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A REVIEW OF EVALUATION OF DIFFERENT MARKETED BRANDS OF LOSARTAN POTASSIUM TABLETS

Kapade Aishwarya Chandrakant*1, Muktapure Vaibhavi Vitthal*2,
Karad Shrinivas Yashwant*3, Ingale Sayli Maruti*4

*1,2,4Student, Department, Pharmaceutics College Latur College Of Pharmacy Hasegaon , Latur India.
*3Lecturer, Department, Pharmaceutics College Latur College Of Pharmacy Hasegaon, Latur India.

ABSTRACT

The present study aims to compare the pharmaceutical equivalence of the same Losartan potassium tablets of different brand manufacturers that are available in the drug market. Six brands of commercial available Losartan potassium film tablets containing 50 mg of Losartan potassium were used in this study. Quality control tests were evaluated for Losartan potassium film tablets. All commercial Losartan potassium film tablets met the criteria specified by quality control test parameters. The dissolution profile was carried out using the apparatus II according to USP guidelines. All different formulations meet the acceptable limits with the official monographs for the quality control tests. The dissolution profiles showed variation between brand to brand drugs. The assay was calculated by using the absorbance 205 nm. All samples attained more than 70% dissolution media within 60 minutes. The result was subjected to statistical analysis is to compare dissolution profiles of different Marketed products. The *In Vitro* dissolution study was carried out with the six brands of 50 mg Losartan Potassium tablets according to FDA dissolution method. The process was done for 2 tablets of each brand; using 900 ml of pH 1.2 0.1 N HCl and pH 6.8 Phosphate Buffer separately as dissolution media; 50 rpm as rotation speed; 37°C ± 0.5°C as media temperature; 10, 15, 20, 30, 45 and 60minutes as sample collection time points. The results were carried out by interpreting data on the % Drug release there were significant differences in the dissolution profiles of the six brands specially when considered according to different media. In pH 1.2 0.1 N HCl all brands showed poor drug release, pH 6.8 Phosphate Buffer gave best results for drug release of most of the brands. The results show the need for constant monitoring of new brands of Losartan Potassium introduced into the drug market to ascertain bioequivalence and conformity with pharmacopoeia standards.

Keywords: Losartan Potassium, Dissolution Study, Dosing Frequency, Pharmacopoeia.

I. INTRODUCTION

Losartan, sold under the brand name cozar among others, is a medication used to treat high blood pressure (hypertension). It is in the angiotensin receptor blocker (ARB) family of medication, and is considered protective of the kidneys. Besides hypertension, it is also used in diabetic kidney disease, heart failure, and left ventricular enlargement. It comes as a tablet that is taken by mouth. It may be used alone or in addition to other blood pressure medication Up to six weeks may be required for the full effects to occur. Common adverse effects include muscle cramps, stuffy nose, dizziness, cough, high blood potassium, and anemia. Severe adverse effects may include angioedema, low blood pressure, and kidney problems. Use during pregnancy may result in harm to the baby. Use is not recommended during breastfeeding. It works by blocking angiotensin II. Losartan was patented in 1986, and approved for medical use in the United States in 1995. It is on the World Health Organization's List of Essential Medicines. It is available as a generic medication. In 2021, it was the eighth most commonly prescribed medication in the United States, with more than 55 million prescriptions. A version combined with hydrochlorothiazide is available which, in 2021, was the 87th most commonly prescribed medication in the United States, with more than 8 million prescriptions. Losartan potassium 2butyl-4-chloro-1-[2-(0-1H-tetra-zol-5-ylphenylbenzyl] imidazole-5-methanol monopotassium salt, was the first of a new class of orally active, non-peptide angiotensin II receptor (type AT1) antagonist for the treatment of hypertension. Losartan has been demonstrated to be superior to previous peptide receptor antagonists and angiotensin converting enzyme (ACE) inhibitors because of its enhanced specificity, selectivity and tolerability. Losartan potassium has a molecular weight of 461; apKa value of 4.9; an aqueous solubility of 3.3 mg mL at pH 7.8" and

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exhibits highly variable and low oral bioavaiability (approximately 33%), Losartan is, therefore, considered class 3 in the biopharmaceutics classification system, because it has high solubility and low permeability.

