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Research Article

Development and Validation of UV-Visible Spectrophotometric Method for Estimation of Dexlansoprazole

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Abstract

Aim: The Proposed study aimed to develop and validate a simple, accurate, precise and cost-effective UV-Visible spectrophotometric method for the estimation of Dexlansoprazole in bulk as well formulation.

Methods: A UV-Visible spectrophotometric method for Dexlansoprazole was developed using water containing 40% acetonitrile as solvent system. After development, proposed method was validated using ICH Q2 (R1) guidelines. Dexlansoprazole solutions were scanned across the UV-visible range to identify its wavelength of maximum absorbance. The linearity of the method was established using seven calibration standards over a concentration range of 1–25 µg/mL. Three different quality control standard solutions of the Dexlansoprazole were used for establishing the accuracy and precision of the proposed method. Validity of the proposed method was established on the basis of accuracy, precision, robustness, ruggedness, limit of detection (LOD), and limit of quantitation (LOQ).

Results: The Dexlansoprazole when dissolved in water containing 40% acetonitrile showed maximum absorbance at wavelength of 282 nm. The developed UV-Visible spectrophotometric method demonstrated excellent linearity across the concentration range of 1–25 µg/mL, with a correlation coefficient (r^2) of 0.999. The intra-day accuracy of the proposed UV-Visible spectrophotometric method in terms of % Difference was in the range of –2.04 to +2.63 whereas the inter-day accuracy was in the range of –2.04 to +2.12. The intra-day precision of the proposed UV-Visible spectrophotometric method in terms of % RSD was found to be in between 1.31 to 1.73 whereas the inter-day precision values were in between 1.59 to 2.00. The variation (% RSD) during the robustness and ruggedness studies of the proposed UV-Visible spectrophotometric method was found to be below 2%. The limit of detection (LOD) and limit of quantitation (LOQ) of the proposed UV-Visible spectrophotometric method was found to be 0.1008 µg/mL and 0.3058 µg/mL respectively, ensuring adequate sensitivity for routine quality control analysis. Proposed method was successfully used for the estimation of Dexlansoprazole in formulation as well as bulk.

Conclusion: A simple, precise, yet cost-effective UV-visible spectrophotometric method was successfully developed for the estimation of Dexlansoprazole. The method utilized a solvent with an economical percentage of the organic phase in aqueous media. The validated UV-Visible method can be efficiently employed for the estimation of Dexlansoprazole.

Keywords: Dexlansoprazole, UV-Visible spectrophotometry, ICH guidelines.

1. INTRODUCTION

Dexlansoprazole is a proton pump inhibitor (PPI) used for the treatment of acid-related gastrointestinal disorders such as gastroesophageal reflux disease (GERD) and erosive esophagitis¹. Dexlansoprazole suppresses the final step of acid production by targeting the H^+/K^+ ATPase enzyme in gastric parietal cells and thereby provides long-lasting relief from gastric acidity²⁻⁴. It is the R-enantiomer of lansoprazole and its enantiomeric purity contributes to its improved bioavailability, better acid control, and a reduced risk of drug interactions as compare to its racemic counterpart⁵. Chemically, dexlansoprazole is described as (R)-2-([3-methyl-4-(2,2,2-trifluoroethoxy) pyridin-2-yl] methyl sulfinyl)-1H-benzimidazole (Figure 1)⁶.

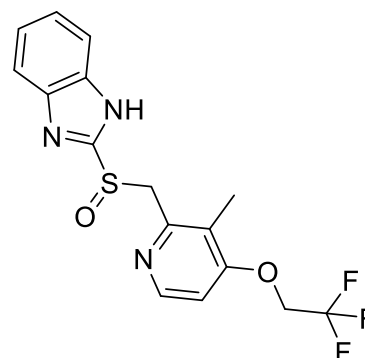


Figure 1 Molecular Structure of Dexlansoprazole

Dexlansoprazole is BCS class II drug, having low solubility but high permeability. It appears as a white to off-white powder and is practically insoluble in water which makes solubility enhancement and accurate quantification essential challenges in its formulation⁷⁻¹⁰.

