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CALIBRATION CURVE METHOD DEVELOPMENT FOR ANALYSIS OF TENATOPRAZOLE

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ABSTRACT

A simple and sensitive UV spectrophotometric method has developed for quantitative estimation of Tenatoprazole of pure drug. Tenatoprazole is antacid. Chemically it is (*RS*)-3-Methoxy-8-[(4-methoxy-3,5-dimethyl-pyridin-2-yl)methylsulfinyl]-2,7,9 triazabicyclo[4.3.0]nona-2,4,8,10-tetraene. Spectral absorbance measurements were made on Systronics double beam UV-VIS Spectrophotometer with 1 cm matched quartz cells. Tenatoprazole was dissolved in distilled water and absorbance was measured at 314.0 nm. Beer Lambert's law was obeyed in the concentration range of 0-50µg/ml. The method was statistically evaluated for accuracy and precision.

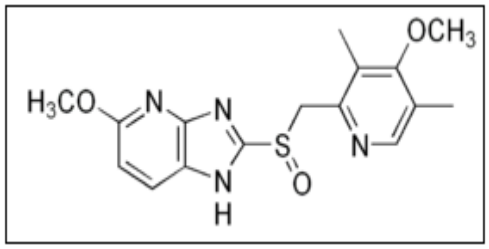
Keywords UV visible spectroscopy, Tenatoprazole, Calibration curve method

INTRODUCTION

UV light is defined as electromagnetic radiation having a wavelength less than that of visible light (400 nm) and greater than that of X-Rays (100 nm). The unit of wavelength used is a nanometer (nm) equal to 10^{-9} meters. Ultraviolet (UV) astronomy concerns celestial observations made in the region of the electromagnetic spectrum[1,2] that extends from the near-visible to the X-ray regime: the near UV, with wavelengths of 3500 to 2000 A^0 the far UV (2000-912 A^0) and the extreme UV (912-100 A^0).

The main types of instruments in used for measuring the emission or absorptions of radiant energy from substance are called by various names such as Photometers, is the instrument which measures the ratio, or some function of the two, of radiant power of electromagnetic beam.

Tenatoprazole is a prodrug of the proton pump inhibitor (PPI) class, which was converted to the active sulfonamide or sulfenic acid by acid in the secretory canaliculus of the stimulated parietal cell of the stomach. This active species binds to luminally accessible cysteines of the gastric H^+, K^+-ATPase resulting in disulfide formation and acid secretion inhibition[3,4,5].



Structure of Tenatoprazole

Drugs which are in solid dosage forms are widely used for the treatment of various diseases & hence analyst needs to develop suitable identification method for analysis. A certain quantity dose of drug was just introduced in the market as tablet dosage for inhibit excess acid secretion.

The efficacy of drug is more the same category so to inhibit the adulteration of drug or to increase the efficacy of drug the standard analysis of drug should be known by Pharmacist. Hence in the present research project attempt has been taken to develop simple, accurate, precise, sensitive as well as less time consuming identification method for simultaneous estimation of the drug Tenatoprazole in tablet dosage form in future[6].

Experimental Method[7]

Calibration curve can be done by Simultaneous equation methods or Vierodt's method, Multi-component method of analysis, Derivative Spectrophotometery, Geometric correction method, Absorption factor method, Difference Spectrophotometry, Orthogonal polynomial functional method, Absorbance ratio method & two wavelength/three wavelength method.

● Calibration Curve Method

1) Selection of solvent: Distilled water is used as solvent.

2) Study of spectra, selection of maximum wavelength for Tenatoprazole:

I. Preparation of standard stock solution:

An accurately weighed quantity, 100mg, of Tenatoprazole was placed in a 100 ml volumetric flask and dissolved in Distilled water. The volume was made up to mark with Distilled water to get concentration of 1000 µg/ml.

II. Study of spectra and selection of maximum wavelength (λ max)

The aliquots of standard stock solution of Tenatoprazole was diluted with 100 ml Distilled water to obtain concentration 10µg/ml Solution was taken in 1cm cell and scanned in range 200nm to 400nm.

III. Study of Beer-Lambert's law

Accurately measured aliquots of standard stock solution ranging from 0.1ml to 4ml were taken in series of 10ml volumetric flask and diluted up to Distilled water the mark with to get Concentration in range of 1-40 µg/ml. The absorbance of each solution was measured at 314.0nm.

