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ANALYTICAL METHOD DEVELOPMENT AND VALIDATION FOR SIMULTANEOUS UV SPECTROPHOTOMETRIC ESTIMATION OF DEXLANSOPRAZOLE AND DOMPERIDONE

Kumara Prasad S. A.[1*], Abhiram M. S.[2] and Raju H. V.[3]

[1]Department of Pharmaceutical Chemistry, Srinivas College of Pharmacy, Valachil, Mangalore, Karnataka, India. 574143.

[2]Department of Pharmaceutical Chemistry, Visveshwarapura Institute of Pharmaceutical Sciences, Bangalore, Karnataka, India. 560070.

[3]Department of Pharmacognosy, Visveshwarapura Institute of Pharmaceutical Sciences, Bangalore, Karnataka, India. 560070.

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***Corresponding Author**
Kumara Prasad S. A.
Department of Pharmaceutical Chemistry, Srinivas College of Pharmacy, Valachil, Mangalore, Karnataka, India. 574143.

ABSTRACT

In the present study, a simple and sensitive UV spectrophotometric absorbance ratio method was developed for the simultaneous estimation of Dexlansoprazole and Domperidone in bulk and pharmaceutical formulations. The absorbance ratio method is based on the measurement of absorbance at two selected wavelengths: one at the isoabsorptive point (279 nm) and the other at the λmax of Domperidone (285 nm). The method was successfully applied to the analysis of Dexlansoprazole and Domperidone in a sample formulation, yielding 55.67 mg of Dexlansoprazole and 28.69 mg of Domperidone, which complies with the labeled claim of 60 mg and 30 mg, respectively. The method obeyed Beer's law in the concentration range of 10–50 µg/ml for Dexlansoprazole and 5–25 µg/ml for Domperidone. The calibration curves exhibited good linearity, with correlation coefficients (r^2) of 0.999 for Dexlansoprazole and 0.998 for Domperidone. The limit of detection (LOD) was determined to be 0.4 µg/ml for Dexlansoprazole and 0.2 µg/ml for Domperidone. The developed method is accurate, precise, and reproducible, making it suitable for routine quality control analysis of Dexlansoprazole and Domperidone in pharmaceutical dosage forms.

KEYWORDS: Dexlansoprazole, Domperidone, Absorbance ratio.

INTRODUCTION

Dexlansoprazole is a new generation proton pump inhibitor used for the management of symptoms associated with GERD and erosive esophagitis and chemically (R)-(+)-2-([3-methyl-4-(2,2,2-trifluoroethoxy)pyridin-2-yl]methylsulfinyl)-1H-benzo[d]imidazole[1]. It is an enantiomer of lansoprazole. Dexlansoprazole inhibits the H/K ATPase enzyme [1-3], which is involved in the secretion of hydrochloric acid, hydrolyzing ATP and exchanging H+ ions from the cytoplasm for K^+ ions in the secretary canaliculus, which results in Hydrochloric acid secretion into the gastric lumen[1,2]. Dexlansoprazole inhibits this effect of H/K ATPase by demonstrating a high degree of activation in the acidic environment.

Domperidone is a prokinetic which works on the upper digestive tract to increase the movement of the stomach and intestine, allowing the food to move more easily through the stomach and Chemically 5-Chloro-1-(1-[3-(2-oxo-2,3-dihydro-1H-benzo[d]imidazol-1-yl)propyl]piperidin-4-yl)-1H-benzo[d]imidazol-2(3H)-one.[2] It is a dopaminergic blocker that increases lower oesophagus sphincter pressure and activates gastric motility. Domperidone facilitates gastric emptying and decreases small bowel transit time by increasing esophageal and gastric peristalsis and by lowering esophageal sphincter pressure. It has strong affinities for the D_2 and D_3 dopamine receptors, which are found in the chemoreceptor trigger zone, located just outside the blood brain barrier, which - among others - regulates nausea and vomiting.

