



FORMULATION AND EVALUATION OF LOSARTAN POTASSIUM HYDROGEL BY CO-POLYMERIZATION TECHNIQUE

S.P. Kale^{1*}, P.N.Bhujadi², P.A.Kale³, S.A.Shendge⁴

Abstract

Losartan sodium is BCS-II class and poorly water soluble drug. The present study was to develop the Losartan Potassium Hydrogel which was prepared by Co-Polymerization method includes Potassium persulfate and Ascorbic acid as a catalyst, Distilled Water as a vehicle, NN Methylene bis Acrylamide as a cross linker, Acrylic acid and Acrylamide as a homopolymer. The evaluation of density, Viscosity, pH, Drug content was determined by different techniques. The RF value of Losartan potassium was determine by using different organic solvent by using TLC techniques. The Characterization of Losartan potassium 15 was done by SEM, TEM, Swelling index, Solubility Study, Particle size and Stability study was performed .The HPLC analysis was carried out Triethylamine Acetonitrile (60:40 v/v) mobile phase is exhibited retention time 5.235 min. and drug content 82.30 %. The appearance study shows colourless liquid solution up to 90 days. That indicates stability of solution. So, Losartan potassium 15 formulation shows increase the bio-availability of Losartan Sodium.

Keywords: Losartan Potassium, SEM, TEM, TLC.

^{1*}Mula Education Society's College of Pharmacy, Sonai, Tal-Newasa, Dist.-Ahmednagar, Maharashtra-414105.

²Mula Education Society's College of Pharmacy, Sonai, Tal-Newasa, Dist.-Ahmednagar, Maharashtra-414105.

³Mula Rural Institute College of Pharmacy, Sonai, Tal-Newasa, Dist.-Ahmednagar, Maharashtra-414105.

⁴Mula Education Society's College of Pharmacy, Sonai, Tal-Newasa, Dist.-Ahmednagar, Maharashtra-414105.

***Corresponding Author:** Sonali P.Kale

*Department of Quality Assurance, MES's College of Pharmacy, Sonai. Savitribai Phule Pune, University, Tal. Newasa, Dist. Ahmednagar, State. Maharashtra, India 414105. Email ID: kalesonali1112@gmail.com

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Introduction

The hydrogel technologies may be applied to food additives, pharmaceuticals, biomedical Implants tissue engineering and regenerative medicines, diagnostics, cellular immobility, separation of biomolecules or cells and barrier materials to regulate biological adhesions and drug carriers. Additionally the ever growing spectrum of functional monomers and macromeres widen its applicability[1]. Hydrophilic gels called hydrogels are cross-linked materials absorbing large quantities of water without dissolving. Softness, smartness, and the capacity to store water make hydrogels unique materials. The ability of hydrogels to absorb water arises from hydrophilic functional groups attached to the polymer backbone while their resistance to dissolution arises from cross-links between network chains[2]. Water inside the hydrogel allows free diffusion of some solute molecules, while the polymer serves as a matrix to hold water together. Another aspect of hydrogels is that the gel is a single polymer molecule, that is, the network chains in the gel are connected to each other to form one big molecule on macroscopic scale. It is natural to expect that the conformational transitions of the elastically active network chains become visible on the macroscopic scale of hydrogel samples. The gel is a state that is neither completely liquid nor completely solid. These half liquid-like and half solid-like properties cause many interesting relaxation behaviors that are not found in either a pure solid or a pure liquid. From the point of view of their mechanical properties, the hydrogels are characterized by an elastic modulus which exhibits a pronounced plateau extending to times at least of the order of seconds and by a viscous modulus which is considerably smaller than the elastic modulus in the plateau region. Hydrogels are three-dimensional, hydrophilic, polymeric networks capable of absorbing large amounts of water or biological fluids[3]. Due to their high water content, porosity and soft consistency, they closely simulate natural living tissue, more than any other class of synthetic biomaterials. Hydrogels may be chemically stable or they may degrade and eventually disintegrate and dissolve. Topical delivery can be defined as the application of a drug containing formulation to the skin to directly treat cutaneous disorders (e.g. acne) or the cutaneous manifestations of a general disease (e.g. psoriasis) with the intent of containing the pharmacological or other effect of the drug to the surface of the skin or within the skin. Topical gels are transparent or translucent semisolid formulations containing a high ratio of

