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ESTIMATION OF LANSOPRAZOLE IN BULK AND FORMULATION BY UV-SPECTROPHOTOMETRIC AREA UNDER CURVE METHOD

M. V. Gadhave[1*], Shamira Patel[1], S. Dhobale[1], S. L. Jadhav[1]

[1]*Department of Quality Assurance Technique, Vishal Institute of Pharmaceutical Education and Research, Ale, Tal- Junnar, Pune, Maharashtra, India.

ABSTRACT

The current work is carried out to for estimation of Lansoprazole in bulk and pharmaceutical dosage form by utilizing area under curve (AUC) method. For this purpose the wavelength range 250-290nm was selected. Distilled water was used as a solvent throughout the work. Linearity was observed in concentration range 2-12µg/ml (r^2 =0.999) for the method. Recovery studies for area under curve were found to be 99.32%. The method developed was validated for linearity, precision, accuracy, LOD, and LOQ as per ICH guidelines[1]. The present method was found to be simple, linear, precise, accurate and sensitive which can be used for routine quality control analysis for spectrophotometric estimation of Lansoprazole in bulk and dosage form.

KEYWORDS

Lansoprazole and Area under curve (AUC).

Author for Correspondence:

Gadhave M. V,
Department of Quality Assurance Technique,
Vishal Institute of Pharmaceutical Education and Research,
Ale, Tal- Junnar, Pune, Maharashtra, India.

Email: luckyshamira1522@gmail.com

INTRODUCTON

Lanosoprazole is a proton pump inhibitor (PPI) and a potent inhibitor of gastric acidity which is widely used in the therapy of gastroesophageal reflux and peptic ulcer disease. Lanosoprazole is unstable at acidic pH values; it must be given in an enteric coated dosage form. The isomer of lansoprazole also has a similar spectrum of activity and toxicities as lansoprazole is Dexlansoprazole. Lansoprazole is an inhibitor of gastric acid secretion and also has antibacterial activity against Helicobacter pylori *in vitro*.

MATERIAL AND METHODS

Chemicals

Lansoprazole was supplied by Macleod's Pharmaceuticals, Sarigam, Gujarat. Lanzol (30) was procured from local pharmacy. Methanol (S.D.) Fine Chemicals, Mumbai, India) was used. All chemicals and reagents were of analytical reagent (AR) grade.

Instrumentation

A Shimadzu (Kyoto, Japan) model UV-1800 double beam UV-Visible spectrophotometer attached with computer operated software UV probe 2.33 with spectral width of 2 nm, wavelength accuracy of 0.5 nm and the pair of 1 cm matched quartz cells, Analytical balance and Mettler Toledo (Model JL1503- C).

Methods

UV-Spectroscopy Methods

Area under curve method

The AUC (area under curve) method was applicable when there is no sharp peak obtained or when broad spectra of the graph are obtained. It involves the calculation of the integrated absorbance with respect to the two selected wavelengths between λ1 and λ2. In the area calculation process item calculates the area bound by the curve and its horizontal axis. The horizontal axis is selected by entering the wavelength range over which area has to be calculated. This range of wavelength have been selected on the basis of repeated observation of the solutions so as to get the linearity between area under curve and concentration. The above-mentioned spectrums were used to calculate AUC. Thus, the calibration curve can be constructed by plotting concentration versus AUC[5,6].

Experimental Work

To check the solubility of lansoprazole

10 mg of Lansoprazole was weighed and solubility of this sample was checked in double distilled water, methanol, ethanol, 1N NaOH, 0.1N HCl.

To identify the λmax of Lansoprazole

10 mg of the pure drug was accurately weighed and dissolved small portion of methanol and volume was made up to 10ml using distilled water to give a standard stock solution of 1000µg/ml. Further 2.5ml of 1000ppm solution was withdrawn and was diluted to 25 ml of volumetric flask and 100ppm solution is prepared. Suitable dilutions were made with distilled water to get standard solutions of concentration: 2, 4, 6, 8, 10, 12µg/ml.

Sample preparation for analysis of infusion formulation

Sample solution was prepared from Lansoprazole Tablet 30 mg. A sample volume equivalent to 10 mg was placed in 10ml volumetric flask; volume was made up with solvent to get the concentration of 1000µg/ml. From this, 2.5 ml of aliquot transferred in 25ml of volumetric flask containing diluent to form 100µg/ml of Lansoprazole stock solution and further dilution of 2, 4, 6, 8, 10, 12ppm and scanned in the range of 200-400nm against water as blank at 281 nm and then drug content of solution was calculated by using standard calibration curve.

