Research Article **CODEN: IJRPJK** **ISSN: 2319 – 9563**

International Journal of Research in Pharmaceutical and Nano Sciences

Journal homepage: www.ijrpns.com

https://doi.org/10.36673/IJRPNS.2021.v10.i03.A24

ARTICULATION AND ESTIMATION OF GASTRORETENTIVE SUPERPOROUS HYDROGEL TABLETS OF LABETALOL HYDROCHLORIDE

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ABSTRACT

Superporous hydrogels (SPHs) were developed to retain the drug within the gastric medium. These systems swell very rapidly within the stomach and maintain their integrity for extended time even within the acidic environment of stomach, while releasing the pharmaceutical active ingredient. The present work focuses on concept of development of superporous hydrogel tablets of Labetalol Hcl, their comparativeness to the marketed delayed release dosage forms. The aim of this study was to prepare Gastroretentive dosage form based on SPH using Labetalol Hcl, a antihypertensive as a model drug for swelling and prolonged drug release characteristics in acidic pH. There are three different polymers in SPHs, such as, sodium alginate, pectin, chitosan and acrylic acid were used with different concentrations by crosslinking technique using formaldehyde as cross linking agent to get the desired sustained release profile over a period of 8-12 hrs. The evaluation studies for SPH were measured by apparent density, mechanical strength, porosity, swelling studies, scanning microscopy (SEM) and FT-IR. All prepared formulations were evaluated for stability, kinetic drug release and *in-vitro* drug release profile, drug content and conclusions were that the proposed gastroretentive drug delivery system based on SPHs is promising for stomach specific delivery of Labetalol hydrochloride.

KEYWORDS

Superporous hydrogels (SPHs), Labetalol Hcl and Gastroretentive.

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INTRODUCTION

Hydrogels have long been established during this field to regulate the discharge of a drug from a standard solid dose formulation. It gradually swells within the aqueous medium and controls drug release by both diffusion and erosion. These sorts of hydrogels are non-cross linked and ultimately dissolve over time within the presence of sufficient water or the swelling medium[1-2]. Superporous

hydrogels (SPHs) are porous hydrophilic crosslinked structures with the power of absorbing aqueous fluids up to a couple of hundred times their own weight. Maximum swelling is usually reached during a fraction of a moment with SPHs having average pores of 200mm in size[3]. A superporous hydrogel (SPH) may be a three dimensional network of a hydrophilic polymer that absorbs an outsized amount of water during a very short period thanks to the presence of interconnected microscopic pores. When applied as drug carriers, these highly swollen hydrogels remain within the stomach for an extended time, releasing most loaded drugs since their volumes are too big to transport through the pylorus and their sheer bulk hinder their transport to subsequent organ via the narrow pylorus. This unique swelling property allows them to be used as gastric retention carriers providing a sustained release through long residence within the stomach. To be used as an efficient gastric retention device, the hydrogels are required to possess not only fast swelling but also following properties like biocompatibility, biodegradability, high swelling capacity and stability in acidic condition[4]. Chitosan, a natural polysaccharide, may be a biocompatible, biodegradable and non-toxic material. Because chitosan has abundant amine groups within the polymer chain, it dissolves in an acidic solution and forms a gel with formaldehyde like and. Thus, within the low pH solution, chitosan hydrogels swell thanks to the presence of the positive charges within the network[5]. Poly (vinyl alcohol) (PVA) may be a documented hydrophilic, biocompatible, and commercially available polymer. Labetalol hydrochloride is an anti-hypertensive belongs to the class of alpha and beta blocking agents which is used to treat high blood pressure. It is slightly soluble in water and is well absorbed from the GIT. Labetalol hydrochloride is rapidly absorbed following an oral dose but undergoes extensive first pass metabolism, resulting in only 25% oral bioavailability. The drug is eliminated rapidly, so repeated daily administration are required to take care of the effective plasma levels. The half-life of Labetalol hydrochloride is approximately 4-6 hours[6]. Thus an attempt has been made to develop a SPH gastroretentive drug delivery system of Labetalol hydrochloride for improving and enhancing the bioavailability.

