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Research Article

UV Spectrophotometric Method Development and Validation for quantitative estimation of Nizatidine

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Abstract

A novel, safe and sensitive method of spectrophotometric estimation in UV-region has been developed for the assay of Nizatidine in tablet formulation. The method was developed are based on the solubility of Nizatidine in 0.1 N HCl (pH 1.2). The drug showed maximum absorbance (λ_{max}) at 325 nm and linearity (Lambert Beer's Range) was found in concentration range of 5-40 µg/ml and the standard curve equation was found to be y = 0.025x + 0.005 and R^2 value 0.998. The results of analysis were validated statistically and by recovery studies. All the parameters of the analysis were chosen according to ICH [Q2(R1)] guidelines.

Key words: Nizatidine, Buffer pH 1.2., UV method, Validation.

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1. Introduction

UV-Visible spectrophotometry is one of the most frequently employed technique in pharmaceutical analysis. It involves measuring the amount of ultraviolet or visible radiation absorbed by a substance in solution. Instrument which measure the ratio, or function of ratio, of the intensity of two beams of light in the U.V-Visible region are called Ultraviolet-Visible spectrophotometers [1].

Nizatidine is chemically, N - [2 - [[[2 - [(dimethylamino) methyl] - 4 - thiazolyl] methyl] thio] ethyl] - N' - methyl - 2 - nitro - 1, 1 – ethenediamine [2]. Figure 1 shows the chemical structure of Nizatidine.

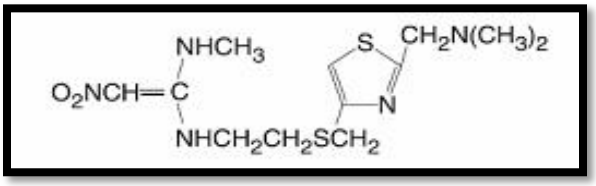


Figure 1: Chemical structures of Nizatidine

It is off-white to buff crystalline solid. Nizatidine has a bitter taste and mild sulfur-like odor. Nizatidine is photosensitive and degrades upon exposure to light hence to be stored in well-closed, light resistant container [3]. Nizatidine act by competitive inhibition of histamine at H_2-receptors of the gastric parietal cells resulting in reduced gastric

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acid secretion, gastric volume and hydrogen ion concentration reduced [4].
The aim of present work was to develop UV spectrophotometric methods for determination of drug content in dosage form. The spectrophotometric methods are better applied for routine analysis as these are: economic (solvents and instruments costs are key factor), rapid (UVanalysis time is less), simple (not required too much training to operate), maintenance free (not washing and no special care for UV), accurate and precise [5].

2. Materials and Methods

Apparatus

A Shimadzu UV/Visible double beam spectrophotometer (Model 1700) with 1 cm matched quartz cells were used in present study for spectral and absorbance measurements.

Reagents and Materials

All chemicals and reagents used were of analytical grades and double distilled water was used throughout the investigation.

- Buffer (pH 1.2):- It was prepared according to I.P.1996
- Standard Stock Solution: Accurately weighed (100 mg) pure drug sample of Nizatidine was transferred to 100 ml (1000 µg/ml) calibrated volumetric flask, dissolved and made up to the mark with Buffer pH 1.2.

Methods

Preparation of 0.1 N Hydrochloric acid (pH 1.2) Solution

Place 50 ml of the 0.2M KCl in a 200 ml volumetric flask. Add 85.0 ml of 0.2 M HCl and then add water to make up the volume.

Preparation of Standard Stock and working stock Solution in 0.1 N Hydrochloric acid (pH 1.2)

Standard stock solution of Nizatidine was prepared by weighed 100 mg of Drug accurately and transferred into 100ml volumetric flask and dissolved in a small quantity of 0.1N HCl. The volume was made up with 0.1N HCl to get a concentration of 1000 µg/ml. From this 10 ml was withdrawn and diluted to 100ml with 0.1 N HCl to get working stock solution of concentration of 100 µg/ml.

Scanning of Drug

Working stock solution (1.0 ml) was taken and transferred to 10ml volumetric flask. Added 0.1N hydrochloric acid and made up the volume up to the mark with same. This drug solution (10µg/ml) was scanned in UV-Visible Spectrophotometer in the wavelength range of 200-400 nm against reagent blank. Wavelength maxima (λ_{max}) were determined from the spectra of respective drug and were used for the further experimentation.
Wavelength maxima (λ_{max}) for Nizatidine = 325 nm

