Advances in Bioresearch
Adv. Biores., Vol 15 (4) July 2024:79-88

Print ISSN 0976-4585; Online ISSN 2277-1573
Journal's URL:http://www.soeagra.com/abr.html
CODEN: ABRDC3
DOI: 10.15515/abr.0976-4585.15.4.7988

Advances in Bioresearch

ORIGINAL ARTICLE

Preparation, Characterization and Evaluation of Superporous Hydrogel Tablet as a Gastroretentive Drug Delivery System of Losartan Potassium

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ABSTRACT
The aim of the present research work was to prepared superporous hydrogel (SPH) tablet containing Losartan potassium which is used to treat hypertension. The gastroretentive dosage form of SPH using Losartan potassium which is an angiotensin II receptor antagonist as a model drug for prolonged drug release in acidic condition. Losartan potassium has short half-life about 1.5 to 2h and less bioavailability (33%), mainly absorbed from proximal part of small intestine. The gas blowing method was used to prepare the superporous hydrogel by involving interpenetrating polymer network. Chitosan, HPMC K100M, Polyvinyl alcohol and glyoxal was used to prepare the SPH formulations. All the formulations were evaluated by swelling time, swelling ratio, porosity. The amount of polymer increased there was an increase in swelling properties. Swelling time was gradually decrease from 20 to 12 mins. The swelling ratio was enhanced by increase in the concentration of polymer. The SPH formulation of F1 to F8 were developed and the dried SPH powder was prepared. The (F8) formulation showed good pre-compressional and post-compressional parameters. The SEM study was clearly revealed the presence of the pores on the interior surface of the superporous hydrogel. The drug release of the best formulation (F8) showed highest drug release up to 8 h with 97.61%. The drug release kinetics of formulation (F8) followed zero-order kinetics model and the correlation coefficient R^2 value is 0.9976 with non-fickian diffusion type of mechanism.
Keywords: *Superporous hydrogel, Losartan Potassium, Sustained release, Chitosan, HPMC K100M, Swelling ratio*

Received 21.03.2024 Revised 23.04.2024 Accepted 24.06.2024

How to cite this article:
Darshana P, Nadeem A. F, Darshan J, Nimita M. Preparation, Characterization and Evaluation of Superporous Hydrogel Tablet as a Gastroretentive Drug Delivery System of Losartan Potassium. Adv. Biores. Vol 15 [4] July 2024. 79-88

INTRODUCTION

Oral sustainable drug delivery systems are mainly employed to improve the bioavailability of basic drugs with short elimination half-life. The drug has limited solubility at higher pH levels administered by this system. The major problem with the oral formulations is the inability to increase their retention time in the stomach and proximal part of small intestine. There are many approaches have been developed which include: the floating system, the swellable and expandable system, or the superporous hydrogel, the high-density system, the mucoadhesive system, the magnetic system. (1)

Hydrogels are the crosslinked polymers which expand in the presence of water while maintaining their shape. According to some researchers it is a swollen polymeric material retaining a significant amount of water in it but without itself being dissolved in water. Hydrogels can be created by polymerization of hydrophilic monomers in the presence of crosslinker. The application of hydrogel in the medical field and specifically in controlled drug delivery system. (2)

The superporous hydrogel is highly bounded microscopic pores of hydrophilic polymer. It absorbs large amount of water in less period of time due to presence of three-dimensional network. (3) SPHs have the ability to quickly swells to a larger size in minutes due to rapid uptake of water through the capillary action. It has sufficient swelling property and mechanical strength to resist pressure from the gastric contraction. For the preparation of SPHs certain excipients also used like, initiators, crosslinkers, foam stabilizers, foaming agents are added into aqueous monomer solution.(4), (5)

Losartan potassium is an orally active nonpeptide angiotensin II receptor antagonist (type AT1) which is mainly used in the treatment of hypertension due to blockade of AT1 receptors. Losartan potassium easily absorbed from the stomach and upper part of small intestine. It has bioavailability of about 33% due to extremely first pass metabolism. The drug achieves peak plasma concentration in 2hrs after an oral dose and has short elimination half-life is about 1.5 to 2hrs respectively. Therefore, It requires two to three times daily dosing in large number of patients, which often leads to frequent dosing and non-compliance. (6)

The interpenetrating polymer network (IPN) of chitosan and HPMC K100M superporous hydrogel was strengthened by polyvinyl alcohol (PVA) and prepared using gas blowing technique and glyoxal used as a crosslinking agent. The SPH formulations then compressed by direct compression method.

