Research Article

Development and Validation of New Analytical Method for Lansoprazole by Area Under Curve Processing

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ABSTRACT

Estimation of Lansoprazole by area under curve method has been developed. The spectrophotometric technique for the estimation of Lansoprazole by area under curve method was carried using methyl alcohol as solvent. The absorbance maximum was 275nm. Beers law obeyed in the range of 30-150µg/ml concentration. The recovery studies determined the accuracy of the purposed technique and the results were established as per ICH guidelines. The results were got satisfactory. The technique was used successfully for the estimation of Lansoprazole in tablet and pure dosage form.

Keywords: Lansoprazole, Area under curve method, Lansoprazole, determination, analytical method.

INTRODUCTION

Lansoprazole is a proton-pump inhibitor (PPI's) belonging to gastric acid inhibitory agents. It powerfully increases intra gastric pH. It is used for short time treatment of active erosive reflux esophagus infection, wounds in the stomach and also in duodenal part of small intestine. This medicine also indicated in long-term controlling action in patients with reflux esophagus infection and to cure duodenal ulcer and in the therapy Zollinger-Ellison syndrome[1-4]. So far only four methods have been reported for the determination of Lansoprazole in pharmaceutical preparations. Literature includes one UPLC method[1], one UV spectrophotometric method[2] and two HPLC methods.[3-4]

Structure

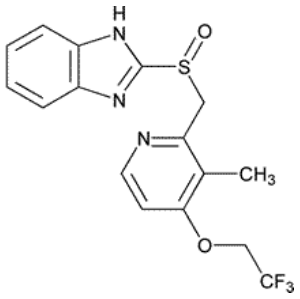

Figure 1: Chemical Structure of Lansoprazole

MATERIAL AND METHODS

a) Materials

Standard drug: Gift sample of Lansoprazole

Tablet Formulation: Brand A- Lanzol 15 (Cipla)

Each Uncoated tablet contains: Lansoprazole IP 15mg

Chemicals and reagents: Methyl Alcohol (AR Grade)

Instrument: A Shimadzu 1800 UV (Shimadzu Japan) spectrophotometer with 1 cm matched quartz cells was used for estimation.

Selection of media: Main criteria of media selection and stability, i.e. drug should be soluble as well as stable for sufficient time in selected media. For present work methanol has been selected as analytical media.

b) Method

Preparation of standard stock solution: The standard stock solution was prepared by taking 50mg of standard powder Lansoprazole pure drug in 25ml of methanol in a 50 ml volumetric flask, shaken vigorously and made the volume up to 50 ml i.e 1000 µg/ml from that solution pipette out 5 ml and added in a another volumetric flask and made the volume up to 50 ml with the help of methanol i.e 100 µg/ml.

Determination of λ max: Taken 5 ml of Lansoprazole from above standard stock solution and transferred into 50 ml volume flask made the volume up to 50 ml i.e 10 µg/ml. The solution was scanned in the UV range 200-400 nm the λ max was found to be 275 nm. The spectrum of Lansoprazole was recorded.

Study of Beer-Lambert's Law

From the standard stock solution of Lansoprazole, appropriate aliquots were pipette out into 50 ml volumetric flask and dilution were made with Methanol to obtain concentrations of 30, 60, 90, 120, 150 µg/ml. The difference in absorbance (dA/dλ) of Lansoprazole were measured in the first derivative mode with n=9 of instrument at 275 nm for Lansoprazole. The calibration curve of the drug was plotted. The concentration range over which the drugs followed linearity was chosen as an analytical concentration range i.e. 30-60 µg/ml for Lansoprazole.

Table 1: Standard calibration table for Lansoprazole at 275 nm

Sr. No.	Conc. µg/ml	Area under curve (AUC)
1	30	10.348
2	60	17.090
3	90	26.197
4	120	34.993

