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RESEARCH ARTICLE

Development and Validation of new UV-Visible Spectrophotometric Method for the Estimation of Losartan in Tablet Dosage Form

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ABSTRACT

A simple, Accurate, precise method was developed for the estimation of Losartan in Tablet dosage form. Solutions of Losartan were prepared in solvent like methanol and UV spectrum of each were recorded by scanning between 200-400 nm. Losartan was found to be linear in a concentration range of 5-25µg/ml. The absorbance of these solutions were noted at wavelength 208 respectively. Calibration curves were plotted using concentration Vs absorbance at wavelength of 208 nm and the slope, intercept and correlation coefficient values were found to be 0.999 respectively. The assay of Losartan was performed with tablets and the % assay was found to be 100.16 which shows that the method is useful for routine analysis. The acceptance criteria of precision is RSD should be not more than 2.0% and the method show precision 0.16. The acceptance criteria of intermediate precision is RSD should be not more than 2.0% and the method show precision 0.09.

Keywords: Losartan, UV-Spectrophotometry

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1. Introduction

Losartan is chemically named as ((2-Butyl-4-chloro-1-{[2'-(1H-tetrazol-5-yl) biphenyl-4-yl] methyl}-1H-imidazol-5-yl) methanol [1]. Losartan is an angiotensin-receptor blocker (ARB) that may be used alone or with other agents

to treat hypertension. Losartan and its longer acting metabolite, E-3174, lower blood pressure by antagonizing the renin-angiotensin-aldosterone system (RAAS); they compete with angiotensin II for binding to the type-1

angiotensin II receptor (AT1) subtype and prevents the blood pressure increasing effects of angiotensin II. Unlike angiotensin-converting enzyme (ACE) inhibitors, ARBs do not have the adverse effect of dry cough. Losartan may be used to treat hypertension, isolated systolic hypertension, left ventricular hypertrophy and diabetic nephropathy. It may also be used as an alternative agent for the treatment of systolic dysfunction, myocardial infarction, coronary artery disease, and heart failure[2].

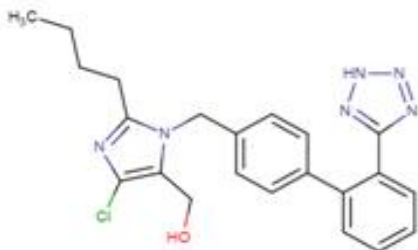


Figure 1: Structure of Losartan

Losartan competitively inhibits the binding of angiotensin II to AT1 in many tissues including vascular smooth muscle and the adrenal glands. Losartan is metabolized to its active metabolite, E-3174, which is 10 to 40 times more potent than losartan and acts as a non-competitive AT1 antagonist. Inhibition of angiotensin II binding to AT1 inhibits its AT1-mediated vasoconstrictive and aldosterone-secreting effects and results in decreased vascular resistance and blood pressure. Losartan is 1,000 times more selective for AT1 than AT2. Inhibition of aldosterone secretion may increase sodium and water excretion while decreasing potassium excretion. Losartan is effective for reducing blood pressure and may be used to treat essential hypertension, left ventricular hypertrophy and diabetic nephropathy [3].

2. Materials and Methods

The chemicals used were purchased from Pharmatrain and standard solutions Ltd.

ASSAY:

Preparation of standard solution:

Accurately weigh and transfer Equivalent to 25 mg of Losartan Working standard into a 100 mL volumetric flask add about 70 mL of Diluent and sonicate to dissolve it completely and make volume up to the mark with the same solvent (Stock solution)[4]. Further pipette 0.6ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluent

Preparation of sample solution:

Pipette 0.6ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluent.

Linearity:

Level – I: Preparation of 5.0µg/ml Losartan solution
Pipette 0.2ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluents

Level – II: Preparation of 10.0µg/ml Losartan solution
Pipette 0.4ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluents [6]

Level – III: Preparation of 15.0µg/ml Losartan solution

Pipette 0.6ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluent

Level – IV: Preparation of 20.0µg/ml Losartan solution

Pipette 0.8 ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluent

Level – V: Preparation of 25.0µg/ml Losartan solution

Pipette 1ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluents [7]

Procedure: Measure the absorbance of the above levels at 208nm. Plot a graph of peak area versus concentration (on X-axis concentration and on Y-axis Peak area) and calculate the correlation coefficient.

