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Development and Validation of Analytical Method for the Assay of Lansoprasole In Marketed Tablet Formulation By RP-HPLC

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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 Methanol and 0.1% OPA (Ortho Phosphoric Acid) in the ratio of 70:30. The column used was C18 and 250 mm length with flow rate of 1.2 ml / min using UV detection at 285nm. The described method was linear over a concentration range of 10-50 µg/ml for the assay of Lansoprazole. The retention time of Lansoprazole was found to be 6.6 min, and all the 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.

Keyword: Lansoprazole, HPLC, Tablets, Assay, UV, Standard, Validation, Linearity, Accuracy, Precision, Ruggedness.

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INTRODUCTION

Lansoprazole, chemically known as 2-[[3-methyl- 4-(2,2,2-trifluoroethoxy) pyridin-2-yl] methylsulfinyl] -1H-benzimidazole. (Mol. Formula: C16H14F3N3O2S, Mol.wt: 369.36, CAS no 103577-45-3)[1, 2]. Lansoprazole is 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 no erosive gastro phageal reflux disease [3, 4]. 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 hyper secretory conditions, such as Zollinger-Ellison syndrome [5-7].

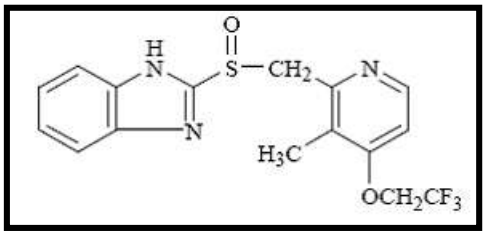

Figure 1 : Chemical Structure of Lansoprazole

From literature review it's found that lot of work was done on UV method development for lansoprazole [5, 6]. Moreover one method on UV spectrophotometry for simultaneous estimation of lansoprazole their combined dosage form has also been reported [7]. But very few methods were reported on estimation of lansoprazole in tablet dosage form for HPLC method [8, 9, 10]. The literature review reveals, few analytical methods reported for the determination of lansoprazole individually, in various biological fluids as well as dosage forms [11, 12]. The aim of the present work was to develop easy, economic, accurate, specific and precise RP-HPLC method for estimation of Lansoprazole in bulk and validation of the newly developed analytical method.

MATERIALS AND METHOD

Material

Lansoprazole was obtained as a gift sample from Alkem laboratories, Mumbai. Lansoprazole tablets were procured from local pharmacy. Mobile Phase was used as diluent of analytical grade. Freshly prepared solutions were employed.

Instruments and Chromatographic Condition

The Chromatographic system consisted of a Agilent Binary pump LC-10ATvp, SIL-10ADvp Auto sampler, CTO-10Avp Column Temperature Oven, SPD-10Avp UV-Visible Detector. Data acquisition was done using chem Station software. The detector is set at a wavelength of 285 nm. The separation was carried out using a mobile phase consisting of Methanol and 0.1% OPA (Ortho

Phosphoric Acid) in the ratio of 70:30. The column used was C18 and 250 mm length with flow rate of 1.2 ml / min. The mixture was filtered through 0.45 µm membrane (Millipore, Bedford, MA, USA) under vacuum, and then degassed by flushing with nitrogen for 5 min. The mobile phase was pumped isocratically at a flow rate of 1.2 ml/min during analysis, at ambient temperature. The rinsing solution consists of a mixture of 50: 50 % v/v of Acetonitrile: HPLC Grade Methanol.

METHOD DEVELOPMENT [13, 14]**:**

Determination of ƛ max (30 PPM):

100 mg weighed amount of lansoprazole was dissolved into 100 ml of volumetric flask with diluent. Pipette out 3 ml and added in 100 ml of volumetric flask dissolved and diluted up to the mark with diluent. This solution was subjected to scanning between 200-400 nm [15, 16].