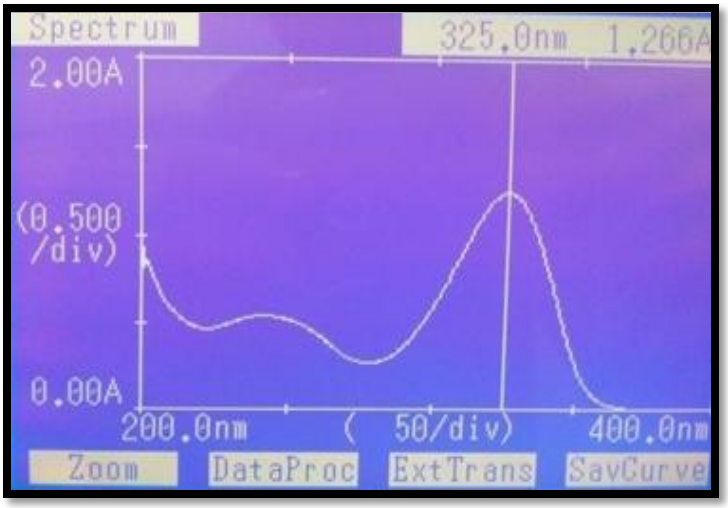


Figure 2. UV Spectrum of and Nizatidine in 0.1N hydrochloric acid (pH 1.2) between 200 -400 nm.

Calibration Curve in 0.1N Hydrochloric acid

Samples were withdrawn from the working stock solution and transferred in 10ml volumetric flask and made up the volume up to 10 ml with 0.1N hydrochloric acid to give a concentration of 10,20,30, 40, 50, 60 µg/ml and so on. The concentration range selected according to Beer's law and absorbances of these solutions were measured against a blank reagent of 0.1N hydrochloric acid using UV – Visible spectrophotometer at wavelength maxima (λ_{max}) for Nizatidine at 325 nm.

Table 1. Absorbance at different concentration of Nizatidine Drug solution

Concentration (µg/ml)	Absorbance
5	0.139
10	0.251
15	0.377
20	0.506
25	0.630
30	0.780
35	0.851
40	1.012

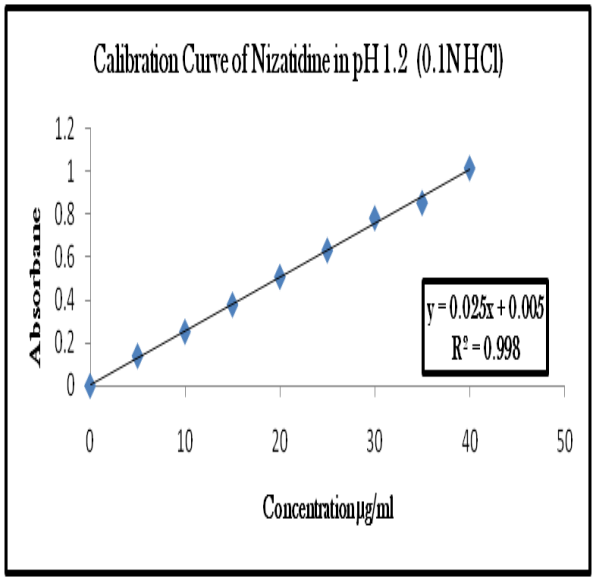


Figure 3. Calibration curve of Drug Nizatidine in 0.1 N HCl

Table 2: Quantitative parameters of spectrophotometric method

Parameters	Value
λ_{max}, nm	325
Beer's law limits, µg/ml	05-40
Regression equation	y = 0.025x + 0.005
Slope	0.025
Intercept	0.005
Correlation coefficient (r^2)	0.998

Analysis of Tablet Formulation

Twenty tablets were weighed accurately and grounded into fine powder. An amount of the powder equivalent to 10 mg of Nizatidine was weighed and dissolved in about 75 ml Buffer pH 1.2. The solution was shaken thoroughly for about 15-20 min, and filtered using Whatman No. 41 filter paper; residue was washed with 20 ml 0.1 N HCl (pH 1.2). Filtrate and washing were transferred to a 100 ml calibrated volumetric flask and 0.1 N HCl (pH 1.2) was added up to the mark (100 µg/ml).

The 10 ml of above filtrate was diluted to 100 ml with 0.1 N HCl. Absorbance was measured at 325 nm wavelength maxima and the concentration of the drug in sample solution was determined from calibration curve. The results of analysis are presented in Table 3 respectively.

Accuracy (recovery test): Accuracy of the method was studied by recovery experiments. The recovery experiments were performed by adding known amounts of the drugs in powdered tablets. The recovery was performed at three levels, 60, 80 and 100% of Nizatidine standard concentration. The recovery samples were prepared in afore

mentioned procedure. Three samples were prepared for each recovery level. The solutions were then analyzed and the percentage recoveries were calculated from the calibration curve.

Table 3. Results of Analysis of Tablet Formulation and Recovery Studies

Brand	Label claim	% Label claim Estimated*	Standard Deviation	% Recovery**
Nizac	100 µg/ml	99.05	0.158	98.75
Axid	100 µg/ml	99.27	0.167	99.08

*Average of six determinations
** Average of Recovery Studies at three different concentration levels

3. Result and Discussion

UV method has been developed for the quantitative estimation of Nizatidine from Tablet formulation. The developed method is based on the solubility of Nizatidine in 0.1N HCl. The results of analysis from tablet formulation were within the permissible limits and the results of recovery studies reflect nil interference from excipients. The developed method was found to be simple, accurate and economical hence can be used for routine analysis of Nizatidine from pharmaceuticals.

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