Table 1: Chemistry Of Losartan Potassium

CHEMISTRY OF LOSARTAN POTASSIUM	
Molecular Weight	461.0 g/mol
Molecular Formula	C22H22ClKN6O
Hydrogen Bond Donor Count	1
Hydrogen Bond Acceptor Count	6
Rotatable Bond Count	8
Exact Mass	460.1180685 g/mol
Monoisotopic Mass	460.1180685 g/mol
Topological Polar Surface Area	77.7
Heavy Atom Count	31
Formal Charge	0
Complexity	526
Isotope Atom Count	0
Defined Atom Stereocenter Count	0
Undefined Atom Stereocenter Count	0
Defined Bond Stereocenter Count	0
Undefined Bond Stereocenter Count	0
Covalently Bonded Unit Count	2

Fig 1: Images of Different Brands

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Table 2: Different Brands and Company name

Brand Name	Company Name	Dose
Losartan	IPCA Laboratories Pvt. Ltd.	50mg
Elsartan	Elder Pharmaceutical Ltd.	50mg
Losanorm	IPCA Laboratories Pvt. Ltd.	50mg
Cozartan	Healing Pharma	50mg
Losakind	Mankind Pharma Ltd.	50mg
Losar	Torrent Pharmaceutical Ltd.	50mg

II. PHARAMACOLOGY

Indications

Losartan is indicated to treat hypertension in patients older than 6 years, reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy (though this benefit may not extend to patients with African heritage), and to treat diabetic nephropathy with elevated serum creatinine and protein urea in patients with type 2 diabetes and hypertension. Losartan with hydrochlorothiazide is indicated to treat hypertension and to reduce the risk of stroke in patients with hypertension and left ventricular hypertrophy (though this benefit may not extend to patients with African heritage).

Pharmacodynamics

Losartan is an angiotensin II receptor blocker used to treat hypertension, diabetic nephropathy, and to reduce the risk of stroke. Losartan has a long duration of action as it is given once daily. Patients taking losartan should be regularly monitored for hypotension, renal function, and potassium levels.

Mechanism of action

Losartan reversibly and competitively prevents angiotensin II binding to the AT_1 receptor in tissues like vascular smooth muscle and the adrenal gland. Losartan and its active metabolite bind the AT_1 receptor with 1000 times more affinity than they bind to the AT_2 receptor. The active metabolite of losartan is 10-40 times more potent by weight than unmetabolized losartan as an inhibitor of AT_1 and is a non-competitive inhibitor. Losartan's prevention of angiotensin II binding causes vascular smooth muscle relaxation, lowering blood pressure.

Angiotensin II would otherwise bind to the AT_1 receptor and induce vasoconstriction, raising blood pressure.

Absorption

Losartan is approximately 33% orally bioavailable. Losartan has a T_{max} of 1 hour and the active metabolite has a T_{max} of 3-4 hours. Taking losartan with food decreases the C_{max} but does only results in a 10% decrease in the AUC of losartan and its active metabolite. A 50-80mg oral dose of losartan leads to a C_{max} of 200-250ng/mL.

Volume of distribution

The volume of distribution of losartan is 34.4±17.9L and 10.3±1.1L for the active metabolite.

Protein binding

Losartan is 98.6-98.8% protein bound and the active metabolite (E-3174) is 99.7% protein bound in serum.

Metabolism

Losartan is metabolized to an aldehyde intermediate, E-3179, which is further metabolized to a carboxylic acid, E-3174, by cytochrome P450s like CYP2C9.1 Losartan can also be hydroxylated to an inactive metabolite, P1.1 Approximately 14% of losartan is metabolized to E3174.1 Losartan can be metabolized by CYP3A4, CYP2C9, and CYP2C10.1 Losartan can also be glucuronidated by UGT1A1, UGT1A3, UGT1A10, UGT2B7, and UGT 2B17.2

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Route of elimination

A single oral dose of losartan leads to 4% recovery in the urine as unchanged losartan, 6% in the urine as the active metabolite. Oral radiolabelled losartan is 35% recovered in urine and 60% in feces. Intravenous radiolabelled losartan is 45% recovered in urine and 50% in feces.

