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ESTIMATION OF LANSOPRAZOLE IN PURE FORM AND IN PHARACEUTICAL DOSAGE FORMS BY RP–HPLC

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ABSTRACT

A simple and precise reverse phase high performance liquid chromatography (RP–HPLC) method is described for the estimation of lansoprazole in pure from as well as in pharmaceutical dosage forms. Chromatography was carried out using a RP C–18 column in isocratic mode, with mobile phase comprising 0.02 M potassium dihydrogen phosphate buffer (pH adjusted to 4.0 with ortho–phosphoric acid) and methanol in the ratio 40 : 60 (v/v). The flow rate was 1.0 mL/min and eluents were monitored at 254 nm. The retention time of Lansoprazole was found to be 1.84 min. The method produced linear response in the concentration range of 0.3–60 µg/mL and the percentage of recovery was ranged from 99.8–100.6. The method was found to be applicable for routine quality control analysis of lansoprazole in pharmaceutical dosage forms.

Key words: RP–HPLC, Lansoprazole, Pharmaceutical dosage forms.

INTRODUCTION

Lansoprazole[1] is an anti ulcer drug. Chemically, it is known as 2–(((3–methyl–4–(2,2,2–trifluoromethoxy)–2–(pyridinyl)–methyl) sulfinyl)–1H–benzimidazole. It acts by inhibiting the enzyme H^+, K^+ ATPase, that is responsible for gastric acid secretion. Literature survey reveals that few HPLC[2–8] methods were reported for the estimation of lansoprazole in human plasma, hence, an attempt was made to develop a simple and precise RP–HPLC method for the estimation of lansoprazole in pure form as well as in pharmaceutical dosage forms.

EXPERIMENTAL

Instrumentation

HPLC measurements were carried out by using a Waters assembly (Water, Milford, MA, USA) equipped with a model 600 controller pump. Detection was carried out with a model 996 photodiode array detector (PDA). The acquisition and treatment of data were made with

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MILLENIUM version 3.1software on Pentium computer. The injector was a 20 µL Rheodyne valve. The column was kept at 30°C using a Water column heater catridge, model 600.

Chemicals and reagents

Lansoprazole was a gift sample from Dr. Reddy's Laboratories, Hyderabad, India. Capsules of lansoprazole [LANZOL30 mg (Cipla) and LEVANT 30 mg (Ranbaxy)] were purchased from the local market. HPLC grade methanol. (E. Merck India LTD, Mumbai), Potassium dihydrogen phosphate of AR grade (Rankem Ltd) and triple distilled water were used for preparing the mobile phase.

Chromatographic conditions

The chromatographic column used ws a 250 x 4.6 mm Partisil C–18 with 5 µm particles. The mobile phase used was 0.02M potassium dihydrogen phosphate buffer (pH adjusted to 4.0 with ortho–phosphoric acid) : methanol (40 : 60 v/v). Both buffer and methanol were filtered through 0.4 µ membrane filter and sonicated before use. The flow rate of the mobile phase was maintained at 1 mL/min. The column was maintained at 30°C and the eluents were monitored at a wavelength of 254 nm. The injection volume was 20 µL.

Procedure

About 50 mg of pure sample of lansoprazole was weighed accurately and transferred to a 50 mL volumetric flask and dissolved in 25 mL of the mobile phase. The solution was sonicated for 15 min and then the volume made up with a further quantity of the mobile phase to get 1 mg/mL solution. Subsequent dilutions of this solution ranging from 0.3 to 60 µg/mL were made in 10 mL volumetric flasks. 20 µL of the each solution was injected five times into the column at a flow rate of 1 mL/min. Evaluation of the drug was performed with PDA detector at 254 nm. Peak area was recorded for all the peaks. The plot of peak area versus the respective concentration gives the calibration curve. The regression of drug concentration over peak area was computed. This regression equation was used to estimate the amount of lansoprazole in pharmaceutical dosage forms.

Assay of lansoprazole in capsule dosage forms

Two commercial brands of capsules (LANZOL, LEVANT) were chosen for testing suitability of the proposed method to estimate lansoprazole in capsule dosage forms. Capsule powder equivalent to 100 mg was taken in 100 mL volumetric flask and 20 mL mobile phase was added. The solution was sonicated for complete solubility of the drug, make up to the mark with the mobile phase and filtered through a 0.4 µ membrane filter. From the filtrate, different aliquots were taken in separate 10 mL volumetric flasks. The contents of the flask were made up to the volume with the mobile phase and mixed well. Each of these solutions (20 µL) was

then injected into the column. From the peak areas, the drug content in the capsules was quantified using the regression equation obtained from the pure sample.

RESULTS AND DISCUSSION

In the selected optimal experimental conditions (Buffer : Methanol 40 : 60 v/v, 1 mL/min, 30°C) Lansoprazole exhibited a well defined chromatographic peak with a retention time of 1.85 min. In Fig. 1, a typical chromatogram obtained under this conditions is shown.

