Available online at www.ijpsdr.com
International Journal of Pharmaceutical Sciences and Drug Research 2013; 5(3): 105-107

Research Article ISSN 0975-248X

Validated RP-UPLC Method Development for Estimation of Lansoprazole in Tablet Dosage Form

Singh Sunil*, Choudhary Nisha, Rai Jyoti, Inamullah, Sharma Surabhi, Yadav Ajit Kumar, Gautam Hemendra, Chaturvedi Shashank, Agrawal Vipin Kumar

Department of Pharmaceutical Chemistry, Invertis Institute of Pharmacy, Invertis University, Bareilly, Uttar Pradesh, India

ABSTRACT
A simple, sensitive and precise isocratic ultra performance liquid chromatographic method for the analysis of Lansoprazole has been developed, validated and used for the determination of compounds in commercial pharmaceutical products. The separation was carried out isocratically on a C_{18} column utilizing a mobile phase consisting of methanol: water (80:20 v/v) at a flow rate of 1.0 mL/min with UV detection at 284 nm. The retention time of Lansoprazole was found to be 3.905 min. The described method was linear over a concentration range of 50-30 µg/ml (r^2 =0·998) for the assay of Lansoprazole. Results of analysis were validated statistically. The results of the study showed that the proposed RP-UPLC 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-UPLC, Method validation and Tablets.

INTRODUCTION

Lansoprazole [1], (Fig. 1) chemically known as 2-[[3-methyl-4-(2,2,2-trifluoroethoxy) pyridin-2-yl] methylsulfinyl] -1H-benzimidazole. Lansoprazole, a member of the proton-pump-inhibitor class of gastric acid inhibitory agent, effectively raises intra gastric pH and is indicated for the short-term treatment of active erosive reflux esophagitis, gastric ulcer, duodenal ulcer, and non erosive gastro esophageal 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. [2]

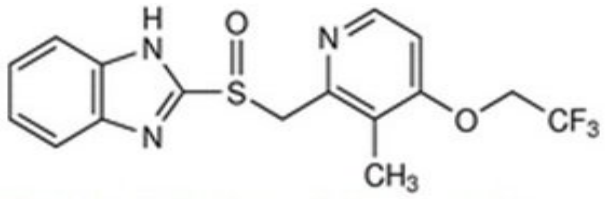

Fig. 1: Chemical structure of Lansoprazole

***Corresponding author: Mr. Sunil Singh,**
Invertis Institute of Pharmacy, Invertis University, Invertis Village, Bareilly-Lucknow Ultraway-24, Bareilly-243123, Uttar Pradesh, India; **Tel.:** +91-8859120888;
E-mail: rssunil29@rediffmail.com, cnisha514@gmail.com

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. [3] 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). [4]

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. [5-6] Review of literatures gives different references for method of development for Lansoprazole and methods regarding development. [7-14] For the estimation of Lansoprazole in tablet dosage form, hence we attempted to develop a simple, accurate, and economical analytical method. This paper describes validated RP-UPLC for estimation of Lansoprazole in tablet dosage form, this paper.

MATERIALS AND METHOD

Drugs and chemicals

Table 1: Analysis of commercial formulation

Drug	Std. wt (mg)	Sample wt (mg)	Avg. wt (mg)	LC (mg)	Std. Area	Sample Area	Amount present (mg)	% Assay
LAN	50.02	60	31.05	30.0	497088	486191	30	100.23%

Table 2: System suitability parameters for RP-UPLC method

Parameter	LAN
Calibration range, µg/ml	5-30
Regression coefficient r^2	0.998
Theoretical plate	3725
Retention time	3.905
Tailing factor	1.098
Asymmetric factor	1.17
HEPT[a]	0.0091
Capacity factor	1.42

Table 3: Validation parameter for RP-UPLC

S. No	Parameter (units)	LAN
1.	**Accuracy**	
	(80%)	82% ± 0.0101
	(100%)	82% ± 0.0051
	(120%)	88% ± 0.0001
2.	**Interday precision**	
	(1^{st} day)	85% ± 0.0031
	(2^{nd} day)	83% ± 0.0003
	(3^{rd} day)	84% ± 0.0035
3.	**Intraday precision**	
	1^{st} hrs	86 ± 0.0069
	2^{nd} hrs	83 ± 0.0015
	3^{rd} hrs	84 ± 0.0069
4.	**LOD**	0.8937
5.	**LOQ**	2.979
6.	**Robustness**	92%±0.005786

Lansoprazole was procured from Lupin pharmaceuticals limited, Pune, India. Methanol and other chemicals were used GR grde. The pharmaceutical dosage form used in this study was junior lanzol-30 labelled to contain 30mg Lansoprazole.