Dexlansoprazole and Domperidone in combination are used to treat gastroesophageal reflux disease (Acid reflux) and peptic ulcer disease by relieving the symptoms such as heart burn, stomach pain or irritation. It also neutralizes the acid in the stomach and promotes easy passage of gas to reduce stomach discomfort.

DRUG PROFILE

DEXLANSOPRAZOLE

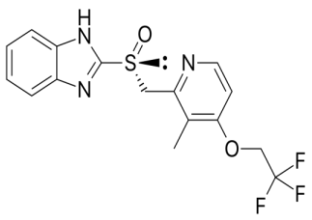

Fig. 1: Molecular structure of Dexlansoprazole.

MOLECULAR FORMULA: $C_{16}H_{14}F_3N_3O_2S$

MOLECULARWEIGHT: 369.36

CHEMICAL NAME: (R)-(+)-2-([3-methyl-4-(2,2,2-trifluoroethoxy)pyridin-2-yl]methylsulfinyl)-1H-benzo[d]imidazole

DESCRIPTION: White to nearly white crystalline powder

MELTING POINT: 139 - 140°C

DOSE: 30 mg taken once per day.

SOLUBILITY: It is freely soluble in dimethylformamide, methanol, dichloromethane, ethanol, and ethyl acetate; and soluble in acetonitrile; slightly soluble in ether; and very slightly soluble in water; and practically insoluble in hexane.

CATEGORY: Proton pump inhibitor

DOMPERIDONE

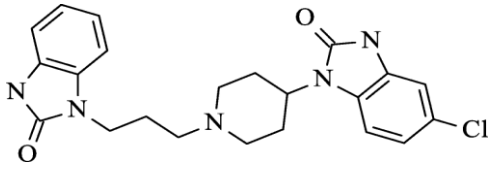

Fig. 2: Molecular structure of Domperidone.

MOLECULAR FORMULA: $C_{22}H_{24}ClN_5O_2$

MOLECULAR WEIGHT: 425.92

CHEMICAL NAME: 5-Chloro-1-(1-[2-oxo-2,3-dihydro-1H-benzo[d]imidazol-1yl)propyl] piperidin-4-yl)-1H-benzo[d]imidazol-2(3H)-one

DESCRIPTION: White or almost white powder

MELTING POINT: 233-236° C

DOSE: 10 milligrams (mg) three to four times daily

SOLUBILITY: Practically insoluble in water, soluble in dimethylformamide, slightly soluble in ethanol (96 per cent) and in methanol.

CATEGORY: Antiemetic and prokinetic (dompamine antagonist)

There was no method reported for the simultaneous estimation of this combination. Review revealed only few analytical methods (UV spectrophotometry, HPLC, HPTLC, LC-MS) methods reported for Dexlansoprazole and Domperidone for individual and other drug combination. Hence it was proposed to develop economical, rapid and simple UV

Spectrophotometric methods for the simultaneous estimation of these drugs in combined dosage forms.

MATERIALS AND METHODS

Instrument used: The SYSTRONICS PC based double beam spectrophotometer with spectral band width 2.0nm wavelength accuracy 0.5nm and matched quartz cells of 1 cm path length was used for all spectral and absorbance measurements.

Chemicals and Reagents: Pure sample of Dexlansoprazole and Domperidone was procured from MSN Laboratories Private Limited. Dosage formulation was procured from local market. Methanol AR grade obtained from S D Fine Chemicals, Mumbai.

Tablet formulation used: DDR-D, manufactured by MSN Laboratories Private Limited containing Dexlansoprazole IP - 60mg and Domperidone IP – 30mg.

Preparation of Standard Stock Solutions of Dexlansoprazole and Domperidone separately in methanol

Weighed accurately 100 mg of DEXL and 100 mg of DOMP separately, transferred into 100 ml Standard flask, dissolved and made up to the volume using methanol. Serial dilutions are done with methanol to get the final concentration of 10µg/ml of DEXL and DOMP.

