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A COMPARATIVE STUDY OF GENERIC VS BRANDED DRUG OF LOSARTAN POTASSIUM USING UV-VISIBLE SPECTRO-PHOTOMETER

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ABSTRACT:

Reliable analytical methods are essential for routine pharmaceutical quality control and comparative evaluation of marketed products. This study aimed to develop and validate a rapid, direct UV–Visible spectrophotometric method for quantitative determination of losartan potassium and its application to selected marketed 25-mg tablets. Losartan potassium was analysed in distilled water using a double-beam UV–Visible spectrophotometer at 247 nm linear at a concentration range of 10–60 µg/mL. The method was predicting excellent linearity ($R^2 = 0.9999$), with regression equation $y = 0.0275x + 0.0007$. LOD and LOQ were 0.6453 and 1.9554 µg/mL, respectively. Accuracy, precision, solution stability and ruggedness were effectiveness. Assay values for five marketed formulations ranged from 89.467% to 109.437%. The method provides a rapid, economical, reproducible and accessible approach for routine quality assessment of losartan potassium tablets.

Keywords: *Losartan potassium; UV–Visible spectrophotometry; analytical method validation; generic tablets.*

1. INTRODUCTION:

Dependable analytical techniques are crucial for ensuring quality control in pharmaceuticals. Losartan potassium, an angiotensin II receptor blocker utilized in the treatment of hypertension, necessitates precise and consistent analysis. UV–Visible spectrophotometry provides a straightforward, quick, cost-effective and widely accessible method. This study employed distilled water as an eco-friendly solvent to develop and validate a direct spectrophotometric technique at 247 nm, which was subsequently applied to five commercially available 25-mg tablet formulations.

2. MATERIALS AND METHOD:

Losartan potassium API – Banglore.

Instrument used in Shimadzu double beam UV /Visible spectrophotometer (Model UV-1700) with spectral band width of 1 nm was used for present study.

SELECTION OF SOLVENT:

For the selection of solvent using solubility of losartan potassium was determined from polar to non – polar solvent, from that distilled water was selected as solvent.

3. PREPARATION OF WORKING STANDARD SOLUTION:

The stock solution (250 µg/mL) was further diluted with distilled water to obtain a working standard solution of the required (10–60 µg/mL) concentration for calibration for analysis.

4. SELECTION FOR WAVELENGTH:

An aliquot of the standard stock solution was further diluted with distilled water to obtain 10 µg/mL solution. The solution was scanned in the UV region between from 200–400 nm using distilled water as the blank. The absorbance was observed at 247 nm, which was selected for all analytical measurements.

5. STABILITY STUDIES:

The stability of the prepared standard solutions was evaluated by measuring the absorbance at 247nm at predetermined time intervals under laboratory conditions. The solutions remained stable during the analysis period without any significant change in absorbance.

6. PREPARATION OF CALIBRATION CURVE:

From the working standard solution suitable aliquots were transferred into a series of volumetric flasks and diluted with distilled water to prepare solution of different concentration (10,20,30,40,50 and 60 µg/mL). The absorbance of each solution was measured at 247 nm against distilled water as blank. A calibration curve was constructed by plotting concentration versus absorbance.

7. QUANTIFICATION OF FORMULATION (Tablet) :

Twenty tablets from each formulation were weighed individually, and the average tablet weight was calculated. The tablets were finely powdered, and an amount of powder equivalent to 25 mg of Losartan Potassium was accurately weighed and transferred into a 100 mL volumetric flask. Distilled water was added, and the solution was sonicated for 15 minutes to ensure complete extraction of the drug. The solution was filtered through Whatman No. 41 filter paper, and the volume was made up to the mark with distilled water. Appropriate dilutions were prepared from the stock solution to obtain the required concentration for analysis.