Acceptance criteria

- Correlation Coefficient should be not less than 0.9990.
- % RSD of peak areas for Solution 1, 2, 3, 4 and 5 should be not more than 2.0 %.

Precision

Preparation of Standard Solution:

Pipette 0.6 ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluents [8]. Measure the absorbance of the Losartan standards at 208 nm for five times and calculate the %RSD. The %RSD for the five replicate absorbance was found to be within the specified limits. The results are summarized (for Losartan)

Intermediate Precision:

To evaluate the intermediate precision (also known as Ruggedness) of the method, Precision was performed on different day by using same dimensions[9].

Id Preparation of Standard Solution: Pipette 0.6 ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluents[10].

ACCURACY

Accuracy Standard Solution Preparation: Pipette 0.6ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluents.

Accuracy 50% Solution Preparation: Pipette 0.6ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluents[11].

Accuracy 100% Solution Preparation: Pipette 0.6ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluents[12].

Accuracy 150% Solution Preparation:

Pipette 0.6ml of the Losartan stock solution into a 10ml volumetric flask and dilute up to the mark with diluents.

ROBUSTNESS

As part of the Robustness, deliberate change in the Wave length. The Wave length was varied at 206 nm to 210nm[14]. Standard solution 15ppm of Losartan was prepared and analysed using the varied wave length along with method wave length. The results are summarized on evaluation of the above results, it can be concluded that the variation in wave length affected the method significantly. Hence it indicates that the method is robust even by change in the wave length ± 1 [15]. The method is robust only in wave length condition

3. Results and Discussions

ASSAY:

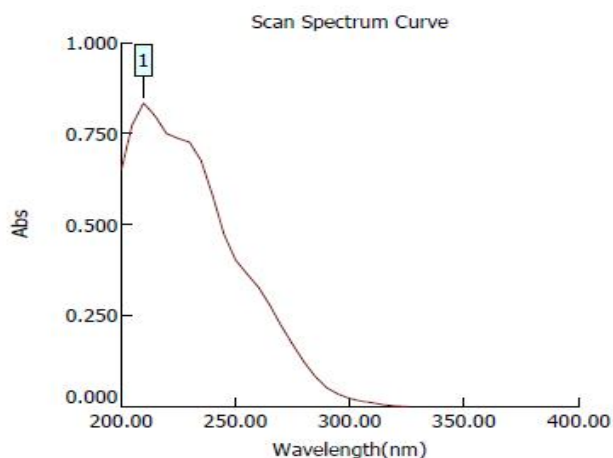


Figure 2: chromatogram for Standard

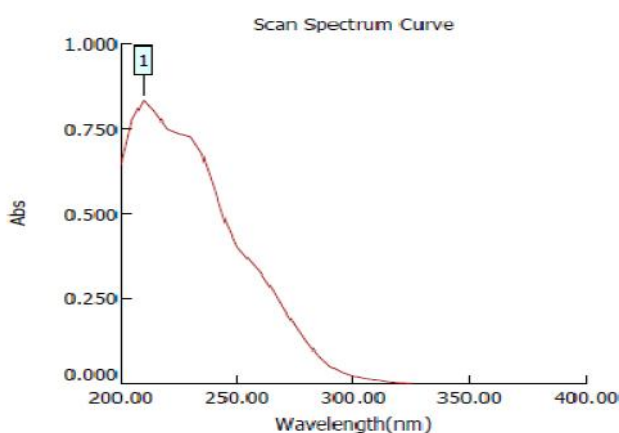


Figure 3: chromatogram for Sample

Table 1: Assay for Losartan

	Label Claim (mg)	% Assay
Losartan	25	100.16

LINEARITY:

The linearity range was found to lie from 5µg/ml to 25µg/ml of Losartan and chromatograms are shown below.