solvent/gelling agent. Thus, hydrogels can imbibe water nearly 10-20 times its molecular weight and hence become swollen[4]. Some examples of Hydrogels include contact lenses, wound dressing super absorbents. Their affinity to absorb water is attributed to the presence of hydrophilic groups such as $-OH$, $-CONH-$, $-CONH_2-$ and $-SO_3H$ in polymers forming hydrogel structures[5]. Hydrogels can be prepared from either natural or synthetic polymers. Natural polymers include dextran, alginate, and pectin and chondroitin sulphate, while synthetic polymers include poly(vinyl alcohol), poly(hydroxyl ethyl methacrylate), poly(ethylene oxide) and poly (N-isopropyl acrylamide). Either natural or synthetic polymers individually have some advantages and disadvantages, but by combining natural and synthetic polymers the physical and biocompatibility properties like in IPN and semi IPN increase[6]. The properties of a hydrogel depend strongly on the interaction of water and the polymer. The former prevents the polymer aggregating to form a compact mass while the polymer prevents water flowing out. Semi-interpenetrating polymer networks (semi-IPN) is a way of blending two polymers where only one is cross-linked in the presence of another to produce an additional non-covalent interaction between the two polymers[7]. Semi-IPNs have been developed as a convenient technique for preparing multi-polymeric material and provided an alternative option to modify the properties of natural polymer-based hydrogels.

Materials and Methods

Losartan Potassium was obtained as a gift sample from Dr. Reddys lab (Hyderabad), N-N Methylene-bis acrylamide, Acrylic Acid, Acrylamide, Potassium, Persulphate, Ascorbic Acid, Acacia Gum, DMSO, DMF, Disodium Hydrogen Phosphate, Hcl and Sodium Dihydrogen Phosphate. Also different types of solvent mainly used like Distilled Water, Ethanol, Methanol, Acetone and Acetonitrile. Different types of instruments mainly used to evaluate the hydrogel Electronic balance, UV-Visible double beam spectrophotometer, Ultra Sonicator, Magnetic Stirrer with hot plate, Digital pH Meter, Viscometer, Centrifugation Machine, Freezer, Digital Electronic Microscope, FTIR, Membrane filtration assembly, Dissolution tester, HPLC, IR spectrophotometer and Transmission Electron Microscopy.

Method for Preparation of Losartan Potassium Hydrogel

Losartan Potassium hydrogel were prepared by the Co-Polymerization method with various ratios of monomers and Cross linking agent. Losartan Potassium hydrogel was prepared by the Co-Polymerization technique with Acacia gum and double distilled water (20 ml) in 50 ml beaker and left undisturbed for 24 hours. After complete dispersion with water, a fixed KPS:ABC ratio (1:1) of the redox initiator is added to the reaction mixture and stirred vigorously. In the second step, the MBA to be added to the reaction mixture with continuous stirring. In the last step, amounts of the monomers to be added to the reaction mixture, with continuous stirring for half hour. The allowed to proceed at various temperatures for a particular time interval. After completion of the reaction, the reaction vessel allow to cool at room temperature. The homopolymer (PAA and PAAM) and unreacted monomers to be remove by washing with acetone. By this method Hydrogel is formed.

Results and Discussion

The prepared formulation of hydrogel of Losartan Potassium were prepared by Co-Polymerization method by using various excipients like Ascorbic acid, Acrylamide, Acrylic acid, Acacia gum. Also the FTIR Spectra of hydrogel shows nominal changes as compared to standard drug. From this data we conclude that hydrogel formed successfully. Also the prepared hydrogel was evaluated for various parameter like determination of density, viscosity, pH, percentage content of drug, particle size, solubility and dissolution rate. Prepared hydrogel