Determination of Absorption maxima of DEXL and DOMP in Methanol

After enabling the initial adjustments and Blank correction using methanol the solution of DEXL and DOMP was scanned separately in the UV region ranging from 200 nm to 400 nm. A broad band of Absorption spectrum was observed with maximum absorption at 285 nm for DEXL and 288 nm for DOMP.

Development of Absorbance Ratio Equation

The absorbance ratio method is a modification of the simultaneous equation method and is based on the fundamental property of a substance that obeys Beer's law at all wavelengths. According to this principle, the ratio of absorbance at any two selected wavelengths remains constant, regardless of concentration or wavelength. This ratio is commonly referred to as the Q-value.

In this method, absorbance is measured at two specific wavelengths: λmax (λ_2) - the wavelength at which one of the components shows maximum absorbance. Isoabsorptive point (λ_1) - the wavelength at which both components exhibit equal absorptivity. By utilizing these

two wavelengths, the concentrations of both components in a mixture can be accurately determined, making the absorbance ratio method a simple and effective tool for simultaneous estimation in pharmaceutical analysis.

$Cx = Qm - Qy / Qy - Qx \times A_1 / a_{x1}$

$Cy = Qm - Qy / Qx - Qy \times A_1 / a_{y1}$

Cx = concentration of x

Cy = concentration of y

Qm = Ratio of absorbance of mixture at $\lambda 1$ and λ_2

Qx = Ratio of absorptivity of x component at $\lambda 1$ and λ_2

Qy = Ratio of absorptivity of y component at $\lambda 1$ and λ_2

Study of overlay spectral characteristics of DEXL and DOMP in Methanol

Accurately 1 ml of each standard drug solution (100 µg/mL) was pipetted separately into 10 ml volumetric flasks, and the volume was made up using methanol. These solutions were then scanned over the entire 200-400 nm range to obtain an overlay spectrum. From the overlay spectra, two specific wavelengths were selected: 279 nm (Isoabsorptive Point) - At this wavelength, both Dexlansoprazole (DEXL) and Domperidone exhibit the same absorbance. 285 nm (λ-max of Dexlansoprazole). This corresponds to the maximum absorbance of Dexlansoprazole. These selected wavelengths were used for the simultaneous estimation of Dexlansoprazole and Domperidone using the absorbance ratio method.

Simultaneous estimation of DEXL and DOMP in dosage forms

Twenty capsules, each containing 60 mg of Dexlansoprazole (DEXL) and 30 mg of Domperidone (DOMP), were accurately weighed and finely powdered using a glass mortar. A quantity equivalent to 60 mg of DEXL and 30 mg of DOMP was accurately weighed and transferred to a 100 ml volumetric flask.

To this, 100 ml of methanol was added, and the mixture was gently swirled for 10 minutes to ensure proper dissolution. The clear supernatant solution was then filtered through Whatman No. 1 filter paper into a 100 ml volumetric flask. The residue was further extracted twice with 20 ml of methanol each time, and the filtrate was combined and made up to 100 ml with methanol. This resulting solution (Solution A) had a concentration of 600 µg/ml of DEXL and 300 µg/ml of DOMP.

From Solution A, an accurately measured 10 ml was transferred into a 100 ml volumetric flask, and the volume was adjusted with methanol to obtain Solution B, with a final concentration of 60 µg/ml of DEXL and 30 µg/ml of DOMP.

A further dilution was prepared by accurately pipetting 4 ml of Solution B into a 10 ml volumetric flask and making up the volume with methanol, yielding a final concentration of 24 µg/ml of DEXL and 12 µg/ml of DOMP.

The absorbance of this solution was measured at 279 nm (isoabsorptive point) and 285 nm (λmax of DEXL). The concentration of each drug was then determined using the absorbance ratio method.

Validation of the method

(a) Linearity and range

Calibration curves were prepared for both the drugs at 279 nm and 285 nm separately. The regression equation, slope and correlation coefficient show that DEXL and DOMP obey Beer's law in the concentration range 10 - 50 µg/ml for DEXL and 5 - 25 µg/ml for DOMP at 279 nm and 285 nm.

