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A comparative study of three brands of losartan potassium tablets by UV Spectrophotometry

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ABSTRACT

A simple, reliable, specific method for the quantitative analysis of Losartan potassium has been developed. The method has shown linearity in the range of 2-10µg/ml and maximum absorbance at wavelength of 205nm. Statistical analysis shows that the method is precise, with reliable regression coefficient. The method is accurate and precise and is extended to pharmaceutical tablets forms and there was no interference from any common pharmaceutical additives and excipients. The results of analysis were validated statistically and by recovery studies.

Key words: Losartan potassium, UV Spectrophotometer, Method Development and Validation.

1. INTRODUCTION

Losartan potassium is a strong anti-hypertensive agent and exerts it action by specific blockade of angiotensin 2 receptors [1-3]. It was the first orally bio available, long acting non peptide. It develops a gradual and long lasting effect as antihypertensive, becoming a new alternative to this frequent chronic disease treatment. Losartan potassium is light yellow solid. Chemically it is 2-butyl-4-chloro-1-[p-(0-1Htetrazole-5-yl phenol)benzyl] imidazole-5-methanol mono potassium salt[4]. Literature survey reveals few UV Spectroscopy methods have been reported for analysis of Losartan potassium [5-9].

The aim of this work is to compare the percentage purity of different brands of Losartan potassium with the labeled claim. Now a days many pharmaceutical companies releasing the drugs for their commercial purpose with insufficient active ingredient in the dosage form as they claimed on the strip. So as to get awareness which pharmaceutical company gives appropriate active ingredient present in released dosage forms, quantitative analysis of marketed dosage forms play a vital role. One of the simple, precise, quantitative method of analysis is U.V Spectroscopy.

2. MATERIALS AND METHOD

2.1. Instrumentation

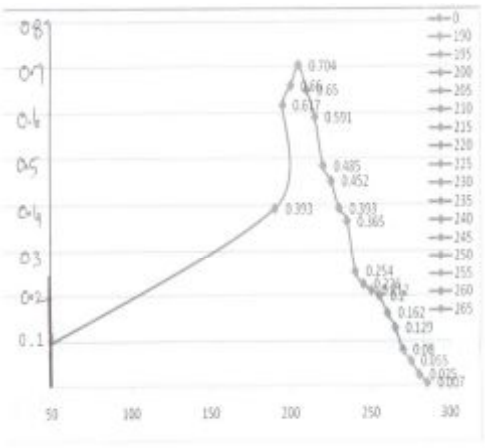
An Elico UV/Visible spectrophotometer SL 164 model with a Spectral band width of 10nm and wavelength accuracy of ±5nm with 1 cm matched quartz cells.

2.2. Methodology

2.2.1. Preparation of Standard Drug Solution

The standard stock solution of Losartan potassium was prepared by dissolving 25mg of each drug in 25ml of volumetric flask separately using distilled water. The standard stock solution was further diluted to get the concentration of 6 µg/ml and the solution was scanned between the range 50 - 300 nm in 1 cm cell against blank and the overlain spectra was recorded.

Figure 1



curve of λmax of losartan potassium.

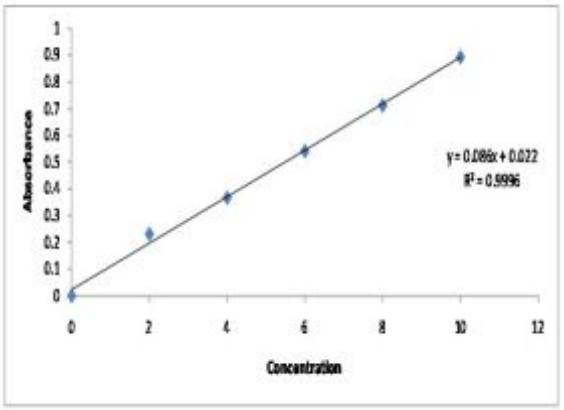
2.2.2. Construction of calibration curve

From the prepared stock (1mg/ml) solution, dilutions were made so as to obtain 2, 4, 6, 8, 10µg/ml, with water. Absorbance of each dilution were measured at 205nm.A graph is plotted by taking absorbance on y-axis and concentration on x-axis.

Table - 1: Absorbance of different concentrations of Losartan potassium at 205nm.

Concentration (µg/ml)	Absorbance
2	0.231
4	0.367
6	0.541
8	0.712
10	0.893

Figure-2: Calibration graph



2.2.3. Analysis of Tablet Formulation

Twenty tablets were weighed and average weight was found. The tablets were triturated to a fine powder. An accurately weighed quantity of powder equivalent to 25,50 mg of Losartan was transferred in to 50 mL volumetric flask and added a minimum quantity of water to dissolve the substance and made up to the volume with the same. The solution was sonicated for 15 minutes, centrifuged for another 15 minutes at 100 rpm and filtered through Whatmann filter paper No. 41. From the clear solution, further dilutions were made and the absorbance of sample solutions were measured at 205nm. The content of Losartan potassium in sample solutions of tablet was calculated. This procedure was repeated for six times.