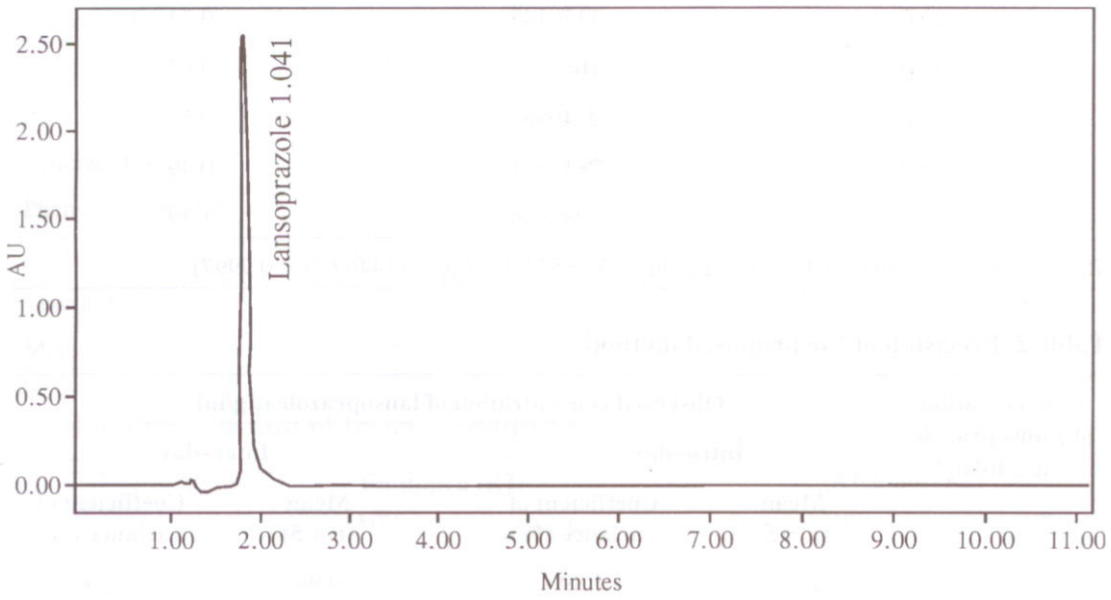

Fig. 1. Model chromatogram for Lansoprazole

The peak areas, from different concentrations set up as above, were reproducible as indicated by low coefficient of variation (1.39%) is shown in Table 1. A good linear relationship was ($r = 0.9997$) was observed between the concentration of the lansoprazole and the respective peak area. The regression curve was constructed by linear regression fitting and its mathematical expression was $Y = 55376.18\ X + 13446.6$ (where Y is the peak area and X is the concentration of the lansoprazole). The intra–day and inter–day variations of the method were determined using five replicate injections of three different concentrations, which were prepared and analyzed on the same day and three different days over a period of two weeks, a low coefficient of variation was observed (Table 2). This shows that the present HPLC method is highly precise.

Table 1. Calibration of the proposed method

Concentration of Lansoprazole (μg/mL)	Mean peak area (n = 5)	Coefficient of variation (%)
0.3	15740	0.63
3.0	163275	0.75
5.0	298835	0.31
10.0	562679	1.15
20.0	1130148	0.23
30.0	1688546	0.67
40.0	2249867	0.54
50.0	2815611	0.49
60.0	3284939	1.39
Regression equation (from 0.3 to 60 μg/mL); Y = 55376.18 X + 13446.6 (r = 0.9997)		

Table 2. Precision of the proposed method

Concentration of Lansoprazole (μg/mL)	Observed concentration of lansoprazole (μg/mL)			
	Intra–day		Inter–day	
	Mean (n = 5)	Coefficient of variance (%)	Mean (n = 5)	Coefficient of variance (%)
10	10.01	1.89	9.99	2.50
20	20.12	1.25	20.08	1.82
40	40.05	0.91	40.00	0.65

To ensure the reliability and accuracy of the method, recovery studies were carried out by mixing a known quantity of drug with preanalyzed sample and contents were reanalyzed by the proposed method. The values are shown in Table 3. About 99.8% of lansoprazole could be recovered from the preanalyzed smaple indicating the high accuracy of the proposed HPLC method.

The drug content in the capsules was quantified using the proposed analytical method. The mean amount of lansoprazole in two different brands of capsule dosage forms is shown in Table 4. The absence of additional peaks in the chromatogram indicates the non interference of the common excepients used in the capsules. The capsules were found to contain 99.5 to 99.9% of

the drug. It can be concluded that the proposed HPLC method is sufficiently sensitive and reproducible for the analysis of lansoprazole in pharmaceutical dosage forms within a short analysis time. The method was duly validated by evaluation of the required parameters.

Table 3. Results of recovery study

Amount of drug added (μg)	Recovery from drug solution		Recovery from capsule solution	
	Mean amount found (n =5)	Mean % recovery	Mean amount found (n =5)	Mean % recovery
10	9.99	99.9	9.98	99.8
15	15.04	100.26	15.09	100.6
30	29.95	99.83	29.97	99.9

Table 4. Assay of lansoprazole in capsule dosage forms

Brand name of the capsule	Labeled amount of drug (mg)	Mean (± s.d.) amount (mg) found by the proposed method (n = 5)	Mean (± s.d) labeled amount (n = 5)
LANZOL	30	29.85 ± 0.21	99.9 ± 0.75
LEVANT	30	29.97 ± 0.17	99.9 ± 0.61

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