8. RECOVERY STUDIES:

The accuracy of the developed method was evaluated by the recovery study. Pre-analysed tablet samples were spiked with known amounts of Losartan Potassium reference standard at 80%, 100%, and 120% levels. The solutions were prepared and analysed under the optimized experimental conditions. The percentage recovery and percentage relative standard deviation (%RSD) were calculated.

9. PRECISION:

The % RSD for all five brands 1.170,3.66,0.783,1.656,1.615 (intra-day) and 1.867,4.71,1.550,1.192,1.180 (inter -day).

10. DISCUSSION:

The developing UV–Visible spectrophotometric method using distilled water and detection at 247 nm provides a simple, economical, and practical approach for quantitative determination of losartan potassium in tablets. Excellent linearity; $R^2 = 0.9999$), satisfactory sensitivity, precision, recovery, and ruggedness confirmed method reliability. Assay values varied among five marketed formulations, with Repace closest to the label claim. However, these differences do not establish pharmaceutical equivalence or bioequivalence. The method is suitable for routine quality control, particularly in resource-limited laboratories.

11. CONCLUSION:

Overall, the developed UV-Visible spectrophotometric method was found to be simple, economical and suitable for the quantitative estimation and comparative evaluation of Losartan Potassium in tablet dosage forms. The study also demonstrated variation in drug content among the selected generic and branded formulations, emphasizing the importance of proper analytical evaluation and quality control of pharmaceutical products. The ruggedness study showed percentage recoveries of 101.53–102.42% with %RSD values of 1.169–1.934% under different analysts and instruments. The low %RSD values indicate good reproducibility and reliability, confirming that the method is rugged for routine analysis of Losartan Potassium.

12. RECOMMENDED FIGURES:

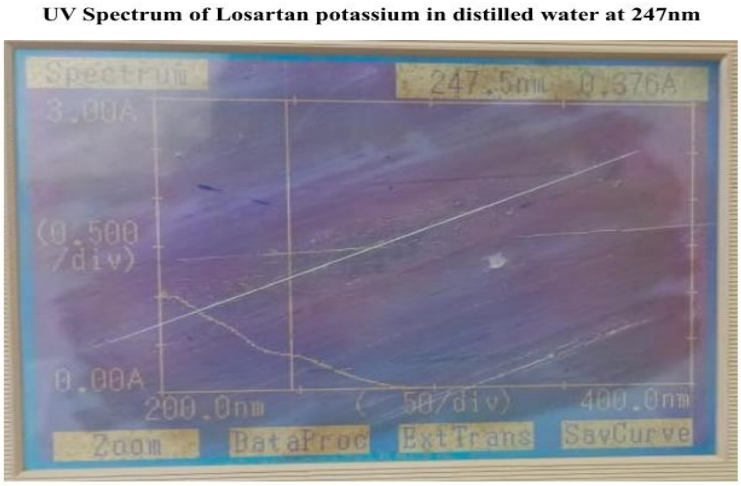

Figure 1: UV absorption spectrum of losartan potassium in distilled water showing the maximum absorption at 247 nm.

