].

The absorption of lansoprazole is rapid, with mean Cmax occurring approximately 1. 7 hours after oral dosing, and relatively complete with absolute bioavailability over 80%. There is no significant food effect if the drug is given before meals. Lansoprazole is 97% bound to plasma proteins. Lansoprazole is extensively metabolized in the liver. Two metabolites have been identified in measurable quantities in plasma (the hydroxylated sulfinyl and sulfone derivatives of lansoprazole).

Lansoprazole belongs to a class of antisecretory compounds, the substituted benzimidazoles, that suppress gastric acid secretion by specific inhibition of the (H , K)-ATPase $^{+\,+}$ enzyme system at the secretory surface of the gastric parietal cell. Because this enzyme system is regarded as the acid (proton) pump within the parietal cell, lansoprazole has been characterized as a gastric acid-pump inhibitor, in that it blocks the final step of acid production [4-6].

For estimation of Lansoprazole in tablet dosage form, hence we attempted to develop a simple, accurate, and economical analytical method. This paper describes validated RP-HPLC for estimation of Lansoprazole in tablet dosage form using phosphate buffer of pH 3.0 and acetonitrile in the ratio of 30: 70. The column used was Phenomenex Luna C-8 with flow rate of 1.0 ml /min using UV detection at 285 nm [7-10].



Lansoprazole

EXPERIMENTAL SECTION

Standard bulk drug of Lansoprazole was provided by Micro Laboratories Ltd., Bangalore. Tablets of Lansoprazole were procured from the local market. All other reagents used were of HPLC grade. HPLC (Shimadzu LC-20AT) method was developed using Phenomenex Luna (C8, 5µ, 250 mm × 4.6 mm id). Mobile phase selected for this method contained 30 parts of phosphate buffer (Adjusted to pH 3.0 with 0.5% orthophosphoric acid) and 70 parts of

acetonitrile. That was filtered through 0.45-micron membrane filter. Flow rate employed was 1.0 ml/min. Detection of eluent was carried out at 285 nm using UV detector. Method was developed. Standard stock solutions of pure drug was made separately in mobile phase containing 40-60µg /ml of Lansoprazole and filtered through a 0.45µ membrane filter. Each solution was injected and a chromatogram was recorded. Mean retention time of Lansoprazole was found to be 8.82 min.

Analysis of formulation:
Twenty tablets of the formulation were weighed and the average weight per tablet was calculated. Twenty tablets were crushed and ground to a fine powder. Powder equivalent to 50 mg of Lansoprazole was weighed and transferred to a 100 ml volumetric flask. The tablet powder was dissolved in the mobile phase and filtered through a membrane filter (0.45µ).From this 5 ml filtered solution pipette out into 50 ml volumetric flask. Then 25 ml of mobile phase is added, and then the volume is made up to mark with mobile phase. The sample solution was ready for the analysis.

After setting the chromatographic conditions and stabilizing the instrument to obtain a steady baseline, the tablet sample solution was loaded in the 10 µl fixed - sample loop of the injection port. The solution was injected and a chromatogram was recorded. The injections were repeated six times and the peak areas were recorded. A representative chromatogram has been given in Figure-1. The peak area ratio of the drug was calculated and the amount of drug present per tablet was estimated from the respective calibration curves. The result of analysis reported in [Table – 1].

Chromatogram for formulation:

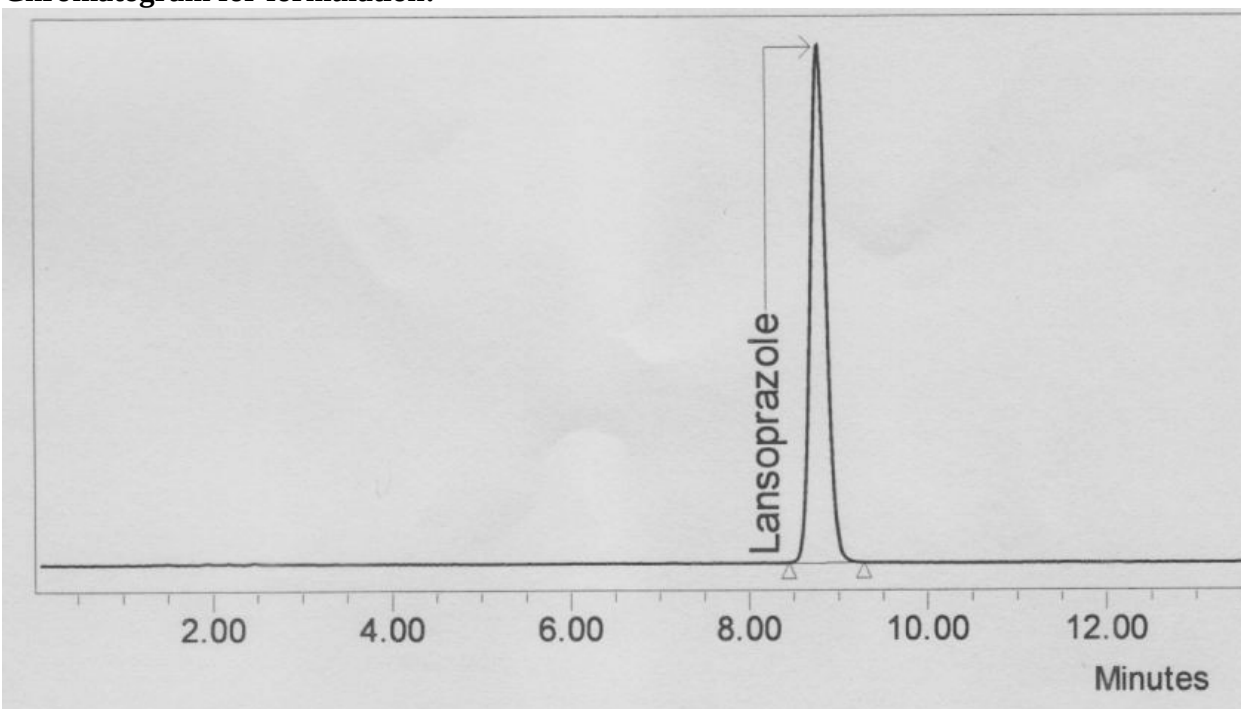


Fig.1

TABLE: 1
Analysis of formulation : Prevacid.
Label Claim : Lansoprazole 30 mg

Drug	Std. wt (mg)	Sample wt (mg)	Avg. wt (mg)	LC (mg)	Std. Area	Sample Area	Amount Present (mg)	% Assay
Lansoprazole	50.02	60.1	32.05	30.0	2150919	2149869	30.02	100.06%

Method Validation:

Linearity and range:

A calibration curve was constructed from five non-zero samples covering the total range of 40-60 µg/ml. The peak area was plotted versus the concentration. The resultant calibration curve with a linear regression coefficient of 0.9992.

Precision:

Intra-assay precision (repeatability) and inter-day (intermediate) precision were determined. The analyses were performed using concentration at five levels, 40,45,50,55, and 60µg/ml. Each concentration was analyzed in triplicate (n = 3) and intra-assay precision was found to be less than 2 % relative standard deviation (RSD) for all samples on all days. Inter-day precision % RSD for analyses conducted on three separate days was found to be less than 2% RSD for the low, middle, and high concentrations studied.

Accuracy:

Accuracy was determined at five concentrations, similar to those used to assess the precision of the method. Each of the solutions was analyzed and the percentage standard deviation was determined. The method showed percentage RSD of less than 2 for all solutions tested which indicated good accuracy of the method.

Robustness:

Robustness was determined by varying the mobile phase flow rate to ±2 min (i.e., 0.8, 1, and 1.2 ml/min), and the ratio in the mobile phase to ±2 ml (phosphate buffer: acetonotrile as 28:72, 30:70, and 32:68). The deliberate changes in the flow rate, and mobile phase ratio did not affect the recovery of the drug which indicated the robustness of the method.

TABLE: 2
Validation Parameters:

	VALIDATION PARAMETER	LANSOPRAZOLE
S. Suitability	Theoretical Plates	4798
	Tailing Factor	1.164
Accuracy	% Recovery	98.74
Linearity	Co-eff. of variation	0.9992
Precision	Intra day: % RSD	0.16
	Inter-day:%RSD	0.27
Robustness	M.P.Ratio: % RSD	1.29
	F. RATE: % RSD	1.23

RESULTS AND DISCUSSION

The developed RP-HPLC method for estimation of Lansoprazole from combined dosage form utilizing C8 column and 0.5 % phosphate buffer and acetonitrile in the ratio of 30:70 as mobile phase. Detection of eluent was carried out using UV detector at 285nm. The method was developed. The run time per sample is just 12 min. Mean retention time of Lansoprazole was found to be 8.82 min. The excipients in the formulation did not interfere in the accurate estimation of Lansoprazole. The method was validated as per ICH guidelines in terms of linearity, accuracy, specificity, intraday and interday precision, repeatability of measurement of peak area as well as repeatability of sample application and the results are shown in [Table –2]. Since none of the methods is reported for estimation of Lansoprazole in dosage form, this developed method can be used for routine analysis of two components in formulation.

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