(b) Accuracy

The absorbances of 80%, 100% and 120% solutions were recorded at wavelengths 279 nm and 285 nm. Concentrations of Dexlansoprazole and Domperidone in each solution were calculated from Absorbance Ratio equation.

(c) Precision

System Precision

The absorbance of six determinations of working solution was recorded at wavelengths 279 nm and 285 nm. The % RSD was calculated for the absorbance of replicates.

Method Precision

The absorbance of six determinations of working solution was taken at wavelengths 279 nm and 285 nm. Concentration of Dexlansoprazole and Domperidone each replicate was calculated from absorbance ratio equation. The % RSD was calculated from the concentrations of Dexlansoprazole and Domperidone.

Inter-day Precision

The absorbance of six determinations of working solution was taken at wavelengths 279 nm and 285 nm on different days. Concentration of Dexlansoprazole and Domperidone each replicate was calculated from simultaneous equation. The % RSD was calculated from the concentrations of Dexlansoprazole and Domperidone six determinations of working solution. The standard deviation and relative standard deviation were calculated.

Intra-day Precision

The absorbance of six determinations of working solution was taken at wavelengths 279 nm and 285 nm on different intervals in the same day. Concentration of Dexlansoprazole and Domperidone each replicate was calculated from simultaneous equation. The % RSD was calculated from the concentrations of Dexlansoprazole and Domperidone six determinations of working solution. The standard deviation and relative standard deviation were calculated.

(d) Limit of Detection (LOD)

For determination of LOD, visualization method was followed. In visualization method lower dilutions of the standard drugs were made and absorbance at 279 nm and 285 nm were recorded.

RESULTS

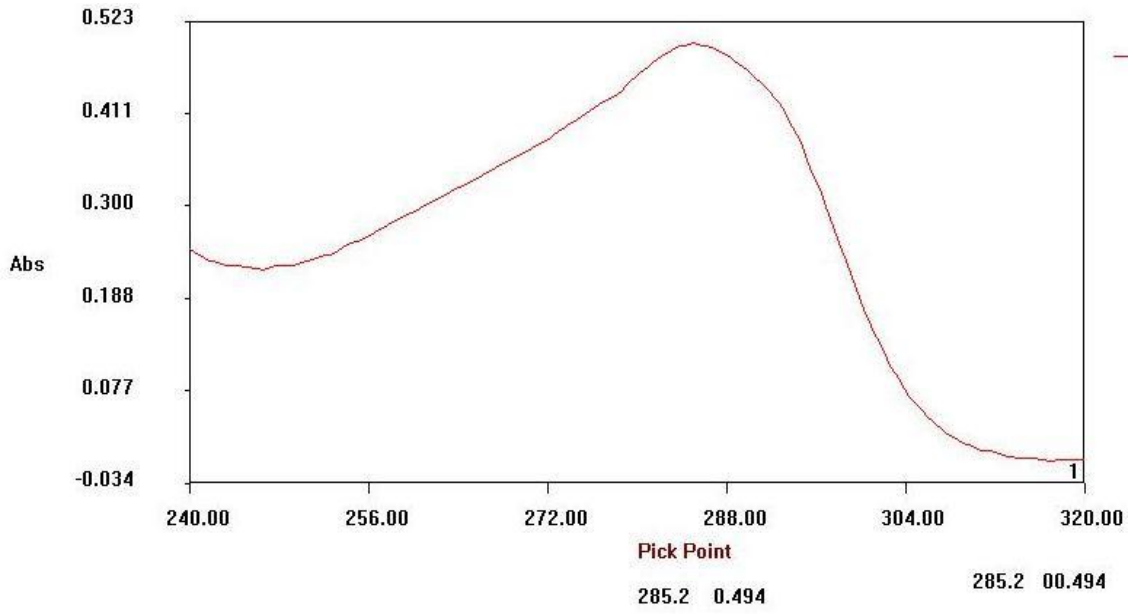

Fig. 3: The UV-Spectra of Dexlansoprazole.

