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UV- SPECTROPHOTOMETRIC DETERMINATION OF TENATOPRAZOLE FROM ITS BULK AND TABLETS

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ABSTRACT

A simple , rapid, sensitive and accurate UV-spectrophotometric method has been developed for estimation of Tenatoprazole from Pharmaceutical formulation. In 0.1N NaOH, Tenatoprazole showed absorbance maxima at 314nm. Linearity was observed in the concentration range of 2-12 µg/ml (r^2 =0.999).The amount of drug estimated from the formulation was found to be in the good agreement with label claim. The recovery studies were carried out at three different levels i.e. at 50%100% and 125%. The method was validated statistically.

KEY WORDS

Tenatoprazole, UV-spectrophotometric method, Tablet formulation and Validation

INTRODUCTION

Tenatoprazole , 3-methoxy-8-[(4-methoxy-3,5-dimethyl-pyridin-2 yl) methyl sulfinyl] 2,7,9-triazabicyclo [4.3.0] nona-2,4,8,10-tetraene. (Fig. 1).It is a prodrug of the proton pump inhibitor (PPI) class, which is converted to the active sulfenamide or sulfenic acid by acid in the secretory canaliculus of the stimulated parietal cell of the stomach. This active species binds to luminally accessible cysteine of the gastric H^+ K^+ - ATP ase resulting in disulfide formation and acid secretion inhibition[1]. Literature review revealed that only HPLC methods are reported for the estimation of Tenatoprazole in rat and dog plasma[2] and stability-Indicating thin-layer chromatographic[3] and chiral separation LC method

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for pharmaceutical dosage forms[4]. But until no UV-spectrophotometric method is reported for its estimation in pharmaceutical dosage forms. So, an attempt is made to develop a simple, cost effective, accurate, precise and sensitive UV-spectrophotometric method for estimation of the drug in bulk and its tablet dosage form.

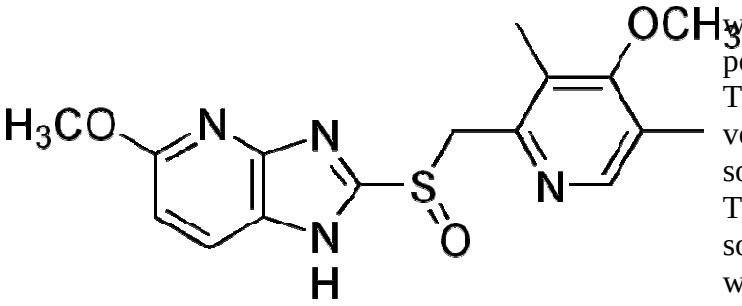

Figure 1 *Structure of Tenatoprazole*

MATERIALS AND METHODS

All the chemicals used were of analytical grade. All the solutions were freshly prepared with double distilled water. The pure drug sample of Tenatoprazole was obtained as gift sample from Dr. Reddy's Lab, Hyderabad. Allegro (enteric coated tablets) containing 40 mg of Tenatoprazole was purchased from SIDEM Pharmacy, U.K. Shimadzu-1700 double beam UV-visible spectrophotometer with 1 cm matched quartz cell was used for all spectral measurements.

(i) Preparation of Calibration Graph:

Standard stock solution was prepared by dissolving 10 mg of Tenatoprazole in 100 ml of 0.1 M NaOH to get concentration of 100 µg/ml .Different aliquots were taken from the stock solution and diluted to 10 ml mark with same solvent to obtain series of concentration. The solutions were scanned on spectrophotometer-1700 (Shimadzu) in the UV-range of 200-400 nm and absorbances were recorded at 314 nm against blank.

(ii) Quantification of Tenatoprazole in Formulation:

Twenty tablets of formulation (allegro) containing 40 mg of Tenatoprazole was accurately weighed to find out the average weight and powdered. Powdered tablet equivalent to 20 mg of Tenatoprazole was transferred in to 100 ml volumetric flask, added 0.1M sodium hydroxide solution to dissolve and made up to the volume. Then the solution was sonicated for 15 min. After sonication, the solution was filtered through whatmann filter paper No.41. From the clear solution, further dilution was made to bring a 6 µg/ml using 0.1M sodium hydroxide solution. The prepared solution was measured at 314nm. The amount of Tenatoprazole present in formulation was determined by using slope and intercept values from calibration graph.

(iii) Interday and Intraday Study :

Repeatability is given by interday and intraday precision. The assay were repeated three times on the same day and one time each on three successive days with solution prepared as in quantification of formulation.

(iv) Recovery Study of Formulation:

In order to ascertain the suitability and reproducibility of the proposed method, known quantities of standard Tenatoprazole solution was added to previously analysed samples and the mixtures were reanalyzed by the proposed method.

