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## AREA UNDER CURVE SPECTROPHOTOMETRIC METHOD FOR DETERMINATION OF DOMPERIDONE AND LANSOPRAZOLE IN BULK

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### Abstract

In the present study evaluate Simple, precise and reliable Area under Curve Spectrophotometric method for determination of Domperidone and Lansoprazole in bulk. The solution of standard and solvent prepared in Methanol: Water (6:4). The quantitative estimation of drug were carried out by using Area under Curve Method values measured at 275.4-295.4 nm for Domperidone and 274.4-294.4 nm for Lansoprazole. The developed method obeyed Beer- Lambert's law in the concentration range of 2-30 µg/ml for both drugs having linear equation  $Y = 0.249x + 0.020$ ,  $Y = 0.239 + 0.119$  with correlation coefficient ( $r^2$ ) of 0.999 for Domperidone and ( $r^2$ ) of 0.999 for Lansoprazole respectively. The method was satisfactory validated as per ICH guideline. There is no significant difference between the performance of the proposed method regarding the mean values and standard deviations. The developed method was successfully applied to estimate the amount of Domperidone and Lansoprazole in combination.

**Keywords:** Domperidone, Lansoprazole, Area under Curve Spectrophotometric Method.

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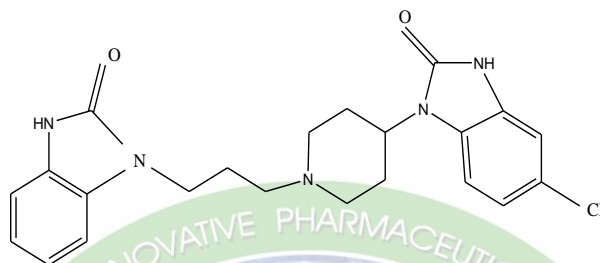
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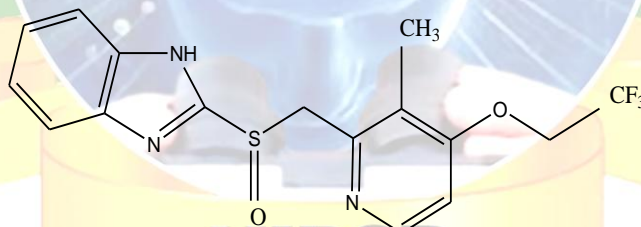
## INTRODUCTION

Domperidone (DOM) is chemically 5-Chloro-1-[1-[3-(2-oxo-1, 3-dihydrobenzimidazol-1-yl)-4-piperidyl]-1, 3- dihydrobenzimidazol-2-one maleate. Domperidone acts as a gastrointestinal emptying (delayed adjunct and peristaltic stimulant). The gastroprokinetic property of domperidone is related to its peripheral dopamine receptor blocking properties [1, 2].



**Domperidone**

Lansoprazole (LANZO) is a substituted benzimidazole,2-[(3-methyl-4-(2, 2, 2-trifluoroethoxy)pyridin-2-yl) methylsulfinyl] -1Hbenzimidazole. 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 ( $H^+/K^+$  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 [3-6].



**Lansoprazole**

Literature survey revealed that various analytical methods like UV spectroscopy [7-11], RP-UPLC [12], RP -HPLC [13-15], available for the estimation of Domperidone and Lansoprazole as single drug or in combination with other drugs. There are few analytical methods available for selective estimation of this combination. But, No Area under Curve method was reported for estimation of these two drugs in combination. Therefore, the focus of present work is to develop a simple, accurate, precise method for the simultaneous estimation of Domperidone and Lansoprazole in combination.

## Experimental Condition

### Instrument

A Shimadzu UV-1800 UV Spectrophotometer with 1.0 cm matched quartz cells was used.

## MATERIAL & METHODS

Standard Gift Sample of Domperidone and Lansoprazole were procured From Cipla Limited Aurangabad and Zydus Cadila Ahmadabad.

### Selection of Solvent

Methanol: Water (6:4) was selected as the solvent for dissolving Domperidone and Lansoprazole.