MATERIAL AND METHODS

Losartan potassium was obtained as a gift sample from Tagoor Laboratories Pvt. Ltd., East Godavari, Andhra Pradesh. HPMC K 100M was purchased from Chemdyes Corporation, Rajkot, Gujrat. Chitosan, Polyvinyl alcohol, Glyoxal, Tween 80, Sodium bicarbonate, Microcrystalline cellulose, Polyvinyl Pyrrolidone, Magnesium stearate were procured from Loba Chemie Pvt. Ltd., Mumbai, Maharashtra. All other reagents and excipients were used of analytical grade.

Method of Preparation of Superporous Hydrogel

Preparation of Drug Loaded Superporous Hydrogel: The gas blowing method is used for the preparation of superporous hydrogel in which hydrocolloid-polymer solution (2% w/v) was prepared in 0.1M glacial acetic acid solution using a homogenized to ensure the polymer dissolves in acid completely. A 10% w/w aqueous polyvinyl alcohol solution was prepared and mixed to the polymer solution by adjusting the pH to 5 with acetic acid. To the prepared polymer solution, 0.2 ml of glyoxal (10% w/w) solution and 0.2ml of tween 80 was added and mixed thoroughly. At the end of the process, 50mg of sodium bicarbonate was added, stirred well and kept aside overnight for formation of polymer network. Further, 50mg of drug was added in 10ml of 0.1 N HCl and mixed to 100mg of superporous hydrogel for 1 h at 40˚C. Then, it was dried in an oven at 40˚C for 24h, finally powdered and stored in a well closed container. The method of preparation of superporous hydrogel is shown in figure 1 and prepared formulation in figure 2. (7).

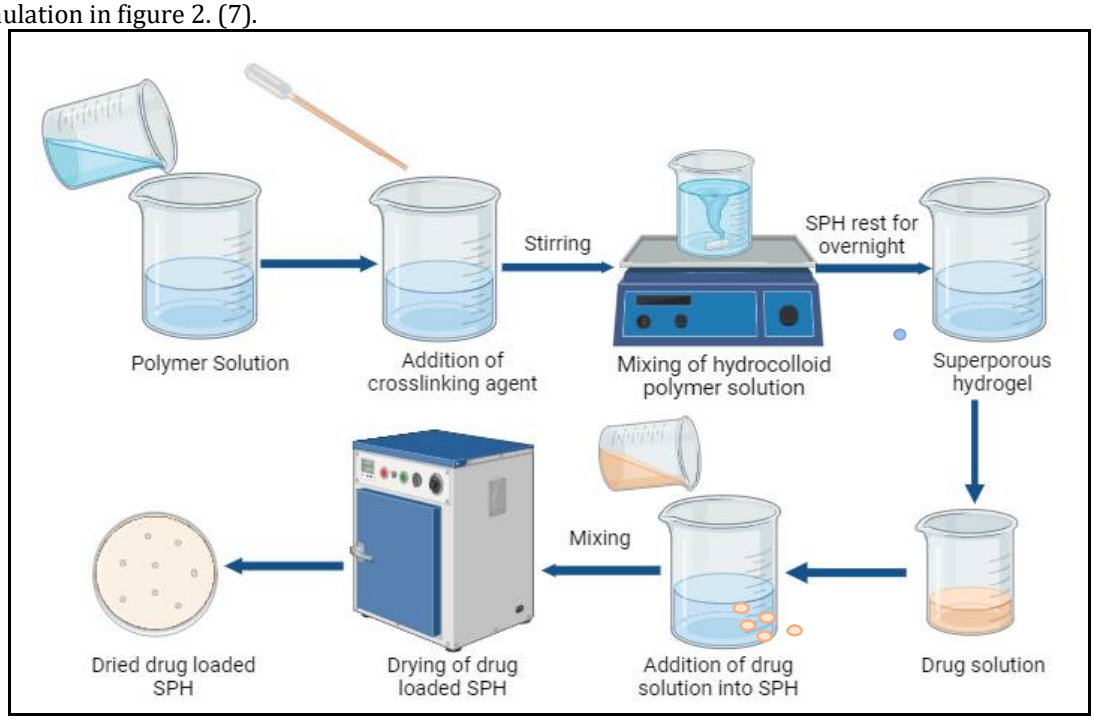
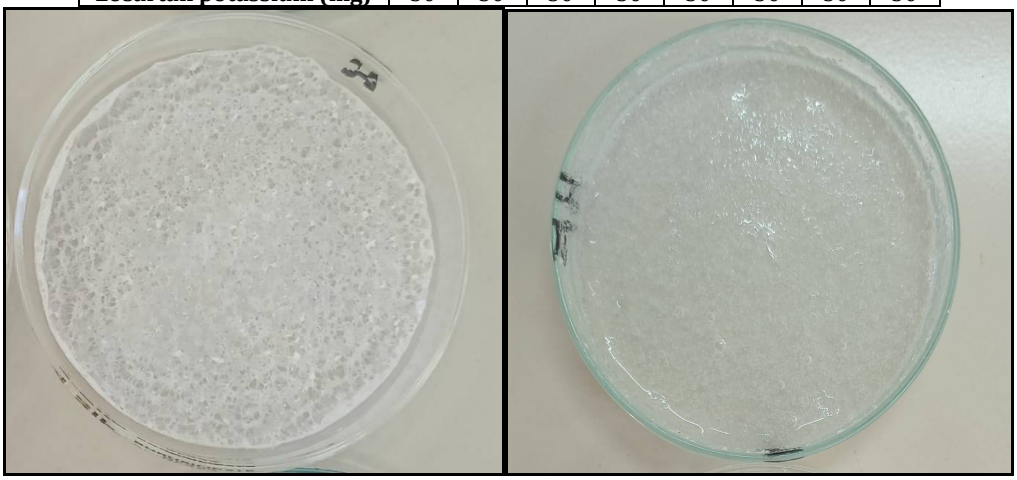