MATERIAL AND METHODS

Materials

Labetalol Hcl was purchased from Yarrow chem products Mumbai. Chitosan and Polyvinyl Alcohol from Himedia labs Mumbai. India. Sodium alginate, Pectin, Span 40, Formaldehyde, Sodium bicarbonate, microcrystalline cellulose, Magnesium stearate were obtained from Aggarwal chemicals Gorakhpur Uttar Pradesh India. All other reagents were of analytical grade.

Methods

Synthesis of drug loaded SPHs

SPHs polymer solution (2%w/v) was prepared by stirring in 0.1M glacial acetic acid solution using a homogenizer until the chitosan dissolves in acid completely. A 10% w/w aqueous PVA solution was prepared and mixed to the polymer solution. To this solution, 0.2ml of formaldehyde solution (10% w/w of the dry weight of chitosan) was mixed. Further, 0.2ml of span 40 was added and mixed thoroughly followed by 50mg of sodium bicarbonate. The prepared mixture was stirred well and kept aside for a night.

100ml of 0.1 N HCL was taken. To this 200mg of drug and 100mg of superporous hydrogel were added and mixed for 1 h at 40-50^{o}C. Then acetone of 2ml was added and the hydrogel was repeatedly washed with distilled water to remove any unreacted material. Further it was dried at 35-40^{o}C for 24h, finally powdered and stored in a well closed container[7,8]. All the formulations are shown in Table No.1.

Formulation of superporous hydrogel tablets

200mg drug equivalent of drug loaded SPHs, microcrystalline cellulose and PVP (5% w/v solution), except magnesium stearate were accurately weighed and transferred to a clean mortar and pestle. The powder blend was mixed for 5 minutes after which magnesium stearate was added and mixed for few more minutes to ensure

complete mixing. After obtain a uniform blend, it was passed through sieve no 60. The obtained powder blend was compressed directly to form uniform tablets.

Estimation of superporous hydrogel

Superporous hydrogel can be estimated by the following parameters:

Physical Appearance

The prepared hydrogels were inspected visually for clarity, color and presence of any particles.

Percent Yield of Superporous hydrogel

Percent yield describes how much of material was obtained after freeze- drying of SPH compared to how much was kept for freeze drying. It can be calculated by the formula,

% yield = Weight of sample after drying**/** Weight of sample before drying X 100

API Content of SPH

Drug content of Superporous hydrogel was measured to know how much amount of drug is present in a particular amount of Superporous hydrogel. Superporous hydrogel required amount was taken in 100ml volumetric flask. About 10ml of buffer is added, mixed well and made up to volume. This mixture was filtered and drug content was measured using UV visible spectrophotometer at the appropriate wavelength 254nm.

Gelation Kinetics

In a polymerization reaction process, viscosity continuously increases until full zero network gel structure is formed. Gelation time generates information about the introduction time of blowing into the formulation. Gelation time was measured by simple tilting method after adjustment of pH to 5.0 with acetic acid. It is determined by the duration of time taken reactant mixture to become viscous and henceforth viscous solution no longer falls in tilted tube position[9,10].

Swelling Studies

Superporous hydrogels estimated by swelling properties. Swelling studies involved swelling time and swelling ratio.

Swelling Time

Swelling time is time taken by the hydrogel to realize its equilibrium swelling point where swelling is stopped. Swelling is generally measured gravimetrically and volumetrically; a texture analyzer is applied to live swelling time. Dried SPH was allowed to hydrate over swelling medium (25ml) at room temperature. At various time intervals, the hydrogel was off from the solution and weighed after excess solution on the surface was blotted.

Swelling Ratio

The dried SPH was allowed to hydrate over deionized H2O at room temperature. The weight of the hydrating sample was measured at time intervals after excess water was removed by gentle blotting. The formula calculated the swelling ratio,

$Qs = Ws\text{-}Wd \times 100 / Wd$

Where Qs is swelling ratio;

Ws is the weight of swelled hydrogel and

Wd is the weight of dried hydrogel[11,12].

Density Measurement

The solvent displacement method was used. Dried SPH was used for density measurement which shows the apparent density of SPHC. A piece of SPH was taken and weighed to determine the mass of piece. A piece of the polymer was immersed in a predetermined volume of hexane in a graduated cylinder and the increase in the hexane volume was measured as the volume of the polymer. The density was calculated as,

Density = M/V

Where,

M= a mass of SPH

V= volume of solvent[13].

