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DEVELOPMENT AND VALIDATION OF UV SPECTROPHOTOMETRIC METHODS FOR SIMULTANEOUS ESTIMATION OF DEXLANSOPRAZOLE AND DOMPERIDONE IN PHARMACEUTICAL DOSAGE FORM

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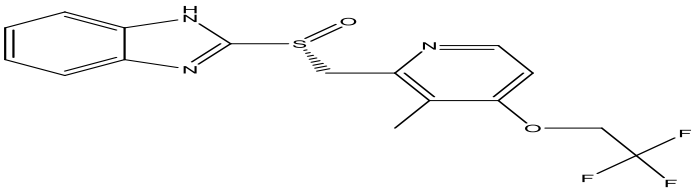
ABSTRACT

A simple and precise UV spectroscopic method was developed for simultaneous estimation of Dexlansoprazole (DXL) and Domperidone (DOM) using methanol as a solvent. The simultaneous estimation was carried out by developing an Absorbance Correction Method wherein at 283 nm, both the drugs show good absorbance, whereas at 293.20 nm, only DXL shows absorbance. DXL was found to be a linear in the concentration range of 5-35 µg/ml at 283 and 293.20 nm and DOM were found to be linear in the concentration range of 5-30 µg/ml at 283 nm. The mean assay percentage of DXL and DOM in the marketed formulation was found to be 101.11% and 99.48%, respectively. LOD and LOQ for DXL were found to be 0.142 and 0.4312 µg/ml, and for DOM, it was found to be 0.095 and 0.290 µg/ml, respectively. The results % Recovery for DXL and DOM were observed in the range of 99.86-101.73 % and 99.71-101.28 % respectively. % RSD for the precision study was found to be less than 2% for both drugs. The developed method can be used for the simultaneous estimation of DXL and DOM from capsule formulation.

KEYWORDS: DXL, DOM, validation, UV Spectroscopic Method, Absorbance Correction Method.

INTRODUCTION

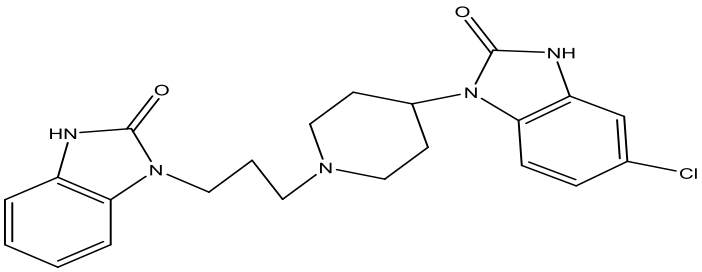
Gastro Esophageal Reflux Disease (GERD) is a prevalent condition affecting the upper gastrointestinal tract, characterized by the backward flow of stomach contents into the esophagus. Common symptoms include heartburn, bleaching, nausea, and vomiting.[1] The increased vulnerability to anxiety and depression among GERD patients stems from factors like acid reflux, heartburn, inherited susceptibility and quality of life.[2] The severity of esophagitis can vary, with more severe cases causing significant erosions, ulcers, and narrowing of the esophagus. Esophagitis can also result in gastrointestinal (GI) bleeding. This repeated reflux irritates the esophageal lining, often leading to inflammation (esophagitis).[3] In this present research work, the drug combination of Dexlansoprazole and Domperidone is selected which is used in the treatment of GERD.



Dexlansoprazole

Figure 1: Structure of Dexlansoprazole.

Dexlansoprazole is a new-generation Proton Pump Inhibitor (PPI) used for the management of symptoms associated with GERD and erosive esophagitis. Dexlansoprazole is the R-enantiomer of Lansoprazole. Compared to the older generation of PPI, Dexlansoprazole has a unique pharmacokinetic profile due to its delayed-release and dual-delivery release system. Dexlansoprazole inhibits the final step in gastric acid production by blocking the (H+, K+) ATPase enzyme.[4]



Domperidone

Figure 2: Structure of Domperidone.