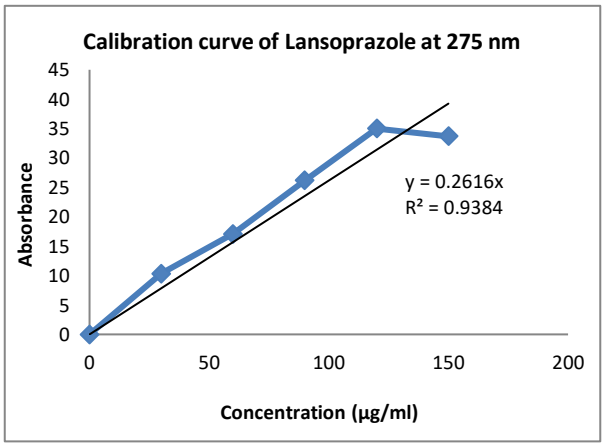

Figure 1: Calibration curve of Lansoprazole at 275 nm

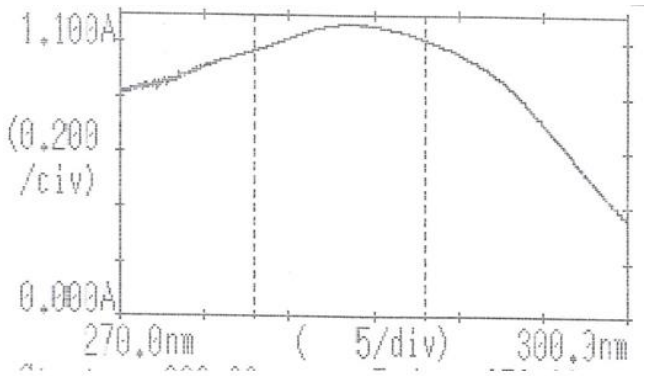

Figure 2: Area under spectrum of Lansoprazole of concentration 30 µg/ml

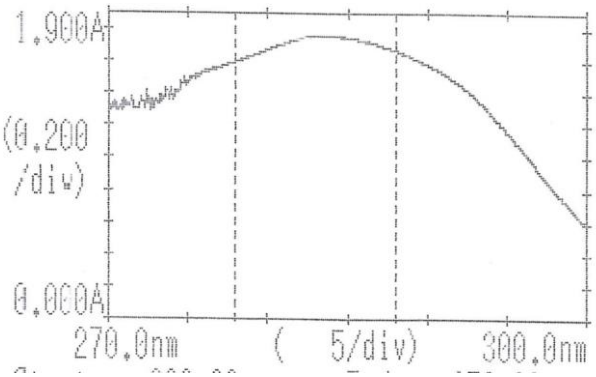

Figure 3: Area under curve of Lansoprazole of concentration 60 µg/ml

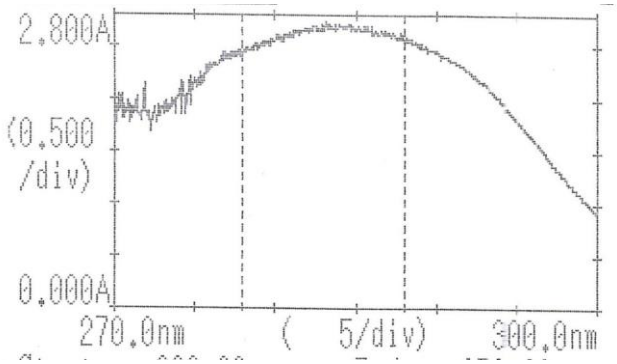

Figure 4: Area under curve spectrum of Lansoprazole of concentration 90 µg/ml.

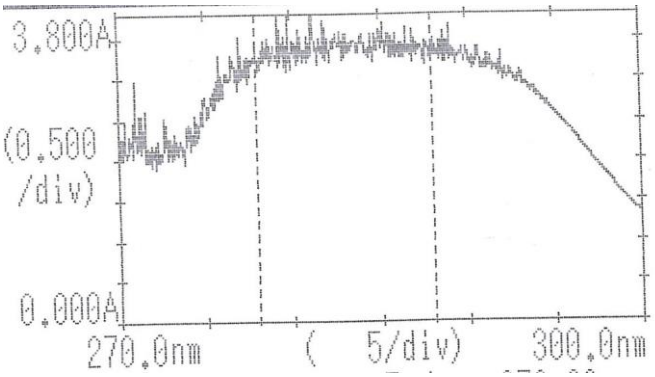

Figure 5: Area under curve spectrum of Lansoprazole of concentration 120 µg/ml.

Table 2: Optimum and regression parameters of the calibration curve

Parameter	Lansoprazole
Linearity range	30-150 µg/ml
Slope	0.21549
Intercept	5.0755
Regression Coefficient	0.938

Validation of proposed method:

A) Estimation of drug from dosage form (Tablet assay study):

Twenty tablets were weighed and finely powdered. A quantity of powder sample equivalent to 15mg of Lansoprazole was taken in volumetric flask and dissolved in methanol. Further dilutions were made to get 50µg/ml of Lansoprazole. These aliquotes were scanned at wavelength of 275nm in Area under curve mode with n=9. The result and statistical parameters for tablet analysis are given below:

Table 3: Assay of Lansoprazole in tablet formulation by AUC method

Drug	Label Claim (mg/tab)	Amount Found (mg/tab)	% of Label claim	Mean %	SD	CV
Lansoprazole	15	15.20	101.33	100.44	0.6640	0.0066
	15	15.12	100.80			
	15	14.92	99.46			
	15	14.95	99.66			
	15	15.12	100.80			
	15	15.09	100.60			

B) Accuracy (Recovery Test)

Accuracy of the method was studied by recovery experiments. The recovery experiments were performed by adding known amounts to tablet. The recovery was performed at three levels 80, 100, 120% of Lansoprazole standard concentration the recover samples were prepared three samples were prepared for each three levels. The solution was then analysed and the percentage recoveries were calculated using formula.

$$\% \text{ Recovery} = \frac{\text{Observed amount of compound in sample}}{\text{Amount of all compound present in sample}} \times 100$$

The recovery values are summarized as below:

Table 4: Results of accuracy parameter of Lansoprazole for tablet dosage form

Level of % Recovery	Amount present (µg/ml)	Amount of standard added (µg/ml)	Total amount recovered (µg/ml)	% Recovery	% mean Recovery	SD	CV
80	15	12	27.52	101.92	101.32	0.4650	0.0046
80	15	12	27.31	101.14			
80	15	12	27.25	100.92			
100	15	15	30.15	100.50	100.43		
100	15	15	30.09	100.30			
100	15	15	30.15	100.50			
120	15	18	33.20	100.60	100.61		
120	15	18	33.15	100.50			
120	15	18	33.25	100.75			

C) Precision Study:

The dilution was made to get concentration of 50µg/ml of Lansoprazole these conc. were scanned at wavelength of 275nm in area under curve mode by four different Analyst. The precision values are summarized as below:

Table 5: Determination of precision of Lansoprazole for AUC method

Sample Number	Assay of Lansoprazole as % of Labelled amount			
	Analyst-1	Analyst-2	Analyst-3	Analyst-4
1	100.25	99.85	99.97	100.12
2	99.95	100.05	100.15	99.80
3	100.10	100.15	99.82	99.96
4	99.94	99.85	99.92	100.15
5	100.20	99.87	100.15	99.95
6	100.05	100.15	99.93	99.85
Mean %	100.08	99.97	99.99	99.97
SD	0.11624	0.13437	0.12179	0.12824
CV	0.0011	0.0013	0.0012	0.0012

RESULTS

The standard solutions of Lansoprazole in methanol (30µg/ml) subjected to scan at the wavelength of 200nm to 400nm at AUC mode and AUC spectra were taken at N=9 using shimadzu 1800 spectronic UV visible spectrophotometer. λmax of Lansoprazole was found to be at 275nm. Therefore, 275nm was selected as λmax for Lansoprazole for the present study. The calibration curve of Lansoprazole was found to be linear in the range of 30-150µg/ml. figure 1.

The technique was subjected to the assay of tablets in marketed dosage brand and adequate results were attained within the acceptable limits as per the content of the label claim for Lansoprazole Table 3.

The recovery experiments were conducted by adding known amounts to tablet. The recovery was performed at three levels 80, 100 and 120% of Lansoprazole standard concentration. The solutions were then analyzed and the percentage recoveries were found to be satisfactory within the acceptable limits as per the content of the label claim for brand Table 4.

The determination range was optimized, accuracy was proved by recovery studies at different concentration levels, precision for Lansoprazole was established through the analysis of samples by four different analyst using same instrument and laboratory Table 5. The method was developed successfully for Lansoprazole in their single dosage form by Area under curve method.

DISCUSSION

Based on the above result, aim of the present study was an attempt for the expansion of analytical techniques for the estimation of some selected single drugs present in their synthetic bulk mixtures and multi-combination formulations for cost efficient custom analysis like dissolution studies, determination of drugs in biological fluids, simultaneous release studies, and simultaneous kinetic studies etc. The other advantage is its applicability for the routine analysis for various routine investigations like dissolutions studies, rate determinations studies, release studies, Pharmaco-kinetic studies, bioavailability studies and other common routine assessment. Another advantage of this technique is its cost-effectiveness and it is the main advantage over high performance liquid chromatographic methods of analytical research. The method employs methyl alcohol as the only solvent and no further reagent is required.

CONCLUSION

The proposed method for selected drug was found to be accurate and precise. However, this method is more reproducible. The results and the statistical parameters reveal that the proposed UV spectrophotometric method is simple, rapid, specific, accurate and precise. The most prominent attribute of spectrophotometric method are their simplicity and rapidity. Result of validation parameters demonstrated that these analytical procedures are suitable for its intended purpose and meets the criteria defined in ICH Q2/B.

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