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## Development and Validation of UV Spectroscopic Method For Estimation Of Lansoprazole In Capsule Dosage Form

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### ABSTRACT

To develop and validate simple, rapid, linear, accurate, precise and economical UV Spectroscopic method for estimation of Lansoprazole in Capsule dosage form. The drug is soluble in analytical grade Methanol. The drug was identified in terms of solubility studies and on the basis of melting point done on melting point apparatus of Equiptronics. It showed absorption maxima were determined in analytical grade Methanol. The drug obeyed the Beer's law and showed good correlation of concentration with absorption which reflect in linearity. The UV spectroscopic method was developed for estimation of Lansoprazole in Capsule dosage form and also validated as per ICH guidelines. The drug is freely soluble in Dimethylformamide, soluble in analytical grade Methanol, sparingly soluble in Ethanol, slightly soluble in Ethyl Acetate, Dichloromethane and Acetonitrile. So, the analytical grade Methanol is used as a diluent in method. The melting point of Lansoprazole was found to be 179-180°C (uncorrected). It showed absorption maxima 285 nm in analytical grade Methanol. On the basis of absorption spectrum the working concentration was set on 10µg/ml (PPM). The linearity was observed between 6-14 µg/ml (PPM). The results of analysis were validated by recovery studies. The recovery was found to be 98.75, 99.00 and 100.80 % for three levels respectively. The % RSD for precision was found to be 0.9039 %. A simple, rapid, linear, accurate, precise and economical UV Spectroscopic method has been developed for estimation of Lansoprazole in Capsule dosage form. The method could be considered for the determination of Lansoprazole in quality control laboratories.

**Keywords:** Lansoprazole, UV Spectrophotometer, Melting Point, Assay Method, Validation, Accuracy, Linearity, Ruggedness, Precision.

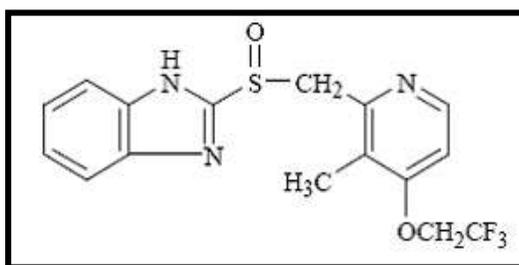
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## INTRODUCTION

Lansoprazole is a substituted benzimidazole, 2-[(3-methyl-4-(2, 2, 2-trifluoroethoxy) pyridin-2-yl) methylsulfinyl] -1Hbenzimidazole. (Mol. Formula: C<sub>16</sub>H<sub>14</sub>F<sub>3</sub>N<sub>3</sub>O<sub>2</sub>S, Mol.wt: 369.36, CAS no 103577-45-3)[1, 2]. It is a strong anti-secretory agent that acts on gastric H<sup>+</sup>/K<sup>+</sup> ATPase of parietal cells. It is used to treat ulcers, gastroesophageal reflux disease and peptic ulcer caused by stress, non-steroidal inflammatory disease [3]. Molecular basis of lansoprazole (LNZ) reveals that it is a proton pump inhibitor that suppress gastric acid secretion by specific inhibition of the enzyme system of Hydrogen/ potassium adenosine triphosphatase (H<sup>+</sup>/ K<sup>+</sup> ATPase) at the secretory surface of the gastric parietal cell and is used in the treatment of various gastric disorders such as gastric and duodenal ulcers, gastro esophageal reflux disease and in pathological hypersecretory conditions [4]. LAN is a weak base and breaks down rapidly in an acidic medium and thus must be administered in the form of enteric-coated granules in capsules, to prevent gastric decomposition and improve their systematic bioavailability [5].



**Figure 1: Chemical Structure of Lansoprazole**

From literature review it's found that lot of work was done on UV method development for lansoprazole with combination of other drugs [6, 7, 8]. Moreover lot of method developed on automated column switching HPLC method, HPLC and also on HPTLC of lansoprazole with their combined dosage form has also been reported [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, 13]. But very few methods were published on UV method for Lansoprazole in single on Capsule dosage form. The aim of the study was to develop a simple, precise, linear, economic and accurate UV method for determination of Lansoprazole in capsule dosage forms.

## MATERIALS AND METHOD

### Instruments:

Shimadzu double beam UV-visible spectrophotometer 1700 Ultra with matched pair

Quartz cells corresponding to 1 cm path length and spectral bandwidth of 1 nm, Bath sonicator and citizen weighing balance.

Melting point apparatus of Equiptronics were used.