Analytical Method Development and Validation

The developed method of the AUC was validated as per guidelines given in ICH guidlines.

Linearity

The linearity of an analytical procedure is the ability of the method to obtain test results which are directly proportional to the concentration of analyte in the sample.

Standard solution of Lansoprazole (2, 4, 6, 8, 10 and 12µg/ml) was pipette out in to a separated series of 10ml volumetric flask. The volume was adjusted to the mark with distilled water and mixed well. The absorbance maxima and area under curve for the solutions was measured at 281nm and range of 250-290nm for two methods respectively against distilled water as blank.

Precision

The precision of analytical procedure expresses the degree of agreement between a series of measurements obtained from multiple sampling of the same homogeneous sample under prescribed conditions. It may be considered at different levels: repeatability, intermediate precision, and reproducibility. It is expressed as standard deviation or coefficient of variation. The repeatability studies were performed by analysis of same solution (2-12µg/ml) on the same day. Intermediate precision of the method was checked by repeating studies on

the two different days. The %RSD of both determinations was calculated.

Accuracy

It is closeness of the result obtained to the true value. It is often expressed as percentage recovery by analyzing known added amounts of analyte. Also, it can be determined by applying the procedure to quantitatively prepared samples.

Sensitivity

The sensitivity of the method was determined in terms of limit of detection (LOD) and limit of quantitation (LOQ).

The LOD and LOQ were calculated by using formula,

LOD= 3.3×σ/S and LOQ= 10×σ/ S.

Where, σ is the standard deviation of regression line and S is the slope of line.

RESULTS AND DISCUSSION

Method validation

The validated method was validated as per ICH guidelines. Preparation of analysed solution has already discussed in the earlier section.

Linearity and Range

Calibration curve for pure drug

Absorbance maxima method

Under the experimental conditions described, the graph obtained for the absorbance maxima for pure drug showed linear relationship (Figure No.2). Regression analysis was made for the slope, intercept and correlation-coefficient values. The regression equations of calibration curve were Y = 0.071x+0.170(r^2 = 0.998) at 279nm for absorption maxima the range was found to be 2-12µg/ml for the UV spectrometry.

Area under curve method

Under the experimental conditions described, the graph obtained for area under curve spectra showed linear relationship (Figure No.4 and Figure No.6). Regression analysis was made for the slope, intercept and correlation coefficient values. The equation is y = 0.565x+1.652 (r^2=0.999) at 229.20-260.20 nm for area under curve spectrophotometry. The range was found to be 2-12µg/ml for area under curve spectrophotometric analysis.

Precision

Precision of the method was verified by repeatability and intermediate study of the sample. Repeatability studies were performed by analyses solution (2-12µg/ml) on the same day. The %RSD of six determinations was calculated. Intermediate precision of the method were checked by repeating studies of the same sample on two different days. The %RSD of the determinations was calculated.

Sensitivity

The limit of detection (LOD) and limit of quantitation (LOQ) were calculated by using the equations LOD= 3.3×σ/S and LOQ= 10×σ/ S, where σ is the standard deviation of the intercept, S is the slope. The LOD and LOQ were found to be 0.0093 and 0.0283 respectively for the area under curve method.

Recovery studies

To stock solution in 3 different volumetric flask, aliquots of 8ml, 10ml and 12ml of the standard stock solution were added, volume was made upto 10ml with water to give concentration of 8µg/ml (80%), 10(100%) and 12(120%). Absorbance was determined at 279 nm. Procedure was repeated 3 times for 80%, 100% and 120% for recovery studies.

Table No.1: Calibration curve of Lansoprazole

S.No	CONC.	ABS
1	2	0.325
2	4	0.452
3	6	0.589
4	8	0.729
5	10	0.901
6	12	1.027

Table No.2: Calibration curve of Lansoprazole Tablet

S.No	Conc.	ABS.
1	2	0.308
2	4	0.469
3	6	0.615
4	8	0.748
5	10	0.895
6	12	1.064

Table No.3: Calibration curve of Lansoprazole by AUC

S.No	Conc.	AUC
1	2	2.715
2	4	3.985
3	6	5.057
4	8	6.224
5	10	7.227
6	12	8.452

Table No.4: Calibration curve by AUC for Lansoprazole formulation

S.No	CONC.	AUC
1	2	1.363
2	4	2.824
3	6	4.239
4	8	5.678
5	10	7.264
6	12	8.671

Table No.5: Regression Analysis Data for Lansoprazole by the AUC method

S.No	Parameter	AUC
1	Wavelength range (nm)	250-300
2	Concentration range (µg/ml)	2-12
3	Slope(m)	0.565
4	Intercept(c)	1.652
5	Correlation coefficient(r^2)	0.999