Preparation of Standard stock solution ( 100 µg/mL)

The stock solution (100 µg/mL) of DOM and LANSO were prepared separately by dissolving accurately about 10 mg of drug in Methanol:Water (6:4) and the volume was made up to 100 ml with same solvent to prepare Standard stock solution (100 µg/mL)

### Determination of $\lambda_{max}$

Both the standard solutions were scanned separately between 400nm to 200nm. The overlain spectrum of both drugs was recorded, Fig. from the overlain spectrum, two wavelengths 285.4nm ( $\lambda_{max}$  of Domperidone) and 284.4 nm ( $\lambda_{max}$  of Lansoprazole) were selected for estimation of drugs.

### Selection of analytical wavelength range (Area under the curve) for analysis

Suitable concentrations of solutions were prepared accurately to determine the range of Domperidone for analysis. The standard solutions were scanned in the spectrum mode of the instrument from 400 nm to 200 nm. The absorbance maxima of these solutions were obtained at wavelength 285.4 nm. The area under the curve between 275.4 nm to 295.4 nm was selected (Fig.1) for Domperidone and 274.4 nm to 295.4 nm was selected (fig.2) for Lansoprazole because the linearity was obtained within these areas with good reproducibility of results.

### Application of Proposed Method for Estimation of DOM and LANSO in Laboratory Solution

In order to see the feasibility of proposed method for estimation of Domperidone & Lansoprazole in marketed pharmaceutical formulations, the method was first tried for estimation of drugs in standard laboratory solution. Accurately about 10 mg of pure drug (DOM) & 10mg of another pure drug (LANSO) was weighed and transferred in the 10 ml volumetric flask & Dissolve in methanol: Water (6:4) to give stock solution of concentration 0.1/1mg/ml (1000µg/ml). Appropriate aliquot portion (1 mL) was transferred to 10mL volumetric flask and diluted with

Methanol: distilled water (6:4) to obtain the concentration of 100µg/mL. appropriate aliquot portion (1.5 mL) was transferred to 5 mL volumetric flask and diluted with same solvent to obtain 30 µg/mL. Area was measured at 275.4 – 295.4 nm & 274.4 – 294.4 nm against solvent as blank. Result is reported in table 1.

### Validation of Proposed Method

The method was validated according to ICH guidelines to study linearity, accuracy, precision, LOD and LOQ.

#### Recovery studies:

To the preanalysed sample solutions (10 µg/mL of Dom and 10 µg/mL of Lanso), a known amount of standard solutions (Dom and Lanso) were added i.e. 8, 10, and 12 µg/mL of Dom and Lanso (standard stock solution) were added, and total concentration of above dilution is measured by using Following equation. The results are reported in Table 2.

#### a) Accuracy [16]

Accuracy of an analytical method is the closeness of the test results obtained by that of the true value. It was done by recovery study. Sample solutions were prepared by spiking at about 80 %, 100 % and 120 % of specification limit to Placebo and analyzed by the proposed method. % Recovery was determined using the formula. Results are shown in Table 2.

#### b) Precision [16]

Precision of an analytical method is the degree of agreement among individual test results. Precision of the method was verified by using stock solutions in the ratio of 1:1 containing 10µg/ml DOM and 10µg/ml of LANSO. System repeatability was done by repeating the assay three times of the same concentration after every two hours on the same day for intraday precision. Intraday precision was carried out by performing the assay sample sets after 24 hours and 48 hours, results are reported in Table 3.

#### c) Linearity and range

Domperidone in the formulation was found to be linear in the concentration range of 2-30 µg/ml while Lansoprazole 2-30 µg/ml at 275.4- 295.4 nm and 274.4 -294.4nm.

#### d) Limit of detection and limit of quantification [17]

The Limit of Detection (LOD) is the smallest concentration of the analyte that gives the measurable response. LOD was calculated using the following formula:

$$\text{LOD} = 3.3 \sigma / S$$



The Limit of Quantification (LOQ) is the smallest concentration of the analyte, which gives response that can be accurately quantified. LOQ was calculated using the following formula

$$\text{LOQ} = 10 \sigma/S$$

Where,

$\sigma$  is standard deviation of the response and

S is the slope of the calibration curve.