shows greater dissolution rate mainly it helpful to increase the bioavailability of Losartan Potassium. Also the particle size of selected Losartan Potassium was found to be 511 nm from this we also conclude that the prepared hydrogel in nano size and suitable for oral administration. Also the stability study reveals that if we store the formulation at room temperature particle size was increase from 459 to 612 nm in 90 days. However in refrigerator there was nominal increase in 459 to 496 nm indicating better stability under this condition and there will be nominal changes in percent drug so that we conclude prepared hydrogel formulation is stable. Assay of drug and excipient mixture is given in above table. If any chemical reaction take place between the drug and excipient, degradation of drug and assay reading of drug and excipient mixture decreases, but there was no chemical reaction between drug and excipient so given drug and excipient mixture was compatible to each other. The results of the stability studies are shown in Table 6. In case of formulation stored at room temperature, the particle size was increased from 456 to 612 nm in 90 days which was measured by Motic digital microscope. However under refrigerated storage conditions, there was a nominal increase from 459 to 496 nm indicating better stability under these conditions. Particle size of the selected formulation (LP 15) was found to be 511 nm as shown in Figure 5. From this we could conclude that the prepared suspension was in nano size and suitable for Oral administration. Polydispersity index (PDI) is the measure of size distribution and generally varies from 0.0 to 1.0.

Preparation of Hydrogel by using Different Excipients

Table 1: Formulation of Losartan Potassium hydrogel by Co-Polymerization.

Sr. No.	Formulation code	LK (mg)	KPS:ABC (mmol)	MBA (mg)	AA (ml)	AAM (gm)	DW (ml)	Mag. Stirring (min)	RPM
1:1 (Ratio)									
1	LP 1	2	2.5:2.5	30	0.75	0.375	20	30	1000
2	LP 2	2	2.5:2.5	30	0.75	0.375	20	30	1100
3	LP 3	2	2.5:2.5	30	0.75	0.375	20	30	1200
4	LP 4	2	2.5:2.5	30	0.75	0.375	20	60	1000
5	LP 5	2	2.5:2.5	30	0.75	0.375	20	60	1100
6	LP 6	2	2.5:2.5	30	0.75	0.375	20	60	1200
7	LP 7	2	2.5:2.5	30	0.75	0.375	20	90	1000
8	LP 8	2	2.5:2.5	30	0.75	0.375	20	90	1100
9	LP 9	2	2.5:2.5	30	0.75	0.375	20	90	1200
1:2 (Ratio)									
10	LP 10	2	2.5:5	30	0.75	0.375	20	30	1000
11	LP 11	2	2.5:5	30	0.75	0.375	20	30	1100
12	LP 12	2	2.5:5	30	0.75	0.375	20	30	1200
13	LP 13	2	2.5:5	30	0.75	0.375	20	60	1000

14	LP 14	2	2.5:5	30	0.75	0.375	20	60	1100
15	LP 15	2	2.5:5	30	0.75	0.375	20	60	1200
16	LP 16	2	2.5:5	30	0.75	0.375	20	90	1000
17	LP 17	2	2.5:5	30	0.75	0.375	20	90	1100
18	LP 18	2	2.5:5	30	0.75	0.375	20	90	1200
1:3(Ratio)									
19	LP 19	2	2.5:7.5	30	0.75	0.375	20	30	1000
20	LP 20	2	2.5:7.5	30	0.75	0.375	20	30	1100
21	LP 21	2	2.5:7.5	30	0.75	0.375	20	30	1200
22	LP 22	2	2.5:7.5	30	0.75	0.375	20	60	1000
23	LP 23	2	2.5:7.5	30	0.75	0.375	20	60	1100
24	LP 24	2	2.5:7.5	30	0.75	0.375	20	60	1200
25	LP 25	2	2.5:7.5	30	0.75	0.375	20	90	1000
26	LP 26	2	2.5:7.5	30	0.75	0.375	20	90	1100
27	LP 27	2	2.5:7.5	30	0.75	0.375	20	90	1200

Drug - Excipients Compatibility Study Appearance Study

Table 2: Appearance Study of Losartan Potassium+ Acrylamide+ Acrylic Acid+ N-N Methylene bis Acrylamide + Potassium Persulphate + Distilled Water