Domperidone acts as a gastrointestinal emptying (delayed) adjunct and peristaltic stimulant. The gastroprokinetic properties of Domperidone are related to its peripherial dopamine receptor blocking properties. Domperidone facilitates gastric emptying and decrease small bowel transit time by increasing esophageal and gastric peristalsis and by lowering esophageal sphincter pressure.[5]

The literature survey revealed that several analytical methods, including LC/MS[6], HPLC[7-16], and UVspectroscopy[17], were reported on the individual drugs and along with the other drugs. Since Dexlansoprazole and Domperidone are a newly introduced fixed-dose combination, one analytical method; has been reported for the simultaneous estimation of these drugs. So, in the present research work, the aim is to develop and validate analytical methods for the simultaneous estimation of Dexlansoprazole and Domperidone.

MATERIALS AND METHOD

Instruments

- UV – Visible Spectrophotometer (Shimadzu – 1700, Software Version – UV Prob 2.32)
- Electronic Weighing Balance (Sartorius- TE-214S)
- Ultrasonicator (RC System-MU1700)

Chemicals

DXL and DOM API were procured as a gift sample from MSN Laboratories Private Ltd, and Walter Healthcare Private Ltd, respectively. Marketed formulation DDR-D is manufactured by MSN Laboratories Private Ltd.

Preparation of Standard Stock Solutions

Preparation of Standard Stock Solution

1. Standard Stock Solution of DXL

10mg of standard DXL was weighed and transferred to a 10 ml volumetric flask. DXL was dissolved in 5ml methanol by gentle shaking, and the volume was made up to the mark with methanol to obtain a final concentration of 1000 µg/ml and labelled as 'Std Stock DXL-A'. From this solution, 1 ml of an aliquot was pipetted out in a 10 ml volumetric flask and the volume was made up to the mark with methanol to obtain a final concentration of 100 µg/ml and labelled as 'Std Stock DXL-B'.

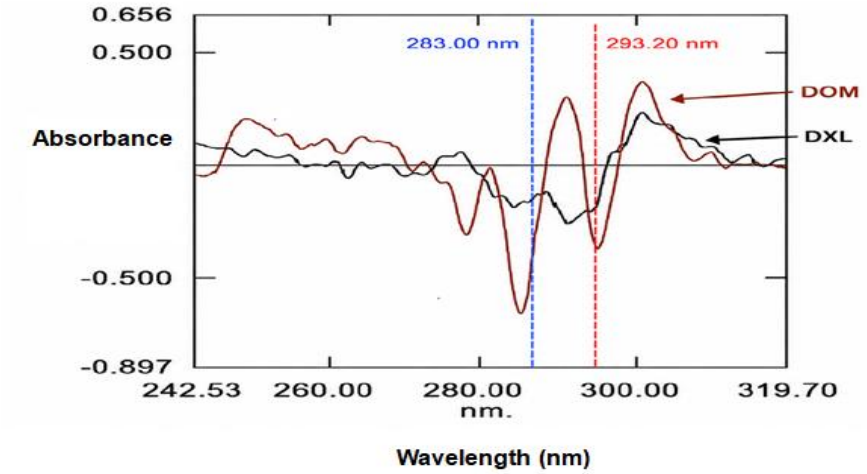
2. Standard Stock Solution of DOM

10mg of standard DOM was weighed and transferred to a 10 ml volumetric flask. DOM was dissolved in 5ml of methanol by gently shaking, and the volume was made up to the mark with methanol to obtain a final concentration of 1000 µg/ml and labelled as 'Std Stock DOM-A'. From this solution, 1 ml of an aliquot was transferred to a 25ml volumetric flask, and the volume was made up to the mark using methanol. This solution was labelled as 'Std Stock DOM-B" (100 µg/ml).