Figure 1: Method of Preparation of Superporous Hydrogel

Table no. 1: Formulations of Superporous Hydrogel

Excipients	F1	F2	F3	F4	F5	F6	F7	F8*
Chitosan (mg)	150	200	250	300	-	-	-	-
HPMC K100M (mg)	-	-	-	-	150	200	250	300
Polyvinyl Alcohol (mg)	200	400	600	800	200	400	600	800
Glyoxal (ml)	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Tween 80 (ml)	0.2	0.2	0.2	0.2	0.2	0.2	0.2	0.2
Sodium bicarbonate (mg)	50	50	50	50	50	50	50	50
Losartan potassium (mg)	50	50	50	50	50	50	50	50



a b

Figure 2:(a) Superporous Hydrogel After Polymerization (b) Drug Loaded Superporous Hydrogel

Method of Preparation of Superporous Hydrogel Tablets: The SPH tablet was prepared by accurately weighing Losartan potassium 50mg equivalent to drug loaded SPHs along with microcrystalline cellulose, polyvinyl pyrrolidone, calcium dihydrogen phosphate, sodium bicarbonate. This powder blend was mixed in a clean mortar and pestle to ensure complete mixing. After this, the uniform blend was passed through sieve no 60#. The prepared powder blend was compressed into tablets by rotatory tablet punching machine.(8)

Table no. 2: Formulations of SPH Tablets of Losartan Potassium

Excipients (mg)	F1	F2	F3	F4	F5	F6	F7	F8*
Losartan Potassium loaded SPH (Equivalent to 50 mg)	58	60	62	64	58	60	62	64
Microcrystalline cellulose	76	69	62	55	76	69	62	55
Polyvinyl pyrrolidone	25	30	35	40	25	30	35	40
Calcium dihydrogen phosphate	20	20	20	20	20	20	20	20
Sodium bicarbonate	15	15	15	15	15	15	15	15
Magnesium stearate	4	4	4	4	4	4	4	4
Talc	2	2	2	2	2	2	2	2
Total weight	200	200	200	200	200	200	200	200

Characterizations of Superporous Hydrogel

Physical Appearance: The physical appearance was simply examined through a visual examination of the superporous hydrogel like color, texture and presence of any particular matter. (8)

Swelling Time: The swelling time was determined by taken the dried superporous hydrogel was immerged in 0.1N HCl. The SPH was taken the required time to achieve the swelling equilibration was noted.

Swelling Ratio: The dried SPH was allowed to moisten in excess amount of 0.1N HCl at room temperature, after removing excess 0.1N HCl with gentle blotting the weight of the moisten sample was recorded. (9) The swelling ratio was calculated as follows:

$$Q_S = \frac{W_s - Wd}{W_d} \times 100$$

Ws is weight of swollen state of SPH and Wd is weight of dried state of SPH.

Density Measurement: The density was measured by the solvent displacement method. The amount of SPH was taken and weighed to determine the mass. It was immersed in certain volume of hexane in a graduated cylinder. The increase in the volume of hexane was determined the volume of the polymer. (10) The measurement of density was calculated by the following formula:

$$\text{Density} = \frac{\text{Mass of hydrogel}}{\text{Volume of hydrogel}}$$

Porosity Measurement: The porosity was measured by the prepared superporous hydrogel was immersed in absolute ethanol for 6 hrs. After absorbing ethanol, the size of SPH become larger. (11) The measurement of porosity was determined by the following formula:

$$\text{Porosity} = \frac{W_2 - W_1}{\rho V}$$

ρ is density of ethanol, V is volume of SPH, W_1 & W_2 are weight of SPH before & after immerged in absolute ethanol respectively.