Aliquots of 0.6ml of sample drug solution of 100 µg/ml were pipetted into each of three 10 ml volumetric flasks. To the first three volumetric

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flasks 0.75 ml, 0.6 ml and 0.3 ml of standard solution of 100 µg/ml was added respectively. The volume was made up to 10.0 ml with 0.1M sodium hydroxide solution and the absorbance was measured at 314 nm against reagent blank. The absorbance values were recorded with the help of standard curve. The total amount and percentage recovery of Tenatoprazole was determined by using the following formula,

$$\% \text{ recovery} = \frac{N \sum xy - \sum x \sum y}{N \sum x^2 - (\sum x)^2} \times 100$$

where, N = Number of observations

X = Amount Added in µg/ml

Y = Amount recovered in µg/ml

(v) Limit of Detection (LOD) and Limit of Quantification (LOQ):

Preparation of calibration curve from the serial dilutions of standard was repeated for six times. The limit of detection and limit of quantification was calculated by using the average value of slope and standard deviation of intercept.

(vi) Ruggedness:

The degree of reproducibility of test results obtained by UV-method of Tenatoprazole was checked by analyzing the drug sample by using single beam and double beam spectrophotometers and different analysts.

RESULT S AND DISCUSSION

The melting point of Tenatoprazole (126º C) was recorded to check the identification of the drug. After considering the solubility, 0.1M sodium hydroxide was selected as solvent. Tenatoprazole, 10 µg/ml solution was prepared and scanned in the UV region. From the spectra , 314 nm was selected as an analyzing wavelength. Stability of the absorbance at λ_{max} 314 nm was also checked for up to 2 hours and 30 minutes

The optical characteristics such as absorption maxima (nm), beer's law limits (µg/ml), molar extinction co-efficient (L mol^{-1} cm^{-1})), sandell's sensitivity (mcg/cm^2 /0.001AU) and correlation coefficient (r) were calculated for the method and shown in Table-1.

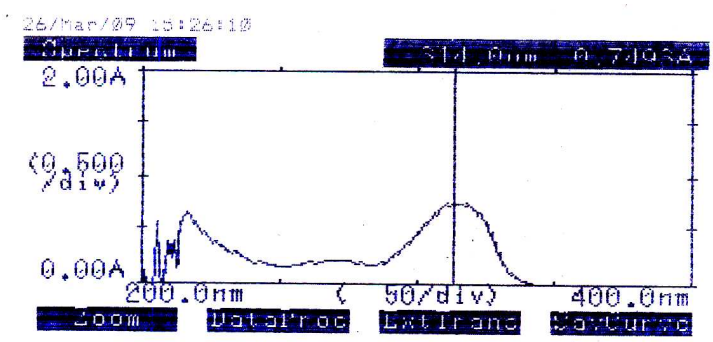

Figure 2 ***UV- Spectrum of Tenatoprazole in 0.1M NaOH***

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Table 1

Optical characteristics of Tenatoprazole

Parameter	Value
λ_{max}(nm)	314
Beers law limit (µg/ml)	02-12
Sandell's sensitivity (µg/cm^2/0.001 A.U)	0.013111076
Molar absorptivity (L mol^{-1} cm^{-1})	2732.654367
Correlation coefficient (r)	0.99949
Regression equation (y=mx+c)	Y=0.076363095(X) +0.002583333
Slope(m)	0.076363095
Intercept(c)	0.002583333
LOD (µg/ml)	0.086653968
LOQ (µg/ml)	0.262587781
Standard error of mean	0.000688645

*Y = mx+c, where 'Y' is the absorbance and c is the concentration of Tenatoprazole in µg/ml

** For six replicates

The analysis of tablet formulation by proposed method was in good agreement (39.70± 0.4490 mg/tablet) with label claim .The recovery studies were carried out at three different levels i.e. 125%, 100% and 50% .The low value of % RSD is indicative of the accuracy of the proposed method. The result of recovery study revealed that the commonly encountered excipients and other additives usually present in the dosage form did not interfere in the proposed method. The precision of the proposed method was studied as an intra-day and inter-day analysis and ruggedness study. The results from validation studies are shown in Table 2.

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Table 2
Summary of validation of Tenatoprazole by proposed method

Parameter	Result
Accuracy (% Recovery)	99.37±1.3816
%RSD	1.3874
Precision (%RSD)	
Intra-day (n=3)	0.3969
Inter-day (n=3)	0.5203
Repeatability (n=6)	99.16±0.4490
Ruggedness (%RSD)	
a.Different analyst	
(i)Analyst I	0.8269
(ii)Analyst II	0.9330
b. Different Instrument	
(i) Single beam spectrophotometer	0.3201
(ii) Double beam spectrophotometer	0.3948

CONCLUSION

The procedure described here is simple, rapid, sensitive, selective and cost effective. It is evident from the results that the recommended procedure is well suited for the assay and evaluation of drugs, in preformulation and dosage forms. It can be applied for direct determination of Tenatoprazole in drug control laboratories.

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