Sr. No.	Time (Days)	Appearance Study of Losartan Potassium+ Acrylamide+ Acrylic Acid+ N-N Methylene bis Acrylamide + Potassium persulphate+ Distilled Water.			
		Acrylamide+Acrylic Acid +L.P.+DW	AA+L.P.+DW	AA+AM+DW	AA+ AM+ N-N MBA+ L.P.+DW
1	1	Clear colorless liquid	Clear colorless liquid	Clear colorless whitish liquid	Clear colorless whitish liquid
2	7	Clear colorless liquid	Clear colorless liquid	Clear colorless whitish liquid	Clear colorless whitish liquid
3	15	Clear colorless liquid	Clear colorless liquid	Clear colorless whitish liquid	Clear colorless whitish liquid
4	30	Clear colorless liquid	Clear colorless liquid	Clear colorless whitish liquid	Clear colorless whitish liquid
5	60	Clear colorless liquid	Clear colorless liquid	Clear colorless whitish liquid	Clear colorless whitish liquid
6	90	Clear colorless liquid	Clear colorless liquid	Clear colorless whitish liquid	Clear colorless whitish liquid

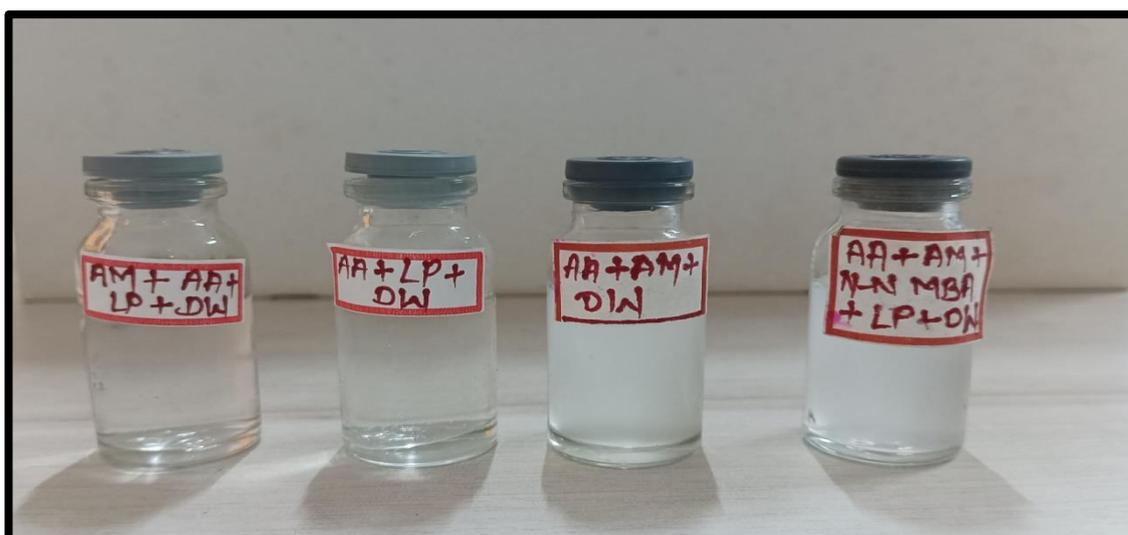


Figure 1: Appearance Study of Losartan Potassium and Excipient Mixture at 90th Day

Appearance study of drug-excipient compatibility is given in above Table 2 and figure 1. Appearance study of drug and excipient mixture

was not showing any color change that indicates drug and excipient mixture was chemically stable.

U.V Spectroscopy Study

Table 3: Compatibility study by assay of drug and excipient mixture

Sr. No.	Time(Day)	Assay of Drug and Excipients Mixture		
		Losartan Potassium + Acrylic Acid	Losartan Potassium + N-N acrylamide	Losartan Potassium + D.W. + Methylenebis acrylamide
1	1	98.65 ± 0.3234	96.67 ± 0.3237	97.34 ± 0.2597
2	7	98.39 ± 0.2013	95.36 ± 0.1499	97.63 ± 0.2137
3	15	97.97 ± 0.3234	95.98 ± 0.2639	96.97 ± 0.3237
4	30	97.35 ± 0.4293	96.98 ± 0.3289	97.14 ± 0.4269
5	60	96.94 ± 0.5733	96.56 ± 0.4233	96.52 ± 0.2323
6	90	96.39 ± 0.1369	96.98 ± 0.3136	97.33 ± 0.3299

Evaluation of Hydrogel Formulations for different Parameter.