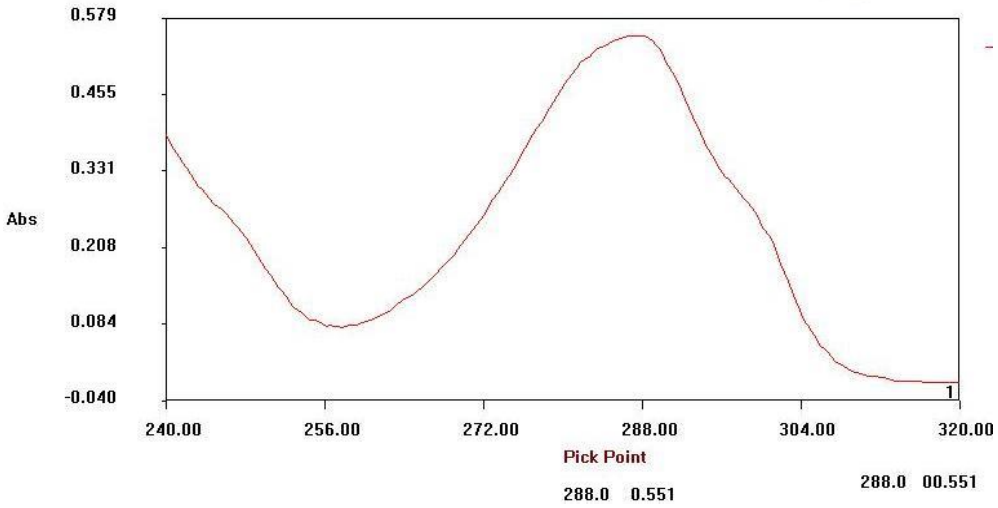

Fig. 4: The UV-Spectra of Domperidone.

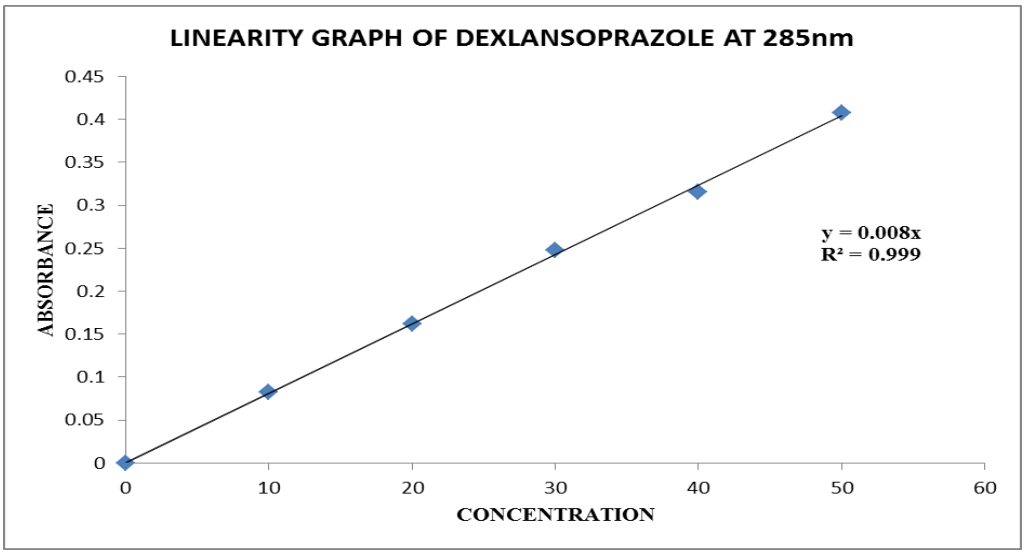

Fig. 5: Calibration curve of DEXL at 285 nm.