Porosity measurement

Dried hydrogels were immersed overnight in absolute ethanol and weighed after excess ethanol on the surface was blotted. The porosity was calculated from the following equation:

Porosity = $(M2- M1/ \rho V)$

Where,

M1 and M2 are the mass of the hydrogel before and after immersion in absolute ethanol, respectively;

ρ is the density of absolute ethanol and V is the volume of the hydrogel[14,8].

Mechanical properties

Mechanical properties or compressibility of SPH is set to accept the strength of SPH to resist at gastric fluid pressure. Chen et al described the strategy to measure the penetration pressure of SPH. The fully swollen hydrogel put longitudinally under the lower punch and weight was successfully applied to the upper touch until the SPH completely fractured. The pressure where SPH fractured is termed as penetration pressure (PP) which is calculated by the following equation: PP = Fu/S

Where

Fu - Ultimate compressive force at complete breakage of polymer and

S - Contact area of the lower touch[9].

Determination of Drug Content

A weight of SPH containing drug in 100ml volumetric flask was treated with about 10ml hydrochloric acid solution of pH 1.2 mixed well and made up to volume[10]. The mixture was filtered and drug content was determined using UV-VIS spectrophotometer[15].

Determination of λmax of drug in 0.1N HCl In 0.1N HCl, the λmax of the drug was found to be 301.7nm shown in Figure No.2.

Fourier transform infrared (FTIR) spectroscopy

The FTIR spectra of the superporous hydrogels and chitosan were recorded over the range of 400 - 4000cm-1 by KBr pellet method using FTIR spectrophotometer.

Scanning electron microscopy

The dried SPH were used for scanning electron microscopy (SEM) studies to determine the morphology of the dried samples (Figure No.2). A JEOL JSM-840 scanning electron microscope (Jeol USA, Inc., Peabody, MA) was used after coating the samples with gold using a Hummer Sputter Coater (Technics, Ltd.). Images were captured using a digital capture card and Digital Scan Generator 1 (JEOL)[16].

Drug Loading

The method of soaking or equilibration was employed for drug loading. In this method the amount of buffer necessary for complete swelling of SPH was determined. Thereafter the drug solution in the determined amount of buffer which was required for complete swelling was prepared. Subsequently, SPH was placed in the drug solution and left until all the drug solution was sucked up. Then the completely swollen SPH loaded with the drug was placed in an oven at 30°C overnight[17].

Stability Studies

The prepared batches are kept in airtight containers and stored in stability chamber at 40°C/75% RH for three months. Results for *in vitro* dissolution studies obtained after three months are compared with the data obtained at the time of preparation.

Evaluation of Degradation Kinetics

The degradation kinetics of the hydrogel is examined by measuring the swelling ratio as a function of water retention. The hydrogel are placed in pH 1.2 (0.1 M HCl) medium at 37°C for 12 h and the samples are periodically weighed at 6 h interval. Water retention capacity (WRt) as a function of time is assessed as in equation.

$WRt = (Wp-Wd|Ws-Wd)$

Where,

Wd = the weight of the dried hydrogel

Ws = the weight of the fully swollen hydrogel,

Wp = the weight of the hydrogel at various exposure times[18].

Determination of Void Fraction

The void fraction inside superporous hydrogels was determined by immersing the hydrogels in HCl solution (pH 1.2) up to equilibrium swelling. The dimensions of the swollen hydrogels were measured and by using the data, sample volumes were determined as the dimensional volume[19]. In the meantime, the amount of absorbed buffer into the hydrogels was determined by subtracting the weight of dried hydrogel from the weight of swollen hydrogel and the resulting values were assigned as the total volume of pores in the hydrogels. Void fraction is calculated by the formula[20-22].

Void fraction= vol. of SPH/ total vol. of Pores

Precompression estimation

Powder blend of Dexlansoprazole SPHs was evaluated for various physiochemical parameters. Bulk density, tapped density, angle of repose and

powder flow studies of the different formulations were studied. The results are shown in Table No.3.

Weight Uniformity Test

The 20 tablets were taken and their weight was determined individually and collectively on a digital weighing balance. The average weight of one tablet was determined from the collective weight. Test was performed as per Indian Pharmacopeia (IP) 2010[23,24].

Hardness

Hardness was determined by taking six tablets from each formulation, using a Monsanto hardness tester, which applies force to the tablet diametrically with the help of an inbuilt spring.

