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Research Article

Analytical estimation of lansoprazole and validation of simple spectrophotometric in bulk and capsule formulation

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ABSTRACT

A simple chemo metrics-assisted spectrophotometric method for the determination of lansoprazole in capsule form is described. Lansoprazole is an active proton-pump inhibitor drug act by irreversibly blocking the hydrogen/potassium adenosine triphosphatase enzyme system (the H^+/K^+ ATPase, or, more common, gastric *proton pump*) of the gastric parietal cell. The UV absorption spectra of the studied drugs were in the range of 200-400 nm. The developed spectrophotometric method is simple, rapid, precise, accurate, reliable and economical when compared to other methods? The method was also applied for capsule formulations. It gives better results in terms of accuracy, precision and linearity over a range of 5- 25 µg/ml for lansoprazole. The limit of detection in capsule dosage form are 2µg/ml, the limit of quantification for capsule are 5µg/ml for pharmaceutical formulation. The % RSD is less than 49.19 %, and the recovery is 111 – 147 % as results the above method can be applied for bulk and finished product of lansoprazole.

Keywords: spectrophotometry; PPI-drug; proton pump inhibitors.

INTRODUCTION

New drug delivery technologies are revolutionizing the drug discovery, development and creating R&D focused pharmaceutical industries to increase the momentum of global advancements. In this regard novel drug delivery system have many benefits, which includes improved thereby by increasing the efficiency and duration of drug activity, increased patient compliance through decreased dosing frequency and convenient trout of administration and improved site specific delivery to reduce unwanted adverse effects. Lansoprazole is an active proton-pump inhibitor drug act by irreversibly blocking the hydrogen/potassium adenosine triphosphatase enzyme system (the H^+/K^+ ATPase, or, more common, gastric *proton pump*) of the gastric parietal cell. Indian pharmacopoeia 1996 volume- I. Lansoprazole is a proton-pump inhibitor (PPI) in the same pharmacologic class as omeprazole. Lansoprazole has been marketed for many years and is one of several PPIs available. Lansoprazole is a racemate [1:1-mixture of the enantiomers dexlansoprazole (Kapidex) and levolansoprazole] Dexlanprantazole is an enantiomerically pure active ingredient of a commercial drug as a result of the 'enantiomeric shift'.

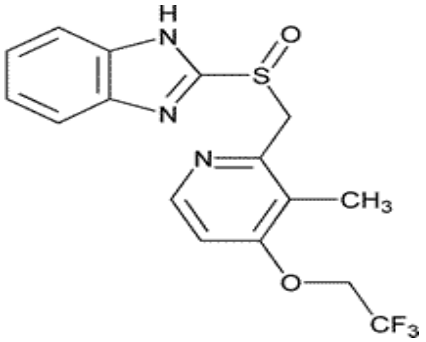

Figure 1: Structure of lansoprazole

A few methods have been reported to estimate lansoprazole. RP-HPLC (Bhavesh H. Patel,2007) has performed HPLC Analysis for Simultaneous Determination of Rabeprazole and Domperidone in Pharmaceutical Formulation, (Roberto Cirilli,2009), (Hisakazu Katsuki, 2001) High performance liquid chromatography assay for the determition of lansaprazole , K. K. Pandya, (1998) has perfomed High-performance thin-layer chromatographic method for the detection and determination of lansoprazole in human plasma and its use in pharmacokinetic , So the present study reports on a newly developed and validated (ICH Guidelines 2005) spectrophotometric estimation of lansoprazole bulk and pharmaceutical formulation by using methanol as a dilution solvent ,which is easy to handle and require less time for the analysis . It is also a simple, highly rapid and economic method.

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MATERIALS AND METHODS

Apparatus

Spectrophotometric measurements were carried out on a computerized UV Double Beam Spectrophotometer Systronics Model Number 2202. The absorption spectra of test and reference solutions were recorded over the range 200-1100 nm. The subsequent statistical manipulation was performed by transferring the spectral data to Microsoft excel 2003 program and processing them with the standard curve fit package and matrix calculations.

Chemicals

Pharmaceutical grade lansoprazole (Shasen Pharmaceutical Pvt. Ltd. Pondichery, India) was used as working standards after confirming their purity and compliance with pharmaceutical requirements. All other reagents used were analytical grade.

Pharmaceutical preparation

The following pharmaceutical preparation was purchased from the local market and subjected to analysis by the proposed procedures; Lanzol, mfd. By Cipla Ltd. Verna India. Estate, Goa, with label claim 30 mg capsule.

PROCEDURE

Preparation of standards solution

Into 100-ml volumetric flask an accurately weighed amount (1 mg) of the studies drugs is dissolved in about 100 ml of methanol. The resulting solution is diluted quantitatively with methanol to obtain the appropriate dilutions for drug according to its linear calibration range or as specified under the analysis of the laboratory prepared mixtures.

Sample preparation

Twenty capsules are weighed and finely powdered. An accurately weighed amount 3.612 gm of sample drug is taken in 500 ml of volumetric flask and dissolved in 300 ml of methanol to prepare first stock solution. 1 ml of the first stock solution is taken and make up the volume up to 10 ml, to get conc. of 10µg.

VALIDATION

Selectivity / specificity

A method is said to be specific when it produces a responses only for a single analyte. Selectivity is the ability of the method produces a response for the analyte in the presence of other interferences, in order to prove that the method chosen was specific and selective.

Linearity and range

Linearity of the concentrations was taken in the range of 5-25 µg/ml for capsule formulations.

