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# SPECTROPHOTOMETRIC ASSAY OF LANSOPRAZOLE IN BUILK AND DOSAGE FORMS

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## ABSTRACT

A simple, sensitive, rapid and accurate spectrophotometric method has been developed for the estimation of lansoprazole in pharmaceutical dosage forms. The method is based on the reaction of each drug having secondary or tertiary or primary amino (aliphatic) group with wool fast blue, the formed complex extracted into chloroform at pH 1.5. The absorbance of ion pair complex form in extractable chloroform layer is measured at the wavelength of maximum absorbance for each drug against the reagent blank (prepared in a similar manner devoid of drug solution) and the amount of drug is determined from the calibration curve made between the absorbance and the amount of drug. The amount of drug is computed from the calibration curve.

**KEYWORDS:** Spectrophotometry, wool fast blue, lansoprazole Pharmaceutical and Formulation.

## INTRODUCTION

Lansoprazole is described chemically as 2-({[3-methyl-4-(2,2,2-trifluoroethoxy)pyridin-2-yl]methane}sulfinyl)-1H-1,3-benzodiazole. Lansoprazole, an acid proton-pump inhibitor similar to omeprazole, is used as an antiulcer drug in the treatment and maintenance of healing of duodenal or gastric ulcers, erosive and reflux esophagitis, NSAID-induced ulcer, Zollinger-Ellison syndrome, and Barrett's esophagus. The literature survey reveals that few methods are available for the determination of lansoprazole in dosage forms includes spectrophotometric method[1-2], capillary electrophoresis[3], RP-HPLC method[4], HPLC

method[5], Voltammetry method[6], in bulk, formulations and in biological samples. The present investigation aims to develop simple, sensitive, accurate, rapid and cost effective spectrophotometric method for the estimation of lansoprazole in its tablet formulations.

## MATERIALS AND METHODS

### Instrument

All measurement were done on Milton Roy 1001spectrophotometer by using 10 mm matched quartz cuvettes.

## MATERIALS

All chemicals used are of A.R. grade and were purchased from S.D. fine chemicals and LOBA-Chemi, Mumbai. Doubled distilled water were used for preparation of solutions.

### Buffer $p^H$ 3.5)

Buffer solution was obtained by diluting a mixture of 50 ml of 0.2M potassium acid phthalate and 8.4 ml of 0.2M HCl to 200 ml with distilled water and the pH is adjusted to 3.5.

### Wool fast blue: (0.5% W/V)

Wool fast blue solution is prepared by dissolving 500 mg of Wool fast blue (Loba) in 100 ml of distilled water.

### Preparation of lansoprazole stock soslution:

An accurately weighed 50 mg of Lansoprazole is dissolved in methanol and the volume is adjusted to 50 ml with methanol. Further dilution is made to obtain the working concentration of 100 μg/ml.

### Preparation of Calibration curve

Various aliquots of the standard lansoprazole solution ranging from 0.5-2.5 ml are transferred into a series of separating funnel. To each flask, 0.5 ml of wool fast blue solution, 1.0 ml of buffer solution of $P^H$ 1.5 and 5 ml chloroform are added, and the final volume was made up to the mark with distilled water. Reaction mixture in each funnel is shaken gently for 5 min and allowed to stand for 5 min so as to separate aqueous and chloroform layers. The chloroform layer is separated out and absorbance is measured at 580 nm, against the reagent blank prepared in similar manner omitting drug solution. Calibration graph is obtained by plotting absorbance values against the concentration of lansoprazole solution. The calibration

curve is found to be linear over a concentration range of 50 to 250 µg/mL of lansoprazole. The amount of lansoprazole present in the sample is estimated from the calibration graph.

**Pharmaceutical formulation of lansoprazole**

Ten tablets of lansoprazole are weighed accurately and finely powdered. An accurately weighed portion of powdered sample, equivalent to 50 mg of lansoprazole was taken in a 50 ml volumetric flask containing 25 ml of chloroform, sonicated for 20 minutes. The resultant solution is filtered through Whatman filter paper No. 41 into another 50 ml volumetric flask. The filter paper was washed several times with chloroform. The washings were added to the filtrate and the final volume was made up to the mark with chloroform and treated as per the Calibration curve procedure. Amount of the drug present in sample was computed from respective calibration curve. The results are presented in table. 2.