Selection of Analytical Wavelength

From the 'Std Stock DXL-B' (100 µg/ml) solution, 2ml of an aliquot was transferred to get a 10 ml volumetric flask and the volume was made up to the mark with methanol to obtain the final concentration of 20 µg/ml. The solution was scanned in the spectrum mode from 200 nm to 400 nm.

From the 'Std Stock DOM-B' (100 µg/ml) solution, 1.25 ml of an aliquot was pipetted out in a 10 ml volumetric flask and the volume was made up to the mark with methanol to get the concentration of 12.5 µg/ml of DOM. The solution was scanned in the spectrum mode from 200 nm to 400 nm. Overlin spectra are shown the figure.



Calibration curve for DXL and DOM, the stock solutions of DXL were diluted to get concentration range of 5-35 µg/ml and absorbance of these solutions were measured at 283 and 293.20 nm respectively. While for DOM the stock solution was diluted to get the concentration range of 5-30 µg/ml and absorbance of these solutions were measured at 283 nm. These zero-order spectra were converted to second-order derivative using $\Delta\lambda$=2 nm and a scaling factor of 100, and spectra and absorbance were observed at 283 and 293.20 nm. Calibration curves were plotted for these drugs as shown in the figure 4, 5 and 6.

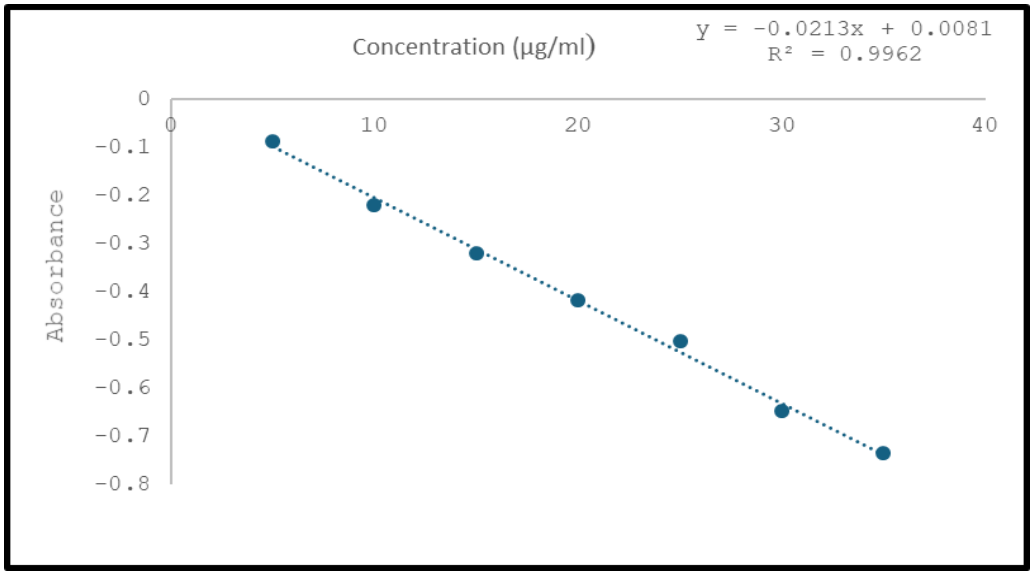


Figure 4: Calibration Curve of DXL at 293.20 nm.