Table 4: Density, Viscosity, pH, % drug content, Particle size analysis and Solubility of Losartan Potassium Hydrogel

Sr. No.	BatchCode	Density (gm/mL)	Viscosity(cps)	pH	% DrugContent	ParticleSize (nm)	Solubility (mg/mL)
Mean ±SD, n=3							
1	LP1	1.4744±0.001	2.710±0.014	5.50±0.02	96.23±0.01	541±0.06	24.66±0.05
2	LP 2	1.3708±0.001	2.826±0.0024	5.48±0.07	97.33±0.01	586±0.07	24.23±0.01
3	LP 3	1.4376±0.0001	2.675±0.002	5.53±0.06	97.24±0.01	524±0.09	24.22±0.01
4	LP 4	1.172±0.0002	2.761±0.0002	5.54±0.03	97.37±0.01	591±0.06	25.21±0.01
5	LP 5	1.4542±0.0001	2.581±0.0001	5.53±0.03	97.93±0.01	585±0.05	25.21±0.01
6	LP 6	1.453±0.001	2.746±0.004	5.44±0.06	97.83±0.02	516±0.05	24.52±0.01
7	LP 7	1.2518±0.0004	2.351±0.0004	5.53±0.04	97.76±0.01	436±0.03	25.88±0.01
8	LP 8	1.4542±0.0001	2.790±0.0001	5.52±0.05	98.67±0.01	461±0.05	24.86±0.01
9	LP 9	1.4556±0.0002	2.584±0.0002	5.42±0.05	98.37±0.01	466±0.03	24.86±0.01
10	LP 10	1.6172±0.0001	2.972±0.0004	5.50±0.01	98.54±0.01	534±0.03	25.33±0.01
11	LP 11	1.5606±0.0001	2.931±0.0001	5.51±0.01	98.98±0.01	563±0.04	25.34±0.01
12	LP 12	1.433±0.0002	2.667±0.0002	5.48±0.02	99.34±0.01	465±0.07	25.69±0.01
13	LP13	1.436±0.0004	2.722±0.0004	5.44±0.01	99.33±0.01	535±0.001	24.77±0.01
14	LP14	1.6166±0.0003	2.851±0.0003	5.51±0.005	98.24±0.01	466±0.09	25.55±0.01
15	LP 15	1.4536±0.0001	2.897±0.0001	5.49±0.01	99.98±0.05	493±0.01	25.22±0.01
16	LP 16	1.3548±0.001	2.568±0.0031	5.52±0.01	99.11±0.01	456±0.02	25.32±0.01
17	LP 17	1.6556±0.001	2.892±0.001	5.53±0.01	98.34±0.01	452±0.02	25.46±0.01
18	LP18	1.3384±0.0058	2.521±0.0058	5.49±0.01	98.52±0.01	572±0.01	25.67±0.01
19	LP19	1.4766±0.001	2.579±0.0010	5.51±0.07	97.85±0.068	389±0.04	25.71±0.01
20	LP 20	1.3674±0.0001	2.513±0.0028	5.48±0.01	98.66±0.083	510±0.05	25.67±0.01
21	LP 21	1.4566±0.0001	2.652±0.0002	5.49±0.03	98.55±0.100	532±0.03	25.93±0.01
22	LP 22	1.6164±0.0001	2.916±0.0002	5.43±0.01	98.77±0.17	463±0.06	24.97±0.01
23	LP 23	1.4896±0.0001	2.738±0.0002	5.47±0.01	98.75±0.023	559±0.03	24.76±0.01
24	LP 24	1.6554 ± 0.0001	2.948 ± 0.0004	5.52±0.02	99.32±0.01	457 ± 0.05	27.73±0.01
25	LP 25	1.4556±0.0001	2.676±0.0002	5.51±0.01	98.22±0.01	424±0.07	25.86±0.01
26	LP 26	1.6536±0.0001	2.926±0.0001	5.49±0.01	99.35±0.01	596±0.08	24.33±0.01
27	LP 27	1.5546±0.0001	2.777±0.0003	5.51±0.01	98.22±0.01	411±0.01	24.77±0.01

Dissolution Study of LP 1- LP 27 Formulations.