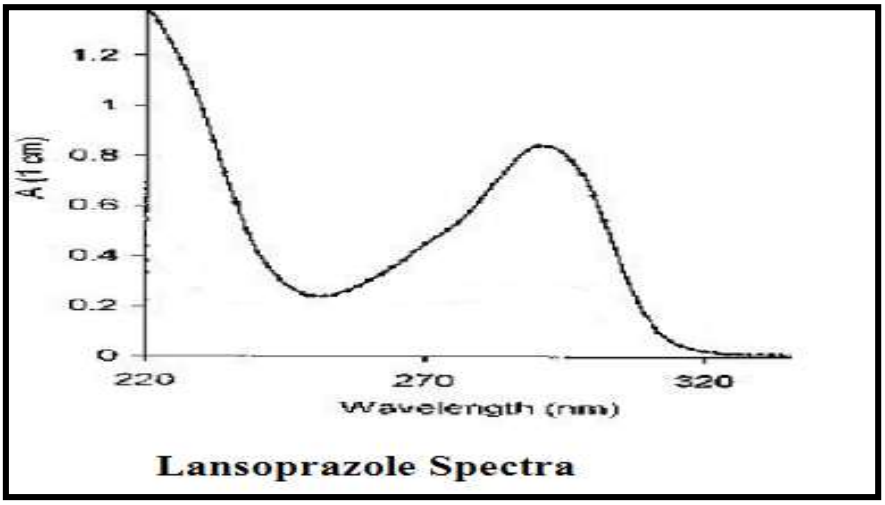

Figure 2 : UV Spectra for Lansoprazole

Preparation of working concentration:

A. Preparation of Standard stock solution:

Standard stock was prepared by dissolving 100 mg of lansoprazole in 100 ml of analytical grade methanol to get concentration of 1000 µg/ml (PPM).

B. Preparation of Standard Solution: (30 PPM)

Pipette out 3 ml from standard stock solution and diluted up to 100ml with diluent to get concentration of 30µg/ml (PPM).

Procedure for sample preparation: (30 PPM)

For analysis of commercial formulations; Twenty tablets are taken weighed it and powdered. The powder equivalent to 100 mg of lansoprazole was accurately weighed and transferred into the 100 ml of volumetric flask, added 60 ml diluent, the solution was sonicated for 20 min. After

sonication cool the flask and diluted upto 100 ml with diluent. Filtered the solution through whatmann filter paper. Pipette out 3 ml of the above solution and diluted up to 100 ml with diluents.

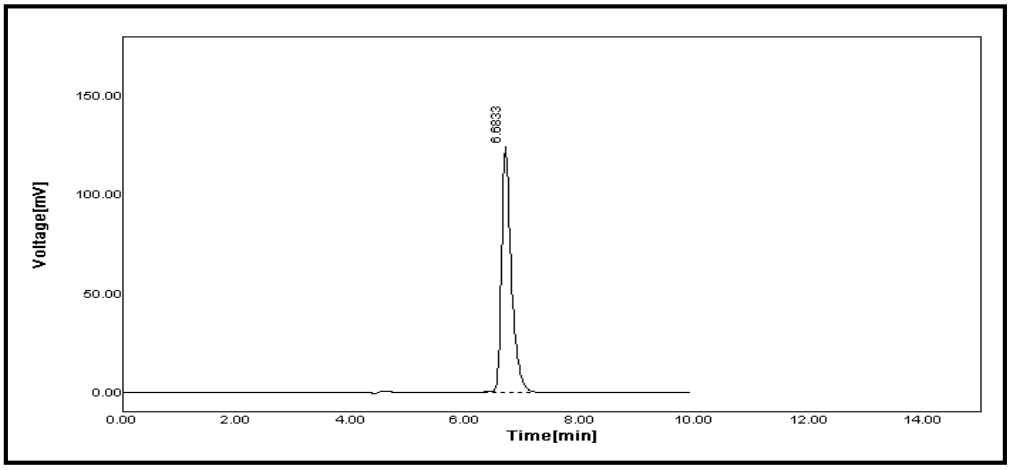

Figure 3:Chromatogram for Lansoprazole Assay

METHOD VALIDATION:

The proposed method was developed by using linearity, accuracy, precision and ruggedness as per ICH guidelines, 1996 [14, 18, 19,].

Linearity:

The linearity of the proposed assay was studied in the concentration range 10 - 50 PPM at 285 nm. The calibration data showed a linear relationship between concentrations.