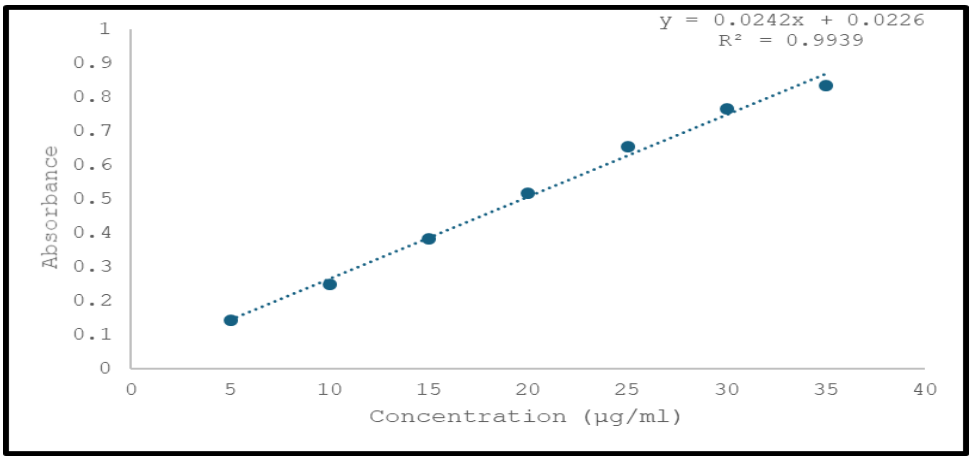


Figure 5: Calibration Curve of DXL at 283 nm.

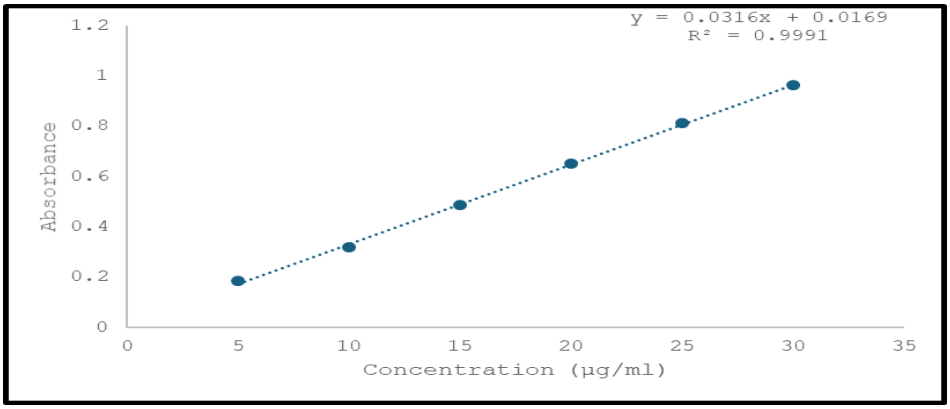


Figure 6: Calibration Curve of DOM at 283 nm.

Table 1: Linear Regression analysis for DXL and DOM.

Drug Parameter	DXL		DOM
Wavelength	293.20 nm	283 nm	283 nm
Beer's Law Limit (µg/ml)	5-35µg/ml	5-35µg/ml	40-250 µg/ml
Correlation Coefficient (R2)	0.9962	0.9939	0.9991
Slope	0.0213	0.0242	0.0316
Intercept	0.0213	0.0226	0.0169
A(1%,1cm)	212	242	318
LOD (µg/ml)	0.142	0.242	0.095
LOQ (µg/ml)	0.431	0.736	0.290

In this method, two wavelengths 283 nm ($\lambda 1$) and 293.20 nm ($\lambda 2$) were selected in such a way that absorbance of DXL is nearly zero at the analytical wavelength of DOM (283 nm).

Analysis of Capsule Formulation

Twenty Capsules of DXL and DOM (DDR-D, MSN Laboratories Private Ltd.) (DXL-60 mg and DOM-30 mg) were weighed and crushed to obtain fine powder, and the average weight was calculated. An accurately weighed tablet powder equivalent to about 10 mg DXL was transferred to a 25 ml volumetric flask and sonicated for 20 minutes with 15 ml of methanol for the extraction of drugs. The volume was made up to 25 ml with methanol. The resulting solution was filtered through Whatman filter paper no. 41, a few ml of the filtrate was discarded, and rest of the solution was used as 'Sample Stock A' (400 µg/ml of DXL, 200 µg/ml of DOM).