Friability

The friability test was performed using friabilator as per IP 2010.

***In vitro* drug release studies**

In vitro drug release from the superporous hydrogels was evaluated in triplicate at 37±0.5°C using a United States Pharmacopoeia (USP) Dissolution Test Apparatus Type 2 (paddle method) at a rotation speed of 50 rpm in 900ml of 0.1M HCl (pH 1.2 buffer) for 6 h[25]. At regular time intervals, 10ml sample of the dissolution medium were withdrawn, replaced with an equivalent volume of fresh dissolution fluid and analyzed for the drug using a UV-Vis spectrophotometer. The release data obtained were fitted into various release models. To determine release mechanism, the parameters n and k of the Korsmeyer-Peppas equation were computed[26].

RESULTS AND DISCUSSION

Compatibility studies

The FTIR studies revealed that there was no drug polymer interaction in any of the formulation as indicated by the principal FTIR peaks of the drug observed at wave numbers of 3186, 1585. 1417, 1253, 1123, 1067 and 702cm-1 confirming the purity of the drug. FTIR spectrum of labetalol hcl in pure state is shown in Figure No.1. Which was observed to be almost similar in all the formulations indicating no significant drug interactions. In the FTIR spectra of chitosan SPHs of labetalol hcl (F8) peaks were observed at 1585, 1417, 1067, 702cm-1.

Porosity of superporous hydrogels depends on the quantity of crosslinking agent. It increases with decrease in hydrocolloid polymer to crosslinking agent ratio. This is often thanks to the incorporation of the upper crosslink density within the polymer structure resulting in the decrease within the occupied volume. Just in case of chitosan, among all hydrocolloid polymers, maximum porosity was found. Additionally, the void fraction of the superporous hydrogels decreased with increased amount of crosslinking agent. The decrease in void volume led to a decrease within the amount of uptake of water into the structure, leading to decrease within the swelling ratio.

Kinetics of swelling is vital due to the gel barrier formed with water permeation. Swelling is additionally an important factor to make sure floating[27,28]. The swelling ratio was within the range 40.00 ± 0.12 to 74.50 ± 0.20. F6 formulation has higher swelling index. the rationale for higher swelling ratio value are often attributed to the work by channeling agent, which allows more penetration of water into the gel layer thereby enhancing the water penetration or retention property. This might be the rationale for more water uptake by formulation from F4, F8 and F9 as shown within the Table No.2.

Mechanical strength was measured in terms of lastingness i.e, the measure of stress required to fracture the piece of formed SPH. To form the third generation superporous hydrogels for his or her effective applications, appropriate mechanical strength is necessesary. The results as shown within the Table No.2 indicate that increase in amount of crosslinking agent increased the strain required for fracture, thus increasing the mechanical stability. The presence of PVA increased the general crosslinking density of the superporous hydrogels by inducing additional PVA- polymer chains. This entanglement significantly improved the structural integrity of the hydrogel and decreased stress relaxation, which enhanced its ability to face up to pressure. Compared to other hydrocolloid polymers,

sodium alginate gave most strong SPHs. SEM studies revealed highly porous structure of Superporous hydrogels of F8 as shown in the Figure No.3.

The flow properties of the powder blend was found to be good for all formulations, as the angle of repose, carr's index and hausner's ratio were in good range. There were no flow problems (flow obstruction, segregation, irregular flow, flooding, etc) observed during the tests. The Compressibility index (or carr's index) and Hausner's ratio are measures of the propensity of a powder or the measures of the powder ability to settle and they permit an assessment of the relative importance of inter-particulate interactions. In a free flowing powder, such interactions are less significant, and the bulk and tapped densities will be closer in value as seen in the results from Table No.3. Good flow of powder blends ensures content uniformity and dose precision of tablets.

The tablets obtained by compression of powder blends containing SPHs of all formulations were found to have good hardness and acceptable % loss in friability test. The weight uniformity was also in acceptable range as per I.P 2010. The drug content in all the formulations were in agreeable quantities. The post compression evaluation results are illustrated in Table No.4.