Half-life

The terminal elimination half life of losartan is 1.5-2.5 hours while the active metabolite has a half life of 6-9 hours.1

Clearance

Losartan has a total plasma clearance of 600mL/min and a renal clearance of 75mL/min.1 E3174, the active metabolite, has a total plasma clearance of 50mL/min and a renal clearance of 25mL/min

1. Pharmacological Classification:-

Angiotensin II Type 1 Receptor Blockers

Agents that antagonize angiotensin ii type 1 receptor. Included are ANGIOTENSIN II analogs such as SARALASIN and biphenylimidazoles such as LOSARTAN. Some are used as ANTIHYPERTENSIVE AGENTS. (See all compounds classified as Angiotensin II Type 1 Receptor Blockers.)

Antihypertensive Agents

Drugs used in the treatment of acute or chronic vascular HYPERTENSION regardless of pharmacological mechanism. Among the antihypertensive agents are DIURETICS; (especially diuretics, thiazide); adrenergic beta-antagonists; adrenergic alpha-antagonists; angiotensinconverting enzyme inhibitors; calcium channel blockers; ganglionic blockers; and vasodilator agents. (See all compounds classified as Antihypertensive Agents.)

III. MATERIAL AND METHOD

Appearance

Appearance is the first most required quality for the acceptance of tablet. General elegance and its identity play a major role for the consumer acceptance. Acceptance of the appearance of batches of the tablet has been done based on the measurement of the following factors like size, color, shape, presence or absence of odor, taste.

Size and shape

Size and shape of a tablet has been determined by its thickness. Size and shape of table plays an important role in its patient compliance as the size of the tablet increases it is not much easier for its administration. Micrometer is the devise which is used to determine the thickness of a tablet.

It can be acceptable if the batch falls within the •±5% of standard deviation.

Organoleptic properties

Color should be distributed uniformly without appearance of any signs of mottling. Colour of the tablet should be compared with the standard colour for comparison.

Uniformity of thickness

To determine the uniformity of thickness random selection of tablets has to be done from each and every batch and need to measure its thickness independently. If the thickness of any single tablet varies then the batch containing that batch will not be dispatched into market.

Hardness

The ability of a tablet to withstand for mechanical shocks is known as hardness. Pfizer hardness tester is the instrument which is used to determine the hardness of tablet. It is expressed in kg/cm2. Take three tablets from each batch and hardness should be determined and the selection of tabled should be done randomly. Trahen the mean and standard deviation values should be determined.

Procedure:-

- Take three tablets from each batch and hardness should be determined and the selection of tabled should be done randomly.

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- Then the mean and standard deviation values should be determined.

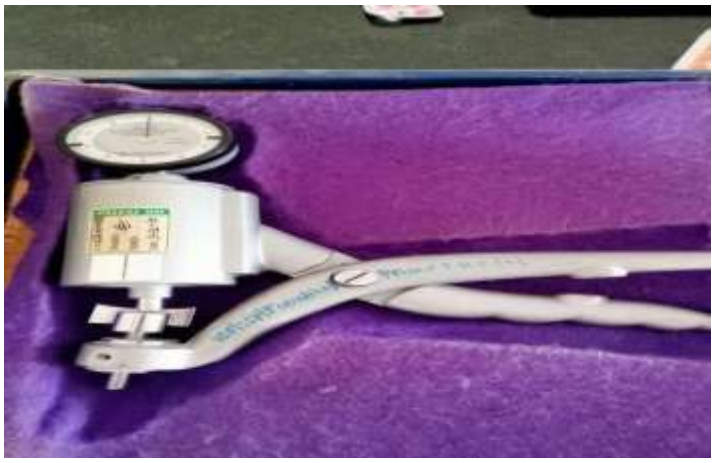

Fig 2: Hardness tester

Friability

Roche friabilator is the equipment which is used for the determination of friability. It is expressed in percentage. Note down the initial weight of the tablets individually (W initial). Tablets are placed in a plastic chamber which revolves at 25 rpm and they are subjected to fall from a height of 6 inches in the friabilator for about 100 revolutions. Then measure the weight of the tablet (W final) and observe any weight difference before tablet and after the friabilator processing. Limits: loss in weight less than 0.5 to 1% of the initial weight of the tablet should be considered as acceptable limits.

Percentage of friability is calculated as:

F = {(W initial) - (W final)/ (W initial)}×100.