Table 5. In-vitro Dissolution Study of Losartan Potassium Hydrogel of LP 1–LP 27 Formulation

Sr.No.	Formulation Code	Cumulative Percent Drug Release, Mean ±SD, n=3					
		Time (min)					
		5	10	15	30	45	60
1	LP 1	13.01±0.28	24.74±0.18	51.75±0.19	77.99±3.6	86.88±0.61	92.31±4.2
2	LP 2	11.55±2.7	20.65± 4.5	32.30±0.84	41.95±1.4	55.76±2.3	65.84±2.11
3	LP 3	11.41±1.1	19.92± 2.6	32.70±3.8	44.53±1.1	56.02±2.05	77.54±2.6
4	LP 4	12.75±1.6	23.75± 3.9	36.42±2.3	52.25±2.9	60.55±4.6	88.29±2.4
5	LP 5	12.14±2.5	18.16± 2.8	37.40±2.6	48.25±2.09	59.60±3.3	79.60±2.4
6	LP 6	7.39±3.7	21.92± 2.7	32.25±3.3	47.08±3.5	57.23±3.3	76.12±2.4
7	LP 7	4.55±2.5	18.53± 2.1	49.12±2.9	57.05±3.8	73.38±3.1	88.96±3.2
8	LP 8	4.3±2.04	18.08± 2.7	26.65±3.5	43.65±2.5	56.66±3.9	73.64±3.7
9	LP 9	4.14 ±1.57	18.73± 2.1	45.19±1.6	66.07±0.36	89.14±0.74	94.99±4.4
10	LP 10	4.61 ±0.53	18.51± 4.5	30.20±3.11	47.80±3.4	64.16±3.7	74.33±3.1
11	LP 11	4.93±0.85	17.60± 2.1	43.0±0.90	62.31±1.6	92.40±0.90	94.96±1.9

12	LP 12	4.50±1.1	17.23±2.8	31.75±2.4	46.03±2.4	65.75±3.2	80.23±3.2
13	LP 13	5.90±1.7	17.25±4.4	35.60±2.7	49.23±0.17	66.30±0.61	82.94±0.72
14	LP 14	7.55±2.0	18.33±3.8	31.88±2.7	46.73±3.72	63.23±2.1	89.56±0.82
15	LP 15	4.17±3.2	21.75±1.64	45.60±1.5	66.90±3.6	79.20±2.04	98.88±2.08
16	LP 16	10.05±2.9	29.03±3.5	42.96±3.6	58.47±2.5	82.14±1.9	92.34±0.71
17	LP 17	4.20±1.6	17.11±3.9	30.47±3.8	48.77±2.4	60.60±2.4	78.32 ±3.8
18	LP 18	3.92±1.3	19.19±3.9	35.88±3.6	55.30±3.7	67.18±3.9	89.63 ±2.6
20	LP 20	4.21±0.45	22.13±1.83	36.43 ±3.6	53.20±3.7	67.80±3.7	92.43±0.89
21	LP 21	3.33±2.1	18.19±4.6	37.40±3.7	55.30±4.5	77.20±3.1	96.31±0.90
22	LP 22	4.15±1.57	19.21±2.8	36.40±2.6	56.60±4.6	78.21±3.2	93.21 ±0.71
23	LP 22	5.23±1.3	20.22±1.63	37.89±3.7	57.80±3.3	79.90±3.2	96.31±1.8
24	LP 24	29.07±1.7	55.75±4.4	80.84±0.17	86.50±0.62	89.333±0.61	96.31±1.8
25	LP 25	5.90±1.3	23.20±1.85	39.20±3.8	49.20±2.6	69.20±3.8	77.20±3.1
26	LP 26	6.30±3.6	27.20±3.9	42.50±0.90	53.20±3.7	77.80±3.6	92.64±4.1
27	LP 27	15.20±3.9	25.30±0.18	54.96±1.2	55.36±2.3	76.35±3.3	90.97 ±0.83