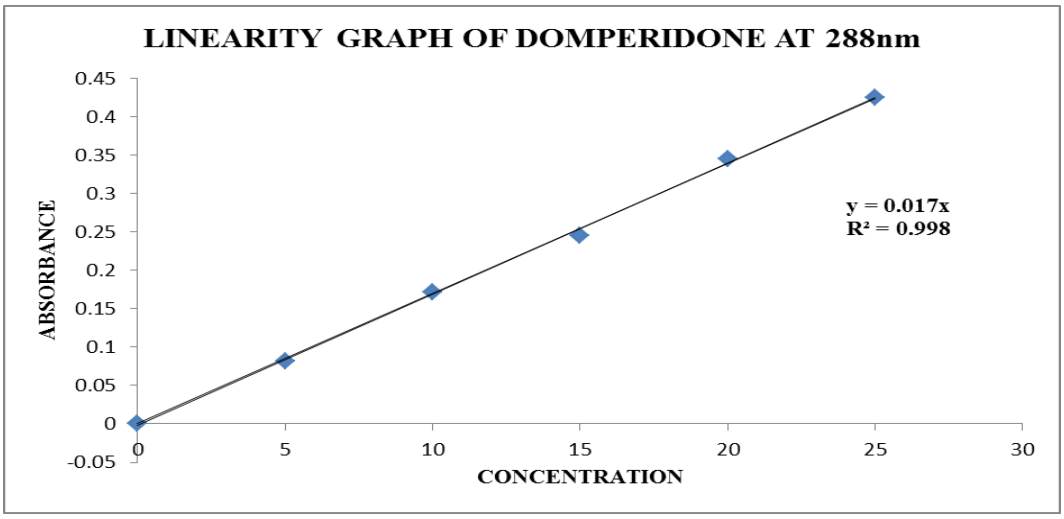

Fig. 6: Calibration curve of DOMP at 288 nm.

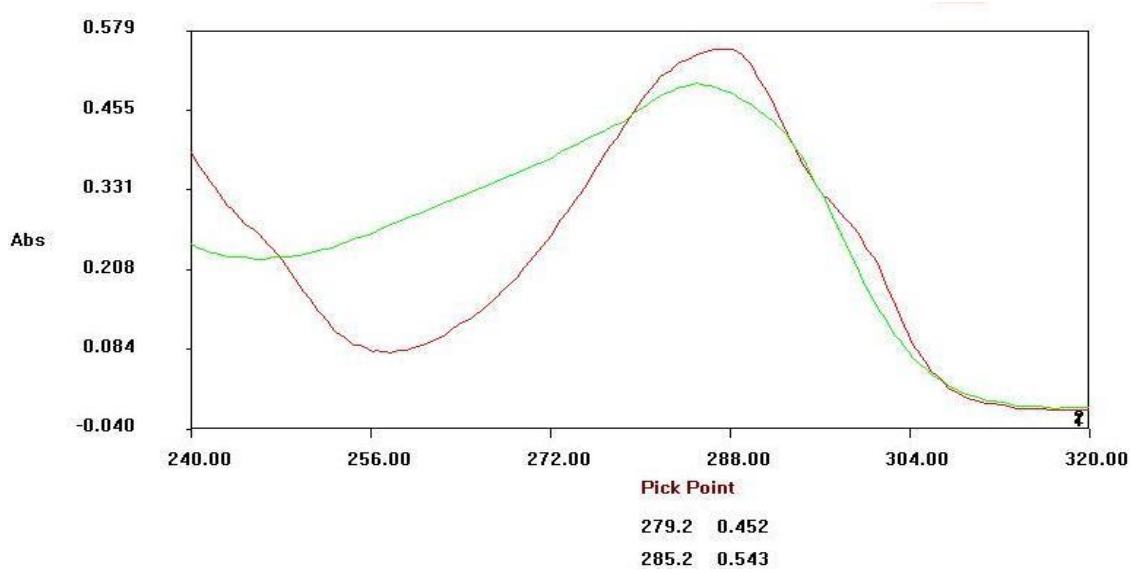

Fig. 7: The Overlay of Dexlansoprazole and Domperidone.

Table 1: Absorptivity Data for Dexlansoprazole and Domperidone.