Table 1: Linearity Studies

Serial No	Sample Concentration	Area
1	10 PPM	511.47
2	20 PPM	1022.94
3	30 PPM	1554.21
4	40 PPM	2054.14
5	50 PPM	2510.26
Correlation Coefficient		**0.999**

Accuracy:

To ensure the accuracy of the method, recovery study was performed by preparing 3 sample solutions of 80, 100 and 120% of working concentration and adding a known amount of active drug to each sample solution and dissolved in 100ml of volumetric flask with diluent and measuring the absorbance at 285nm.

Table 2: Accuracy Studies

Spectrophotometric Method			
Accuracy (%)	**Conc. Added (PPM)**	**Conc. Found (PPM)**	**Recovery (98-102%)**
80	24	23.5	98
100	30	30.4	99
120	36	36.5	101

Precision:

The precision of the method was demonstrated by inter-day and intra-day variation studies. Five sample solutions were made and the % RSD was calculated.

Table 3: Precision Studies

Sr. No.	**Sample Solution**	**Area**
1	Sample solution-1	1527.58
2	Sample solution-2	1530.57
3	Sample solution-3	1529.25
4	Sample solution-4	1528.96
5	Sample solution-5	1531.47
Mean		1529.57
SD		1.5037
% RSD		0.0983

Ruggedness:

Ruggedness is a measure of the reproducibility of a test result under normal, expected operating condition from instrument to instrument and from analyst to analyst.

Table 4: Results for Ruggedness Studies

	Analyst	**Results**	**Mean**	**% Assay**	**% RSD**
1	Analyst 1	1532.54 1531.74	1532.14	99.97	1.01
2	Analyst 2	1530.45 1532.75	1531.6	98.55	

RESULTS AND DISCUSSION

Solubility of lansoprazole

Solubility test was passed as per criteria.

Table 5: Results for solubility studies

Sr. no.	**Title**	**Result**
1	Dimethyl formaldehyde [DMF]	Freely Soluble
2	Methanol	soluble
3	Ethanol	Sparingly soluble

Results for linearity for assay method of lansoprazole

The linearity of method was determined at concentration level ranging from 10 to 50 µg/ml (PPM). The correlation coefficient value was found to be **(R^2) 0.999.**