Till date, there are numerous analytical methods available for the estimation of Dexlansoprazole. Some of the methods requires high end instrumentation whereas some of the methods involves complex preparations before analysis with compromised limits of detection and quantification. Considering the said disadvantages, it was envisaged that development of precise UV-Visible spectrophotometric method involving simple sample preparation for the estimation of Dexlansoprazole would be worth¹¹⁻¹⁵.

2. MATERIAL AND METHODS

2.1 Instrumentation:

For the method development, pre-calibrated double-beam UV-visible spectrometer (UV-530, Jasco) with Spectra Manager software was used. Quartz cells measuring 3 cm in length and 1 cm in path length were employed for the spectral measurements. For precise weighing, an analytical balance (Essae, Vibra HT) with an internal calibration mode was utilized.

2.2 Material:

Dexlansoprazole was purchased from TCI Chemicals (India) Pvt. Ltd., Chennai. Acetonitrile was purchased from Merck. For the study, all the chemicals used were of at least analytical grade.

2.3 Preparation of standard stock solutions:

Initially, 100 mg of Dexlansoprazole was accurately weighed and transferred to volumetric flask of 100 ml capacity. Sufficient quantity of mixture of acetonitrile and water (40:60 v/v) was added to volumetric flask containing Dexlansoprazole and flask was subjected to ultrasonic water bath for 5 minutes. The volume was made up to 100 ml with the mixture of acetonitrile and water (40:60 v/v) and the solution was designated as Stock-I. Stock-I was suitably diluted with mixture of acetonitrile and water (40:60 v/v) so as to achieve the solution having concentration 20 µg/ml (Stock-II).

2.4 Determination of wavelength of maximum absorbance ($\lambda_{\max}$):

Stock-II solution was used for the determination of wavelength of maximum absorbance ($\lambda_{\max}$). The spectrophotometer was set in Spectrum Measurement mode and the Stock-II solution of Dexlansoprazole was scanned over the wavelength range of 200 to 800 nm. The scanning process was repeated five times using a fresh Stock-II solutions.

2.5 Preparation of calibration curve:

Stock-I solution was diluted suitably with mixture of acetonitrile and water (40:60 v/v) so as to achieve the solution of strength 100 µg/ml (Stock-III). Stock-III solution was diluted suitably using a mixture of acetonitrile and water (40:60 v/v) so as to achieve the

seven calibration standards viz. CAL-STD-1 (1 µg/mL), CAL-STD-2 (2 µg/mL), CAL-STD-3 (4 µg/mL), CAL-STD-4 (8 µg/mL), CAL-STD-5 (16 µg/mL), CAL-STD-6 (20 µg/mL) & CAL-STD-7 (25 µg/mL). Spectrophotometer was set in Fixed Wavelength Measurement mode and absorbance of each CAL-STD was measured at pre-measured wavelength of maximum absorbance of 282 nm. The aforementioned procedure was repeated five times to ensure the reproducibility of the results. The results were expressed in terms of mean $\pm$ SD.

2.6 Method Validation

The developed UV-Visible spectrophotometric method of Dexlansoprazole was validated using the ICH Q2 (R1) guidelines. Said method was assessed for its linearity, accuracy, precision, robustness, ruggedness, limit of detection (LOD), and limit of quantitation (LOQ).

2.6.1 Linearity and Range: Seven pre-defined calibration standards as mentioned above were used to establish the linearity of the developed UV method. Calibration curves of absorbance vs. concentration were subjected to linear least-squares regression analysis. The suggested method's linearity was established by using the r^2 value. The range of the developed UV method was stated to be in between the upper and lower concentration limits with satisfactory linearity.