Table - 2: Results of analysis of Losartan potassium in pharmaceutical formulation at concentration of 6µg/ml

PHARMAceutical Formulation BRAND NAME	LABELLED AMOUNT(mg)	AMOUNT FOUND(mg)	PERCENTAGE PURITY OF DRUG
Lorsar 25 (S_1)	25	24.583	98.33
Losanarm 25 (S_2)	25	24.582	98.32
Zilos 25 (S_3)	25	23.33	93.32
Losar 50 (S_4)	50	49.999	99.99
Losanaram 50 (S_5)	50	47.916	95.82
Zilos 50 (S_6)	50	45.833	91.66

2.2.4. Validation of Developed Methods

2.2.4.1. Linearity

For the linearity study, the drug solution was further diluted with was to get the final working standards of concentration ranges as Losartan potassium (2-10 µg/ml). Calibration curve (n = 6) was plotted between concentration and absorbance of drug.

2.2.4.2. Precision

The precision of the method was confirmed by repeatability and intermediate precision. The repeatability was performed by the analysis of formulation was repeated for six times with the same concentrationinterinter day and intra day. The amount of each drug present in the tablet formulation was calculated. The % RSD was calculated.

2.2.4.3. Accuracy

To check the accuracy of the developed method and to study the interference of formulation excipients, analytical recovery experiments were carried out by using standard addition method in three different concentrations. From the total amount of drug found, the percentage recovery was calculated. This procedure was repeated for three times for each concentration. The % RSD was calculated.

Table - 3: Data for Precision study

	Intraday precision		Interday precision	
Trade name	% content	%RSD	% content	%RSD
Lorsar 25 (S_1)	99.87	0.90	99.7	0.89
Losanarm 25 (S_2)	100.21	1.02	100.1	1.06
Zilos 25 (S_3)	99.99	0.95	99.9	0.97
Losar 50 (S_4)	99.28	0.96	99.3	0.98
Losanaram 50 (S_5)	100.31	1.05	100.5	1.08
Zilos 50 (S_6)	100.7	1.2	100.8	1.3

Table - 4: Data for Recovery studies

Trade name	Con (µg/ml)	Level	Amount found	% Recovery	Mean % recovery	%RSD
		50%	6.010±0.01	100.3		
Lorsar 25 (S_1)	4µg/ml	100%	7.999±0.04	99.89	100.61	0.515
		150%	9.98±0.01	99.79		
		50%	6.05±0.02	100.30		
Losanarm 25 (S_2)	4µg/ml	100%	7.98±0.06	99.84	99.87	0.560
		150%	9.99±0.01	99.87		
		50%	5.98±0.01	99.67		
Zilos 25 (S_3)	4µg/ml	100%	7.99±0.01	99.78	99.76	0.480
		150%	9.99±0.02	99.78		
		50%	5.99±0.01	99.89		
Losar 50 (S_4)	4µg/ml	100%	7.99±0.01	99.89	99.86	0.90
		150%	9.99±0.02	99.78		
		50%	5.98±0.02	99.87		
Losanaram 50 (S_5)	4µg/ml	100%	8.00±0.02	99.76	99.78	0.60
		150%	9.98±0.04	99.86		
		50%	5.99±0.02	99.89		
Zilos 50 (S_6)	4µg/ml	100%	8.01±0.04	99.85	99.7	0.560
		150%	9.90±0.10	99.67		

3. RESULTS AND DISCUSSIONS

UV Spectrophotometric method was used to quantitative analysis of Losartan potassium which has shown accurate, reliable and precise results and so can be considered as alternative method for percentage purity determination and quantitative analysis of Losartan potassium. Based on the result obtained, the amount of drug obtained, percentage purity is less when compared to that of labeled claim.S_4 brand drug has shown its active ingredient amount as that of specified on labeled claim.

The proposed method is based upon direct estimation of Losartan potassium tablets estimated at 205 nm. The mean percentage content of drug was found to be within the limit which is determined by taking average of six readings (Table 2).

The developed method was validated as per ICH guidelines for repeatability, intermediate precision and recovery studies. The precision of the method was checked in terms of Inter-day and Intra-day, where methods were repeated on six different days and also repeated on six different time periods in same day. The results were given in (Table 3) and shows % RSD of less than 2 % at each level clearly indicated that the method is precise enough for the analysis of the drug.

The accuracy of the method was proved by performing recovery studies in the commercially available formulations (Table 4). The Values were between 98-101% indicates that proposed method is accurate for the analysis of drug and there is no interference from the excipients present in the formulations.

4. CONCLUSION

A method was developed for the determination of tablets which is simple, quick,reliable, inexpensive and simple. The results indicate that the described method can be used for quantitative analysis of the compound.

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