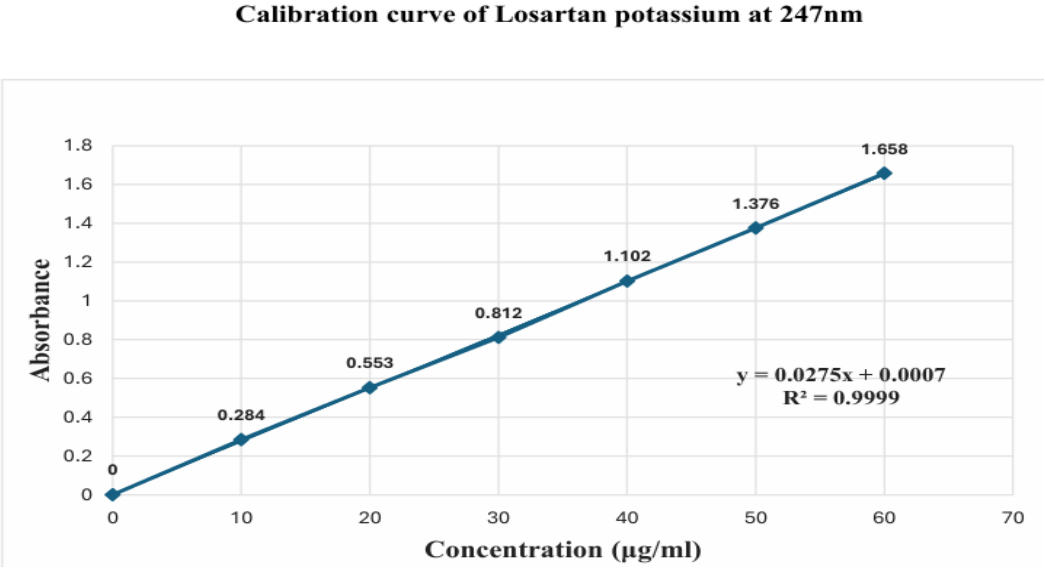

Figure 2: Calibration plot of losartan potassium at 247 nm over the concentration range of 10–60 µg/mL.

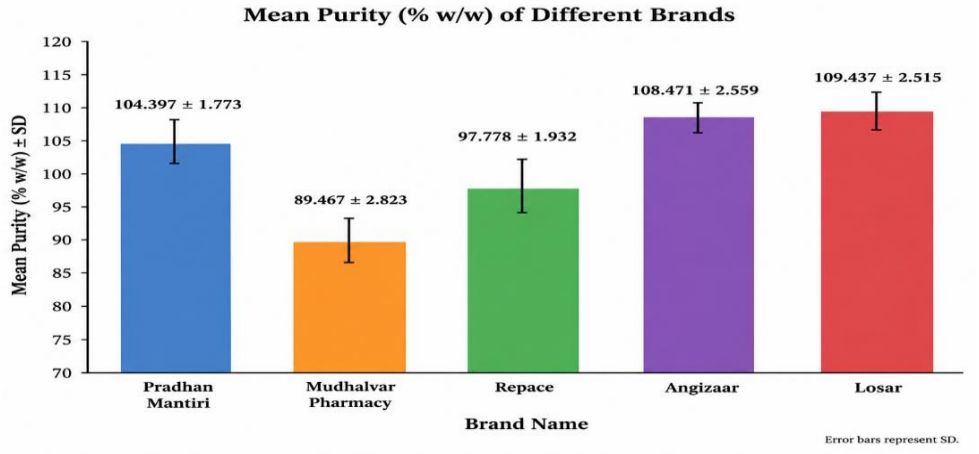

Figure 3: Comparative mean assay of five marketed 25-mg losartan potassium tablet formulations.

13. RECOMMENDED TABLES:

Table 1. Calibration data for losartan potassium at 247 nm

AVERAGE OF LINEARITY VALUES

S.NO	CONCENTRATION (µg/ml)	ABSORBANCE*
1	10	0.284
2	20	0.553
3	30	0.812
4	40	1.102
5	50	1.376
6	60	1.658

*Mean of six observations

Table 2: Validation characteristics of the proposed UV–visible method

PARAMETERS	AT 247 nm
Beer's law range (µg/ml)	10-60
Regression equation (y = mx+c)	Y= 0.0275x+0.0007
Slope (m)	0.0275
Intercept (c)	0.0007
Correlation coefficient (r^2)	0.9999
Sandell's sensitivity (µg/cm^2/0.001 A.U)	0.0364
LOD (µg/ml)	0.645277
LOQ (µg/ml)	1.955386

*Mean of six observations

Table:3 Comparative Analysis of Assay Results for Selected Losartan 25 mg Tablet Formulations.