Apparatus

Shimadju LC ETAP UPLC system

The LC system consists of pump (Shimadzu LC-260 AD) with universal loop injector (Helminton syringe) of injection capacity 20µL. Detector consists of photodiode array detector (PDA) for separation column used was phenomenex luna C_{18} (5µm×25cm×4.6mm). The equipment was controlled by a PC work station equipped with LC Solution software. The volume capacity of the reservoir was greater than 500 ml. The mobile phase velocity was within 1-2 ml/min.

Preparation of mobile phase

The mobile phase was prepared by mixing 80ml methanol with 20ml water. Further the method was optimized by changing the concentration of mobile phase and the results are reported. From the study it was found that best result was obtained in a quality separation in terms of peak symmetry, resolution, reasonable run time and other parameters by use of 80:20(v/v) ratio mixture of methanol: water as mobile phase. The flow rate was determined by testing the effect of different flow rate on the peak area and resolution, flow rate of 1 ml/min found optimum. The mobile phase was sonicated for 15 min and then it was filtered through a 0.45 membrane filter paper.

Preparation of standard stock solutions

The standard stock solution of 1000µg/ml of LAN was prepared by accurately weighing 50mg drug separately in methanol in 50ml volumetric flask. The working dilutions were in the range of 5-30µg/ml for LAN respectively and prepared by further dilutions for calibration curves.

Preparation of standard solutions for linearity study

A calibration curve was plotted over a concentration range of 5-30µg/ml for LAN. Accurately measured standard stock solution of LAN (0·5, 1·0, 1·5, 2·0, 2·5, 3·0) were transferred to a separate series of 10mL of volumetric flask and diluted to the mark with methanol. From the standard stock solutions different dilutions were prepared for each drug having concentration. Then 20µL of these solutions were injected into the LC system with the help of Hamilton syringe. Then the chromatograms were recorded at 284nm, from the chromatogram it was cleared that LAN retention time 3.905 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 methanol and filtered through a membrane filter (0.45µ). The residue was washed twice with solvent and the combined filtrate was made up to 100ml mark. After that 10 ml of the above solution was diluted up to 100 ml solvent. Six replicate of sample solutions were prepared of required concentrations. Then 20uL of each replicate were injected into the system and their chromatograms were recorded. From the chromatograms it was observed that LAN was eluted at 3.905 min respectively. A representative chromatogram has been given in Fig. 2. 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 and system suitability parameters for Lansoprazole is reported in Table 1 & 2.

Method Validation

Recovery studies

To study the accuracy of the proposed methods, recovery studies were carried out by standard addition method at three different levels (80%, 100% and 120% of the test concentration as per ICH guidelines). A known amount of drug was added to pre analyzed capsule powder and percentage recoveries were calculated. The result of recovery studies was satisfactory **(Table-3).**

Linearity and range

The linearity of Lansoprazole was found within range between 5-30µg/ml.

Precision

The precision of the method, as intra-day repeatability was evaluated by performing six independent assays of the test sample preparation and calculating the %RSD. The intermediate (interday) precision of the method was checked by performing same procedure on different days by another person under the same experimental conditions as shown in Table 3.

LOD and LOQ

The LOD and LOQ of Lansoprazole are calculated by Mathematical equation.

LOD= 3.3×standard deviation ÷ slope

LOQ=10×standard deviation ÷ slope

The LOD of Lansoprazole was found to be 0.8937µg/ml and LOQ of Lansoprazole was found to be 2.979µg/ml as shown in Table-3.

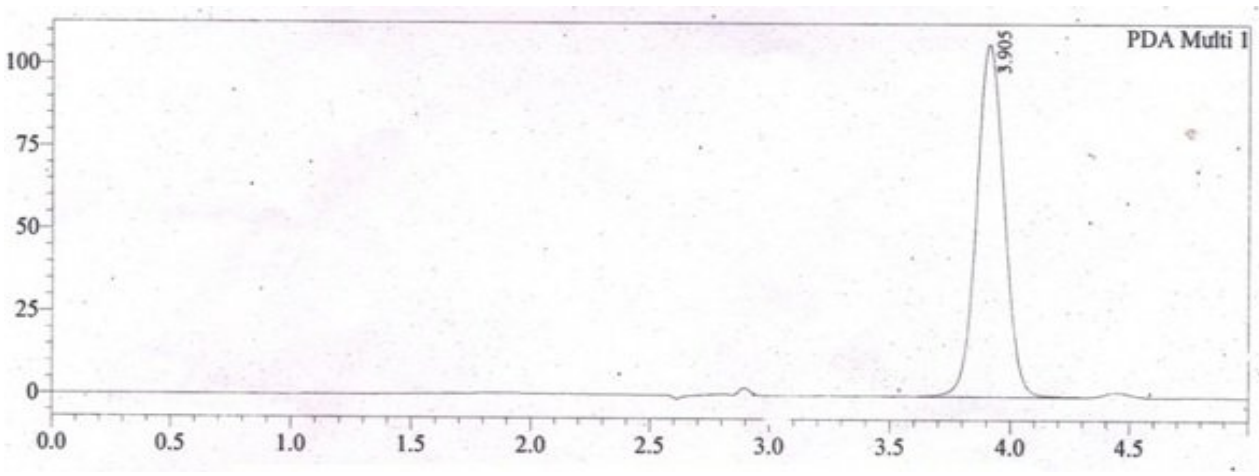

Fig. 2: Chromatogram of Lansoprazole at RT-3.905

Robustness

Robustness of proposed method was performed by changing the UV analyst and remaining condition was keeping constant as shown in Table-3.