2.6.2 Accuracy:

Accuracy of the proposed UV-Visible spectrophotometric method was established using quality control standards (QC-STD). Three distinct Dexlansoprazole quality control standards, viz QC-STD-1, QC-STD-2 and QC-STD-3 having nominal concentration of 1.5 µg/mL, 13 µg/mL and 24 µg/mL respectively were prepared in quintuplicate and used for the proposed study. Said QC-STD were analyzed for its Dexlansoprazole content using proposed UV-Visible spectrophotometric method at three different time intervals in a day. Said process of QC-STDs preparation and its analysis for Dexlansoprazole content was repeated every day for the three consecutive days. The intra-day and inter-day accuracy of the proposed method was established in terms of % Difference which was calculated using following formula.

$$\% \text{ Difference} = \frac{(\text{Mean Measured Concentration} - \text{Nominal Concentration})}{\text{Nominal Concentration}} \times 100 \quad \dots\dots\dots (1)$$

2.6.3 Precision:

The precision of the proposed UV-Visible spectrophotometric method was established in terms of % Relative Standard Deviation (RSD) using the same QC-STDs as that of accuracy studies. The intra- and inter-day precision was established by analyzing the QC-STDs for its Dexlansoprazole content at three different time intervals in a day and repeating the analysis for three consecutive days. The % RSD was calculated using following formula

$$\% \text{ RSD} = \frac{\text{Standard Deviation (SD)}}{\text{Mean}} \times 100 \quad \dots\dots\dots (2)$$

2.6.4 Robustness:

Robustness of the proposed UV-Visible Spectrophotometric method was established by using two different solvent mixtures. Pre-defined QC-STDs in quintuplicate were separately prepared in two solvent mixtures (acetonitrile: water in a ratio of 38:62 and 42:58 v/v). All the samples were analyzed for its Dexlansoprazole content and results were expressed in Mean $\pm$ % RSD. The % RSD values ≤ 2 were considered to be an indicator of the robustness of the proposed UV-Visible spectrophotometric method.

2.6.5 Ruggedness:

The ruggedness of the proposed UV-Visible spectrophotometric method was demonstrated by performing the Dexlansoprazole sample analysis using two different UV-Visible Spectrophotometers. Dexlansoprazole solution (13 μ g/mL) in triplicates was analyzed by using two distinct instruments (BIOAGE and V-530 JASCO), recording the absorbance and demonstrating the variation in terms of % RSD. The method was considered to be rugged in case of ≤ 2 % RSD.

2.6.6 Limit of Detection (LOD): The LOD of the developed UV method was calculated by using the following formula,

$$LOD = \frac{3.3 \times SD}{S} \dots \dots \dots (3)$$

Where, SD= Standard deviation of Y-intercepts

S= Slope of the calibration curve

2.6.7 Limit of Quantitation (LOQ): The LOQ of the developed UV method was calculated by using the following formula

$$LOQ = \frac{10 \times SD}{S} \dots \dots \dots (4)$$

Where, SD= Standard deviation of Y-intercepts

S= Slope of the calibration curve

2.7 Estimation of Dexlansoprazole in marketed formulations and the bulk:

Proposed validated UV-Visible spectrophotometric method was used for the estimation of Dexlansoprazole in its commercial, marketed formulations and the bulk API. Capsule formulations of two different brands of the Dexlansoprazole having 30 and 60 mg strength were procured from the local market of the Chhatrapati Sambhajanagar, Maharashtra, India. Five capsules of each brand were selected for the studies. The contents of each capsule were collected and weighed separately. The contents equivalent to 50 mg of the Dexlansoprazole were dissolved in water-acetonitrile (60:40 v/v) co-solvent system and diluted to 50 ml using calibrated volumetric flask. The solutions were sonicated for 15 minutes using ultrasonic water bath. After sonication, solutions were filtered through 0.22 μ m syringe filter. Resultant solutions were diluted in the ratio of 1:10 v/v using water-acetonitrile (60:40 v/v) co-solvent system. Dilutions were mixed thoroughly using vortex mixer. Said solutions were again diluted in the ratio of 1:4 v/v using water-acetonitrile (60:40 v/v) co-solvent system and analyzed for its Dexlansoprazole content using pre-validated UV-Visible spectrophotometric method. Similarly, 50 mg of bulk Dexlansoprazole was dissolved and diluted suitably using water-acetonitrile (60:40 v/v) co-solvent system and the Dexlansoprazole content was estimated using the pre-validated method.