**Table 1: Optical Characteristics Of The Proposed Method.**

| parameters | Proposed method |
|---|---|
| Wavelength (nm) | 580 |
| Beer's limits, mcg/ml | 50-250 |
| Sandell's, sensitivity, (µg $cm^{-2}$) | 0.0253 |
| Molar absorptivity, (L $mol^{-1}$ $cm^{-1}$) | $1.65x10^3$ |
| Regression equation, Y* | Y= 0.003x+0.0019 |
| Correlation coefficient, (r) | 0.999 |
| Intercept (a) | 003 |
| Slope (b) | 0.0019 |

**Table 2: Assay And Recovery Of Lansoprazolen Tablet Formulations.**

| S.No | Sample (mg) | *Amount Found(mg) ±S.D* | % Label claim | %RSD* | *$t_{cal}$ |
|---|---|---|---|---|---|
| 1 | 30 | 30.01±0.16 | 100.03 | 0.5644 | 0.1321 |
| 2 | 30 | 30.05±0.17 | 100.16 | 0.5903 | 0.6305 |
| 3 | 30 | 29.99±0.07 | 99.96 | 0.2510 | 0.2976 |

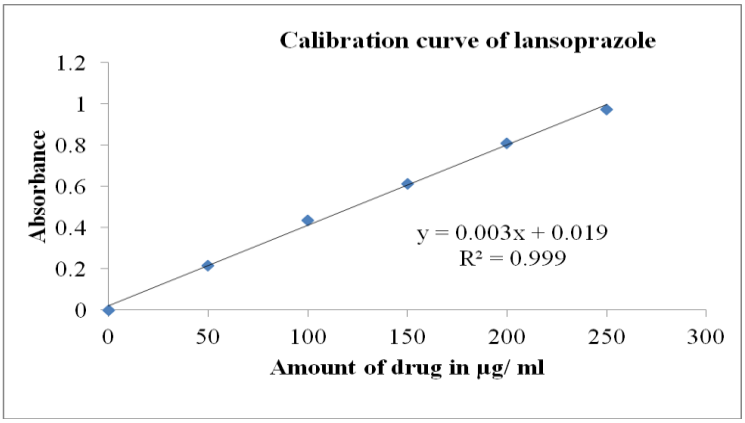


**Fig. 1: Calibration curve of lansoprazole.**

## RESULTS AND DISCUSSION

In this method the lansoprazole treated with wool fast blue dye at pH 1.5. The resultant solution is extracted with chloroform. The ion pair complex is formed in extractable chloroform layer. The absorbance of the extractable ion pair complex is measured at 580 nm against the reagent blank (prepared in a similar manner devoid of drug solution). The calibration curve (concentration vs absorbance) is linear over the range of 50-250 µg/mL of lansoprazole. The optical characteristics of the proposed method such as absorption maxima, Beer´s law limits, molar absorptivity and Sandell´s sensitivity are presented in Table 1. The molar absorptivity and Sandell´s sensitivity values show that method is sensitivity. The regression analysis using method of least squares was made for the slope (b), intercept (a) and correlation coefficient (r) obtained from different concentrations and results are summarized in the Table 1. The value of correlation coefficient was 0.999, which indicates the good linearity of calibration lines. The percent relative standard deviation calculated for five measurements of lansoprazole is shown in Table 2. The % RSD is less than 2, which indicates that the method has good reproducibility. The values of standard deviation values are low, indicates high accuracy and reproducibility of the method. The‘t’ values calculated are compared well with the theoretical value of 2.78 there by indicating that there is no significant difference between proposed method and official method. There is no effect of additives and excipients such starch, calcium lactose and glucose in the concentrations those present in general pharmaceutical preparations.

## CONCLUSION

The proposed method is found to be simple, precise, accurate and time saving, reproducible and can be conveniently adopted for routine analysis of estimation of lansoprazole in bulk drugs samples and pharmaceutical formulations.

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