Void Fraction Determination: The dried hydrogel was submersed in 0.1 N HCl until equilibrium was attained. The dimensional volume of the swollen hydrogel was measured. Meanwhile, the total volume of pores inside the SPHs was determined by the amount of buffer absorbed into the hydrogel and eliminating the mass of a dried SPH from the mass of swollen SPHs. (12) The void fraction determined by the following equation:

$$\text{Void Fraction} = \frac{\text{Dimensional volume of superporous hydrogel}}{\text{Total volume of pores}}$$

Water Retention Capacity: The water retention capacity of hydrogel was evaluated by swelling ratio. The hydrogel was remained in pH 1.2 of 0.1N HCl medium at 37˚C. (13) The time required for calculating the water retention capacity (WRt) are as follows:

$$\text{WRt} = \frac{(W_p - Wd)}{(Ws - Wd)}$$

Wd is weight of dried state of SPH, Ws is weight of swollen hydrogel, Wp is weight of completely swollen hydrogel at different time interval 15, 30, 45, 60 mins.

Determination of Drug Content: The weight of SPH containing 100 mg of drug was taken in a100 ml volumetric flask. From this stock solution, the required amount of dilution was prepared by adding 10 ml of 0.1N HCl of pH 1.2 mixed well, and makeup to the volume. This mixture was filtered and drug content was determined using a UV- visible spectrophotometer (UV- 1700, Shimadzu, Japan) at 204nm. (14)

Scanning Electron Microscopy (SEM): The SEM was performed to determine the size and morphology of SPH. The sample were dusted on a double-sided tape on an aluminium stub. After coating the sample using a Hummer Sputter Coater, a scanning electron microscope was used having 5kV accelerating voltage and chamber pressure of 0.6 mmHg. A JEOL JSM- 7900F scanning electron was used (Technics, Ltd.). The Digital capture card and Digital Scan Generator were used to capture images of SPH.(15) (16)

Precompression Characterization: The powder blend of Losartan potassium loaded SPHs was evaluated for various physiochemical parameters. Angle of repose, bulk density, tapped density, compressibility index, and hausner's ratio of powder flow studies of the different formulations were studied. The results are shown in table 4.

Angle of Repose: The angle of repose and flow speed of the powder mixture was determined by pouring the SPH powder mixture through a wide funnel that raised vertically. (17)

$$\tan\theta = \frac{h}{r}$$

$$\text{Bulk density} = \frac{\text{Mass of powder}}{\text{Bulk volume}}$$

$$\text{Tapped density} = \frac{\text{Mass of powder}}{\text{Tapped volume}}$$

Carr's index or compressibility index: The bulk and tapped density were used to calculate the Carr's index to measure the flow properties and compressibility of powder. The calculation of the compressibility index was determined as follows:

$$\text{Compressibility index} = \frac{\text{Tapped density} - \text{Bulk density}}{\text{Tapped density}} \times 100$$

Hausner's ratio: The hausner's ratio can be used to estimate the flow characteristics of the powder. (18) The hausner's ratio can be calculated by the following formula:

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

Post- Compressional Evaluations Parameters of Superporous Hydrogel Tablet

Hardness: The hardness was measured by randomly selected 10 tablets from each formulation. The hardness was measured using Monsanto® manual hardness tester and the average value for the tablets was measured.

Thickness: The thickness was measured by randomly selected 5 tablets from each formulations, and the average thickness of the tablet was calculated using vernier calliper. (7)

Weight Variation: During compression of tablet, the tablets were randomly checked to ensure that uniform weight of tablet were being made. The weight variation was done by selecting 20 tablets randomly, and the average weight was calculated for each formulation.

Friability: The friability testing was done by selecting 20 tablets randomly from each formula. Roche friabilator was used at a speed of 25 rpm and then rotated for 100 revolutions for 4 minutes, dropping the tablets to a distance of 6 inches. The tablets were dusted and reweighed to calculate the % friability was calculated. (19)

$$F\% = \frac{\text{Initial wt. of tablet} - \text{Final wt. of tablet}}{\text{Initial wt. of tablet}} \times 100$$

***In-vitro* % Drug Release Study:** The drug was released *in-vitro* from the prepared superporous hydrogel tablet using the USP type II (paddle type) dissolution apparatus containing 900ml of 0.1N HCl in 1.2 pH at 37˚C ± 0.5˚C at a rotational speed of 50 rpm. The aliquots sample of 5ml were withdrawn at certain times and the constant volume of dissolution beaker was maintained by adding fresh dissolution medium. The UV- spectrophotometer was used to analyse the sample at 204nm. (20)