3. RESULTS AND DISCUSSION

3.1 Determination of the wavelength of maximum absorbance

Quantitative UV analysis requires the identification of the wavelength at which absorbance is maximum. For identifying the wavelength of maximum absorbance, Dexlansoprazole solutions having concentration 20 μ g/ml were scanned over the range of 200 to 800 nm repeatedly using spectrum measurement mode. After spectra acquisition, each spectrum was subjected to spectral analysis using in-built software module and wavelength of maximum absorbance was found to be 282 nm.

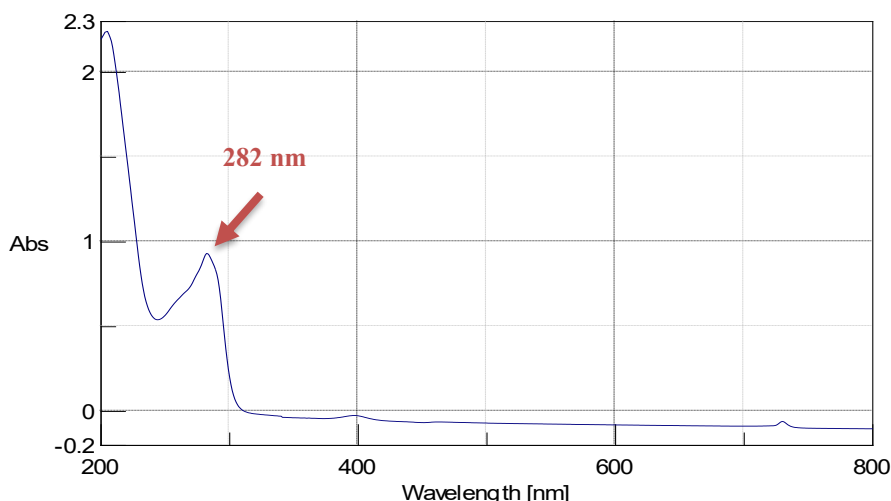


Figure 2 UV-Visible Spectra of Dexlansoprazole

3.2 Preparation of a calibration curve

An equation expressing the correlation between concentration and response is required for the quantification of unknown samples using a UV-visible spectrophotometer. Compared to the graphical method, the equation method is more accepted and used universally. Considering the value of the quantitative analysis of Dexlansoprazole, the calibration curve was constructed using seven distinct calibration standards viz 1µg/mL, 2µg/mL, 4µg/mL, 8µg/mL, 16µg/mL, 20µg/mL and 25µg/mL. Each calibration standard was analyzed five times for its absorbance at 282 nm in the fixed wavelength mode. Table 1 shows the mean absorbance values $\pm$ SD.

Table 1: Calibration standard data for Dexlansoprazole

Concentration (µg/mL)	Absorbance (Mean $\pm$ S.D.)
1	0.0406 $\pm$ 0.0011
2	0.0829 $\pm$ 0.0012
4	0.1597 $\pm$ 0.0021
8	0.3136 $\pm$ 0.0013
16	0.6352 $\pm$ 0.0034
20	0.8005 $\pm$ 0.0131
25	0.9757 $\pm$ 0.0152

3.3 Method validation

After analytical method development, it becomes essential to validate the said developed method. The validation of the developed analytical method assures its reliability. There are typical guidelines namely ICH Q2 (R1) available for the validation of the analytical methods which are extensively used by the academia and the industries worldwide. There are various parameters of the analytical method validation. The set values and the limits of the parameters if obtained within the range during validation demonstrates the authentication and the reliability of the said analytical methods. In case of Dexlansoprazole, the developed method was validated using following parameters.

3.3.1 Linearity and Range: Seven pre-defined calibration standards covering range of 1 to 25 µg/mL when analyzed demonstrated excellent linearity. The calibration standards and related mean absorbance values are displayed in Table 1. The five replicate calibration curves showed excellent linearity over ($r^2 > 0.999$) with consistent slopes and intercepts, confirming the method's linearity and range as illustrated in figure 3 (A-E).