Sl. No.	Dexlansoprazole					Domperidone				
	Conc. µg/ml	279nm		285nm		Conc. µg/ml	279nm		285nm	
		abs	a_{x1}	abs	a_{x2}		abs	a_{y1}	abs	a_{y2}
1	**10**	0.095	0.0095	0.065	0.0065	**5**	0.093	0.0186	0.103	0.0206
2	**20**	0.190	0.0095	0.130	0.0065	**10**	0.187	0.0187	0.205	0.0205
3	**30**	0.286	0.0095	0.194	0.0064	**15**	0.279	0.0186	0.308	0.0205
4	**40**	0.382	0.0095	0.270	0.0067	**20**	0.373	0.0186	0.410	0.0205
5	**50**	0.475	0.0095	0.325	0.0065	**25**	0.466	0.0186	0.512	0.0204
--	**---**	**MEAN**	**0.0095**	**MEAN**	**0.0065**	**--**	**MEAN**	**0.0186**	**MEAN**	**0.0205**

Table 2: Result of standard mixture.

Std mixture conc. (µg/ml)	Abs at 279nm	Abs at 285nm	Concentration obtained(µg/ml)		Amount obtained in %	
			DEXL	DOMP	DEXL	DOMP
24:12	0.446	0.398	23.57	11.94	98.2	99.5

Table 3: Result of dosage form.

Capsule mixture conc. (µg/ml)	Abs at 279nm	Abs at 285nm	Concentration obtained(µg/ml)		Amount of drug in capsule (mg)		Amount obtained in %	
			DEXL	DOMP	DEXL	DOMP	DEXL	DOMP
24:12	0.425	0.380	22.27	11.48	55.67	28.69	92.78	95.63

Validation of the method

(a) Linearity and range

Table 4: Linearity report of Dexlansoprazole and Domperidone at 279 and 285 nm.

Parameters	Dexlansoprazole		Domperidone	
	279 nm	285 nm	279 nm	285 nm
Linearity range (µg/ml)	10 - 50µg/ml	10 - 50µg/ml	5 - 25µg/ml	5 - 25µg/ml
Regression equation	0.0095x	0.0066x - 0.0006	0.0186x	0.0205x + 0.0003
Correlation coefficient	0.998	0.999	0.997	0.998
Slope	0.0095	0.0066	0.0186	0.0205

(b) Accuracy Determination.

Table 5: Recovery Data of Standard Mixture.

Level (%)	Sample conc. (µg/ml)		Total Conc. (µg/ml)		Amount of std recovered(µg/ml)		% Recovery of standard	
	DEXL	DOMP	DEXL	DOMP	DEXL	DOMP	DEXL	DOMP
80%	24	12	43.2	21.6	42.7	20.8	98.84	96.29
100%	24	12	48	24	47.2	23.8	98.33	99.16
120%	24	12	52.8	26.4	51.5	25.9	97.53	98.10

(c) Precision

Table 6: Inter-day Precision Data of Dexlansoprazole and Domperidone.

Replicates	Date interval	Concentration in µg/ml	
		Dexlansoprazole	Domperidone
1	20-09-23	23.97	11.97
2	21-09-23	23.96	11.95
3	22-09-23	23.95	11.97
4	23-09-23	23.99	11.94
5	25-09-23	23.97	11.98
6	26-09-23	23.98	11.96
Mean	-----	**23.97**	**11.96**
Standard deviation	-----	**0.0141**	**0.0141**
%RSD	-----	**0.0588**	**0.1178**

Table 7: Intra-day Precision Data of Dexlansoprazole and Domperidone.

Replicates	Time interval	Concentration in µg/ml	
		Dexlansoprazole	Domperidone
1	10:30AM	23.94	11.95
2	11:30AM	23.93	11.94
3	12:30PM	23.99	11.98
4	1:30PM	23.94	11.94
5	2:30PM	23.95	11.98
6	3:30PM	23.98	11.93
Mean	-----	**23.95**	**11.95**
Standard	-----	**0.0248**	**0.0219**

deviation			
%RSD	-----	0.1039	0.1832

(d) Limit of Detection (LOD).

Table 8: LOD Data of Dexlansoprazole.