Procedure:-

- Select 20 tablets randomly, dedust and weigh (Wo).
- Place the tablets in the friabilator drum, switch on the apparatus adjusting the timer at 4 min. and the speed at 25 rpm.
- At the end of this operation, remove the tablets from the friabilator, dedust and reweigh (Wf). (Any tablet that breaks up should be rejected before reweighing).
- N.B. if the value of friability (% loss) is less than or equal to 1%, the batch is accepted.

Weight variation test

Random selection of 20 tablets from each batch should be done and note down the weight of the tablet individually and check for any variation in its weight. According to US Pharmacopeias small variations in the weight is negligible and can be accepted. Below is the acceptable limit of percentage deviation in weight variation.

Disintegration test: -

Disintegration is defined as the process of breakdown of tablet into small particles. Disintegration time of a tablet is determined by using disintegration test apparatus as per IP specifications. Place each tablet in each 6 tubes of the disintegration apparatus a then add a disc to each tube containing 6.8 pH phosphate buffer. The temperature of the buffer should maintain at 37±2°C and run the apparatus raised and lowered for 30 cycles per minute. Note down the time taken for the complete disintegration of the tablet without any remitants.

Procedure:-

- To remove or dissolve the coat, immerse the tablet in distilled water for 5min.
- Put the tablet in the apparatus in water or HCL for 30min at 37oC (according to the U.S.P).
- If one or two tablets fail to disintegrate, repeat on 12 tablets. So 16 tablets from the 18 must completely disintegrate within the time.

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- If two or more not disintegrated the batch is rejected.

Fig 3: Roche Friabilator

Fig 4: Disintegration apparatus

Dissolution Test:-

- Dissolution is a process in which a solid substance solubilizers in a given solvent (mass transfer from the solid surface to the liquid phase.)
- Dissolution testing measures the extent and rate of solution formation from a dosage form, such as tablet, capsule, ointment, etc.
- The dissolution of a drug is important for its bioavailability and therapeutic effectiveness.

Procedure:-

- Place 1000 ml of dissolution medium dict. walk, 0-1 N HC, Phosphate buffer) into vessel.
- Then this vessel immersed in water bath and maintain temp. 37*C-0.5*C Now placed tablet to type [basket/ paddle].
- Starts and speed maintain at 100 RPM or acc to monograph (in I.P.)
- After specified time interval (acc to monograph in IP take 5-10 ml of sample (or specified) from vessels and refill vessels with 5-10ml Fress medium.
- Now, this sample is tested by U.V. spectroscopy or some other suitable analytical method.
- Now, find the big amount which released sample and match with standards.
- It all 6 tablets passed test then okay, but one /two fails then do this again for additional 6 tablets.
- If tablets still fails the test, then an additional 12 tablets are tested.
- Now, the tablets are acceptable if the average of all 24 tablets are less than Q and not more than 2 tablets are less than Q-15%.

Fig 5: USP II Dissolution Apparatus

Preparation of sample solution: 1 tablet in each basket is allowed to dissolve in 900 ml of media maintaining other dissolution parameters. 5 ml of filtered sample is collected for each time point along with same volume of media replacement. These 5 ml samples are diluted up to 10 ml with the same media and mixed well.

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The different dissolution requirements according to the different pH dissolution media

Preparation of pH 0.1 N HCl solution as dissolution media: 8.3 ml 37% HCl solution is added into distilled water to prepare per liter of pH 1.2 0.1 N HCl solution as dissolution media after the pH adjustment by dilute HCl solution.

Preparation of standard solution: Losartan Potassium working standard is weighted accurately equivalent to 25 mg of Losartan Potassium in a 50 ml volumetric flask and volume up to 50 ml with methanol to dissolve and dilute the Losartan Potassium with the help of sonication. 1 ml solution is transferred to another 50 ml volumetric flask and volume up to the mark with the dissolution medium and mixed well.

Preparation of sample solution: 1 tablet in each basket is allowed to dissolve in 900 ml of media maintaining other dissolution parameters. 5 ml of filtered sample is collected for each time point along with same volume of media replacement. These 5 ml samples are diluted up to 50 ml with the same media and mixed well.

Comparative dissolution in pH 6.8 0.2 M phosphate buffer solution as dissolution media

Preparation of pH 6.8 0.2 M phosphate buffer solution as dissolution media: 896 mg Sodium Hydroxide and 6.8045gm Potassium Dihydrogen Phosphate is added into distilled water to prepare per liter of pH 6.8 0.2 M phosphate buffer solution as dissolution media after the pH adjustment by dilute Phosphoric acid or Sodium Hydroxide solution.