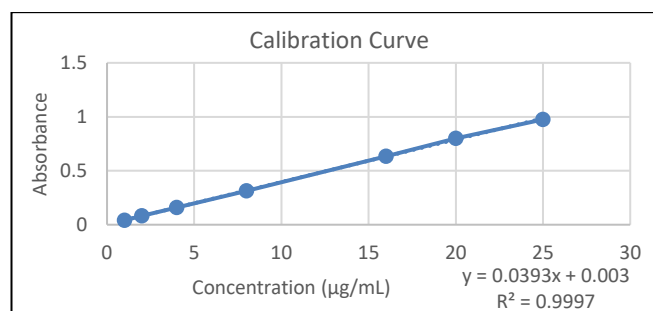


Figure 3 (A) Calibration curve replicate 1

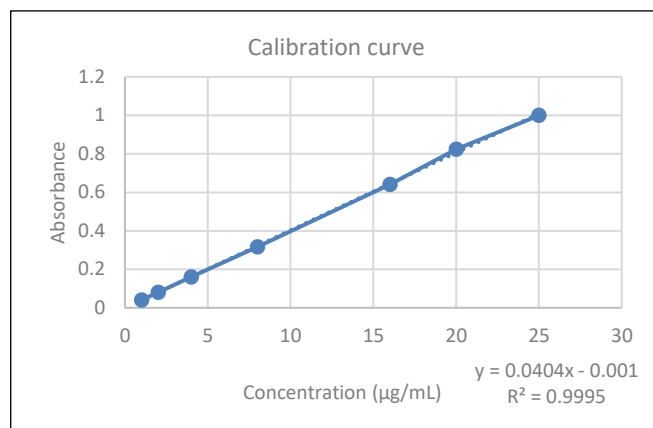


Figure 3 (B) Calibration curve replicate 2

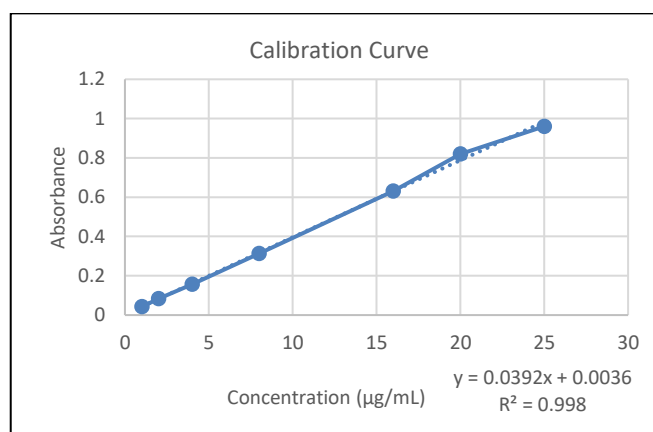


Figure 3 (C) Calibration curve replicate 3

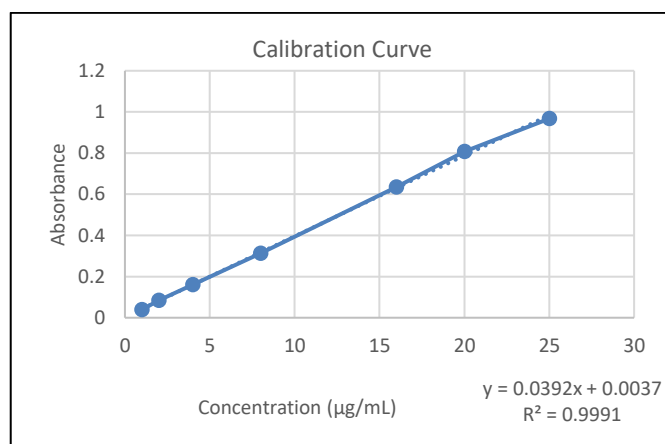


Figure 3 (D) Calibration curve replicate 4

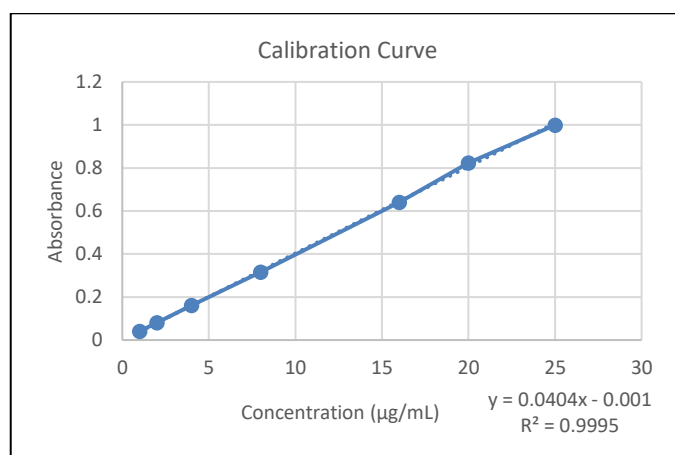


Figure 3 (E) Calibration curve replicate 5

According to linearity analysis, the developed UV method was found to be linear over the pre-defined concentration range of calibration standards.

3.3.2 Accuracy: The closeness of agreement between the experimental value and the nominal reference value is known as accuracy. For the results to be dependable at every stage of the determination process, accuracy must be ensured over the analytical method's entire

calibration range. The intra- and inter-day % Difference values are shown in Table 2 & 3 respectively.

The intra-day accuracy in terms of % Difference was found to be in the range of -2.04 to +2.63 whereas Inter-day accuracy was found to be in the range of -2.04 to +2.12. Based on the obtained values, it was envisaged that the proposed analytical method of Dexlansoprazole was accurate.

Table 2: Intra- day accuracy data of the UV method for Dexlansoprazole

Concentration Level	Nominal Concentration (µg/mL)	Mean Measured Concentration (µg/mL)	% Difference
LQC	1.5	1.51	0.66
	1.5	1.47	-2.04
	1.5	1.48	-1.35
MQC	13	12.83	-1.32
	13	13.12	0.91
	13	12.99	-0.077
HQC	24	24.65	2.63
	24	24.47	1.9
	24	24.12	0.49

Table 3: Inter- day accuracy data of the UV method for Dexlansoprazole

Concentration Level	Nominal Concentration (µg/mL)	Mean Measured Concentration (µg/mL)	% Difference
LQC	1.5	1.47	-2.04
	1.5	1.48	-1.35
	1.5	1.51	0.66
MQC	13	12.71	-2.2
	13	13.04	0.30
	13	13.19	1.44
HQC	24	24.46	1.88
	24	24.26	1.07
	24	24.52	2.12