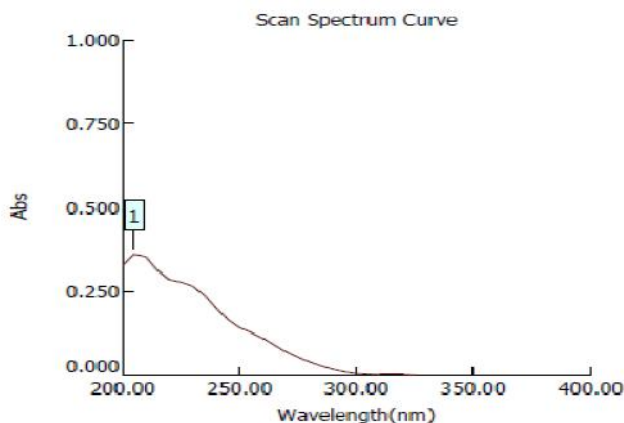


Figure 4: chromatogram for linearity concentration-5µg/ml of Losartan

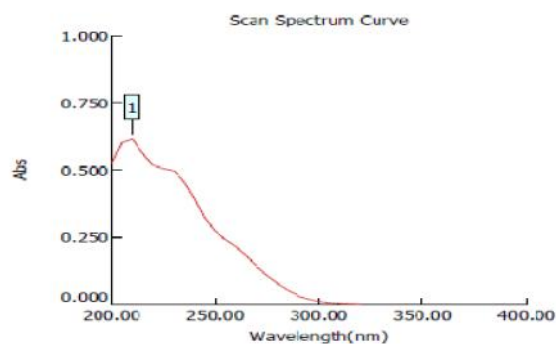


Figure 5: chromatogram for linearity concentration-10.0 µg/ml of Losartan

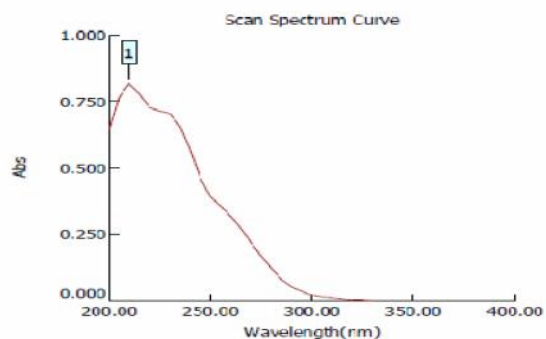


Figure 6: chromatogram for linearity concentration-15.0 µg/ml of Losartan

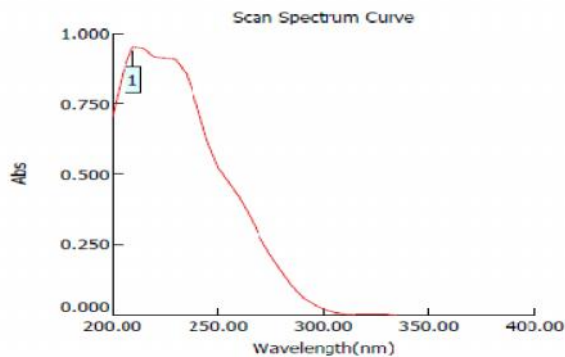


Figure 7: chromatogram for linearity concentration-20.0 µg/ml of Losartan

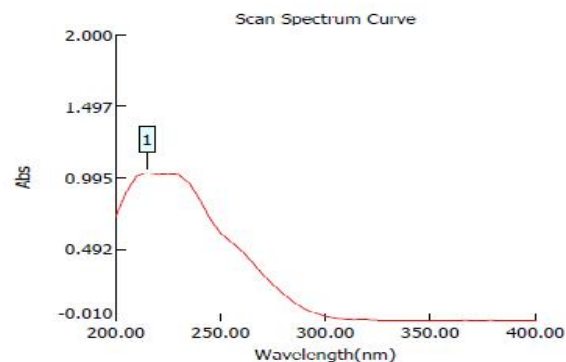


Figure 8: chromatogram for linearity concentration-25µg/ml of Losartan

Table 2: Area of different concentration of Losartan

S.No	Losartan	
	Concentration (µg/ml)	Absorbance
1	5.0µg/ml	0.459
2	10.0µg/ml	0.617
3	15.0µg/ml	0.808
4	20.0µg/ml	0.963
5	25.0µg/ml	1.13

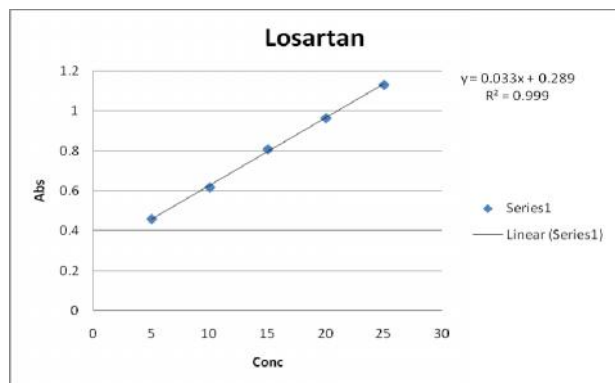


Figure 9: calibration graph for Losartan

PRECISION: Precision of the method was carried out for both sample solutions as described under experimental work. The corresponding chromatograms and results are shown below.