### Materials:

Pharmaceutical grade lansoprazole (LAN) was received from Alkem laboratories, Mumbai, India. Lansoprazole Capsules were procured from local pharmacy. Methanol used was of analytical grade. Freshly prepared solutions were employed.

### Method development:

#### A. Determination of $\lambda$ 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 [16, 17].

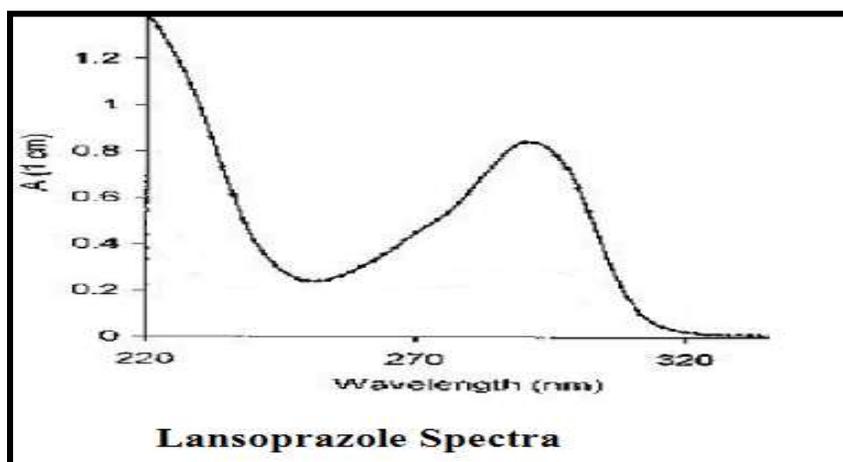


Figure 2: Calibration Curve

#### B. Preparation of Working concentration

##### 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  $\mu\text{g/ml}$  (PPM).

##### Preparation of Standard solution:

Pipette out 1 ml from standard stock solution and diluted up to 100 ml with analytical grade Methanol to get concentration of 10  $\mu\text{g/ml}$  (PPM).

#### C. Procedure for UV reading

##### Blank Solution: (For Auto zero)

Fill the cuvette with analytical grade Methanol. Wipe it with tissue paper properly then placed inside the chamber. Note down the reading.

**Standard Solution:**

Fill the cuvette with standard solution. Wipe it with tissue paper properly then placed inside the chamber. Note down the reading.

**Sample Solution:**

Fill the cuvette with sample solution. Wipe it with tissue paper properly then placed inside the chamber. Note down the reading.

**D. Procedure for sample preparations**

For analysis of commercial formulations; twenty Capsules are taken weighed [A] it then empty the shell and weighed empty shells of capsules [B]. Calculate powder weight using formula [A-B]. The powder equivalent to 100 mg of Lansoprazole was accurately weighed and transferred into the 100 ml of volumetric flask, added 70 ml analytical grade Methanol, close the stopper of flask with Parafilm tape, the solution was sonicated for 20 min. After sonication cool the flask and diluted upto 100 ml with analytical grade Methanol. Filtered the solution through whatmann filter paper. Pipette out 1 ml of the above solution and diluted up to 100 ml with analytical grade Methanol. The absorbance was measured at 285 nm [18, 19, 20]. The absorbance was recorded:

**Table 1: Absorbance of Dosage Form**

Cipla Pharmaceutical Limited [Lanzol - 30] (30 mg)		
Sr. no.	Sample	Absorbance
1	Blank	0.0001
2	Standard	0.6285
3	Sample	0.6214

**Table 2: Dosage Form Specifications**

Type	Company	M.D.	E.D.	Batch No.	Average weight (g)	Assay (%)
1	Cipla Pharma LTD (30 mg) [Lanzol - 30]	08/2018	09/2021	DCV0845	0.0687	98.9

**E. Method of validation**

The proposed method was developed by using linearity, accuracy, precision and ruggedness as per ICH guidelines, 1996 [18, 19, 20].

**Linearity:****Table 3: Linearity Studies**

Sr. no.	Sample Concentration	Absorbance
1	6 PPM	0.3745
2	8 PPM	0.5145
3	10 PPM	0.6261
4	12 PPM	0.7516

5	14 PPM	0.8845
<b>Correlation coefficient</b>		<b>0.999</b>

The linearity of the proposed assay was studied in the concentration range 6 - 14 PPM at 285nm. The calibration data showed a linear relationship between concentrations.

#### 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 analytical grade Methanol and measuring the absorbance at 285nm.