Stability Study of Hydrogel

Table 6: Results of the Stability Studies of Hydrogel

Sr.No.	Time(Day)	Stability Data of Hydrogel			
		Particle Size (nm)		Drug Content (%)	
		Room Temp.(25°C)	Refrigerator(2-4°C)	Room Temp.(25°C)	Refrigerator(2-4°C)
1	Initial	456±1.03	454 ±1.03	98.86 ±0.02	98.63 ±0.02
2	10	565±1.12	460 ±1.05	97.36 ±0.14	97.26 ±0.15
3	20	578 ±1.15	466±1.15	99.34 ±0.45	99.39 ±0.81
4	30	595 ±1.17	472 ±1.17	99.96 ±0.75	98.19 ±0.19
5	45	615±2.05	475 ±1.87	97.39 ±0.12	97.15 ±0.16
6	60	630 ±2.2	476±1.19	99.65 ±0.27	99.37 ±0.56
7	90	612 ±2.25	496 ±1.19	99.58 ±0.45	99.69 ±0.14

Mean ±SD, n=3

Identification and Characterization of Losartan Potassium by FT-IR Absorption Spectroscopy.

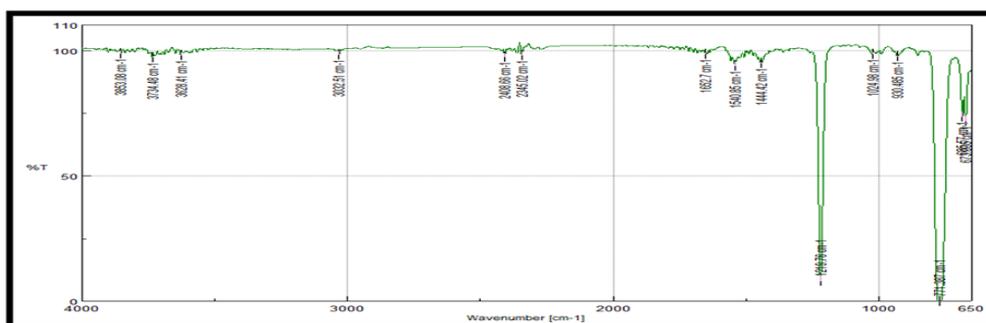


Figure 2: FT-IR Spectra of Losartan Potassium.

FT-IR ν max (KBr, cm^{-1}): 3032 (Ar-CH Stretching), 1602 (Ar-C=C Stretch), 1489 (Ar-C=C Stretch), 1540 (Ar-C=C Stretch), 1444 (Ar-C=C Stretch), 810 (P-disubstituted benzene CH

def.), 771 (O-disubstituted benzene CH def.), 1219 (C=N Stretch), 685 (C=Cl Stretch), 685 (C=Cl Stretch), 2890, 2900 (CH₃, CH₂, CH Stretch), 1444 (CH def.).

FT-IR Spectra of Losartan Potassium Hydrogel (LP-15)

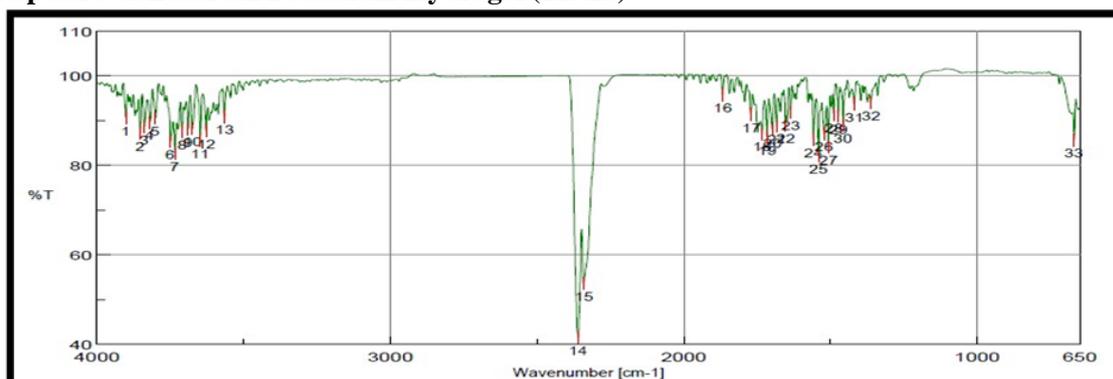


Figure 3: FTIR Spectra of Losartan Potassium Hydrogel

FT-IR ν max (KBr, cm⁻¹): 3035 (Ar-CH Stretch), 1456 (Ar-C=C stretch), 1507(Ar-C=C stretch), 1585(Ar-C=C stretch), 1609(Ar-C=C stretch), 775 (O-disubstituted benzene), 1362(C=N

Stretch), 771.38(C-Cl), 2855, 2890(CH₃, CH₂, CH Stretch), 1473,1488(CH def), 1652(C=O), 3455(NH₂-NH Stretch), 3576(OH Stretch).