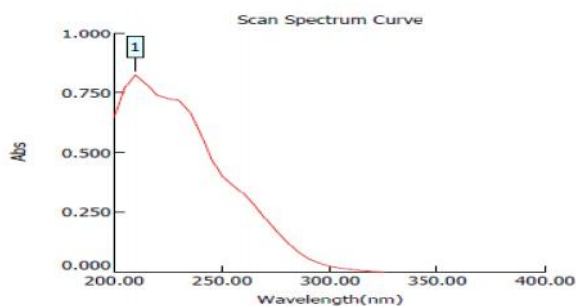


Figure 10: chromatogram for injection -1

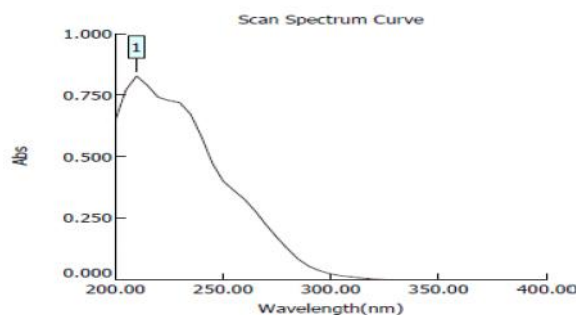


Figure 11: chromatogram for injection-2

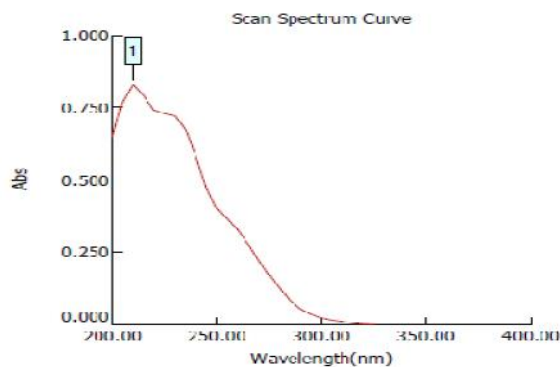


Figure 12: chromatogram for injection-3

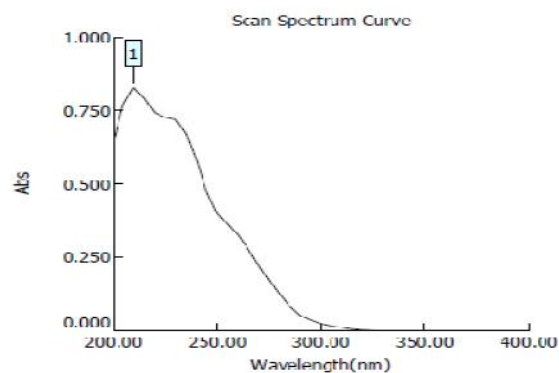


Figure 13: chromatogram for injection-4

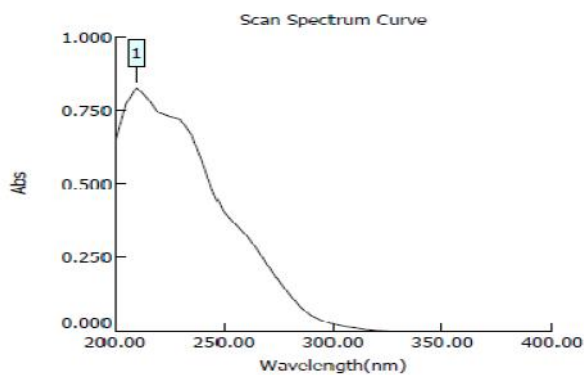


Figure 14: chromatogram for injection-5

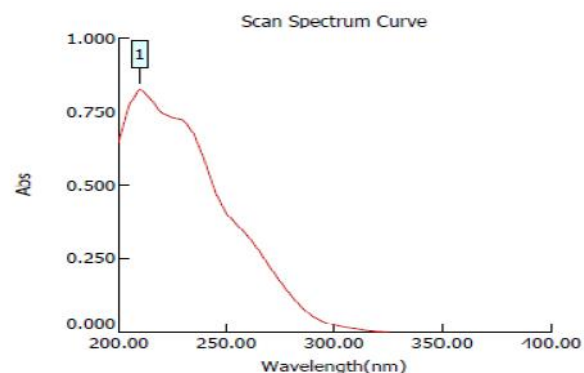


Figure 15: chromatogram for injection-6

Table 3: Results of Precision for Losartan

Injection	absorbance
Injection-1	0.826
Injection-2	0.826
Injection-3	0.828
Injection-4	0.829
Injection-5	0.829
Injection-6	0.828
Average	0.827
Standard Deviation	0.0013
%RSD	0.16

INTERMEDIATE PRECISION:

There was no significant change in assay content and system suitability parameters at different conditions of ruggedness like day to day and system to system variation.