Preparation of standard solution: Losartan Potassium working standard is weighted accurately equivalent to 25 mg of Losartan Potassium in a 50 ml volumetric flask and volume up to 50 ml with methanol to dissolve and dilute the Losartan Potassium with the help of sonication. 1 ml solution is transferred to another 50 ml volumetric flask and volume up to the mark with the dissolution medium and mixed well.

Preparation of sample solution: 1 tablet in each basket can dissolve in 900 ml of media maintaining other dissolution parameters. 5 ml of filtered sample is collected for each time point along with same volume of media replacement. These 5 ml samples are diluted up to 50 ml with the same media and mixed well.

CALIBRATION CURVE OF LOSARTAN POTASSIUM

1. Preparation of standard solution-

100 mg of Losartan Potassium was accurately weighed and transferred to a 100 ml volumetric flask containing 30 ml of distilled water and sonicate for 15 minutes. This was further diluted up to the mark with buffer pH 6.8 to obtain drug concentration of 100 µg/ml. From this solution, 1 ml was further diluted using same .Solvent to obtain drug concentration solution of 10 ug/ml as a working standard solution .

2. Preparation of working solution-

From standard solution pipette out 2, 4, 6, 8, 10, 12 µg/ml respectively. These 2,4,6, 8, 10, 12, ml. Transfer to 100 ml volumetric flask & make volume up to 100 with buffer 6.8 to get 2,4...12 µg/ml conc. Measure the absorbance at 205 nm using UV-visible spectrophotometer. Plot graph between Conc. vs. Abs. Calculate coefficient of correlation (should between 0.9-1) & slope.

IV. RESULT AND DISCUSSION

1) Size and Shape:-

Table 3: Size and Shape Evaluation Parameter of Different Brands

Sr. No.	Brand Name	Size		Shape
		Diameter	Thickness	
1	Losatan-50	1.5cm	1cm	Round
2	Elsartan-50	1.5cm	1cm	Round
3	Losanorm-50	1.3cm	1cm	Round
4	Cozartan-50	1.5cm	1cm	Round
5	Losakind-50	1.3cm	1cm	Round
6	Losar-50	1.6cm	1cm	Oval

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2) **Hardness: -** The Fizer hardness tester was used to determine tablet hardness.

Table 4: Hardness Evaluation Parameter of Different Brands

Sr. No.	Brand Name	Hardness (Kg/sqcm)
1	Losatan-50	3.5
2	Elsartan-50	1.5
3	Losanorm-50	2.3
4	Cozartan-50	3.2
5	Losakind-50	2.0
6	Losar-50	3.5

3) **Friability: -** Roche friabilator is the equipment was used for the determination of friability.

Table 5: Friability Evaluation Parameter of Different Brands

Sr. No	Brand Name	Wt. of 10 Tablets(g m)	Wt. of 10 Tablets After Friability (gm)
1	Losatan-50	2	1.5
2	Elsartan-50	1.9	1.8
3	Losanorm-50	1.7	1.6
4	Cozartan-50	1.9	1.8
5	Losakind-50	1.4	1.3
6	Losar-50	1.6	1.5

4) Weight Variation:-

Table 6: Weight Variation Evaluation Parameter of Different Brands

Sr. No.	Brand Name	Wt. of Single Tablets(gm)	Wt. of 10 Tablets(gm)
1	Losatan-50	0.3	2
2	Elsartan-50	0.3	1.9
3	Losanorm-50	0.3	1.7
4	Cozartan-50	0.3	1.9
5	Losakind-50	0.3	1.4
6	Losar-50	0.3	1.6

5) **Disintegration Test: -** using disintegration test apparatus distegration of 6 various brand tablet of losartan potassium was carried out.