HPLC Chromatogram of Losartan Potassium

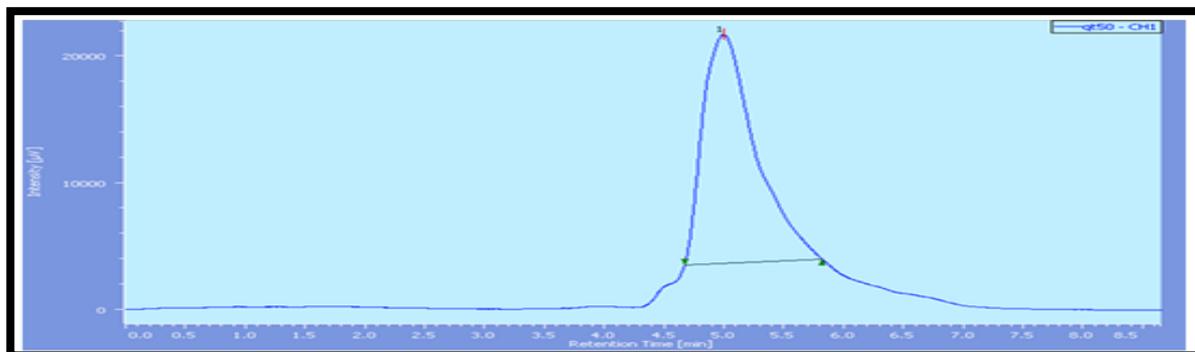


Figure 4: HPLC Chromatogram of Standard Losartan Potassium

Retention time- 5.235, Peak Area (μV/sec) – 549192, % Area- 100, Symmetric factor- 1.72

HPLC Chromatogram of Selected Formulation LP 15

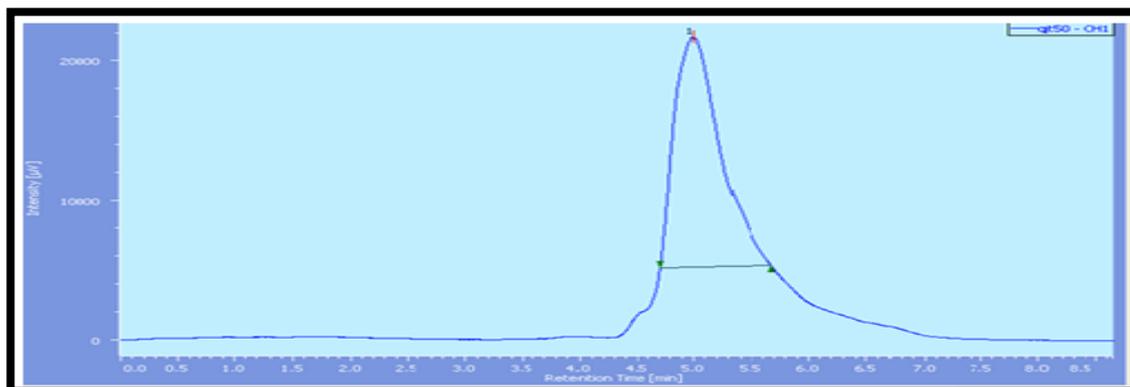


Figure 5: HPLC Chromatogram of Selected Formulation LP 15.

Retention time-5.256, Peak Area (μV/sec) - 452155, % Area-100, Symmetric factor- 1.612

Conclusion

A series of Losartan Potassium hydrogel have been prepared with the use of Co-Polymerization technique was found to be LP 1-LP 27 in the range of 1.172-1.655 gm/ml. LP 15 formulation was studied for their appearance, density, viscosity, pH, % drug content, particle size, solubility. Particle size of LP 15 formulation was found to be 511 nm. LP 15 formulation batch showed maximum drug release i.e. 99.98% in 1 hour. (Table 4). In vitro drug release study of pure drug was found to be 99.88% (Table 5). Consequently hydrogel represents a promising alternative to current delivery system aiming to improve the bioavailability of drug with low solubility.

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