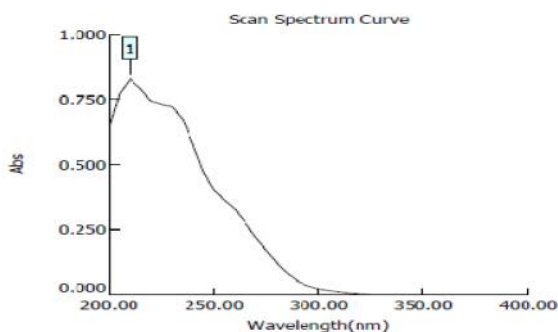


Figure 16: chromatogram for injection-1

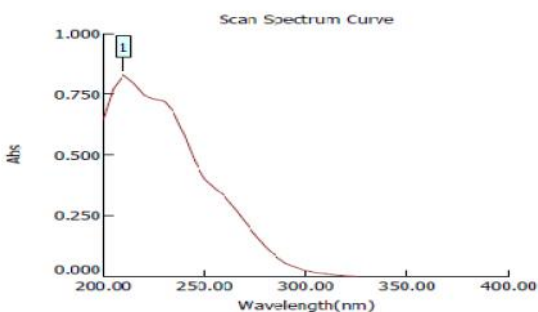


Figure 17: chromatogram for injection-2

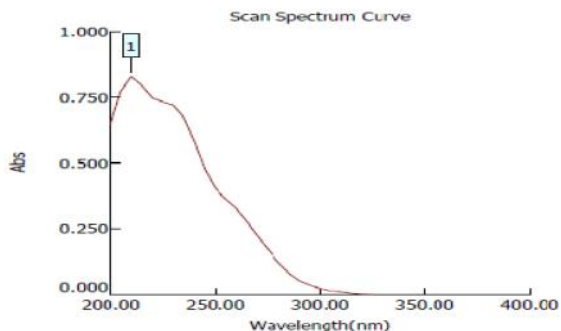


Figure 18: chromatogram for injection-3

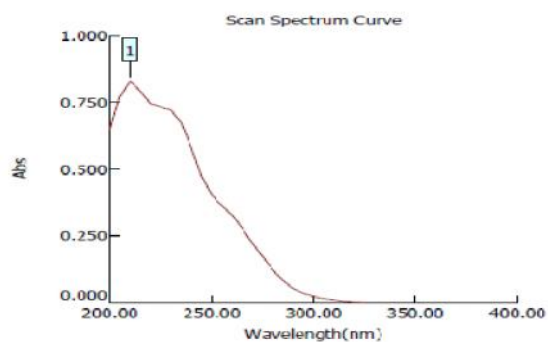


Figure 19: chromatogram for injection-4

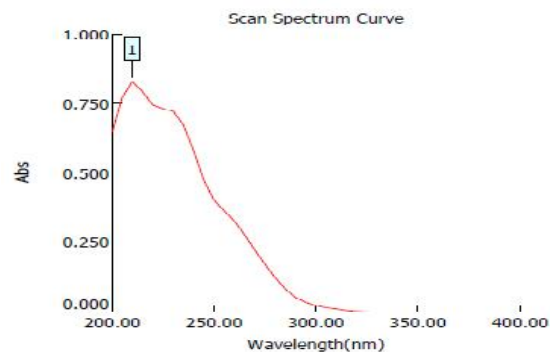


Figure 20: chromatogram for injection-5

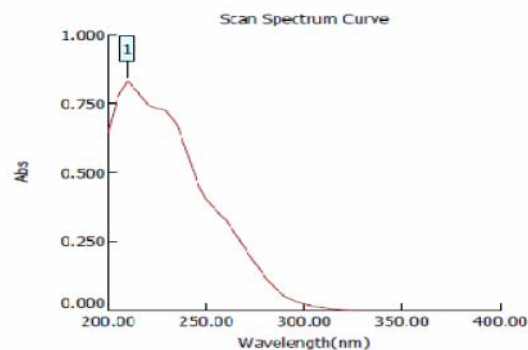


Figure 21: chromatogram for injection-6

Table 4: Results of Intermediate precision for Losartan

Injection	Absorbance
Injection-1	0.831
Injection-2	0.831
Injection-3	0.83
Injection-4	0.83
Injection-5	0.83
Injection-6	0.832
Average	0.830
Standard Deviation	0.0008
%RSD	0.09

ACCURACY: The accuracy study was performed for 50%, 100% and 150 % for Losartan. Each level was injected in triplicate into chromatographic system. The area of each level was used for calculation of % recovery.