RESULTS AND DISCUSSION

Physical Appearance: The superporous hydrogel was characterized for its various physical properties as follows:

Table 3: The physical appearance of superporous hydrogel is given below:

S. No.	Physical Appearance	Observed
1.	Colour	White
2.	Texture	Opaque
3.	Particular matter	Absent

Swelling Studies: It includes the swelling time and the swelling ratio of the formulated SPH. The required swelling time for the SPH was slowly decreased as the polymer concentration was increased. The swelling ratio was determined in 0.1N HCl until swelling equilibrium was reached. The interconnected pores present in polymer network allow more water to enter into the hydrogel by capillary force. The HPMC K100M has better swelling property as compared to chitosan. The swelling ratio graph is shown in figure 3.

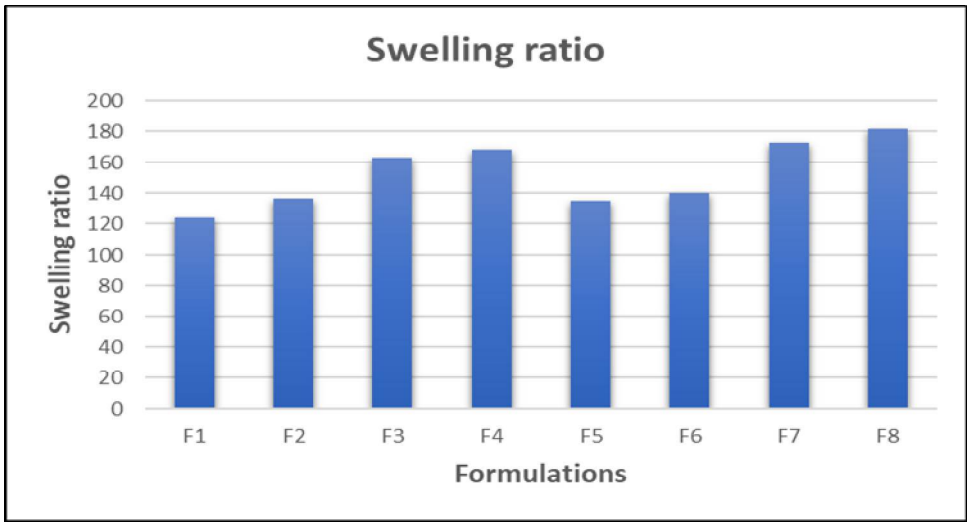


Figure 3: Graph of Swelling Ratio Determination

Density Measurement: The density of superporous hydrogel was increased as the concentration of glyoxal was increased. The polymer network was formed more strongly by the addition of higher amount of crosslinking agent. The values of density are given in table 4.

Porosity Measurement: The porosity of SPH depends on the crosslinking agent. As the concentration of glyoxal was increased, the porosity was moderately decreased. This is because of higher amount of crosslinking agent within the polymer structure which create tighter network of polymer. The results of porosity measurement are given in table 4.

Void Fraction: As the concentration of crosslinker was enhanced, the void fraction of the SPH was decreased. The amount of buffer absorbed by the polymer structure was increased, resulting in increased in void volume this will lead to more swelling ratio. The values of void fraction are given in table 4.

Water Retention Capacity: The capacity to retain water into the SPH was enhanced with the increase in the swelling ratio of the polymer. This is due to the polymer channels that are created inside the superporous hydrogel allow more water penetration through the capillary channels and improved water retention with less degradation of polymer. The water retention capacity is given in table 4.

Table no. 4: Characterizations of Various Formulations of Superporous Hydrogel

Formulations	Swelling Time (min)	Swelling ratio	Density (gm/cm^3)	Porosity (%)	Void Fraction (ml/gm)	Water retention capacity
F1	19.00±0.38	124.23±0.52	0.97±0.03	23.76±0.23	1.83±0.06	0.57±0.06
F2	18.25±0.67	136.25±0.68	0.83±0.07	38.21±0.53	2.13±0.05	0.60±0.38
F3	16.20±0.52	163.50±0.29	0.74±0.04	41.58±0.82	2.45±0.12	0.79±0.14
F4	17.00±0.36	168.06±0.82	0.62±0.06	43.70±0.35	3.17±0.09	0.85±0.06
F5	20.30±0.21	134.73±0.50	1.03±0.08	25.48±0.18	2.06±0.17	0.61±0.42
F6	16.50±0.70	140.20±0.34	0.95±0.02	34.36±0.34	2.27±0.22	0.76±0.06
F7	15.05±0.30	172.50±0.90	0.86±0.08	42.54±0.26	2.68±0.03	0.81±0.09
F8*	12.00±0.17	181.70±0.16	0.64±0.09	46.26±0.24	3.42±0.13	0.94±0.07

(Standard deviation n=3)

Pre-Compressional Parameters of SPH Tablet: The resultant powder blend of SPH was then evaluated for precompression parameter such as angle of repose, bulk density, tap density, carr's index and hausner's ratio. The values of pre-compression parameters are given in table 5.