Formulation	Label claim	Mean assay (%)	SD	%RSD
Pradhan Manthiri	25 mg	104.397	1.773	1.698
Mudhalvar Pharmacy	25 mg	89.467	2.823	3.156

Repace	25 mg	97.778	1.932	1.976
Angizaar	25 mg	108.471	2.559	2.359
Losar	25 mg	109.437	2.515	2.298

The mean assay values observed ranged from 89.467% to 109.437%.

Table 4. Comparative assay of marketed losartan potassium tablets

QUANTIFICATION OF LOSARTAN POTASSIUM FORMULATION (TABLET)

Brand name	Label claim (mg/tab)	Amount present (mg/tab)	%purity* (%w/w)	Mean purity (%w/w)	SD	%RSD
Pradhan Mantiri	25 25 25 25 25 25	26.595 25.341 26.437 26.130 25.903 26.190	106.380 101.364 105.748 104.520 103.612 104.760	104.397	1.773	1.698
Mudhalvar Pharmacy	25 25 25 25 25 25	21.678 22.430 21.908 23.410 22.984 21.790	86.712 89.720 87.632 93.640 91.936 87.160	89.467	2.823	3.156
Repace	25 25 25 25 25 25	24.170 24.908 24.991 23.890 24.710 23.998	96.680 99.632 99.964 95.560 98.840 95.992	97.778	1.932	1.976
Angizaar	25 25 25 25 25 25	27.890 26.983 27.913 26.547 26.913 26.461	111.560 107.932 111.652 106.188 107.652 105.844	108.471	2.559	2.359
Losar	25 25 25 25 25 25	27.413 26.190 27.913 27.410 27.903 27.327	109.652 104.760 111.652 109.640 111.612 109.308	109.437	2.515	2.298

*Mean of six observations

Table 5. Intraday and Interday precision results.

Sample	Sample Number	Label claim (mg/ml)	% purity* (%w/w)		Mean purity (%W/W)		SD		%RSD	
			Intra day	Inter day	Intra day	Interday	Intraday	Interday	Intraday	Interday
PRADHAN MANTIRI	1 2 3 4 5 6	25 25 25 25 25 25	106.37 104.98 103.64 103.79 106.45 105.64	102.73 103.78 102.65 100.56 106.08 104.91	105.145	103.45	1.2310	1.932	1.1707	1.867
MUDHALVAR PHARMACY	1 2 3 4 5 6	25 25 25 25 25 25	86.21 91.8 89.54 91.92 92.87 84.98	93.65 82.98 92.98 87.98 86.32 91.67	89.263	101.94	3.278	4.210	3.660	4.71
REPACE	1 2 3 4 5 6	25 25 25 25 25 25	99.13 98.57 98.45 100.56 98.74 99.34	100.76 97.06 100.45 97.57 99.75 98.54	99.13	99.021	0.776	1.534	0.783	1.550
ANGIZAAR	1 2 3 4 5 6	25 25 25 25 25 25	105.06 107.54 105.64 102.87 103.36 106.05	105.73 104.86 105.63 102.56 103.5 104.78	105.087	104.51	1.7406	1.245	1.6563	1.192
LOSAR	1 2 3 4 5 6	25 25 25 25 25 25	103.87 105.93 102.86 102.76 101.76 105.64	100.404 101.76 100.67 103.14 102.90 102.88	103.79	101.95	1.676	1.203	1.615	1.180

*Mean of six observations

Table 6. Recovery studies at 80%, 100% & 120% levels

RECOVERY STUDY (MUDHALVAR PHARMACY)

% Concentration	Sample amount* (µg/ml)	Amount spiked* (µg/ml)	Estimated amount* (µg/ml)	Recovered amount* (µg/ml)	Average* % recovery	SD	%RSD
80	15	12	27.28	12.45	103.78	2.47	2.38
100	15	15	90.56	15.15	101.28	0.97	0.96
120	15	18	98.48	17.83	99.08	2.25	2.27

*Mean of three observations

TABLE-09
RECOVERY STUDY (PRADHAN MANTIRI)