Table No.6: Result of interday and intraday precision

S.No	Parameters	±S.D.*	RSD	%RSD*
1	Interday	0.0585	0.009	0.975
2	Intraday	0.0656	0.010	1.00

*n=6

Table No.7: Data of Recovery studies

S.No	Level of mean recovery (%)	% mean recovery	SD*	%RSD
1	80%	101.12%	0.0721	1.20
2	100%	99.32%	0.0595	0.991
3	120%	100.23%	0.0651	1.08

Table No.8: Assay Results for estimation of Lansoprazole in Pharmaceutical Formulation

S.No	Parameter	Label claimed	Amount found	%Label clamed
1	AUC	10µg/ml	9.93	99.32

Table No.9: Summary Data of Validation Parameters

S.No	Parameter	AUC Method
1	Linearity	2-12
2	Regression equation	y =0.565x+1.652
3	Correlation Co-efficient	r^2=0.999
4	LOD(µg/ml)	0.0093
5	LOQ(µg/ml)	0.0283
6	Precision	
7	Interday	0.975%RSD
8	Intraday	1.00%RSD

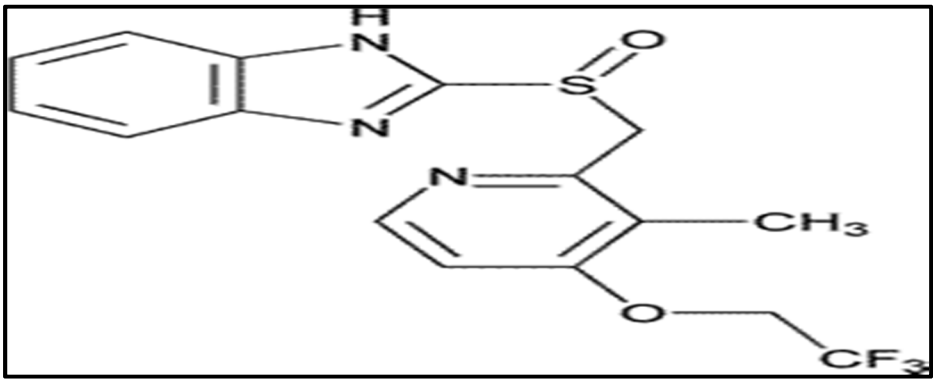

Figure No.1: Chemical structure of Lansoprazole

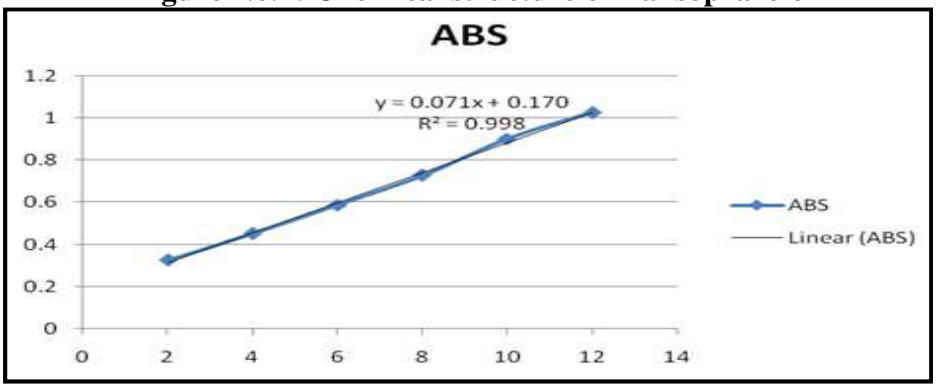

Figure No.2: Calibration of Lansoprazole (Pure Drug)

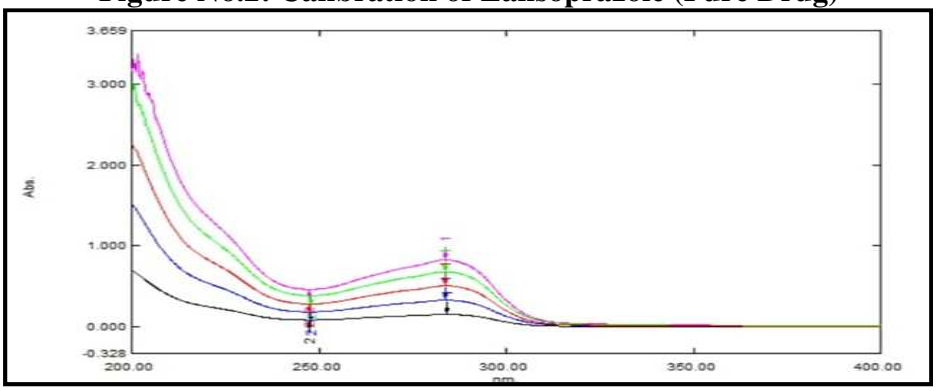

Figure No.3: Overlay of spectra of Lansoprazole (pure drug)