Table 7: Disintegration Test Evaluation Parameter of Different Brands

Sr. No.	Brand Name	Disintegration Time (min)
1	Losatan-50	10
2	Elsartan-50	14
3	Losanorm-50	19

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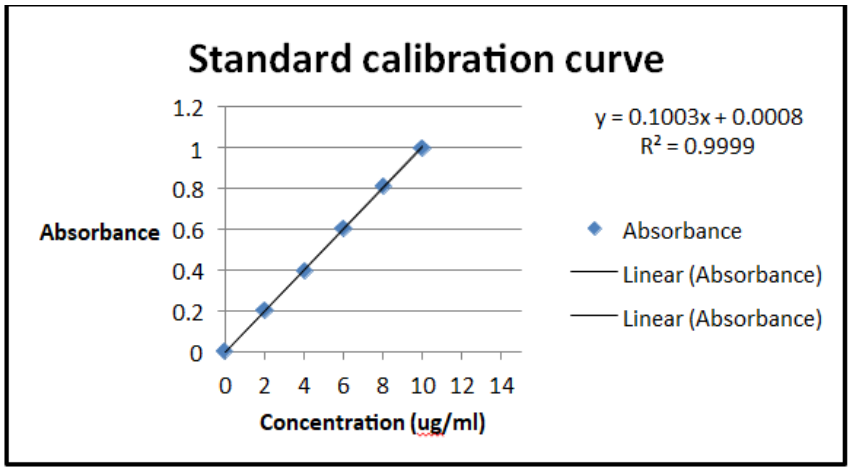
4	Cozartan-50	21
5	Losakind-50	18
6	Losar-50	14

Calibration curve of Losartan Potassium

Table 8: Standard Calibration Curve of Losartan Potassium

Sr. no.	Conc.ug/ml	Absorbance
1	**0**	**0**
2	**2**	**0.202**
3	**4**	**0.400**
4	**6**	**0.603**
5	**8**	**0.810**
6	**10**	**0.999**



6) Dissolution Test:-

dissolution of various brand of losartan potassium tablet was carried out by using dissolution apparatus in various dissolution media like in pH 0.1 N HCL and pH 6.8 buffer solution then The absorbance was taken with UV visible spectrophotometer (Shimadzu® UV-1700, Kyoto, Japan), connected to a computer loaded with Shimadzu UV PC version 3.9 software. Spectra of Losartan Potassium standard were built in the range from 400 to 200 nm using 1 cm quartz cuvettes in the fast scan speed, 2.0 nm data interval and 2 nm band widths. The percentage of drug release (DR %) was assayed at the wavelength of 205 nm.

Table 9: Representation of dissolution of different brands of Losartan potassium 50 mg tablet in pH 0.1N HCl solution as dissolution media

Time (in minutes)	Losatan	Elsartan	Losanorm	Cozartan	Losakind	Losar
0	**0**	**0**	**0**	**0**	**0**	**0**
10	4.33	3	3.06	3.48	0.69	0.45
20	5.95	7.19	4.14	5.29	3.66	5.24
30	6.85	16.6	5.44	8.44	6.69	7.53
40	10.32	24.41	9.21	13.79	13.98	12.4
50	10.34	32.79	15.77	22.5	21.73	16.42

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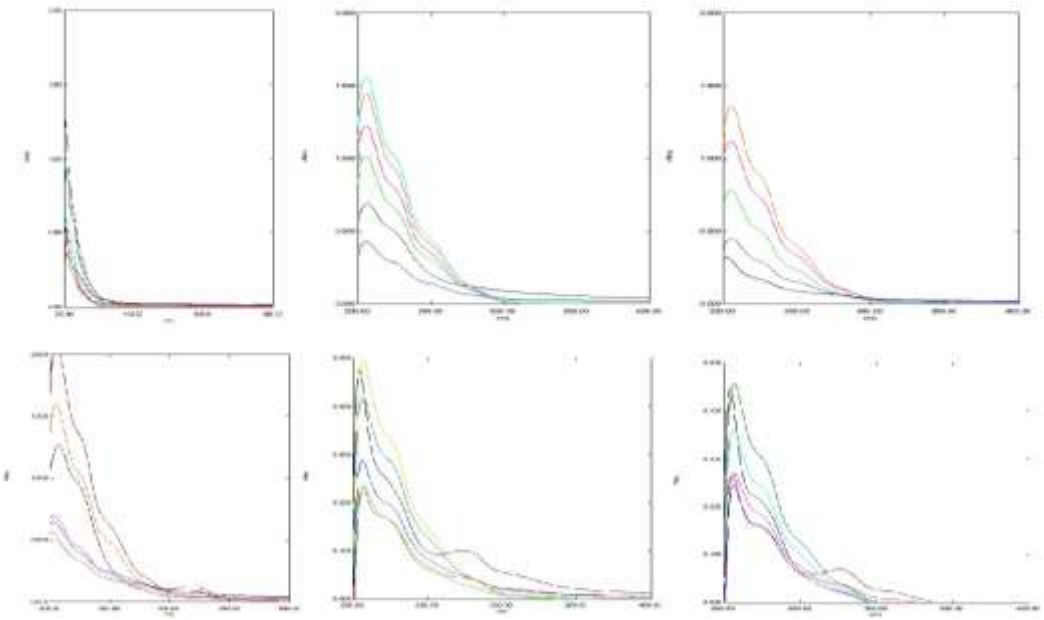
60	13.98	37.98	25.22	29.88	27.63	21.24