From this solution, 1.0 ml of the aliquot was pipetted out and transferred to a 10 ml volumetric flask. The volume was made to the mark with methanol to obtain a solution with a final concentration of 60 µg/ml of DXL and 30 µg/ml of DOM. This solution was scanned in the range of 200-400 nm. The spectrum was converted into a second-order derivative with $\Delta\lambda$=2 and a scaling factor of 10' and amplitude was measured at 283 nm and 293.20 nm. To calculate the % purity of DXL and DOM, the A1% 1cm values were used at the respective analytical wavelength of the drugs. The results are shown in Table 2.

Analyte	Label Claim	Mean % Assay	% RSD
DXL	60 mg	99.65±0.2404	0.2413
DOM	30 mg	99.16±1.2122	1.2224

Method Validation

The proposed method was validated in accordance to ICH guidelines. Accuracy of the method was determined using recovery study by standard addition method at three different levels 80%, 100% and 120% of assay concentration and percentage recovery were calculated. Precision of the method was determined using Intermediate precision: Intra-day precision, Inter-day precision, Variation by different analyst and Repeatability study. LOD and LOQ was determined by following formula.

$$\text{LOD} = 3.3 \times \frac{\text{Standard Deviation of y-Intercepts of Six Calibration curves}}{\text{Average Slope of Six Calibration Curves}}$$

$$LOQ = 10 \times \frac{\text{Standard Devation of y-Intercepts of Six Clibration curves}}{\text{Average of Slope of Six Calibration curves}}$$

RESULTS AND DISCUSSION

To develop absorbance correction method for simultaneous of DXL and DOM, the drug solutions were prepared in suitable concentration (35 µg/ml of DXL and 30 µg/ml of DOM) in methanol. These solutions were scanned from 200-400 nm and overlay spectra was observed for selection of analytical wavelength. It was observed that at 293.20 nm DXL was showing good absorbance where DOM is showing zero absorbance. So, 293.20 nm was selected as an analytical wavelength for DXL. The concentration of DXL was determined as a single drug estimation using A1% 1 CM value as 212. To determine DXL absorbance at 283 nm, A=abc, equation was used and absorbance of DXL at 283 nm was calculated using A1% 1cm value as 318 at 283 nm. Using this method, the absorbance of marketed formulation (DDR-D) (DXL-60 mg and DOM-30 mg) was measured at 293.20 nm and 283 nm and amount of drugs present were found using A1%1cm values of the respected drugs at their analytical wavelength are given in Table 2. Mean percentage assay of DXL and DOM were found as 99.48 % and 101.11 % respectively. The developed absorbance correction method for simultaneous estimation of DXL and DOM was validated as per ICH guidelines and was found linear in the concentration range of 5-35 µg/ml for DXL with R2 value as 0.9958 at 293.20 nm and that for DOM the method was linear in the concentration range of 5-30 µg/ml with R2 value as 0.9981 at 283 nm. As the R2 value is more than 0.999 the method showed satisfactory linearity in the selected range. Accuracy was determined by standard addition method (80%, 100% and 120% of the assay level), %recoveries of DXL and DOM were found to be in the range of 98.86-101.73 % and 99.71-101.58 % respectively. Precision of the method was determined using intra-day precision and inter-day precision. It was found that %RSD for all these studies and both the drugs were less than 2%. LOD and LOQ of DXL were found to be 0.142 and 0.431 µg/ml at 293.20 nm, respectively. LOD and LOQ of the DOM were found to be 0.095 and 2.90 µg/ml at 283 nm, respectively.

CONCLUSION

A simple, precise, and sensitive UV-spectrometric method utilizing the absorbance correction technique has been developed for the simultaneous estimation of Dexlansoprazole and Domperidone. The developed method was rigorously validated according to ICH guidelines, and the results of the assay and validation studies were satisfactory. Therefore, this method can be successfully applied for routine analysis of Dexlansoprazole and Domperidone in the marketed formulations within the pharmaceutical industry.

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