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DEVELOPMENT OF UV SPECTROPHOTOMETRIC METHOD FOR ESTIMATION OF NIZATIDINE IN PHARMACEUTICAL DOSAGE FORM

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Abstract: In this present research work we have developed a validated UV spectrometric method for estimation of Nizatidine in pure and pharmaceutical dosage form. The developed method is accurate, cost efficient for the estimation of Nizatidine in pure and pharmaceutical dosage form. Based on measurement of absorption of UV light, the spectra of Nizatidine in dimethyl sulphoxide (DMSO) as a solvent show maximum absorption wavelength (λmax) at 315 nm. The calibration curve was plotted over the concentration range from 1-22 µg/ml of Nizatidine with correlation coefficient 0.999. Validation was performed as per ICH Q2 guidelines for linearity, precision, and recovery. This method has good reproducibility with % RSD less than one. The limit of detection (LOD) and limit of quantification were found to be 0.0473and 0.1414 respectively by simple UV spectroscopy. Thus this proposed validated method can successfully applied for estimation of Nizatidine in quality control ,routine analysis work in pharmaceutical dosage forms.

Keywords: Nizatidine, spectrophotometric method, ICH Q2 guidelines

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INTRODUCTION

Chemically Nizatidine is N-(2-[(2-[(dimethylamino)methyl]thiazol-4-yl)methylthio]ethyl)-N-methyl-2-nitroethene-1,1-diamine.[1]

Nizatidine is odourless, white crystalline powder.[2] It is freely soluble in water, slightly soluble in ethanol.[3] Nizatidine is a competitive, reversible inhibitor of histamine at the H_2-receptors, particularly those in the gastric parietal cells. By inhibiting the action of histamine on stomach cells, Nizatidine decreases stomach acid production. Nizatidine had no demonstrable anti androgenic action. Full-dose therapy for problems treat with Nizatidine lasts no long than 7 weeks. It has been demonstrated that treatment with a reduced dose of Nizatidine is effective as maintenance therapy following healing of active duodenal ulcers.[4]

It has molecular formula $C_{12}H_{21}N_5O_2S_2$having mol.wt. 331.46 g/mol [5, 6.]

OBJECTIVE OF PRESENT RESEARCH WORK:

1. Till the present day there is no valid UV spectophotometric method available for estimation of Nizatidine using dimethyl sulphoxide as a solvent.
2. The goal of our present research work was to developed a validated UV spectrometric method for estimation of Nizatidine in pure and pharmaceutical dosage form.
3. Use this method for quality control and analysis of drugs in pharmaceuticals containing Nizatidine.
4. To develope rapid, economic, and reproducible UV spectroscopic method for quality control of pharmaceutical formulations containing Nizatidine.

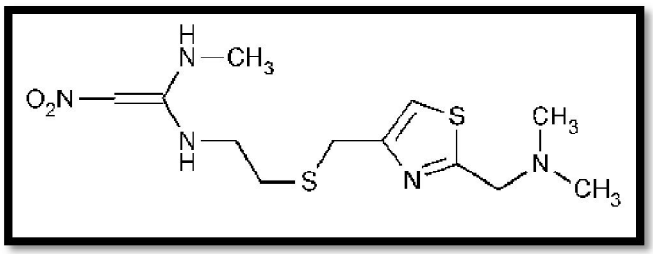

Figure no. 1- Structure of Nizatidine

MATERIALS AND METHODS

Instrumentation, Reagents and Chemicals:

Instrument used were:

UV-Visible double beam spectrophotometer Shimadzu UV1800 with one cm matched quartz cells. Electronic Balance. The absorption spectra of reference and test solution were carried out in a one cm quartz cell over the range of 200-400 nm.

Material:

Pure samples:

Nizatidine was kindly gifted by Watson Pharma, Goa, India.

Reagents and Chemicals:

Dimethyl sulphoxide was obtained from Loba Chemie.Ptv. Ltd. Mumbai, India other chemicals & reagents used were of analytical grade.

Preparation of standard stock solution:

I Stock solution

Standard drug solution of Nizatidine was prepared by dissolving 100 mg of pure Nizatidine in small amount of dimethyl sulphoxide in 100 ml volumetric flask and this solution was in the volume was adjusted with dimethyl sulphoxide as a solvent the resultant solution gives the concentration of 1mg/ml ie.1000 µg/ml.

II stock solution

From I stock solution :10 ml solution was taken and then diluted up 100 ml with same solvent in a volumetric flask and the concentration of this stock was 100µg/ml.