Accuracy

Accuracy of proposed method from excipents was determined by recovery experiments. Recovery experiments were carried out in three levels of concentrations. The amounts of standard recovered were calculated in the terms of mean recovery with the upper and lower limits of % relative standard deviation.

Precision

It is expressed as the percentage coefficient of variation (% CV) which is calculated as per the following expression.

$$\% CV = (\text{standard deviation} / \text{mean}) \times 100$$

Intraday precision

It was determined by calculating the % coefficient of variation (% CV) of the results obtained in the same day.

Interday precision

It was determined by calculating the percentage coefficient of variation (% CV) of the results obtained over at least two days.

Table 1: System suitability parameter

Parameters	Lansoprazole capsule
Linearity & range (µg/ml)	5-25
Equation	Y= 0.0758+ 0.007
R^2	0.9805
LOQ	2
LOD	5

Table 2: Accuracy Parameters

S.No	Concentration µg/ml	absorption	% recovery
1	5	0.432	132%
2	10	0.813	124%
3	15	1.439	147%
4	20	1.505	115%
5	25	1.811	111%

Table 3: Precision Parameter

Parameters	Lansoprazole capsule
Concentration (µg/ml)	5-25
Mean	15
SD	0.4806
RSD	49.19
% recovery	147%
N	5

RESULTS & DISCUSSION

System suitability

System was evaluated for reproducibility by injecting the six replicates of lansoprazole (1µg/ml) dilution. The coefficient of variation obtained are given table no 1. System was suitable for the determination of lansopra-

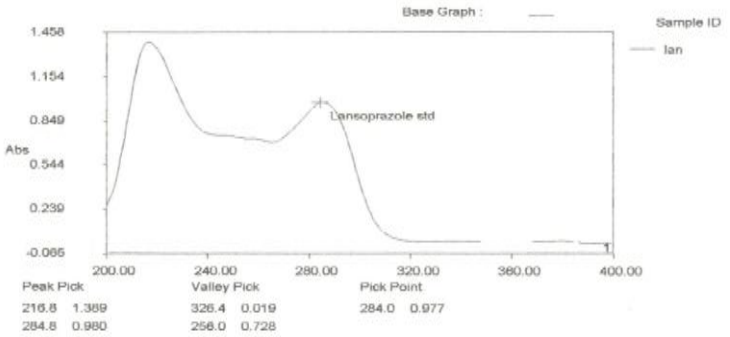

Figure 2: UV spectrum for lamivudine sta

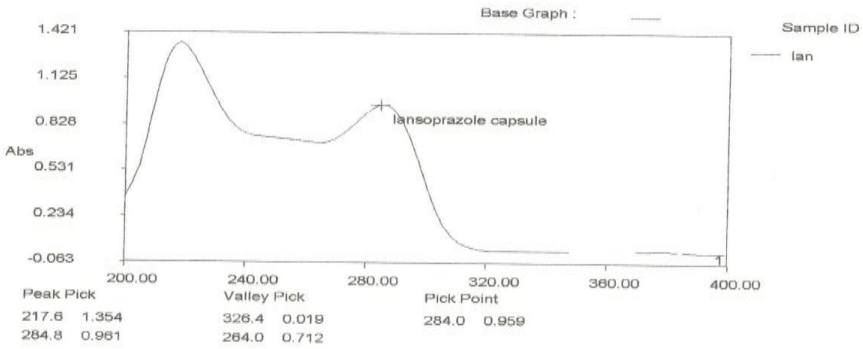

Figure 3: UV spectrum for lansoprazole capsule

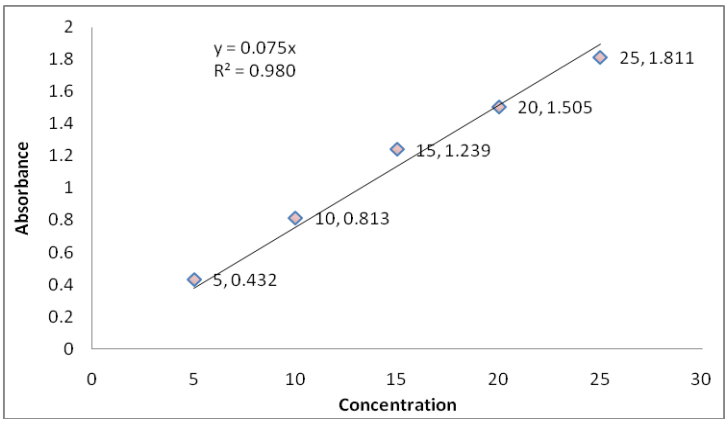

Figure 4: Linearity curve for lansoprazole capsule formulation

zole because the results were reproducible for the analyte.

Sensitivity

The limit of detection value for lansoprazole capsule were obtained as 5µg/ml. from this limit of quantification determined as 2µg/ml for capsule formulation

Linearity and range

The linearity of the concentration was taken in the range of 5-25µg/ml for both tablet and liquid formulation and the values are given in table no: 1 and figure no: 3

Accuracy

The mean absolute recovery of lansoprazole in the methanol is111-147% .the values are given in table no: 2 & figure no: 1 – 2 respectively

Precision

By precession studies the relative standard deviation value were obtained as less than 8% for capsule the value were given in table 3 respectively.

CONCLUSION

Finally with the above result it is concluded that the developed method is simple, rapid and accurate which can be applied to the estimation of lansoprazole in bulk and pharmaceutical formulation with minimum errors.

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