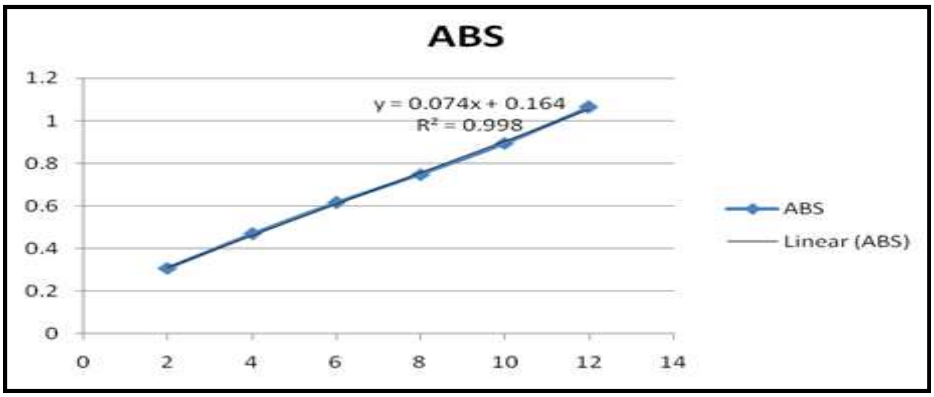

Figure No.4: Calibration of Tablet of Lansoprazole

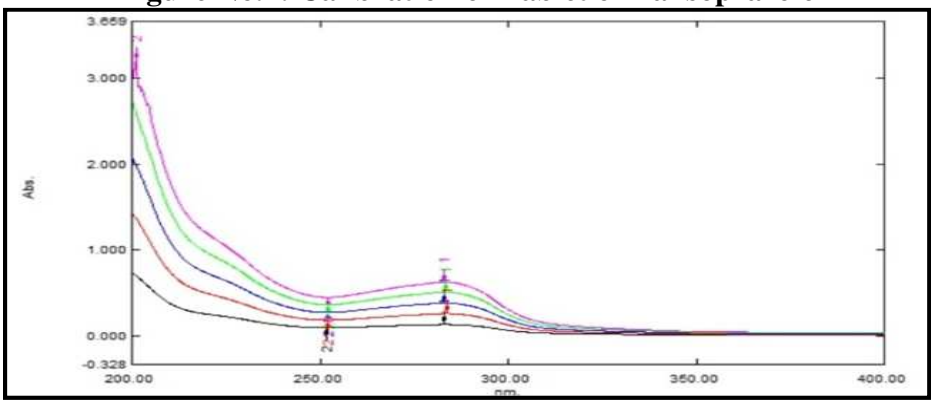

Figure No.5: Overlay of spectra of Lansoprazole (marketed formulation)

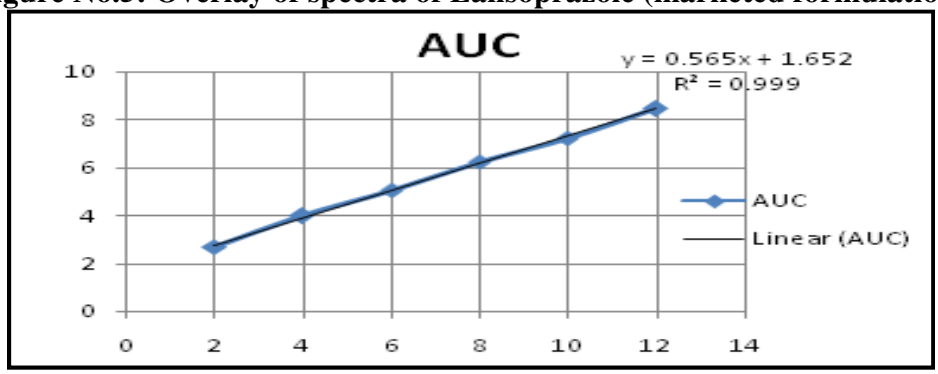

Figure No.6: Calibration curve for Lansoprazole by AUC (pure Drug)