RESULTS

Sr. No	Concentration (µg/ml)	Absorbance
1	5	0.3442
2	10	0.6885
3	15	1.0327
4	20	1.3770
5	25	1.7212
6	30	2.0655
7	35	2.4097

A graph was plotted as Concentration Vs Absorbance as shown below

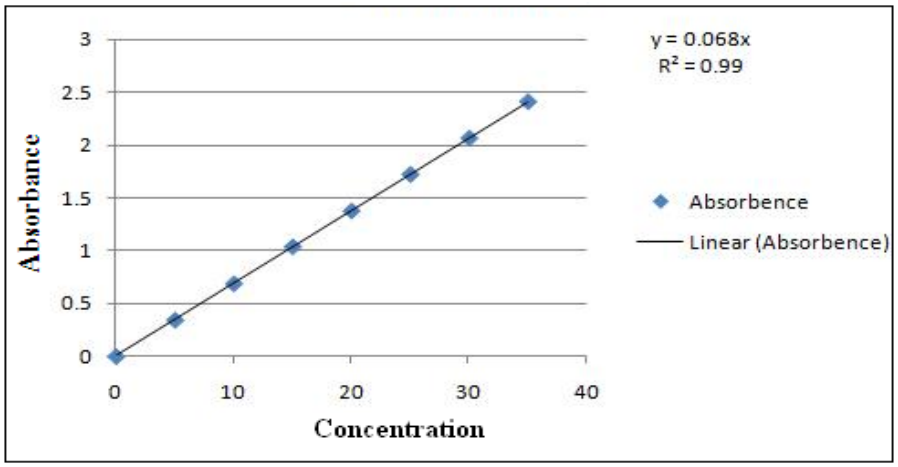


Fig. No. 1 Calibration curve of Tenatoprazole

Parameter	At 314.0 nm
Concentration range (µg/ml)	5-35
Slope	0.068
Correlation coefficient	0.99

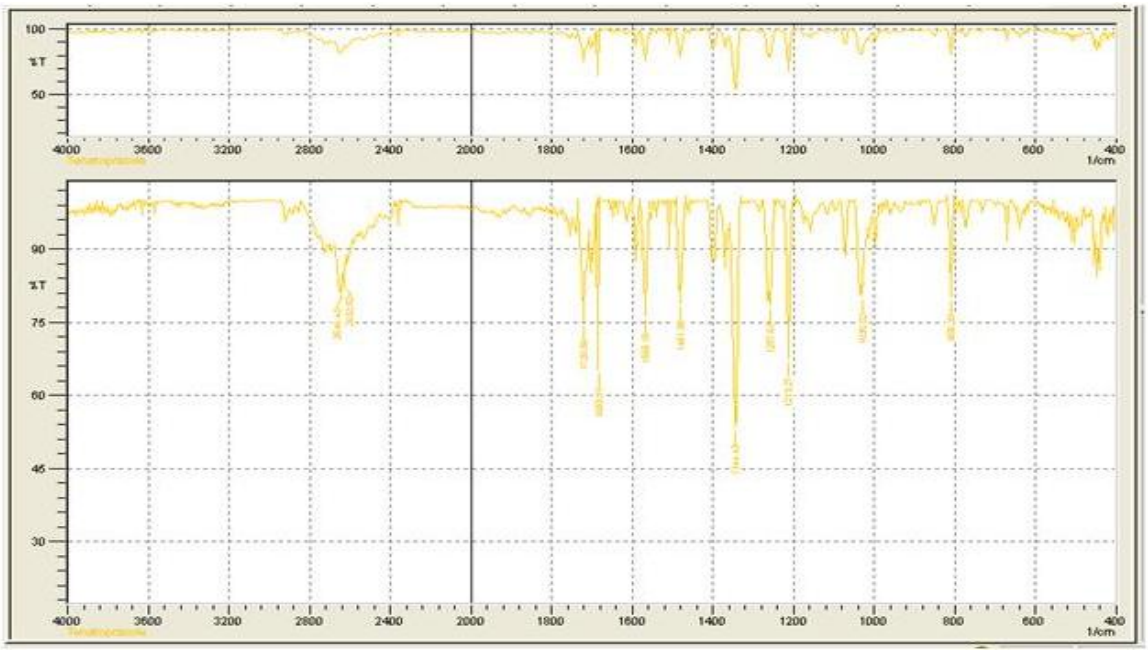
Summary & Statistical results of Ruggedness studies[1]

Parameter	Statistical data	Calibration curve method
Intraday	Mean	92.5
	±S.D.	0.288
	R.S.D.	0.00288
	C.V.	0.31135
Interday	Mean	94.88
	S.D.	0.30854
	R.S.D	0.003085
	C.V.	0.3251
Different analysis	Mean	93.77
	±S.D.	0.1078
	R.S.D.	0.0010780
	C.V.	0.11496

Linearity and range

Study of linearity and range was performed as per ICH/ USP recomindation. Tenatoprazole was found to be linear in the range of 98-103% of drug with R^2=1 at selected wavelength for calibration curve method.

IR spectra of Tenatoprazole drug



DISCUSSION AND CONCLUSION

In distilled water, Tenatoprazole exhibits absorption at 314.0 nm. The linearity was observed in concentration range of 0-40 µg/ml. The amount of Tenatoprazole estimated by proposed method was in good agreement with the label claim. The low % RSD value indicates that method is accurate. The proposed method is simple, accurate, economical and be used in routine analysis of Tenatoprazole from tablet formulation.

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