Concentration (µg/ml)	Absorbance at 285 nm	Absorbance at 279 nm
0.5	0.0185	0.0142
0.4	0.0126	0.0101
0.3	----	----

Table 9: LOD Data of Domperidone.

Concentration (µg/ml)	Absorbance at 285 nm	Absorbance at 279 nm
0.3	0.0198	0.0151
0.2	0.0140	0.0110
0.1	----	----

DISCUSSION

The present study focused on the development and validation of a simple, accurate, and precise UV spectrophotometric absorbance ratio method for the simultaneous estimation of Dexlansoprazole (DEXL) and Domperidone (DOMP) in bulk and pharmaceutical formulations. The absorbance ratio method is based on the measurement of absorptivities at two selected wavelengths: λ-max (λ_2): The wavelength at which one of the components exhibits maximum absorbance (285 nm for DEXL, 288 nm for DOMP). Isoabsorptive point (λ_1): The wavelength where both components show equal absorptivity (279 nm). The absorptivity values at these wavelengths were determined as at 279 nm: 0.0095 (DEXL), 0.0186 (DOMP) and at 285 nm: 0.0065 (DEXL), 0.0205 (DOMP).

The proposed method was successfully applied to the estimation of Dexlansoprazole and Domperidone in a marketed formulation. The sample analysis results demonstrated the accuracy of the method, yielding: 55.67 mg of Dexlansoprazole and 28.69 mg of Domperidone. These values were in good agreement with the labeled claims of 60 mg (DEXL) and 30 mg (DOMP), indicating the reliability of the method for routine analysis.

- ✓ In method Validation, the method showed excellent linearity within the concentration ranges: Dexlansoprazole: 10–50 µg/ml and Domperidone: 5–25 µg/ml.
- ✓ The correlation coefficients (r^2) were found to be 0.999 for DEXL and 0.998 for DOMP, confirming the linear relationship between absorbance and concentration.

- ✓ Accuracy was evaluated through recovery studies by spiking known concentrations of standard drug at 80%, 100%, and 120% levels. The results showed percentage recoveries of: 97.53–98.84% for Dexlansoprazole and 96.29–99.16% for Domperidone. These values comply with the acceptance criteria (90–110%), confirming the method's accuracy.
- ✓ The precision of the method was assessed through method precision, system precision, and interday precision studies. Method Precision (%RSD of Assay) result was Dexlansoprazole: 0.1135% and Domperidone: 0.1178%. System Precision (%RSD of Absorbance Values) at 279 nm: 0.3603% at 285 nm: 0.4497%. Interday Precision (%RSD of Assay on Different Days): Dexlansoprazole: 0.0588% Domperidone: 0.1178% Since all %RSD values were below 2%, the method demonstrated high precision and reproducibility.
- ✓ Limit of Detection (LOD): Dexlansoprazole: 0.4 µg/ml and Domperidone: 0.2 µg/ml. These results indicate the high sensitivity of the method for detecting low concentrations of the drugs.

Overall Findings: The developed UV spectrophotometric absorbance ratio method was found to be simple, precise, accurate, and reproducible for the simultaneous estimation of Dexlansoprazole and Domperidone in bulk and pharmaceutical dosage forms. The validation parameters confirm its suitability for routine quality control analysis in pharmaceutical industries.

CONCLUSION

The Absorbance Ratio Method developed for the simultaneous estimation of Dexlansoprazole and Domperidone in bulk and pharmaceutical dosage forms was found to be simple, precise, accurate, and cost-effective. The method involves measuring absorbance at 279 nm (isoabsorptive point) and 285 nm (λmax of Dexlansoprazole), requiring only basic calculations using absorbance ratio equations.

The validation parameters demonstrated linearity, accuracy, precision, and sensitivity within the specified range. The method provides reliable results that comply with label claims, making it suitable for routine quality control analysis in pharmaceutical industries. Additionally, the method is rapid and economical, requiring minimal sample preparation, making it a viable alternative to more complex analytical techniques.

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