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Research article

UV SPECTROPHOTOMETRY METHOD FOR THE ESTIMATION OF DEXLANSOPRAZOLE IN BULK AND PHARMACEUTICAL FORMULATIONS

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ABSTRACT

The main objective was to develop and validate the UV spectrophotometric method for the estimation of Dexlansoprazole in bulk and its tablet dosage formulations as per ICH guidelines. Distilled water is used as asolvent. The λ_{max} of the dexlansoprazole was found to be 284 nm. The linearity in the concentration range 5-30 µg/mlwith co relation co efficient of 0.9996. The accuracy studies of proposed method was performed at three different levels, 20%, 40%, 60% and recovery was found to be in the range of 100.82%. The limit of detection and limit of quantification were found to be 0.0383 and 0.1160 µg/ml respectively. The %RSD less than 2 which indicates the accuracy and precise of the method the above method was a rapid tool for routine analysis of Dexlansoprazole in the bulk and its tablet dosage forms.

Keywords: Spectrophotometry, Visible spectrophotometers, Infra-Red Spectroscopy.

INTRODUCTION

Calibration curve is plotted using concentration (x-axis) Vs absorbance (y-axis) with the value of 5 or more standard solutions. A straight line is drawn through maximum number of points. This line is called line of best fit. By interpolating the absorbance of the sample soluti In this method a calibration curve is plotted using concentration (x-axis) Vs absorbance (y-axis) with the value of 5 or more standard solutions. A straight line is drawn through maximum number of points. This line is called line of best fit. By interpolating the absorbance of the sample solution and using the calibration curve, the concentration of the drug amount and percentage purity can be calculated.

Dexlansoprazole
Molecular weight: 369.363g g/mol

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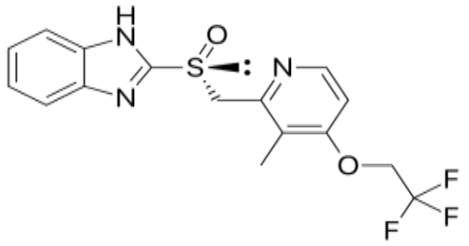

Molecular formula: $C_{16}H_{14}F_3N_3O_2S$
Chemical name: 2-[(R)-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridinyl]methyl]sulfinyl]-1H-benzimidazole

MATERIALS AND METHODS

Materials

Pure drug sample dexlanzoprazole were generously gifted by "Dr. Reddy's Laboratories, Hyderabad. Capsule formulation of Dexilant 60 mg of Dexlansoprazole (purchased from a local pharmacy).

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Reagents and Chemicals Used

All the chemicals used were of analytical grade and HPLC grade-Qualigens India Ltd.

Instrument Specifications

Instruments employed for the study were Shimadzu-1700 double beam UV-visible spectrophotometer with a pair of 10mm matched quartz cells.

UV Spectrophotometric Method

Selection of solvent

The solubility of drug was determined in a variety of solvent as per IP standards. Solubility was carried out in non-polar to polar solvents. The common solvent was found to be methanol for the analysis of dexlansoprazole for the proposed method.

Preparation of Standard Stock Solution

100 mg of dexlansoprazole raw material was weighed separately and transferred into 100 ml standard flask, dissolved in methanol and made upto the volume with same solvent which contain 1000µg/ml. From that the solution further dilutions were made by diluting 1ml to 100ml with the same solvent to obtain10µg/ml.

Selection of λ max

From the UV spectra 284 nm was selected as the λ_{max} of the dexlansoprazole.

Calibration Graph

In this method aliquots of stock solution of dexlansoprazole (25 ml of 1000µg/ml) were transferred into 100ml volumetric flask and made up to the mark with methanol further dilution are made upto (2-10 ml of 250 µg/ml) and transferred into 50 ml volumetric flask and made upto the mark with methanol. The absorbance of the different solutions of different concentrations was measured at 284 nm against blank. The calibration curve was plotted using concentration Vs absorbance. The curve obtained was linear with the concentration range of 10-50 µg /ml.

Validation of Proposed Method

The method was validated according to ICH guidelines in order to determine the limit of detection and limit of quatification, precision and recovery studies

Limit Of Detection (LOD) and Limit Of Quantification (LOQ)

The limit of an individual analytical procedure is the lowest amount of analyte in a sample that can be detected but not necessarily quantitated as an exact value. The quantification limit of an individual analytical procedure is the lowest amount of analyte in a sample that can be quantitatively determined with suitable precision and accuracy.