**Table 4: Accuracy Studies**

Accuracy (%)	Qty weighed (mg)	Qty found (mg)	Recovery (98-102%)
80	8	7.9	98.75
100	10	9.9	99.00
120	12	12.1	100.80

#### 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 5: Precision studies**

Sr. No.	Sample Solution	Absorbance
1	Sample Solution 1	0.6208
2	Sample Solution 2	0.6212
3	Sample Solution 3	0.6298
4	Sample Solution 4	0.6185
5	Sample Solution 5	0.6145
<b>MEAN</b>		<b>0.6210</b>
<b>SD</b>		<b>0.0056</b>
<b>% RSD</b>		<b>0.9039</b>

#### 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 6: Results for Ruggedness Studies**

Sr. No.	Analyst	Results	Mean	% Assay	% RSD
1	Analyst 1	0.6266	0.6239	99.3	0.0712
		0.6211			
2	Analyst 2	0.6218	0.6236	99.2	
		0.6254			

## RESULTS AND DISUCSSION

### 1. Solubility of Lansoprazole

Solubility test was passed as per criteria.

**Table 7: Results for solubility studies**

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

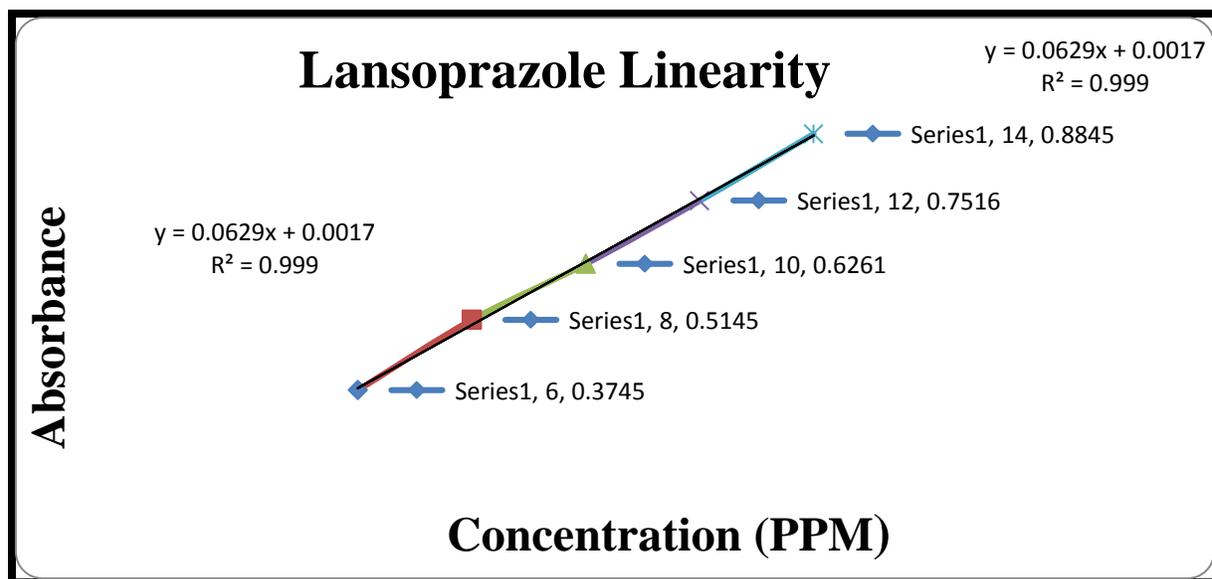
### 2. Melting point of Lansoprazole

The melting point of Lansoprazole was found to be 179-180°C (uncorrected).

### 3. Results for linearity for assay method of Lansoprazole

The linearity of method was determined at concentration level ranging from 6 to 14 µg/ml (PPM).

The correlation coefficient value was found to be ( $R^2$ ) **0.999**.



**Figure 3: Lansoprazole Standard Curve**

### 4. 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 - 4. 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% as per ICH Guidelines.

### 5. Results for precision for assay method of Lansoprazole

The % RSD for different sample of precision was found to be 0.9039 and it is within acceptance criteria as per ICH Guidelines represented in Table - 5.

### 6. Results for ruggedness for assay method of Lansoprazole

The %RSD for different sample of ruggedness was found to be 0.0712 and it is within acceptance criteria as per ICH Guidelines represented in Table - 6.

## CONCLUSION

A method for the estimation of Lansoprazole in Capsule form has been developed. From the spectrum of Lansoprazole, it was found that the maximum absorbance was 285 nm in analytical grade Methanol. A good linear relationship was observed in the concentration range of 6-14 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 Capsule dosage forms. Hence, the method could be considered for the determination of Lansoprazole in quality control laboratories.

## ABBREVIATIONS

1. LAN - Lansoprazole
2. PPM - Parts per Million
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

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