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Spectrophotometric estimation and validation of hydrochlorothiazide in tablet dosage forms by using different solvents

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ABSTRACT

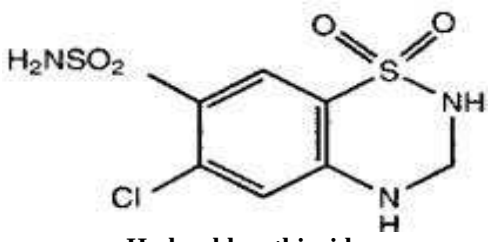
The method for the estimation of hydrochlorothiazide in tablet dosage form has been developed. This analytical method developed for the estimation of hydrochlorothiazide in bulk fluids showed maximum absorbance at λmax of 272 nm in distilled water and in 0.01N NAOH between 200 nm and 400 nm of UV scan. Linearity studies indicated that estimation of hydrochlorothiazide between 5.00µg /ml to 30.00 µg /ml in distilled water and 1.00µg/ml to 30.00µg/ml in 0.01N NAOH were found to be linear with regression equation of y = 0.043x+0.198; (r2 = 0.999) and y=0.059+0.029;(r2 =0.998). The method developed was validated for accuracy, linearity, limit of detection and limit of quantitation studies. The above analytical parameters indicated that the developed UV Spectrophotometric method of hydrochlorothiazide was simple, accurate and reproducible. Also the biggest advantage is of using distilled water and 0.01N NAOH as solvent for the first time saving organic solvent exposure and also stable solvent is less expensive.

Keywords: Hydrochlorothiazide,, physicochemical characterization, UV Spectrophotometric Method, validation. 272.0nm λmax of hydrochlorothiazide.

INTRODUCTION

This method is simple, accurate and results of analysis have been validated statistically and by recovery studies. Hydrochlorothiazide produced its significant prolongation of half-life due to decrease in hydrochlorothiazide elimination. The official monographs describe the procedure for individual assay of hydrochlorothiazide, and hydrochlorothiazide combination. However, no spectrophotometric method has been reported for the quantitative determination of hydrochlorothiazide drugs from their combined formulations with distilled water and 0.01N NAOH as solvent. Hydrochlorothiazide (HCTZ), 6-chloro-3,4-dihydro-2H-1,2,4-benzothiadiazine-7-sulfonamide 1,1-dioxide, which is widely used in antihypertensive pharmaceutical preparations, reduces active sodium reabsorption and peripheral vascular resistance. The review of the literature revealed that no method is yet reported for the simultaneous estimation of both the drugs in combined dosage forms. Present work describes too

simple, accurate, reproducible, rapid and economical method for estimation of HCTZ in tablet formulation.



Hydrochlorothiazide

MATERIALS AND METHODS

Instrumentation:
A double-beam Jasco UV-2075; UV Visible spectrophotometer, spectral bandwidth of 2nm,wavelength accuracy ±0.5nm and a pair of 1-cm matched quartz cells was used to measure absorbance of the resulting solution.

Materials:
Standard sample of hydrochlorothiazide were obtained and hydrochlorothiazide tablets (25mg hydrochlorothiazide tab.Aquazideh manufactured by SUN Pharma), were purchased from local market.

Solvent:
Distilled water and 0.01N NAOH of analytical reagent grade was selected as common solvent for developing spectral characteristics of drug. The selection was made after assessing the solubility of the drugs in different solvents.

Preparation of standard Stock solutions:
Hydrochlorothiazide (10mg each) were accurately weighed and dissolved separately in 100ml of distilled water and 0.01N NAOH to give stock solutions (100µg/ml).From the standard stock solution,.0.5,1.0,1.5,2.0 and 2.5 ml was diluted upto 10 ml and to get 5,10,15,20,25 µg/ml HCTZ was analyzed for linearity, accuracy and precision, and scanned between 200-400nm.

Method:
In this method, from the spectra of drug at 272.0nm (λmax of hydrochlorothiazide) was selected for analysis. The calibration curves for hydrochlorothiazide were plotted in the concentration range of 5-25µg/ml .The absorbtivities values were determined for the drug at the wavelength of 272.0nm .

Application of the proposed method for the determination of HCTZ in tablet dosage form:
Twenty tablets were weighed and average weight was calculated. The tablets were crushed into fine powder. Tablet powder equivalent to 25mg of HCTZ was transferred separately to 100ml volumetric flask and ultrasonicated for 10min .The volume was made upto the mark with distilled water and 0.01N NAOH. The resulting solution was then filtered through a whatmann filter paper (No. 41).Aliquot portion was appropriately diluted with distilled water and 0.01N NAOH to get final concentration of 20µg/ml of HCTZ. The concentrations of HCTZ were determined by measuring absorbance of sample at 272.0nm in spectrum mode and values were substituted in respective formulae to obtain the concentration.

Validation:
The methods were validated with respect to linearity and accuracy.

Accuracy:
To ascertain the accuracy of the proposed methods, recovery studies were carried out by standard addition method at three different levels 80%, 100% and 120%. Percentage recovery by this method was found in range of are shown in table (2).