The Angle of repose, Bulk density, tapped density of different formulations of the SPH powder blend was indicated the good flow properties. Carr's index and Hausner's ratio was calculated and the results showed better compressibility.

Table no. 5: Flow Properties of Losartan Potassium Loaded SPH of Different Formulations

Formulations	Angle of repose (ɵ)°	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's Index (%)	Hausner's Ratio
F1	30.43±0.52	0.48±0.01	0.54±0.06	12.06±0.03	1.13±0.03
F2	32.13±0.21	0.52±0.04	0.61±0.05	14.47±0.02	1.16±0.06
F3	25.23±0.33	0.47±0.05	0.54±0.09	12.96±0.05	1.14±0.09
F4	30.62±0.46	0.53±0.06	0.60±0.08	12.04±0.02	1.13±0.08
F5	26.56±0.65	0.51±0.05	0.59±0.04	14.23±0.04	1.16±0.09
F6	27.31±0.87	0.54±0.02	0.67±0.07	19.20±0.01	1.12±0.16
F7	25.55±0.51	0.46±0.03	0.55±0.05	16.23±0.02	1.19±0.06
F8	28.18±0.72	0.48±0.05	0.56±0.16	13.49±0.01	1.15±0.02

(Standard deviation n=3)

Post Compressional Parameters of SPH Tablet

Superporous hydrogel tablets of Losartan potassium was prepared using dried SPH, MCC, PVP, calcium dihydrogen phosphate, sodium bicarbonate, by direct compression on rotatory tablet punching machine. These prepared tablets were further evaluated for post compressional parameters like hardness, weight variation, friability, drug content and *in-vitro* drug release study. The results of all evaluation parameter expect *in-vitro* drug release study are given in table 6.

The hardness and thickness of the prepared SPH tablet was found to be in good range. The weight variation was found for the designed formulation was acceptable as per IP. According to Indian pharmacopoeia 2018, all the tablets was passed weight variation test as the average weight variation was within ±7.5%. The weight variation values range from 194.00±0.72 to 202.24±0.34. The friability of various formulations was evaluated by Roche Friabilator and found in acceptable range of friability % less

than 1. The % drug content of SPH was determined by UV- spectrophotometer and was found to be in the range of 95.63±0.27 to 99.13±0.36.

Table no. 6: Post Compressional Parameters of Different Formulations of SPH Tablet

Formulations	Hardness (kg/cm^2)	Thickness (mm)	Weight variation (mg)	Friability (%)	Drug content (%)
F1	6.13±0.032	4.27±0.029	198.35±0.73	0.63±0.35	95.76±0.59
F2	6.80±0.045	4.30±0.027	197.96±0.89	0.47±0.19	96.53±0.27
F3	5.35±0.025	4.21±0.023	201.06±0.53	0.38±0.46	98.18±0.64
F4	5.50±0.030	4.22±0.018	200.45±0.48	0.25±0.23	96.03±0.42
F5	6.26±0.055	4.00±0.019	194.00±0.72	0.86±0.75	97.45±0.19
F6	5.54±0.051	4.10±0.041	195.62±0.24	0.55±0.56	95.63±0.27
F7	5.42±0.065	4.28±0.032	200.53±0.94	0.42±0.40	98.24±0.23
F8*	5.56±0.025	4.24±0.010	202.24±0.34	0.20±0.61	99.13±0.36

(Standard deviation n=3)

Scanning Electron Microscopy: The SEM images of superporous hydrogel formulation (F8) containing HPMC K100M was clearly showed that the large numbers of interconnected pores which indicates the channel made by the polymer network. The presence of pore responsible for the water retention into the hydrogel. The magnification of the micrographs is ×1000, and the scale bar indicates the size 10µm. The SEM image is shown in figure 4.

