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STATISTICAL VALIDATION OF A NOVEL BIOANALYTICAL METHOD FOR DETERMINATION OF THIAMINE HYDROCHLORIDE

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ABSTRACT

Sophisticated analytical methods viz. HPLC and HPTLC which are being employed for analysis are relatively expensive and hence need for simple analytical methods arises, that has been applied in the developed method for routine determination of Thiamine in pharmaceutical formulations and bulk dosage forms. The method is based on the formation of colored species due to binding of thiamine with sodium carbonate and folin-ciocalteu reagent in water to produce a blue colored chromogen (λ_{max} at 740 nm). Statistical analysis of the developed method exhibited Sandell's Sensitivity of 0.01030 and % RSD of the method was found to be 0.67 indicating that the method is highly reproducible, based on the principle of absorption visible spectrophotmetry for the determination of thiamine in bulk and pharmaceutical formulations. The method is reliable and can be employed for the routine determination of thiamine in various pharmaceutical formulations.

Keywords: Thiamine, Analysis, Spectroscopy, Molar absorptivity, Beer's Law.

INTRODUCTION

Thiamine or thiamin or vitamin B_1 and also called as the thio-vitamine (sulfur-containing vitamin) is the first vitamin of the water-soluble B complex group category of vitamins. It undergoes extensive phosphorylation in the liver to form thiamine pyrophosphate (TPP), a coenzyme that plays vital role in the HMP shunt pathway of sugars and also during the oxidative decarboxylation of pyruvate to acetyl-CoA in addition to the catabolism of sugars and amino acids. In yeast, TPP is also required in the first step of alcoholic fermentation.

All living organisms use thiamine in their biochemistry, but it is synthesized in bacteria, fungi, and plants. Animals must obtain it from

their diet. Insufficient intake in birds produces a characteristic polyneuritis, and in mammals results in a disease called beriberi affecting the peripheral nervous system (polyneuritis) and the cardiovascular system, In less deficiency, it include malaise, weight loss, irritability and confusion.

Only a few, HPLC[3,4] LC-MS[5] , Polarimetry[6] Spectrophotometric[7-14] methods appeared in the literature for the determination of Thiamine and its derivatives in bulk and pharmaceutical formulations. As the number of available procedures that could be of utility to a small-scale industry were found to be less the author has proposed a simple, sensitive and standard method as described below for the routine quality control analysis of thiamine in formulations and dosage forms.

EXPERIMENTAL

Instrumentation:

Spectral and absorbance measurements are made with Genesis 10UVS, UV – Visible split beam spectrophotometer manufactured by Thermo Scientific,

Reagents:

All the chemicals used were of analytical grade. All the solutions were freshly prepared with double distilled water. Freshly prepared solutions were always used. For this method, freshly prepared solutions of 20% sodium carbonate and folin-ciocalteu reagent (1: 3 Diluted) were prepared.

Standard and Sample solution of Thiamine:

About 100 mg of Thiamine was accurately weighed on a digital single pan balance and dissolved in 100 ml of water in a volumetric flask to prepare a solution that has a concentration equal to 1 mg/ml standard solution and further dilutions were made with the same solvent to obtain a solution of 100µg/ml for the proposed method.

Assay Procedure:

To a series of 10 ml volumetric flasks containing different samples of thiamine ranging from 0.4 to 2.0 ml (1ml = 100 µg) and aqueous solutions of 20% sodium carbonate (2 ml), were added to all the flasks and kept aside for 10 minutes with occasional shaking and then the solution was made up to the mark in all the flasks Folin-ciocalteu reagent (1.5 mL) is added and the absorbance of the blue colored solution was measured at 740 nm against the corresponding reagent blank. The amount of Thiamine was computed from the corresponding calibration curve.

RESULTS AND DISCUSSION

The proposed methods are based on reduction of the aromatic groups present in thiamine by folin ciocaltaeu reagent followed by complex formation with sodium carbonate to form a blue colored complex with λ_{max} at 740 nm**.** The optical characteristics such as absorption

maxima, Beer's law limits, molar absorptivity and sandell's sensitivity for these methods are presented in Table-1. The regression analysis using the method of least squares was made for the slope (a), intercept (b) and correlation coefficient (r) obtained from different concentrations was summarized in Table-1. The precision and accuracy were found by analyzing six replicate samples containing known amounts of the drug and the results are summarized in Table-1.

The proposed methods are simple and sensitive with reasonable precision and accuracy. These can be used for the routine determination of thiamine in quality control analysis.

TABLE-1 Optical characteristics, precision and accuracy of the proposed method

Parameter	M_2
Name of the Method	Sodium carbonate and Folin Ciocaltaeu method
λ_{max} (nm)	740
Beer's law limits(µg /ml)	4-20
Molar absorptivity (1 mole^{-1} cm^{-1})	1.9174 x 10^4
Sandell's sensitivity (µg /cm ^{2}/0.001 absorbance unit)	0.0130
Regression equation (Y = a+ bc)	
Slope (b)	0.0097
Intercept (a)	- 0.4649
Correlation coefficient (r)	0.9999
Standard deviation	0.0107
% Relative standard deviation	0.67
% Range of Error (Confidence limits)	
0.05 level	0.5669
0.01 level	0.8388

* Y= a + bx, where'Y'is the absorbance and x is the concentration of niacin in Mg/ml, ** for six replicates.

TABLE- 2 Assay and recovery of Thiamine in Bulk Dosage forms

Bulk Dosage forms	**Labelled amount**	**Percent recovery by proposed method**
Pack 1	10 mg	9.5
Pack 2	10 mg	9.6
Pack 3	10 mg	9.68
Pack 4	10 mg	10.05

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