LOD & LOQ of Domperidone was found to be 0.96  $\mu\text{g/ml}$  & 2.97  $\mu\text{g/ml}$  respectively.

LOD & LOQ of Lansoprazole was found to be 0.60  $\mu\text{g/ml}$  & 1.89  $\mu\text{g/ml}$  respectively.

## RESULT & DISCUSSION

The UV visible spectroscopic method for the Domperidone and Lansoprazole by Area under Curve was found to be simple, accurate, economical and reproducible. The drug concentrations were found to be linear in the range of 2-30  $\mu\text{g/ml}$  and the correlation coefficient value of 0.999 for both drugs indicates that developed method was linear. Intra-day and inter-day precision results in terms of percent relative standard deviation values were found to be 0.1815 and 0.070 for Domperidone and 0.1314 and 0.0322 for Lansoprazole respectively thus the method is observed as precise. The accuracy of the method was assessed by recovery studies at three different levels i.e. 80%, 100%, 120%. The values of standard deviation were satisfactory and the recovery studies were close to 100%. The % RSD value is  $\leq 2$  indicates the accuracy of the method. The Limit of Detection and Limit of Quantitation values of Domperidone were found to be 0.95  $\mu\text{g/ml}$  & 2.97  $\mu\text{g/ml}$  and for Lansoprazole were found to be 0.60  $\mu\text{g/ml}$  & 1.89  $\mu\text{g/ml}$  respectively. The method can be used for routine quality control analysis of Domperidone and Lansoprazole in bulk.

Table 1: Analysis of DOM and LANSO in laboratory mixture

Drug	Sample Solution Con. in $\mu\text{g/ml}$	% estimation	Mean	S.D.	% RSD
DOM	30	100.01	99.97	0.0357	0.0251
		99.94			
		99.98			
LANSO	30	99.99	99.98	0.0358	0.0252
		99.95			
		100.01			

**Table 2: Accuracy result for DOM and LANSO**

Drug	Sample solution conc. In µg/ml	Accuracy Level	Total amount added (µg/ml)	% Recovery	Mean % Recovery	% RSD
DOM	30	80	8	100.11	99.85	0.3541
		100	10	99.45		
		120	12	100.01		
LANSO	30	80	8	100.95	100.41	0.4658
		100	10	100.15		
		120	12	100.13		

**Table 3: Precision Study**

Paramater	Intra Day		Inter – Day	
	DOM	LANSO	DOM	LANSO
Sample solution conc. in µg/ml	30	30	30	30
AUC ( Mean)	3.5073	3.1856	3.5103	3.1906
% RSD	0.1815	0.1314	0.0700	0.0321

**Table 4: Summary of Validation Parameter**

Parameter	Domperidone	Lansoprazole
λ Range (nm)	275.40- 295.40	274.4- 295.4
Beer's law limits (µg / ml)	2-30µg/ml	2-30µg/ml
Regression equation (Y*)	Y = 0.249x+0.020	Y= 0.239x + 0.119
Slope (b)	0.249	0.239
Intercept (a)	0.020	0.119
Correlation coefficient (r2)	0.999	0.999
Limit of Detection (LOD)	0.960	0.601
Limit of Quantitation (LOQ)	2.979	1.898
Accuracy (Mean % Recovery)	99.85	100.41
Precision ( % RSD)	0.070	0.032

