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Research Article

Method development and validation of hydrochlorothiazide in tablet dosage form by UV spectroscopy

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ABSTRACT

A simple, reproducible and efficient spectroscopic method development and validation of hydrochlorothiazide in tablet dosage form. The drug was ermined by using methanol as a solvent for this study, which is determined by spectrophotometrically at 224-nm.the percentage recovery study of the drug for the proposed method range from 99-100%w/v indicating no interferences of the tablet excipients, by using methanol as a solvent. Linearity was obtained in the concentration range 10-50 µg/ml for the hydrochlorothiazide with correlation coefficient of 0.9916. The result analysis was validated statistically and recovery studies confirmed the accuracy and precision of the proposed method.

Keywords: Hydrochlorothiazide; Methanol; UV spectrophotometer.

INTRODUCTION

Hydrochlorothiazide (Indian Pharmacopoeia, volume,-2, 2007) belongs to Thiazide class of diuretics, acting on the kidneys to reduce sodium (Na) reabsorption in the distal convoluted tubule. This increases the osmolarity in the lumen, causing less water to be reabsorbed by the collecting ducts. (Braun Robert D, 2006). This leads to increase urinary output .it is chemically 6-chloro-1, 1-dichloro-3, 4, dihydro -2H-1, 2, 4-benzoliadiazine-7-sulphanomide1, 1-dioxide.its molecular weight is 297.7.

There are very few methods (Lastra, et al., 2003) (Dougles A Skoog 1996,4-7) appearing in the literature for the method development and validation of hydrochlorothiazide in tablet dosage for, since these methods were based on RP-HPLC, (P. D Sethi, 50-53) electrophoresis (Nafisur Rahman et al*., 2006*) *only* but there was no method has been developed by using methanol as a solvent in UV spectrophotometrically and also this procedure was convenient for determination of the hydrochlorothiazide in tablet dosage form in 224 nm, thus an attempt was made to develop a simple, precise and economical method for development and validation of hydrochlorothiazide in uv spectroscopy by tablet dosage form.

EXPERIMENTAL

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Hydrochlorothiazide was obtained as a gift sample from madras pharmaceuticals pvt.ltd, Pondicherry, India. Hydrochlorothiazide tablets were procured from local pharmacy all the chemicals and reagents were of analytical grade. Double distilled water was used throughout the experiment. Asysronics UV double beam spectrophotometer (2202) with 1 cm quartz cells were used for the estimation.

Preparation of standard solution for calibration curve

Weigh accurately 0.025gm of hydrochlorothiazide was taken in to 100ml of standard flask, and added small volume of methanol and shake well after that make up to the volume with 100 ml (stock solution), from this solution 10 ml and transferred in to 50 ml standard flask and made up to 50 ml with methanol (which is consist of 50 µg/ml used for the analysis), from the above solution, the sample solution was prepared from five different concentrations using methanol as a solvent like 10,20,30,40,and 50µg/ml were used for the calibration curve analysis.

Assay

Twenty tablets weighed, each tablet contains 25 mg of hydrochlorothiazide were weighed ,finely powdered and an amount of powder sample equivalent to 25mg of hydrochlorothiazide was taken in 100ml volumetric flask and dissolved in 3 x 30 ml of acetone by shaking for 5-10minutes and extracted by sonication to ensure complete solubility of the drug. The excipients were separated by filtration, finally combined the residues of the extract and make up the residues in the methanol to produce 100ml.from the above solution 10ml was taken and make up to 50 ml with methanol for the analysis. A typical UV spectrum obtained from a standard and sample is shown in figure 1 and 2.