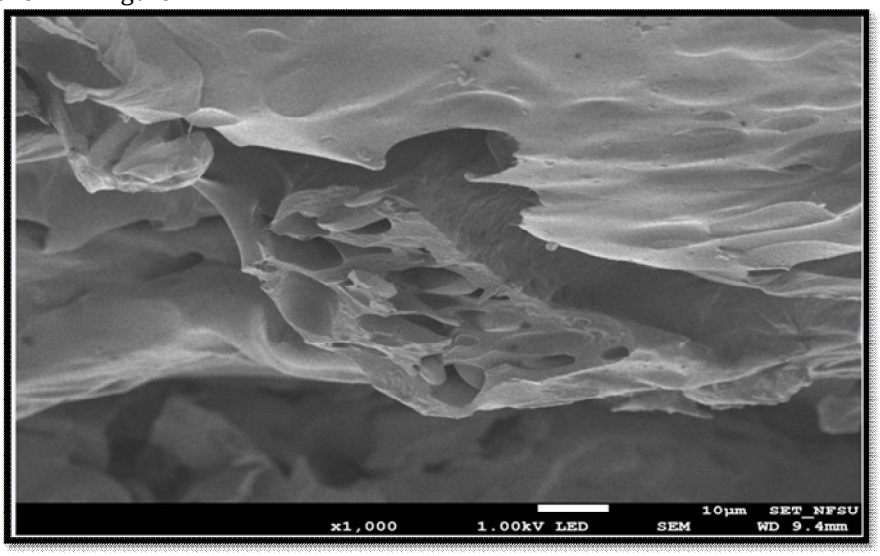


Fig 4: SEM Study Shows the Interconnected Microscopic Pores

***In-vitro* % Drug Release:** All the SPH tablet formulation was released the drug in a sustained manner throughout maximum 8 h. The drug release of the best formulation (F8) was showed highest drug release up to 8 h with 97.61%. The amount of hydrocolloid polymers increases, the drug was released for prolong period of time through gastro-retention. This is because of the high swelling ratio of SPH due to the increased concentration of polymer. This will result in enhanced bioavailability and drug half-life through gastro-retentive drug delivery system. The drug release profiles of the Losartan potassium loaded SPHs are shown in figure 5.

Table no. 7: *In-vitro* Dissolution Study Between Cumulative % Drug Release VS Time

	Cumulative % Drug Release							
Time (hrs)	**F1**	**F2**	**F3**	**F4**	**F5**	**F6**	**F7**	**F8***
0	0	0	0	0	0	0	0	0
1	10.69	8.66	14.35	11.63	15.34	9.96	13.61	16.69
2	16.37	18.58	23.63	22.46	28.19	14.03	24.13	29.17
3	27.76	33.71	32.74	36.56	34.78	29.05	38.96	37.46
4	38.05	47.12	49.58	45.23	42.18	43.12	52.02	48.05
5	52.82	61.23	63.96	56.79	53.45	55.56	61.35	62.82
6	65.23	77.45	75.03	71.14	62.48	67.28	72.62	75.23
7	78.32	90.76	87.41	80.22	77.95	82.36	83.96	88.34
8	89.26		95.32	92.57	93.21	94.73	95.15	97.61