% Concentration	Sample amount* (µg/ml)	Amount spiked* (µg/ml)	Estimated amount* (µg/ml)	Recovered amount* (µg/ml)	Average* % recovery	SD	%RSD
80	15	12	26.58	11.58	96.61	1.09	1.13
100	15	15	29.82	14.82	98.86	2.31	2.34
120	15	18	33.38	18.38	102.18	3.25	3.18

*Mean of three observations

TABLE-10
RECOVERY STUDY (LOSAR)

% Concentration	Sample amount* (µg/ml)	Amount spiked* (µg/ml)	Estimated amount* (µg/ml)	Recovered amount* (µg/ml)	Average* % recovery	SD	%RSD
80	15	12	26.89	11.89	99.13	2.27	3.30
100	15	15	30.15	15.15	101.04	1,35	1.34
120	15	18	32.95	18.17	100.97	2.13	2.11

*Mean of three observations

TABLE-11
RECOVERY STUDY (REPACE)

% Concentration	Sample amount* (µg/ml)	Amount spiked* (µg/ml)	Estimated amount* (µg/ml)	Recovered amount* (µg/ml)	Average* % recovery	SD	%RSD
80	15	12	27.12	12.12	101.05	2.86	2.83
100	15	15	29.72	14.72	98.21	5.98	6.09
120	15	18	33.42	18.42	102.38	0.73	0.71

*Mean of three observations

TABLE-12
RECOVERY STUDY (ANGIZAAR)

% Concentration	Sample amount* (µg/ml)	Amount spiked* (µg/ml)	Estimated amount* (µg/ml)	Recovered amount* (µg/ml)	Average* % recovery	SD	%RSD
80	15	12	28.39	12.39	103.27	3.44	3.33
100	15	15	30.65	15.65	104.36	5.54	5.31
120	15	18	33.26	18.26	101.51	1.28	1.26

*Mean of three observations

Table 7. Ruggedness assessment under different analysts and instruments

(MUDHALVAR PHARMACY)

Sample	Type of ruggedness	Average* %recovery	SD	% RSD
LOSARTAN POTASSIUM	Analyst-1	89.078	3.258	3.658
	Analyst-2	90.098	2.078	2.306
	Instrument-1	89.476	1.991	2.226
	Instrument-2	89.461	2.182	2.439

*Mean of six observations

(PRADHAN MANTIRI)

Sample	Type of ruggedness	Average* %recovery	SD	% RSD
LOSARTAN POTASSIUM	Analyst-1	101.5	1.151	1.134
	Analyst-2	101.78	1.322	1.299
	Instrument-1	100.23	1.207	1.204
	Instrument-2	100.64	1.075	1.058

*Mean of six observations

(LOSAR)

Sample	Type of ruggedness	Average* %recovery	SD	% RSD
LOSARTAN POTASSIUM	Analyst-1	103.67	0.963	0.929
	Analyst-2	103.03	2.024	1.964
	Instrument-1	103.006	1.788	1.736
	Instrument-2	103.73	1.410	1.360

*Mean of six observations

(REPACE)

Sample	Type of ruggedness	Average* %recovery	SD	% RSD
LOSARTAN POTASSIUM	Analyst-1	98.13	1.124	1.146
	Analyst-2	98.95	1.821	1.841
	Instrument-1	97.94	1.208	1.233
	Instrument-2	98.90	1.178	1.191

*Mean of six observations

(ANGIZAAR)

Sample	Type of ruggedness	Average* %recovery	SD	% RSD
LOSARTAN POTASSIUM	Analyst-1	102.42	1.659	1.169
	Analyst-2	102.20	1.794	1.755
	Instrument-1	102.02	1.589	1.588
	Instrument-2	101.53	1.964	1.934

*Mean of six observations

14. Ethical Approval:

Not applicable to the present analytical study, provided that no human or animal subjects were involved.

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