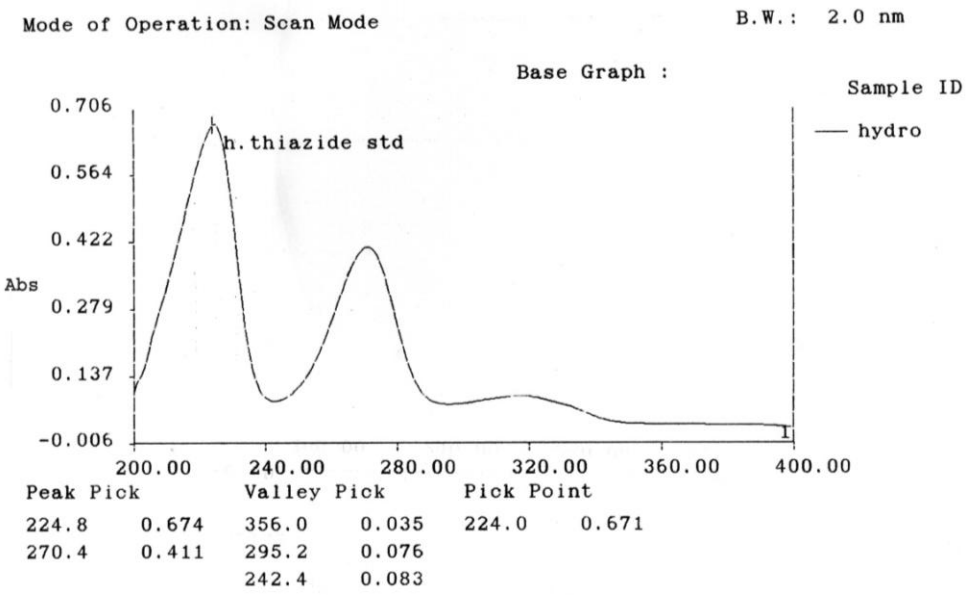

Figure 1: UV curve for standard hydrochlorothiazide at 224nm

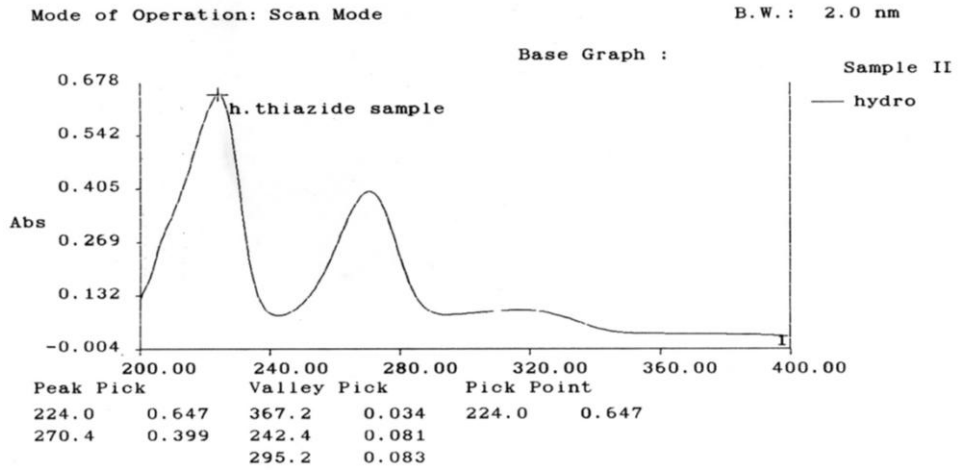

Figure 2: UV curve for sample hydrochlorothiazide at 224nm

RESULTS AND DISCUSSION

The objective of the study was to develop the method of hydrochlorothiazide under the suitable spectral conditions. Estimation of hydrochlorothiazide by UV spectroscopy method was carried out. The standard and sample solutions were prepared and the UV spectrums were recorded. The spectrums of standard and sample solutions were presented in figures 1 and 2.

The absorbance of standard and sample solution was calculated. The assay procedure was repeated according to mean concentration of standard and sample were calculated .the percentage of recovered of individual drug found in formulation were calculated and presented in Table 1. The result of analysis shows that the amounts of drug were in good agreement with the label claim of the formulation.

Table 1: Percentage recovery for hydrochlorothiazide

Drug	Labeled amount	amount taken for assay (gm)	Ultraviolet spectroscopy determination	
			Amount found	% Label claim
Hydrochlorothiazide	25mg	0.1510	24.17mg	99.71%

Method of validation

The method was validated in accordance with ICH guidelines for linearity, accuracy, precision, specificity, ruggedness and robustness (ICH, 1996).

Linearity

Linearity was assessed with the aid of serially diluted calibration solution as mentioned above. The standard and sample were taken separately. Calibration curves

were plotted on the basis of triplicate analysis of each calibration solutions. Linear concentrations were obtained over the range studied with correlation coefficients ≥ 0.99 for the drug. The regression equation was y = 0.02172x.its shown in tables no 2 & 3.

Table 2: linearity study for hydrochlorothiazide

S.No	Concentration of hydrochlorothiazide ((µg/ml)	Absorbance (nm)
1	10	0.156
2	20	0.215
3	30	0.364
4	40	0.489
5	50	0.640

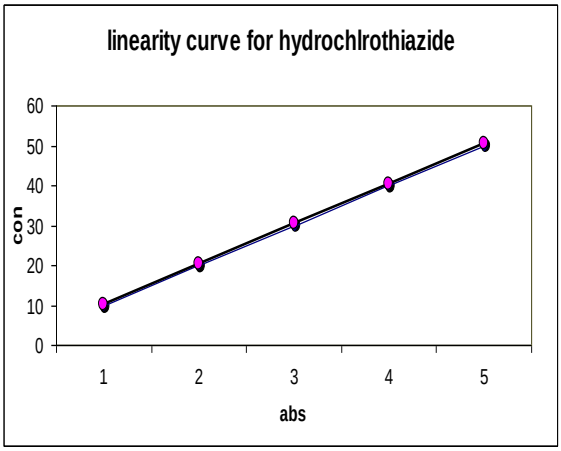

Figure 3: Linearity study for hydrochlorothiazide

Table 3: Linearity parameters for hydrochlorothiazide

Slope	0.01242
Intercept	0.0002
Correlation	0.991607
RSD	99.16

Precision

The precision of the method was done by replicate (n=5) analysis of tablet preparations. The precision was also studied in terms of intraday changes in absorbance of drug solution on the same day and on three different days over a period of one week. The intra-day and inter day variations was calculated in terms of percentage relative standard deviation and the results are given in Table 4.

Table 4: Precision study for hydrochlorothiazide

Drug name	Labeled amount (mg per dose)	Amount found (mg per dose)	Recovery (% n=5)
Hydrochlorothiazide	25	24.17	99.71% w/v

CONCLUSION

The proposed method of estimation of hydrochlorothiazide by UV spectroscopy in tablet dosage forms is simple, precision, specific and highly accurate and less λ max for analysis would be recorded, so it can definitely be employed for the routine analysis. Hence this method development and validation of hydrochlorothiazide tablet dosage form in UV method is suitable for quality control; of raw materials and formulations and also for dissolution studies. It can be used for bioequivalence studies in Pharma.

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