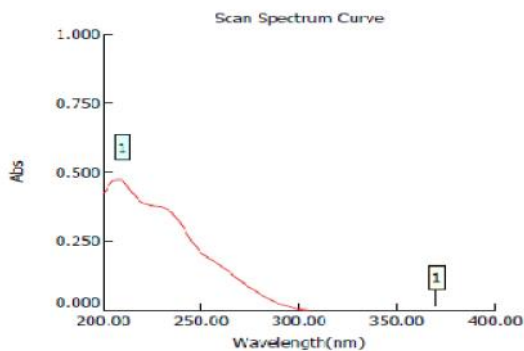


Figure 22: Chromatogram showing accuracy 50% injection-1

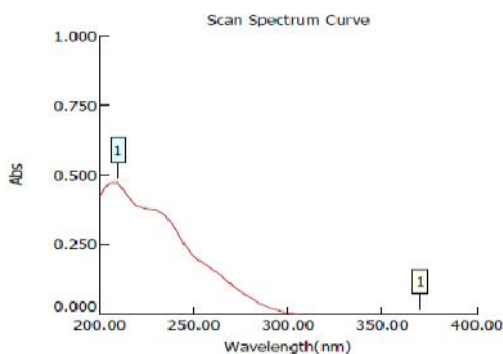


Figure 23: Chromatogram showing accuracy 50% injection-2

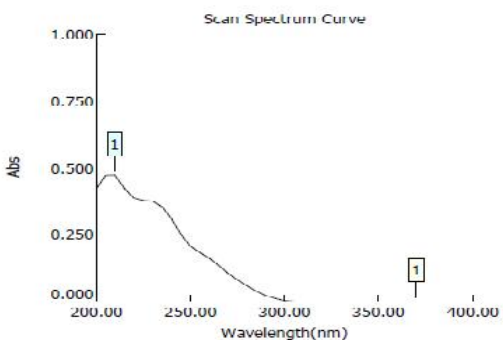


Figure 24: Chromatogram showing accuracy 50% injection-3

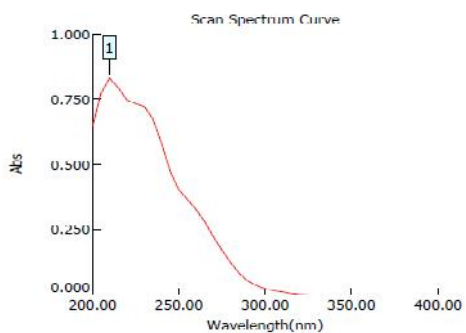


Figure 25: Chromatogram showing accuracy 100% injection-1

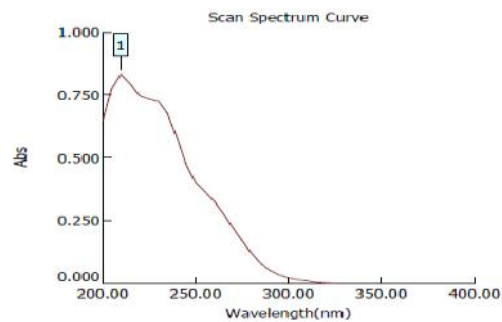


Figure 26: Chromatogram showing accuracy 100% injection-2

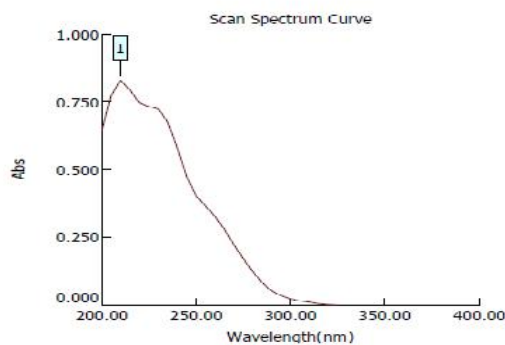


Figure 27: Chromatogram showing accuracy 100% injection-3

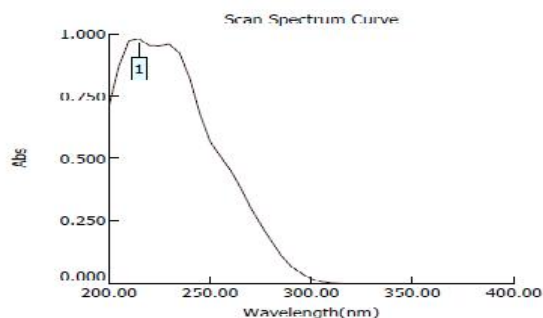


Figure 28: Chromatogram showing accuracy 150% injection-1

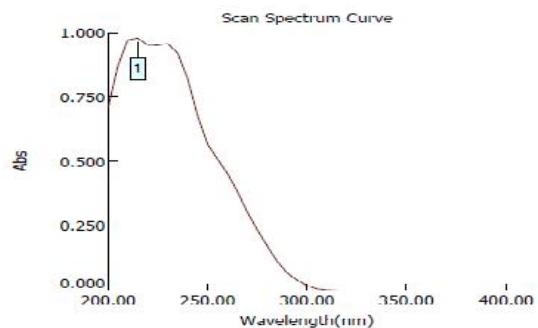


Figure 29: Chromatogram showing accuracy 150% injection-2

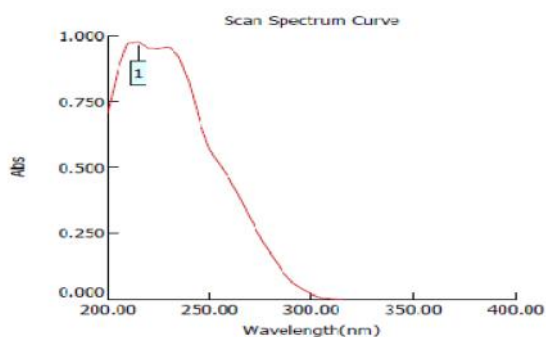


Figure 30: Chromatogram showing accuracy
150%injection-3

4. Conclusion

The estimation of Losartan was done by UV-Visible Spectroscopy. The assay of Losartan was performed with tablets and the % assay was found to be 100.16 which show

that the method is useful for routine analysis. The linearity of Losartan was found to be linear with a correlation coefficient of 0.999, which shows that the method is capable of producing good sensitivity. The acceptance criteria of precision is RSD should be not more than 2.0% and the method show precision 0.16. The acceptance criteria of intermediate precision is RSD should be not more than 2.0% and the method show precision 0.09. The method is robust in wave length condition within the limits respectively. The developed UV-Visible spectroscopic method for the analysis of Losartan was validated according to ICH guidelines. The results obtained on the validation parameters met the ICH and USP requirements. The method found to be simple, accurate, precise and linear. The method was found to be having suitable application in routine laboratory analysis with high degree of accuracy and precision.

Table: Accuracy results of Losartan

%Conc.	Abs	Amount added(m)	Amount found(m)	% Recovery	Mean Recovery
50%	0.422	12.5	12.75	101.9%	100.23%
100%	0.828	25	25.01	100.04%	
150%	1.225	37.5	37.0	98.67%	

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