Linearity:
The linearity was obtained in the concentration range of 5-30µg/ml and 1-30µg/ml for hydrochlorothiazide in distilled water and in 0.01 N NAOH respectively, which obeys Beer-Lambert's law.

Limit Of Quantitation studies (LOQ) of Hydrochlorothiazide:
The LOD and LOQ by proposed methods were determined using calibration standards. LOD and LOQ were calculated as 3.3s/S and 10s/S, respectively, where S is the slope of the calibration curve and s is the standard deviation of response ,are shown in table(2)

Table No:1 Results of analysis of API

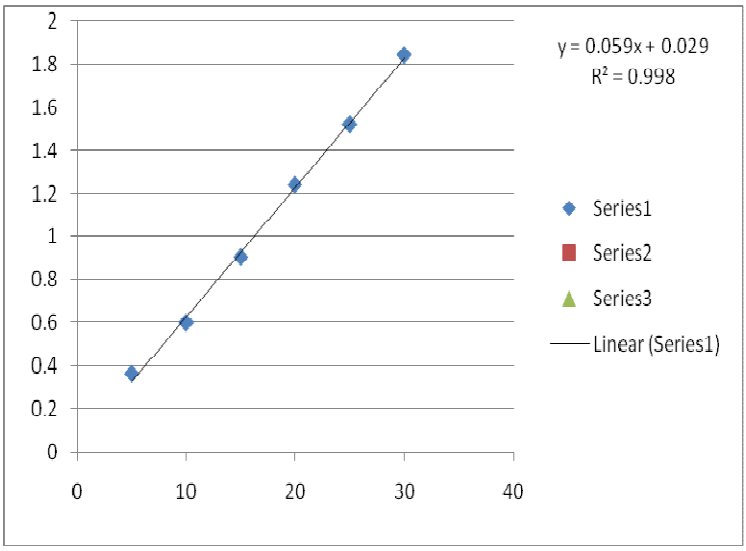
Sr.no	Conc. µg/ml	Absorbance at 272nm		S.D	
		Distilled water	0.01N NAOH	Distilled water	0.01N NAOH
1	5	0.422	0.364	0.343	0.470
2	10	0.620	0.6004		
3	15	0.850	0.904		
4	20	1.377	1.26		
5	25	1.778	1.52		

Table No:2 Results of analysis of Tablet

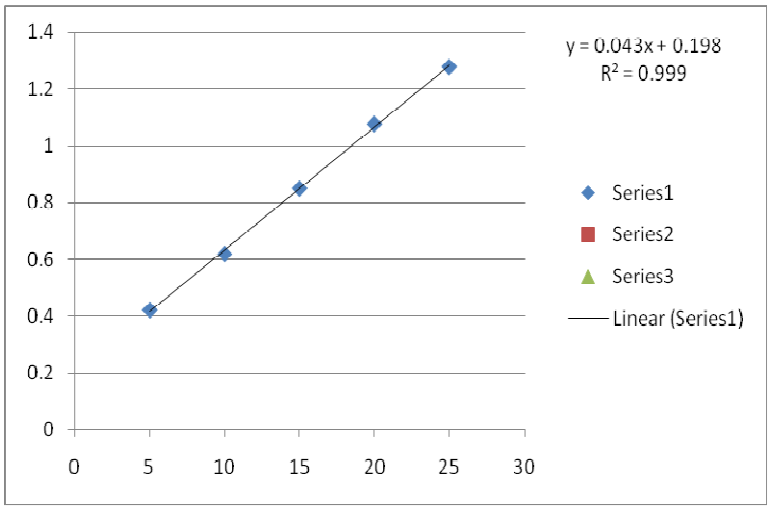
Solvent	Label Claim	Amount Found(mg/tab)	Amount Taken		% Recovery	LOD	LOQ	C.V
			%	mg/ml				
Distilled Water	25mg/ml	24.69	120	30	98.76	0.05	0.218	1.372
			100	25	98.73			
			80	20	98.76			
0.01N NAOH	25mg/ml	24.78	120	30	99.01	0.53	0.173	1.88
			100	25	99.12			
			80	20	99.12			