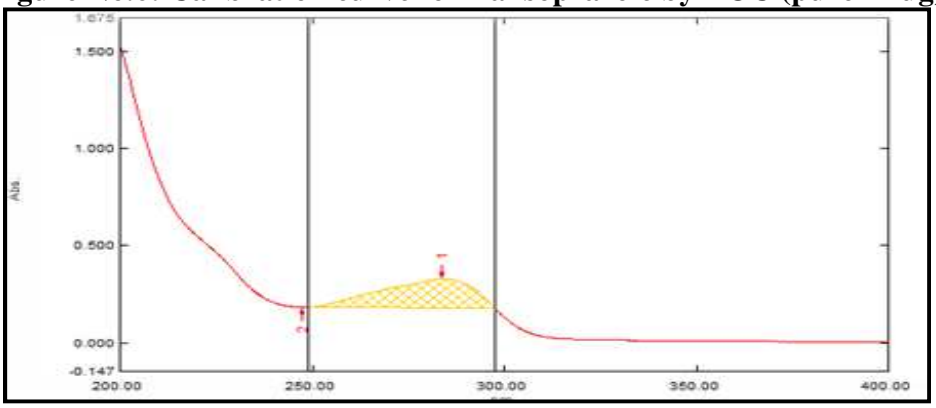

Figure No.7: Area between 250-300nm selected for Lansoprazole (10µg/ml)

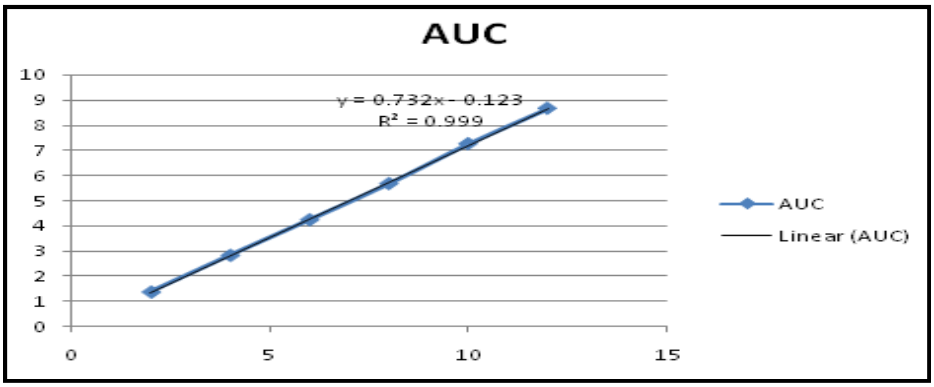

Figure No.8: Calibration curve by AUC for Lansoprazole formulation

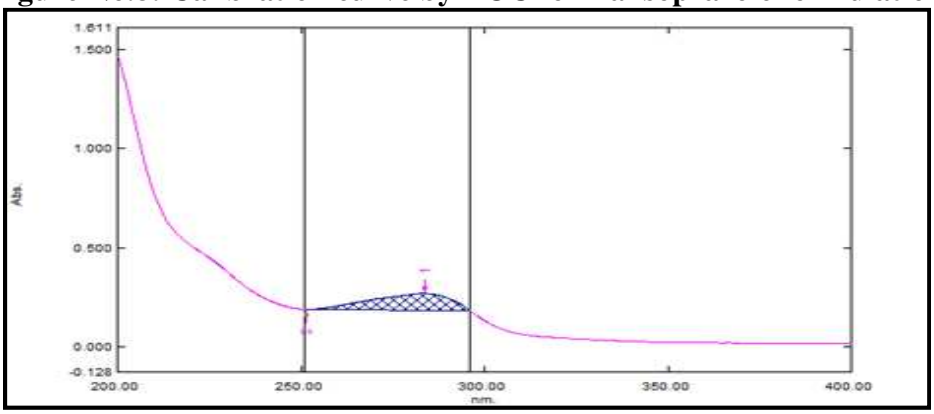

Figure No.9: Area between 250-300nm selected for Lansoprazole Tablet formulation (10µg/ml)

CONCLUSION

Simple UV spectrophotometric methods have been developed and validated for the determination of Lansoprazole and its tablet formulation. The results of the validation parameters show that the UV spectrophotometric methods were found to be accurate, precise and sensitive. Because of cost-effective and minimal maintenance, the present UV spectrophotometric methods can be preferred at small scale industries and successfully applied and suggested for the quantitative analysis of Lansoprazole in pharmaceutical formulations for quality control, to assure therapeutic efficacy the economy and time are essential factors.

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CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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