Determination of Lambda Max. (λ max):

10µg/ml solution was prepared by withdrawing 10ml of solution from II stock solution and further diluted with dimethyl sulphoxide to get concentration solution. This solution was then scanned at wavelength of 200 to 400 nm against blank. The λmax was found to be at 315 wavelengths where absorbance was maximum at this wavelength. Hence this is considered as absorption maxima which are used for preparation of calibration curve. **(Figure no. 2)**

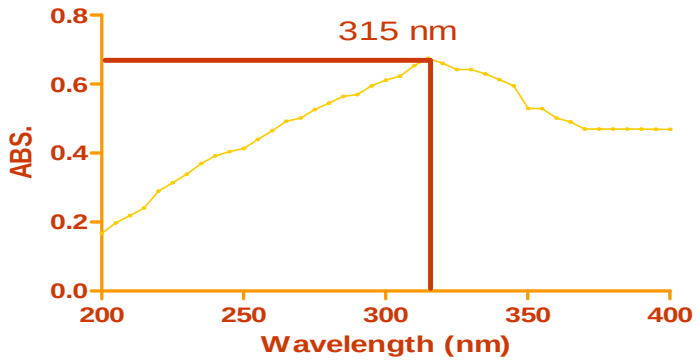

Figure no. 2: Determination of λ max of Nizatidine

Preparation of Calibration Curve:

I Stock solution

Standard drug solution of Nizatidine was prepared by dissolving 100 mg of pure Nizatidine in small amount of dimethyl sulphoxide in 100 ml volumetric flask and then the volume was adjusted with dimethyl sulphoxide the resultant solution gives the concentration of 1mg/ml ie.1000 µg/ml.

II stock solution

From I stock solution 10 ml solution was taken and then diluted up 100 ml with same solvent in a volumetric flask and then the concentration of this stock was 100µg/ml. From this II stock solution 1, 2,6,6,8,10,10,12,14,16,18,20,22 and 24 ml solutions were pippetted and volume was made to 100 ml using dimethyl sulphoxide as a solvent to get concentrations of 01,02,04,06,08,10,12,14,16,18,20,22 and 24µg/ml respectively. The absorbance of these solutions was measured at 315 nm (λ max of Nizatidine**)** . The standard calibration curve was obtained for data of concentration v/s absorbance; standard calibration curve data reported in **(Table no.1, Figure no.3)**

Table 1: Calibration data for the method development for Nizatidine.

Sr. No.	Concentration (µg/ml)	Absorbance at 314nm ± standard deviation
1	1	0.161±0.002
2	2	0.267±.00273
3	4	0.576±0.00247
4	6	0.836±0.0036
5	8	1.124±0.00308
6	10	1.451±0.00264
7	12	1.702±0.00305
8	14	1.912±0.00360
9	16	2.226±0.0024
10	18	2.620±0.00307
11	20	2.715±0.0021
12	22	3.217±0.00234

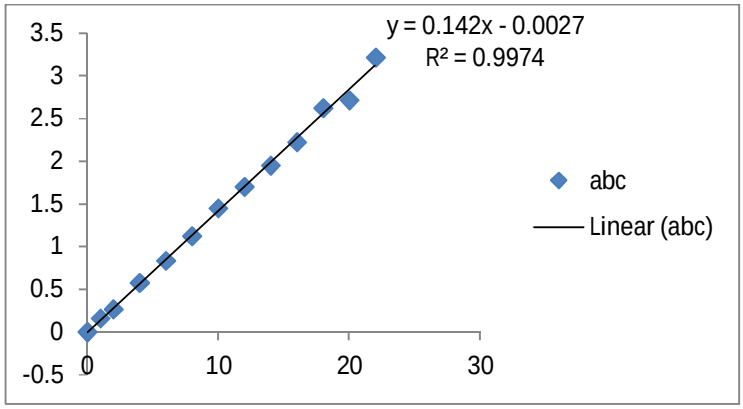

Figure. 3: Calibration Curve of Nizatidine

VALIDATION METHOD:

Linearity and Range:

The linearity of response obtained between 2 to 22µg/ml concentration. The calibration curve was obtained by plotting the absorbance versus concentration data and treated by linear regression analysis (Table no. 3).

