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Research Article

VALIDATED COLORIMETRIC METHODS FOR THE ESTIMATION OF TENELIGLIPTIN IN TABLETS

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ABSTRACT

Two simple sensitive and precise methods A and B were developed for the estimation of teneligliptin in bulk drug as well as in pharmaceutical dosage form. Method A is based on the formation of a red colored chromogen by reaction of teneligliptin with potassium thiocyanate in presence of ferric chloride, which has an absorption maximum at 554nm. Method B is based on the formation of an orange colored complex by complexation reaction of teneligliptin with 2, 2'- bipyridyl in the presence of ferric chloride which has an absorption maximum at 421nm. The proposed methods are statistically validated and found to be useful for the routine determination of teneligliptin in tablets.

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INTRODUCTION

Teneligliptin (TNG) is used to help control blood sugar levels in patients affected by type -2 Diabetes^{1, 2}. Teneligliptin works by inhibiting the activity of an enzyme known as DPP-4. This enzyme is responsible for degrading ingredients such as GLP-1 (Glucagon-like peptide 1), which are needed by the body to control blood sugar. Blocking the action of DPP-4 leads to increase in GLP-1 levels. GLP-1 helps to increase the release of insulin, which in turn lower blood glucose levels, thereby making this medicine effective in controlling type-2 diabetes^{3, 4}.

Chemically it is [(2S, 4S)-4-[4-(3-Methyl-1-phenyl-1H-pyrazol-5-yl)-1-piperazinyl]-2-pyrrolidinyl]-3-thiazolidinyl methanone hydrobromide.⁵ The available methods for analysis of this drug in biological fluids and pharmaceutical products are RP-HPLC method^{6, 7}, LC-

MS method⁸ and HPTLC method.⁹ The present work deals with the estimation of TNG in tablets by visible spectrophotometric methods. In Method A, TNG reacts with potassium thiocyanate and ferric chloride to form a red chromogen, which absorbs intensively at 554nm. In method B, TNG forms an orange coloured complex with 2, 2'- bipyridyl and ferric chloride which exhibited λ_{max} at 421nm. The method is alternative and comparable in specificity and accuracy to chromatography methods, which although highly specific and accurate, are more time consuming, performed in several steps and are rather expensive.

MATERIALS AND METHODS

Instrumentation: All spectral and absorbance measurements were made on UV-Vis Spectrophotometer -1900s.

Reagents:

1. Potassium thiocyanate (2% w/v)
2. Ethanol (95% w/v)
3. 2, 2'Bipyridyl (0.1% w/v)
4. Ferric chloride (5% w/v)

All reagents used were of analytical grade.

Preparation of standard solution:

A 1 mg/ml stock solution of TNG was prepared by dissolving 100 mg of drug in 100 ml of ethanol.

Sample preparation:

Twenty tablets were weighed and powdered. A quantity equivalent to 100mg of TNG was weighed accurately, transferred to a beaker, dissolved in ethanol, filtered through whatmann filter paper No. 1 into a 25 ml volumetric flask and made up to volume with ethanol to get a concentration of 1mg/ml.

Assay:**Method A:**

Appropriate aliquots of TNG were pipetted out into a series of 25 ml volumetric flasks. To each flask 2 ml of potassium thiocyanate and 2ml ferric chloride reagent were added, mixed thoroughly and made up to volume with ethanol. The λ_{max} of the red coloured chromogen was found to be 554nm (Figure-1). The absorbance of the red coloured chromogen was measured at 554 nm against the reagent blank. The red chromogen was stable for more than 3 hours. The analytical curve was constructed by plotting concentration versus absorbance.

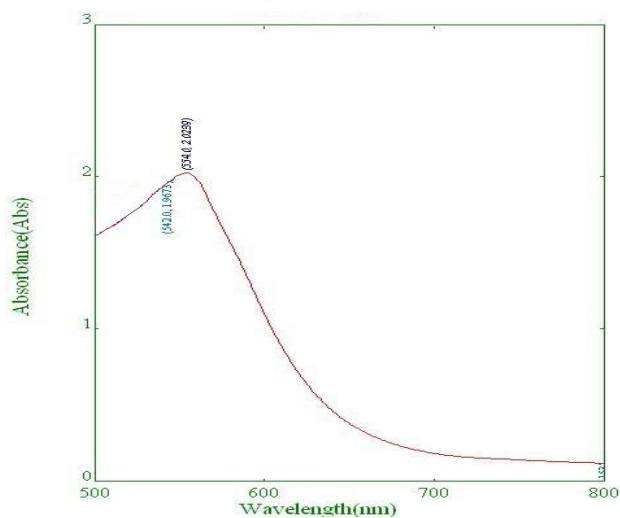


Figure 1: λ_{max} of the red chromogen by Method A

Method B:

Appropriate aliquots of TNG were pipetted out into a series of 25 ml volumetric flasks. To each flask 2ml of ferric chloride (5% w/v) and 3 ml of 2,2'bipyridyl (0.1% w/v) were added, heated on a boiling water bath for 15 minutes, cooled and then made up to volume with ethanol. The λ_{max} of the orange coloured chromogen was

found to be 421nm (Figure-2). The absorbance of the orange coloured chromogen was measured at 421 nm against the reagent blank. The amount of TNG was computed from the calibration curve obtained by plotting concentration versus absorbance.

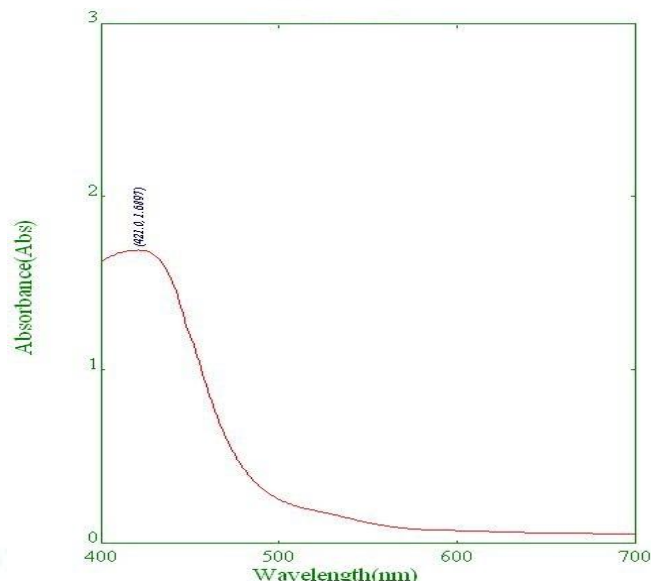


Figure 2: λ_{max} of the orange chromogen by Method B

Sample Analysis:

Pharmaceutical formulation of TNG was successfully analyzed by the proposed methods. Appropriate aliquots were subjected to the above methods and the amount of the TNG was determined from the calibration curves. The results of sample analysis are furnished in table- 2.

RESULTS AND DISCUSSION

The optical characteristics such as absorption maxima, Beer's law limits, Molar absorptivity and Sandell's sensitivity are furnished in table-1. The regression characteristics like slope (b), intercept(a), correlation coefficient(r), percent relative standard deviation (%RSD) and standard error (SE) obtained from different concentrations were calculated and the results are summarized in table-1.

To study the accuracy and reproducibility of the proposed methods, recovery experiments were carried out by adding a known amount of drug to pre-analyzed sample and the percentage recovery was calculated. The results are furnished in table-2. The results indicate that there are no interference of other ingredients present in the formulation. Thus, the proposed methods are simple, sensitive, precise, accurate and reproducible and useful for the routine determination of TNG in bulk drug and its pharmaceutical dosage form.

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Table 1: Optical characteristics, Precision and Accuracy of the proposed methods

Parameter	Method A	Method B
λ_{max} (nm)	554nm	421nm
Beer's law limit($\mu\text{g/ml}$)	0.1 - 0.6	0.2 - 1.6
Molar absorptivity ($\text{Lmol}^{-1}\text{cm}^{-1}$)	40.61×10^3	43.03×10^3
Sandell's sensitivity ($\mu\text{g/cm}^2/0.001$ absorbance unit)	0.01786	0.019916
Regression equation(*y)		
Slope(b)	0.13714	0.76735
Intercept(a)	-0.08413	0.003134
Correlation co-efficient (r)	0.9999	0.9941
% RSD	0.144	0.078
Standard error(SE)	0.0177	0.171

*y = a+bc where c is the concentration of TNG in $\mu\text{g/ml}$.

Table 2: Assay and recovery of TNG in the dosage form (tablets)

Method	Labelled amount (mg)	Amount obtained (mg)*	Percentage recovery**
A	20.00	19.95	100.01
B	20.00	20.24	99.99

*Average of six determinations ** Average of three determinations

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