3.3.3 Precision: Precision refers to the degree of scatter among repeated measurements, showing how consistent the results are. An analytical method is expected to provide reproducible outcomes. The developed UV methods intra- day and inter-day precision was determined at three different levels viz. 1.5 µg/mL, 13µg/mL, and 24µg/mL of Dexlansoprazole. Tables 4 and 5 represents the % RSD values of intra- and inter-day

precision. Intra-day precision in terms of %RSD of the proposed UV Visible spectrophotometric method was found to be in the range 1.31 to 2.06, whereas inter-day precision of the proposed method was found to be in between 1.22 to 2.13. The lower values of % RSD demonstrated the precision of the proposed analytical method of Dexlansoprazole.

Table 4: Intra-day precision data of the UV method for Dexlansoprazole

Concentration Range (µg/mL)	Morning			Afternoon			Evening		
	Mean	SD	% RSD	Mean	SD	% RSD	Mean	SD	% RSD
1.5	1.47	0.026	1.76	1.48	0.030	2.05	1.50	0.026	1.73
13	12.72	0.184	1.45	13.02	0.269	2.06	13.19	0.173	1.31
24	24.46	0.349	1.43	24.26	0.458	1.88	24.52	0.379	1.54

Table 5: Inter-day precision data of the UV method for Dexlansoprazole

Concentration Range (µg/mL)	Day 1			Day 2			Day 3		
	Mean	SD	% RSD	Mean	SD	% RSD	Mean	SD	% RSD
1.5	1.53	0.024	1.62	1.47	0.031	2.13	1.48	0.028	1.90
13	13.24	0.159	1.24	13.21	0.160	1.22	12.96	0.260	2.00
24	24.65	0.327	1.32	24.47	0.312	1.28	24.12	0.385	1.59

3.3.4 Robustness: The ability of a method to produce consistent results despite small, deliberate variations in analytical conditions is known as robustness. It is an essential analytical technique parameter since normal usage might result in small, inadvertent changes to method parameters like pH and solvent composition, which can hinder the method's effectiveness. It is anticipated that the performance of the analytical method should be unaffected by such a modification. Such a modification should not affect the analytical

method's performance. As a result, a reliable analytical procedure can be selected for the further analysis.