Precision:

Precision of the method was analyse to repeatability and determined by analyzing 10 µg/ml of Nizatidine for six times the results are reported in **(Table no. 2)**

Table no. 2: Data showing Repeatability of Absorbance's

Sr. No.	Conc. (µg/ml)	Wavelength (nm)	Absorbance	Mean± S.D.	%R.S.D
1	10	315	0.853	0.843±0.00275	0.312
2		315	0.854		
3		315	0.854		
4		315	0.854		
5		315	0.856		
6		315	0.865		

S.D-Standard Deviation, R.S.D-Relative Standard Deviation

Precision:

Precision of the method was studied as intra-day and inter day variations. Intraday precision was determined by analyzing 04, 08, 12, µg/ml of Nizatidine for three times within the day. Inter-day precision was determined by analyzing same concentration of solutions daily for three days; the results are reported in **(Table no. 4)**

Table no 3: Validation parameters for Nizatidine

Sr. No.	Parameters	Results
1	Absorption maxima (nm)	315 nm
2	Linearity range (µg/ml)	2-22µg/ml
3	Standard Regression Equation	y = 0.136x - 0.027
4	Correlation coefficient (R^2)	R^2 = 0.999
5	Specificity	A 6 µg /ml solution of Nizatidine in solvent dimethyl sulphoxide at UV detection of 315 nm will show an absorbance value of 0.857±0.00275

6	Accuracy (% Recovery)	99.80
7	Precision RSD Repeatability (n=6)	0.341
	Intra-day(n=3)	0.2796
	Inter-day(n=3)	0.3183
8	Molar Absorptivity	$4.1479*10^4$ L/mol.cm.
9	LOD	0.0471µg/ml
10	LOQ	0.1423 µg/ml

n=no. of determinations, LOD=Limit of Detection, LOQ =Limit of Quantification, RSD= Relative Standard Deviation

Table no. 4: Results for Intra-day and Inter-day precision of Nizatidine

Drug	Conc. (µg/ml)	Intra-day Mean Abs.	Absorbance ± S.D.	%RSD	Inter-day Mean Abs	Absorbance ± S.D.	%RSD
Nizatidine	6	0.574	±0.00254	0.435	0.562	±0.00253	0.450
	8	1.142	±0.00360	0.315	1.237	±0.00264	0.213
	12	1.734	±0.002080	0.119	1.714	±0.0045	0.262
Mean %RSD				0.2899			0.3087

Standard Deviation and Relative Standard Deviation (S.D and R.S.D)

Recovery Study:

To analyse the accuracy of developed method, it was applied to analyse commercially available Nizatidine tablet (AXID 150 mg.-RANBAXY). Fifty tablets accurately weighted and powdered. The amount of the tablet powder equivalent to 100 mg of Nizatidine accuarately weighted and transferred to the 100 ml volumetric flask. The drug content of preparation was calculated using the standard calibration curve and amount of drug estimated by this method is given in (**Table no. 5)**.

Table no. 5: Determination of Accuracy by Percentage Recovery Method.

Drug	Tablet amount (µg/ml)	Level of addition(%)	Amount added (µg/ml)	Amount recovered (µg/ml)	%Recovery	Average % Recovery
Nizatidine	10	80	6	11.989	99.88	99.83
	10	100	8	13.972	99.80	
	10	120	10	15.938	99.79	

RESULTS AND DISCUSSION:

This method has been made to develop rapid , precise and accurate analytical method. The proposed method based on UV spectrometric absorption in UV reason using dimethyl sulphoxide as a solvent, maximum absorbance was found to be at 315 nm LOD and LOQ were found to be 0.0470 and 0.1423 respectively. The proposed showed molar absorptivity $4.1419*10^4$ L/mol.cm. The calibration curve of Nizatidine plotted at 315 nm (Figure no. 3) and linear relationship was obtained between 2-22 µg/ml. The accuracy of the method was determined by calculating mean percentage recovery it was found to be 99.83% (**Table no.5)**. Further precision was calculated as repeatability, inter and intraday variations and %RSD was less than one given in **(Table no. 4)**.

CONCLUSION:

An UV spectrophotometric method for Nizatidine in pure and pharmaceutical dosage form has been developed and validated in DMSO Solvent.

REFERENCES

1. http://en.wikipedia.org/wiki/Nizatidine .

2. http://www.rxlist.com/femara-drug.htm.

3. http://www.drugs.com/mmx/Nizatidine.html.

4. http://en.wikipedia.org/wiki/Nizatidine.

5. Havaldar V.D., Kulkarni A.S., Dias R.J., Aloorkar N.H., Mali K.K. Floating matrix tablet of atenolol: formulation and in vitro evaluation.Asian Journal of Pharmaceutical. 2009; 2(1)286-91.

6. Anitha K., Sandeep G., Raju J., Reddy V.,Reddy P.. Formulation and evaluation of alfuzosin hydrochloride floating tablets. Der Pharmacia Sinica 2010; 1(3):46-54.

7. Arora S., Ali J., Ahuja A., Khar R.K., Baboota S. Floating drug delivery systems: A review. American Association Pharmaceutical Science Technology, 2005;6(3):47.