The detection limit (LOD) for the proposed method was calculated using the following equation

$$\mathbf{LOD = 3.3\ S / K}$$

Where 'S' is the standard deviation of replicate determination values under the same conditions as for sample analysis in absence of the analyte and 'K' is the sensitivity namely the slope of the calibration graph. The limit of quantification (LOQ) was defined as

$$\mathbf{LOQ = 10\ S / K}$$

Quantification of formulation

20 capsules of Dexilant (containing 60mg of Dexlansoprazole) were weighed accurately and average weight was found. The content of the capsule powder equivalents to 100mg of Dexlansoprazole was weighed and transfer into 100ml volumetric flask and add a minimum quantity of solvent methanol to dissolve the substance by using ultrasonicator for 15 minutes and made upto the volume with the same (1000µg/ml). The content was filtered through the whatmann filter paper No.41. From the clear solution, further dilutions were made by diluting 25ml to 100ml volumetric flask with solvent to obtain 250µg/ml. Further 6ml to 50 ml volumetric flask with the same solvent and the concentration was found to be 30µg/ml. The amount of dexlansoprazole present in formulation was determined. The procedure was repeated for 6 times for each percentage.

Recovery Studies

The recovery experiment was done by adding known concentration of Dexlansoprazole raw material to pre-analysed formulation. The content of the capsule powder equivalent to 100 mg of dexlansoprazole was weighed accurately and transfer into a series of three 100 ml standard flask. To that raw material Dexlansoprazole (20%, 40%, 60%) were added, dissolved with minimum quantity of methanol and made upto the mark with the same solvent. The content was kept in a sonicator for 15 minutes, after sonication the solutions were filtered through whatmann filter paper no.41. From the clear solution 25ml was transferred to 100ml standard flask and made upto the volume with the same solvent. Further 6 ml was measured and transferred in to 50 ml volumetric flask and made upto the volume with the same solvent. Then the absorbance was measured at 284 nm. The absorbance was used for the determination of Dexlansoprazole. The procedure was repeated for 3 times for each percentage recovery.

The repeatability of the method was confirmed by the analysis of formulation and repeated for 6 times

with the same concentration. The amount of each drug present in the tablet formulation was calculated. The percentage RSD was calculated.

RESULTS AND DISCUSSION

A Simple and accurate method developed for the determination of Dexlansoprazole in bulk and in pharmaceutical dosage form. The developed method was UV spectroscopy.

From the solubility profile methanol was used for the analysis of Dexlansoprazole. The spectrum was recorded at 284 nm for Dexlansoprazole. The selected wavelength was used for the analysis of drug. Beer's law obeys the concentration range from 5-30µg/ml for Dexlansoprazole. The calibration graph was plotted. The correlation values for the drug were found to be 0.999. The optical parameters were calculated.

Table 1. Optical Characteristics of Dexlansoprazole by UV-Spectroscopy

Parameters	Method
λ-max (nm)	284
Beer's law limit (µg/ml)	10-50
Sandell's sensitivity (µg/cm^{2}0.001A.U)	0.02331
Molar absorptivity (L mol^{-1}cm^{-1})	13915.47
Correlation coefficient	0.9992
Regression equation (y=mx+C)	Y= 0.0123X-0.0012
Slope (m)	0.0123
Intercept (C)	0.0012
LOD (µg/ml)	0.55
LOQ (µg/ml)	1.66

Table 2. Quantification of Formulation- Dexlansoprazole

S.No	Drug Label Claim	Amount found (mg)*	(%) Purity	Average (%)	SD	%RSD
1	Dexilant Capsule 60 mg	60.19	100.31	100.48	0.5169	0.5144
2		60.28	100.46			
3		59.81	99.68			
4		60.27	100.45			
5		60.45	100.75			
6		60.75	101.25			

Table 3. Recovery Study Data of Pre Analysed Formulation

Drug name	%	Amount present (µg/ml)	Amount Added (µg/ml)	Amount Found (µg/ml)	Amount Recovered	% Recovery	Average	SD	%RSD
Dexlansoprazole	20	30.00	6.0	36.04	6.04	100.66	100.47	0.6462	0.6431
	40	30.00	12.0	42.12	12.12	101.00			
	60	30.00	18.0	47.95	17.95	99.72			