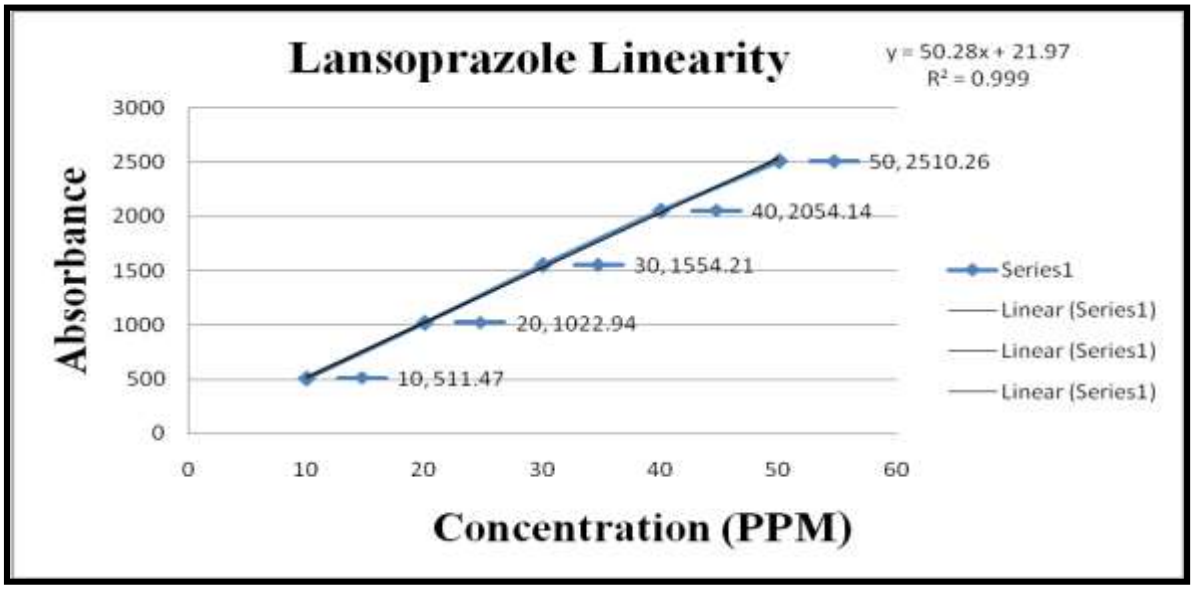

Figure 4: Lansoprazole Standard Curve

Results for accuracy for assay method of lansoprazole

The accuracy of the method was determined by recovery experiments. The recovery studies were carried out and the percentage recovery were calculated and represented in Table - 3. The high percentage of recovery indicates that the proposed method is highly accurate. Accuracy results were found within acceptance criteria that are within 98-102%.

1. Results for precision for assay method of lansoprazole

The % RSD for different sample of precision was found to be 0.1 and it is within acceptance criteria represented in Table - 4.

2. Results for ruggedness for assay method of lansoprazole

The %RSD for different sample of ruggedness was found to be 01.01 and it is within acceptance criteria represented in Table - 5.