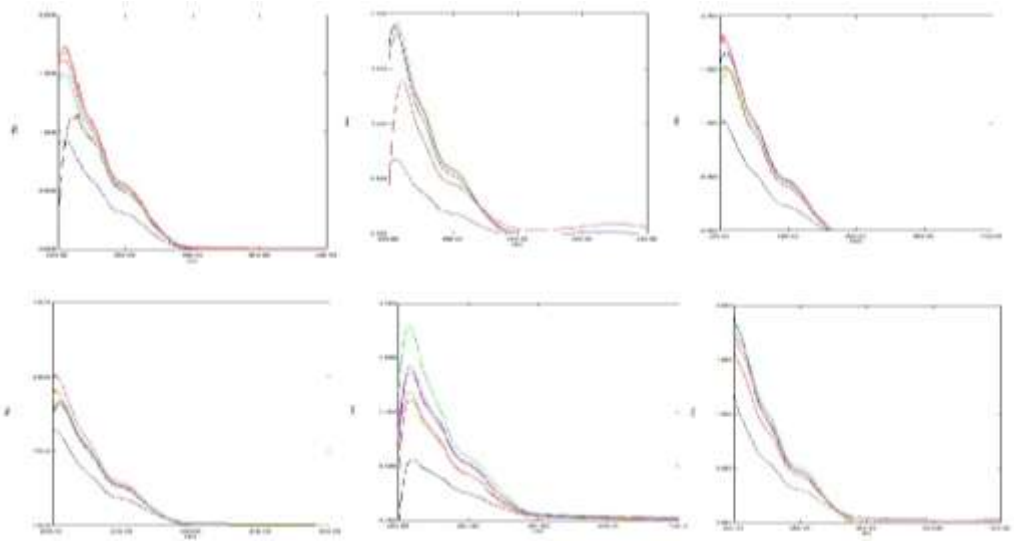
Table 10: Representation of dissolution of different brands of Losartan potassium 50 mg tablet in pH 6.8 ph buffer solution as dissolution media

Time (in minutes)	Losatan	Elsartan	Losanorm	Cozartan	Losakind	Losar
0	**0**	**0**	**0**	**0**	**0**	**0**
10	32.24	52.19	59.42	38.58	26.89	20.12
20	48.18	73.96	86.97	58.83	34.1	33.20
30	60.51	90.2	93.79	73.82	57.62	48.23
40	74.06	95.62	94.14	85.93	83.83	63.58
50	85.74	98.57	95.86	92.57	91.57	79.2
60	86.5	99.09	96.39	94.3	92.89	85.52

1) 0.1N HCL :-



2) Buffer Solution:-



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V. CONCLUSION

The results obtained from this investigation of six different brands of Losartan potassium film tablets in the local market indicated that all the tablets met the criteria specified by quality control test parameters. There were significant differences in the dissolution profiles of the six brands specially when considered according to different media. In pH 1.2 0.1 N HCl all brands showed poor drug release, pH 6.8 Phosphate Buffer gave best results for drug release of most of the brands but among them one Elsartan brand having more % drug release than other brands of Losartan. But all the brands of Losartan achieve pharmacopoeia specifications. The results show the need for constant monitoring of new brands of Losartan Potassium introduced into the drug market to ascertain bioequivalence and conformity with pharmacopoeia standards.

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I would like to express my sincere gratitude to all those who contributed to the successful completion of this study on the evaluation of different marketed brands of Losartan Potassium tablets.First and foremost, I extend my deepest appreciation to my Professor for their invaluable guidance, support, and encouragement throughout this research. Their expertise and insights were instrumental in shaping the study.

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