RESULTS AND DISCUSSION

The developed RP-UPLC method for estimation of Lansoprazole from combined dosage form utilizing C_{18} column with a mobile phase consisting of methanol: water (80:20 v/v) at a flow rate of 1.0 mL/min. Detection of eluent was carried out using UV detector at 284nm. The method was developed. The run time per sample is just 10 min. Mean retention time of Lansoprazole was found to be 3.905min. 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 3. Since none of the methods is reported for estimation of Lansoprazole in dosage form, this developed method can be used for routine analysis of components in formulation.

Thus it can be concluded that Lansoprazole can be quantified by the proposed RP-UPLC method using an isocratic mobile phase consisting of water:methanol (20:80) using a UV detector at 284nm. The proposed method is simple, sensitive, rapid, accurate and precise. It can be applied successfully for the estimation of Lansoprazole in bulk and its pharmaceutical formulations

ACKNOWLEDGEMENT

The authors are thankful to Lupin pharmaceuticals limited, Pune, India for provided the gift sample of Lansoprazole and also thankful to the management, Invertis Institute of Pharmacy, Invertis University, Bareilly to providing the equipment and facility for entire duration of research work.

REFERENCES

1. Brummer RJ, Geerling BJ, Stockbrugger RW. Initial and chronic gastric acid inhibition by Lansoprazole and Omeprazole in relation to meal administration. Digestive Disease and Sciences. 1997; 42(2):132–137.
2. Tang G, Serfaty-Lacronsniere C, Camilo ME, Russell RM. Gastric acidity influences the blood response to a beta-carotene dose in humans. Americal Journal of Clinicle Nutrition. 1996; 64(6):22–26.
3. Tolman KG, Sanders SW, Buchi KN, Karol MD,Jennings DE, Ringham GL. The effects of oral doses of Lansoprazole and omeprazole on gastric pH. Journal of Clinicle Gastroenterology. 1997; 24:65-70.
4. Fitton A, Wiseman L, Pantoprazole: A review of its pharmacological properties and therapeutic use in acid-related disorders. Drugs. 1996; 51:460–482.
5. Matheson AJ, Jarvis B. Lansoprazole: An update of its place in the management of acid-related disorders. Drugs. 2001; 61:1801–1833.
6. Bown RL. An overview of the pharmacology, efficacy, safety and cost-effectiveness of Lansoprazole. International Journal of Clinicle Practice. 2002; 56:132-139.
7. Karol MD, Granneman GR, Alexander K. Determination of Lansoprazole and five metabolites in plasma by ultra-performance liquid chromatography. Journal of Chromatography B: Biomedical Sciences and Applications. 1995; 9:182-186.
8. Singh S, Patel K, Agarwal VK, Chaturvedi S. Stability Indicating HPTLC Method for Simultaneous Determination of Valsartan and Hydrochlorothiazide in Tablets. International Journal of Pharmacy and Pharmaceutical Sciences. 2012; 4(4):68-471.
9. Singh S, Patel K, Agarwal VK, Chaturvedi S. Simultaneous estimation of S(-) Amlodipine Besylate Hemipentahydrate and Losartan Potassium in Combined Dosage Form by Using UV-Spectroscopy. Der Pharmacia Lettre. 2002; 4(3):897-905.
10. Singh S, Yadav AK, Gautam H. First Order Derivative Spectrophotometric Determination of Telmisartan in Pharmaceutical Formulation. Bulletin of Pharmaceutical Research. 2012; 2(2):83-86.
11. Singh S, Dubey N, Jain DK. Simultaneous estimation of cefpodoxime proxetil and clavulate potassium combined dosage form using UV-Spectroscopy and reverse phase liquid chromatography. International Journal of Biomedical and Pharmaceutical Sciences. 2011; 5(1):57-60.
12. Patel K, Singh S, Sahu P, Trivedi P. Development and validation of stability indicating assay method for naratriptan by ultra performance liquid chromatography. Der Pharmacia Lettre. 2011; 3(6):102-107.
13. Singh S, Yadav AK, Gautam H. Simultaneous Estimation of Valsartan and Hydrochlorothiazide in Solid Dosage Form Using UV Spectroscopy. Bulletin of Pharmaceutical Research. 2011; 1(3):10-12.
14. Singh S, Dubey N, Jain DK. Simultaneous Estimation of Atorvastatin, Clopidogrel and Aspirin in Capsule Dosage forms using UV-Spectroscopy. Asian Journal of Research in Chemistry. 2010; 3(4):885-887.