LINEARITY CHROMATOGRAMS

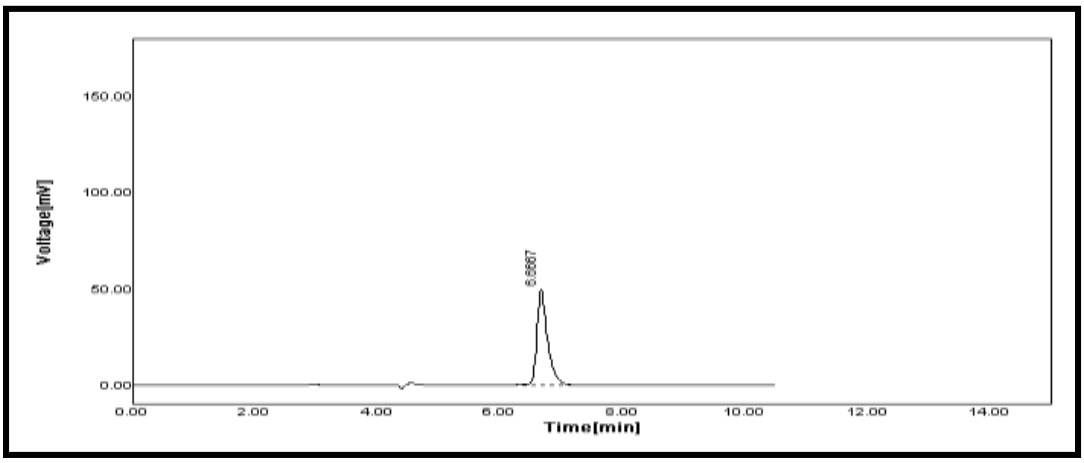

Figure 5 : Chromatogram for 10PPM

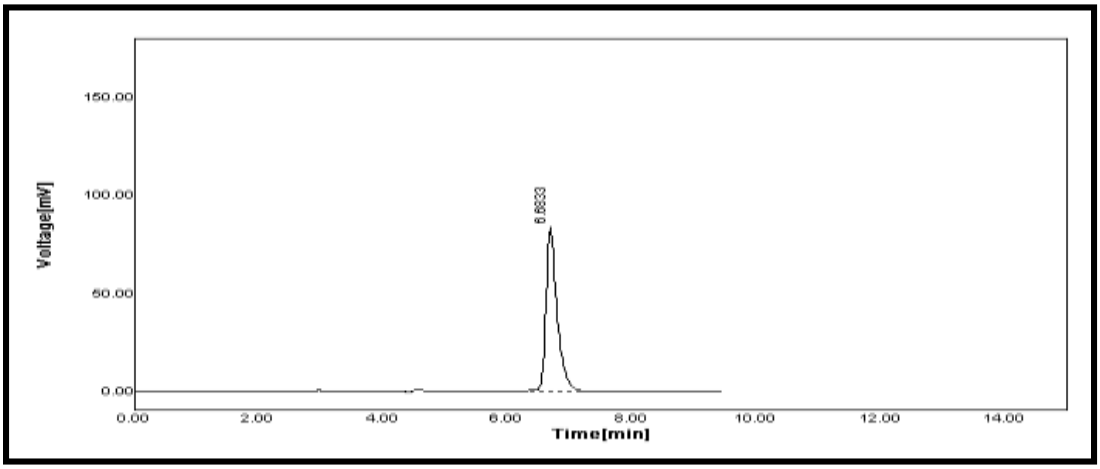

Figure 6 : Chromatogram for 20PPM

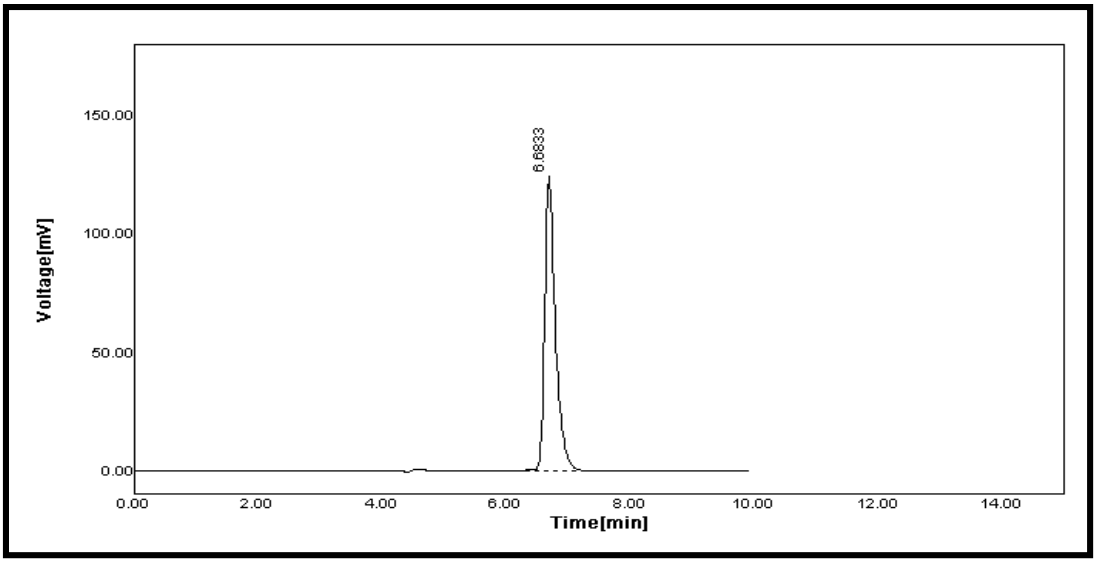

Figure 7 : Chromatogram for 30PPM

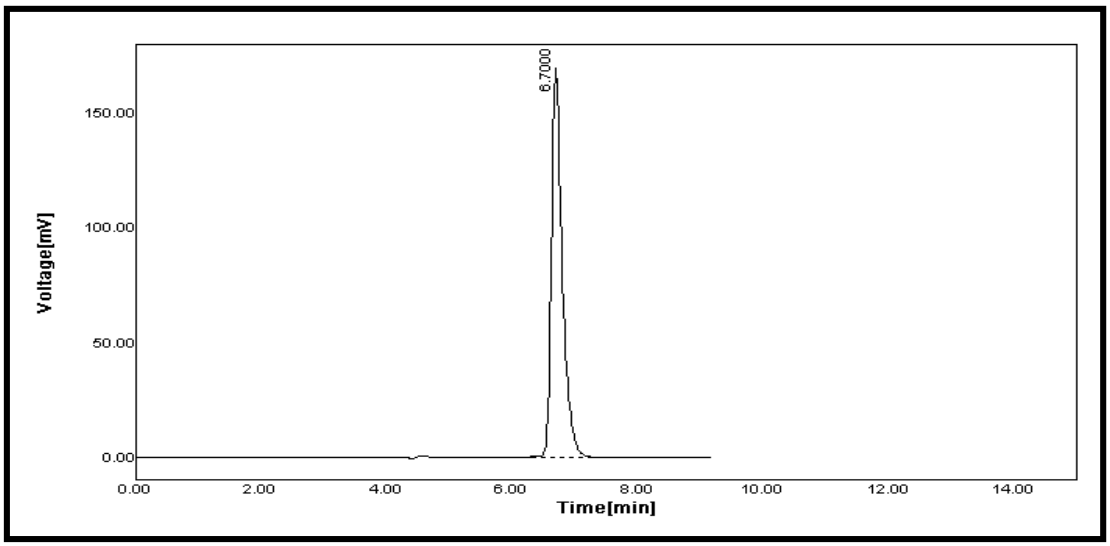

Figure 8 : Chromatogram for 40PPM

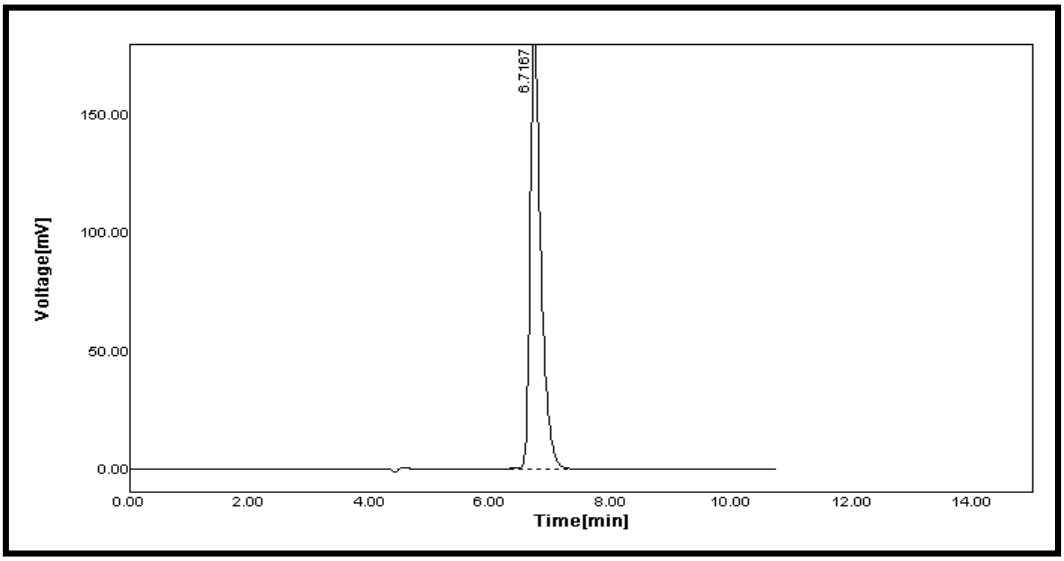

Figure 9 : Chromatogram for 50PPM

CONCLUSION:

A method for the estimation of lansoprazole in tablet form has been developed. From the spectrum of lansoprazole, it was found that the maximum absorbance was 285 nm in mobile phase. A good linear relationship was observed in the concentration range of 10-50 µg/ml (PPM). The high percentage recovery indicates high accuracy of the method. This demonstrates that the developed spectroscopic method is simple, linear, accurate, rugged and precise for the estimation of lansoprazole in solid dosage forms. Hence, the method could be considered for the determination of lansoprazole in solid dosage form at quality control laboratories.

ABBREVARTIONS

1. PPM - Parts per Million

2. nm - Nanometer
3. HPLC - High Performance Liquid Chromatography
4. UV - Ultra violet
5. HBV - Hepatitis B virus
6. DNA - Deoxyribonucleic acid
7. HIV - Human Immunodeficiency Virus
8. ICH - International Council for Harmonization
9. RSD - Relative Standard Deviation
10. SD - Standard Deviation
11. Qty - Quantity
12. C - Celsius
13. M.D. - Manufacturing Date
14. E.D. - Expiry Date
15. RP – Reverse Phase
16. HPLC – High Performance Liquid Chromatography

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