*Mean of six observations

Table 4. Precision Study for Formulation (Dexilant)

Drug Name	Sample Number	Labeled Amount (mg/tablet)	Amount Found (mg)	Percentage Obtained (%)	Average (%)	SD	%RSD
Dexlansoprazole	1	60	60.3	100.5	100.44	0.8160	0.8124
	2	60	59.8	99.66			
	3	60	60.4	100.66			
	4	60	59.6	99.33			
	5	60	60.9	101.5			
	6	60	60.6	101.0			

Fig. 1. UV spectra of Dexlansoprazole

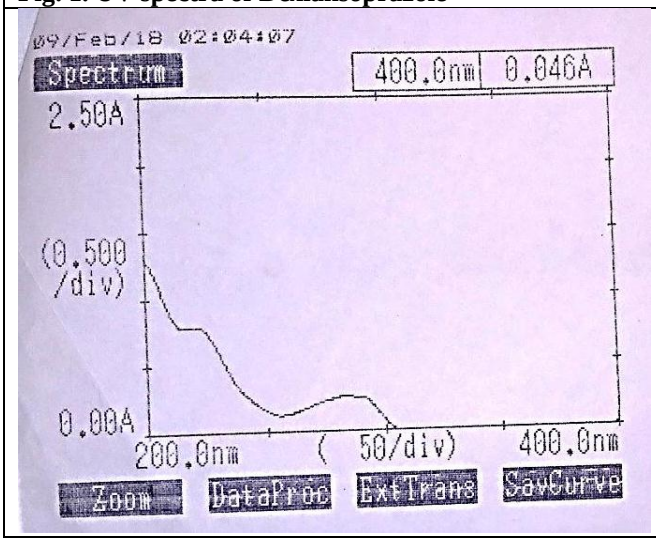
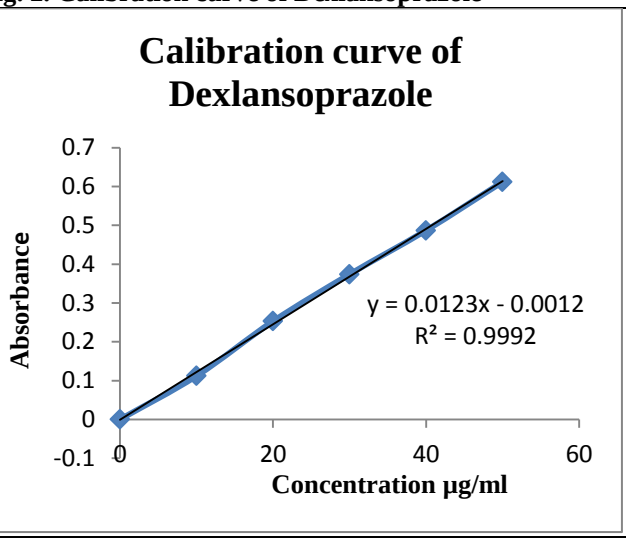


Fig. 2. Calibration curve of Dexlansoprazole



Dexilant capsule containing 60 mg of Dexlansoprazole were selected for the analysis. The percentage of the drug in the formulation was found to be 100.48%. The precision of the method was confirmed by the repeatability studies. The percentage RSD was found to be 0.5144. The accuracy of the method was confirmed by recovery studies. To the pre analysed formulation the different amount of raw material were added. The amount of drugs was calculated. The percentage of recovery was found to be in the range from 99.72 to 101.0%. Hence it is suggested the proposed UV spectroscopy method can be effectively applied for the routine analysis of Dexlansoprazole in tablet formulation. The procedure was repeated for six times. The optical parameters like correlation co-efficient, slope, intercept, sandell's sensitivity, molar absorptivity were calculated and presented in table 1.

SUMMARY AND CONCLUSION

A simple, rapid, precise and accurate UV METHOD was developed for the determination of Dexlansoprazole in bulk and tablet dosage form. The developed UV method for the estimation of Dexlansoprazole in the tablet dosage form and also raw material analysis are precise, accurate and simple. This method can be effectively followed for the routine analysis of Dexlansoprazole.

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