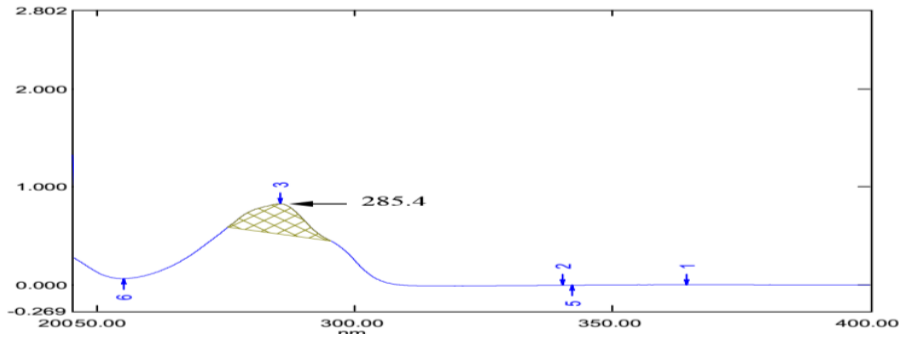


Fig. 1: AUC Spectrum of Domperidone

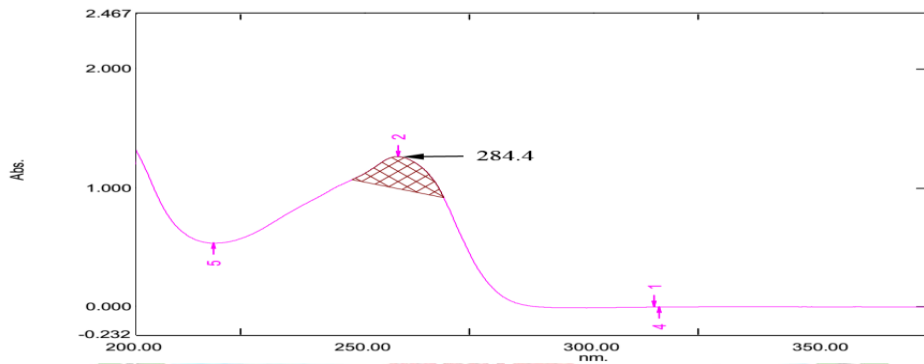


Fig. 2: AUC Spectrum of Lansoprazole

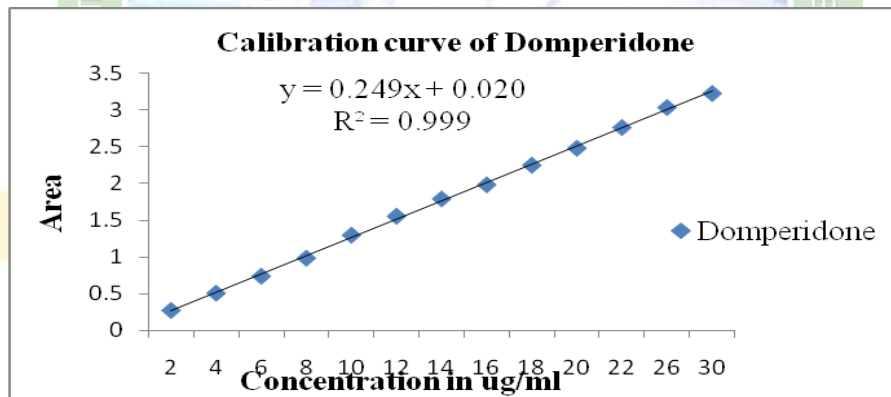


Fig. 3: Calibration curve of Domperidone

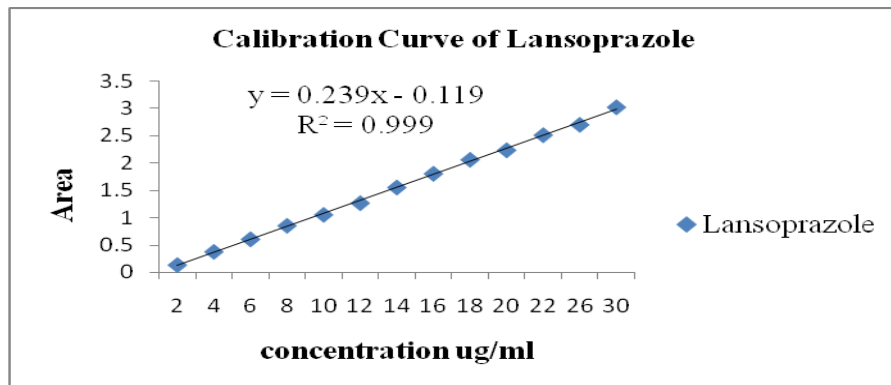


Fig.4: Calibration curve of Lansoprazole

## CONCLUSION

The UV spectroscopic AUC method for the analysis of Domperidone by First order derivative Area under Curve was found to be simple, precise, and accurate; can be used for assay of bulk drug and pharmaceutical dosage formulations.

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