RESULTS AND DISCUSSION

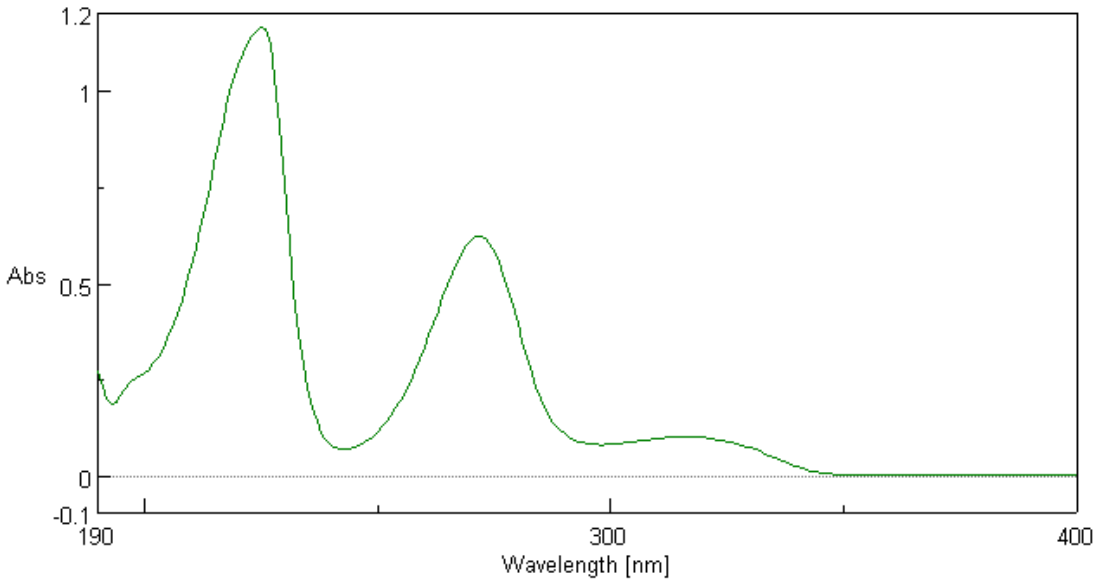
From the proposed method, it was found that hydrochlorothiazide obeys linearity within the concentration range 5-30µg/ml and 1-30µg/ml in distilled water and in0.01N NAOH .Percentage label claim for HCTZ in tablet, by this methods was found in the range of 98.13% and 99.12% in distilled water and in 0.01N NAOH respectively. Coefficient of variation (CV) were calculated, which was found to be less than 2% indicating the method has good reproducibility. Accuracy of proposed methods was ascertained by recovery studies and results are expressed as 98.13% and 99.12% recovery. Percent recovery HCTZ by the method, was found in range of 98.76% to 99.12%, value of standard deviation 0.343 and 0.470 in distilled water and in 0.01N NAOH respectively.



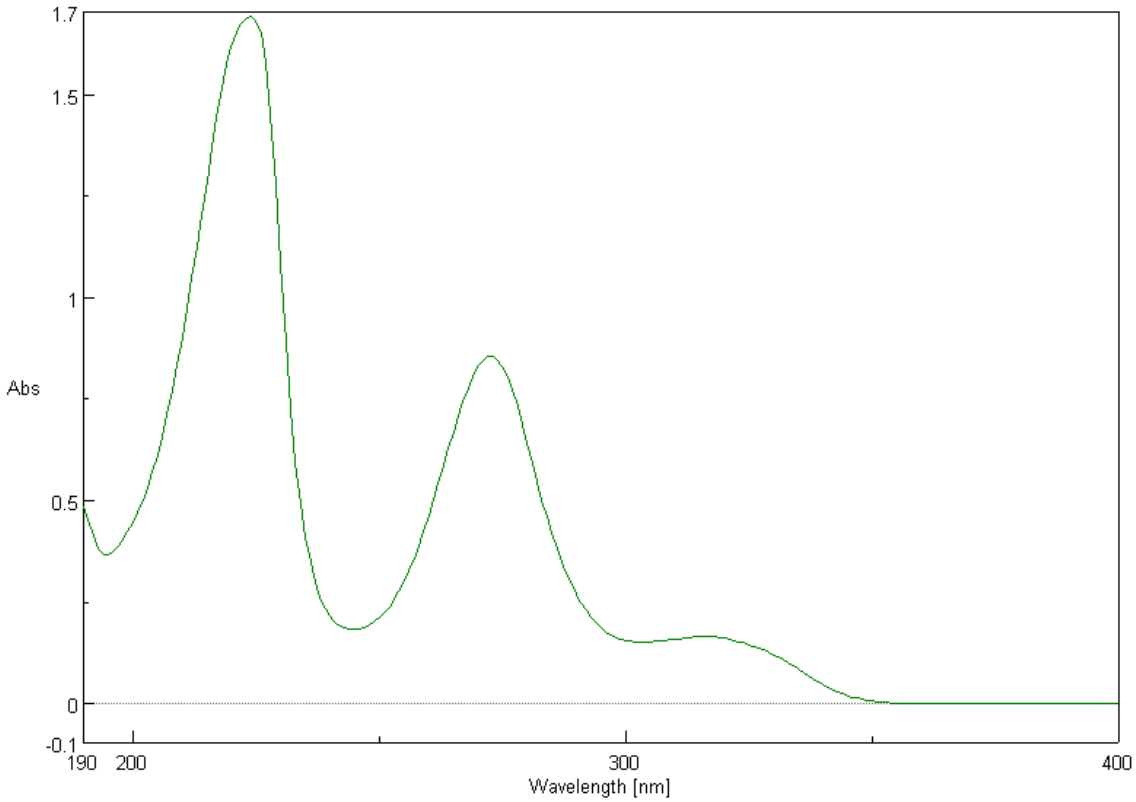
Fig(1): Linearity of HCTZ using 0.01N NAOH



Fig(2): Linearity of HCTZ using Distilled Water



Fig(3) : Spectra of HCTZ in 0.01N NAOH



Fig(4) : Spectra of HCTZ in Distilled Water

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