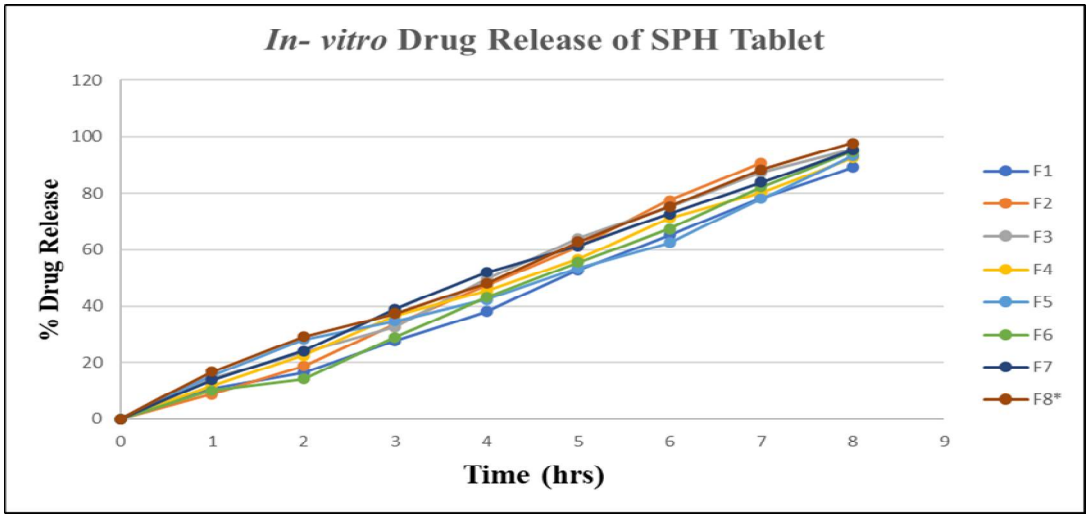


Fig 5: Graphical Representation of Cumulative % Drug Release VS Time

Drug release kinetics: The *In-vitro* drug release data was plotted in different kinetics model. The SPH formulation was fitted good by linear regression analysis according to zero-order, first order kinetics, Higuchi, Korsmeyer- Peppas, Hixson kinetics model. The formulation (F8) followed the zero-order kinetics with non-fickian diffusion type of mechanism of showing the drug release. The value of correlation coefficient R^2=0.9976 for zero-order kinetics which shows the formulation was released the drug in sustained manner. The zero-order kinetics graph plot is shown in figure 6.

Table no. 8: The Mathematical model of drug release kinetics of formulation (F8)

S. No.	Mathematical Model	Correlation coefficient R^2
1	Zero-order kinetics	0.9976
2	First order kinetics	0.8092
3	Higuchi model	0.9254
4	Korsmeyer-Peppas model	0.9333
5	Hixson model	0.9235

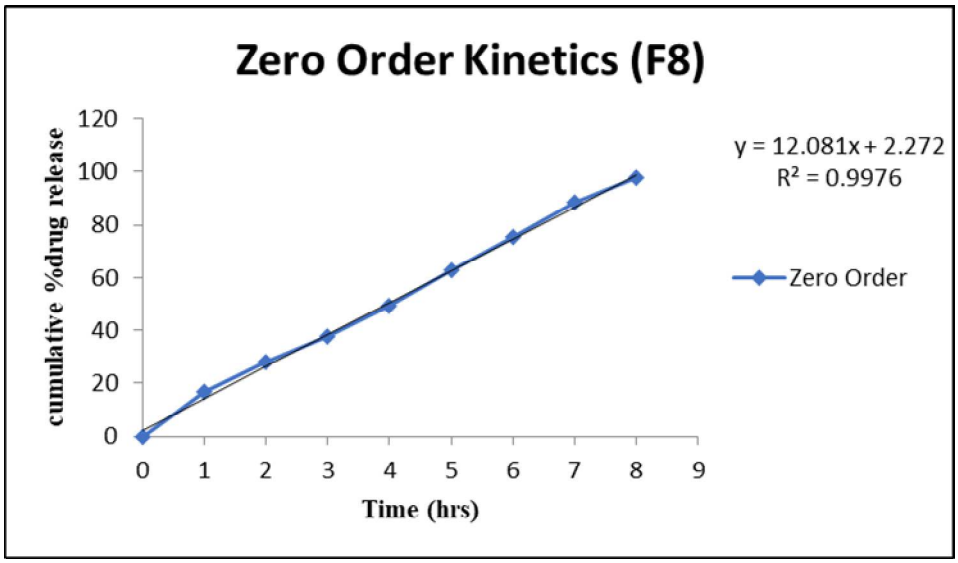


Fig 6: Zero-Order Kinetics Model Plot (F8)

CONCLUSION

The gastroretentive drug delivery system of Losartan potassium was effectively prepared with all the desired properties. It was delivered the drug in sustained manner and to the specific site of absorption. The SPH tablet of Losartan potassium enhance the bioavailability and biological half-life of drug. It will provide better systemic effect for the treatment of hypertension. All the SPH formulations were effectively prepared and the drug was release in a sustained manner over the prolonged period of time through gastro-retention. On comparison of both type of polymer formulation, HPMC K100M showed

good swelling properties than chitosan. The swelling time was gradually decreased as the polymer concentration was increased. The swelling time was found to be in the range of 12.00±0.17 to 20.30±0.21. The SEM images of SPH was clearly showed the large numbers of interconnected pores which indicates the channel made by the polymer network. The best formulation (F8) was prepared by direct compression containing SPH of HPMC K100M cross linked with glyoxal exhibited good swelling ratio as well as post compressional evaluations are within the pharmacopeial limits. It was concluded that the best formulation (F8) which released the drug up-to 8 h with percent drug release 97.61%. The drug release kinetics of (F8) formulation followed zero-order kinetics model and the correlation coefficient R^2 value is 0.9976 with non-fickian diffusion type of mechanism.

ACKNOWLEDGEMENTS
The authors are thankful to Tagoor Laboratories Pvt. Ltd., East Godavari, Andhra Pradesh, for me the gift sample of Losartan potassium. We are also thankful to the staff and management of Indore Institute of Pharmacy, Indore for providing their support to the study and other necessary facilities like internet connection, library and other support to carry out the research work.

CONFLICT OF INTEREST
The authors declare that there is no conflict of interest.

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