In order to prove the robustness of the proposed analytical method of Dexlansoprazole, solvent composition was intentionally modified. Modification of the composition of the co-solvent solution did not affect the method performance. The $\leq 2\%$ RSD values as shown in Table 6, suggested that the proposed analytical method of Dexlansoprazole is robust.

Table 6: Robustness data of the UV method for Dexlansoprazole.

Concentration (µg/mL)	Acetonitrile: Water (V/V)	Absorbance (Mean $\pm$ S.D.)	% RSD
1.5	38:62	0.0612 $\pm$ 0.0040	1.96
13	38:62	0.4942 $\pm$ 0.0044	0.91
24	38:62	0.9285 $\pm$ 0.0081	0.87
1.5	42:58	0.0620 $\pm$ 0.0028	0.48
13	42:58	0.5018 $\pm$ 0.0015	0.33
24	42:58	0.9446 $\pm$ 0.0059	0.51

3.3.5 Ruggedness: An analytical method's ruggedness is its capacity to withstand changes in external factors that affect its performance, such as modifications to labs, equipment, and analysts. The robustness of the suggested UV-visible method was assessed using two distinct UV-visible spectrophotometers from the two

different laboratories of the institution. Dexlansoprazole solution (13µg/mL) when analyzed in triplicates by using two distinct UV-visible spectrophotometer showed the % RSD values ≤ 2 (Table 7). The lower % RSD values indicated that proposed analytical method of Dexlansoprazole is rugged.

Table 7: Ruggedness data of the UV method for Dexlansoprazole.

Concentration (µg/mL)	Instruments	Absorbance (Mean $\pm$ S.D.)	% RSD
13	JASCO	0.5018 $\pm$ 0.0016	0.3457
13	BIOAGE	0.5147 $\pm$ 0.0011	0.5987

3.3.6 Limit of Quantification (LOQ) and Limit of Detection (LOD): The lowest concentration that can be examined with reasonable precision and accuracy is represented by LOQ. Table 8 displays the LOD and LOQ of the suggested UV method, which were determined to be 0.1008 and 0.3058 µg/mL, respectively.

Table 8: LOD & LOQ data for UV method for Dexlansoprazole.

LOD	0.1008µg/mL
LOQ	0.3058µg/mL

The suggested method would be appropriate for assessing materials containing lower amounts of Dexlansoprazole.

Table 9: Dexlansoprazole content in commercial formulations

Sr.	Formulation	Brand Name & Manufacturer	Label Claim / Purity	Assay (Mean ± S.D.)
1.	Capsule	Deltone, Alembic	60 mg	60.34 ± 0.47
2.	Capsule	DDR 30, MSN	30 mg	29.96 ± 0.29
3.	Bulk API	TCI	≥ 95%	96 ± 0.55

CONCLUSION

A UV-visible spectrophotometric method is sensitive, accurate, and exact for estimating Dexlansoprazole. The method that was created proved to be resilient and strong, with the ability to determine the amount of Dexlansoprazole.

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Conflict of Interest Regarding the research authorship and/or publication of this paper, the author(s) have stated that they have no potential conflicts of interest.

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3.4 Estimation of Dexlansoprazole in marketed formulations and the bulk:

Analytical methods are developed and validated with an intention to its application for the routine analysis. Before its application in routine analysis, it becomes mandatory to establish its ability to analyze the routine samples. In line with the same, the proposed analytical method of Dexlansoprazole was utilized for the analysis of marketed formulations of the Dexlansoprazole. The results of the analysis of marketed formulations are depicted in Table 9. The proposed method was able to estimate the Dexlansoprazole content in the two marketed formulations with sufficient accuracy as the obtained results are matching with the label claims of the commercial formulations.

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