The *in-vitro* dissolution study was performed for all formulations and the results are shown in Table No.5 and Figure No.4. *In-vitro* drug release studies showed that SPHs were the appropriate tool for extending the drug release. All formulations containing SPHs showed more than 8 hrs of drug release. The drug release profiles of the drug from the SPHs are shown in figure. The release of the drug was found to be dependent to the amount of hydrocolloid polymer and crosslinking agent and as the amount of hydrocolloid polymer increased. Drug release was found to be inversely related to the amount of crosslinking agent or low amount of hydrocolloid polymer where the openings are less and release is also low. Among all formulations, F8 showed extended release of drug upto 12 hrs. *In-vitro* drug release data of all the formulations was subjected to goodness of fit test by linear regression analysis according to zero order and first order kinetic equations, Higuchi‟s and Korsmeyer-Peppas models to ascertain the mechanism of drug release[29-32]. The results of linear regression analysis including rate constants and regression coefficients are summarized in Table No.6. The F8 was found to follow zero order kinetics with non-fickian diffusion type of mechanism of drug release since the value of n, the time exponent, calculated from this equation was found to be in between 0.45 to 0.89. In drug release profiles of all formulations except in F2 and F3, the release mechanism is assumed to be non-fickian.

Table No.1: Formulations with hydrogel polymer-superporous hydrogel

S.No	Ingredient %w/w	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Labetalol Hcl	200mg	200mg	200mg	200mg	200mg	200mg	200mg	200mg	200mg
2	Chitosan	2	--	--	3	--	--	--	4	--
3	Poly Vinyl Alcohol	4	4	4	4	4	4	4	4	4
4	Sodium alginate	--	--	2	--	--	3	--	--	4
5	Formaldehyde	10	10	10	10	10	10	10	10	10
6	Pectin	--	2	--	--	3	--	--	4	--
7	Span 40	0.2ml	0.2ml	0.2ml	0.2ml	0.2ml	0.2ml	0.2ml	0.2ml	0.2ml
8	Sodium Bicarbonate	50mg	50mg	50mg	50mg	50mg	50mg	50mg	50mg	50mg

Table No.2: Physical estimation of all SPHS formulations

S.No	Formulations	Swelling ratio	Porosity (%)	Void Fraction (ml/gm)	Water retention capacity	Tensile strength (kPa)
1	F1	46.35 ± 0.22	36.3 ± 2.2	1.42 ± 0.04	0.633	09.63 ± 3.56
2	F2	59.00 ± 0.10	58.3 ± 3.1	1.25 ± 0.06	0.776	08.18 ± 2.57
3	F3	41.00 ± 0.11	66.4 ± 2.5	1.15 ± 0.00	0.529	11.53 ± 3.42
4	F4	71.60 ± 0.81	73.2 ± 4.2	0.98 ± 0.12	0.972	12.03 ± 1.76
5	F5	53.75 ± 0.55	44.2 ± 3.3	1.33 ± 0.06	0.703	08.79 ± 2.98
6	F6	73.50 ± 0.21	79.2 ± 1.5	0.85 ± 0.11	0.708	12.09 ± 1.26
7	F7	47.48 ± 0.26	89.2 ± 2.1	0.72 ± 0.16	0.652	15.42 ± 5.87
8	F8	69.50 ± 0.17	81.2 ± 4.1	0.95 ± 0.12	0.929	18.45 ± 3.28
9	F9	68.40 ± 0.31	68.4 ± 2.5	1.15 ± 0.05	0.930	09.03 ± 2.94

Table No.3: Pre-Compression parameters of all SPHS Formulations

S.No	Formulations	Angle of repose	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's Index	Hausner's Ratio
1	F1	33.31 ± 0.512	0.534 ± 0.033	0.408 ± 0.013	15.18 ± 0.19	1.17 ± 0.11
2	F2	34.39 ± 0.739	0.538 ± 0.008	0.419 ± 0.017	15.13 ± 0.41	1.17 ± 0.45
3	F3	35.36 ± 0.629	0.542 ± 0.421	0.455 ± 0.121	15.11 ± 0.32	1.18 ± 0.19
4	F4	33.38 ± 0.321	0.533 ± 0.296	0.400 ± 0.073	16.03 ± 0.84	1.19 ± 0.02
5	F5	34.07 ± 0.631	0.540 ± 0.583	0.408 ± 0.066	15.05 ± 0.71	1.17 ± 0.07
6	F6	32.38 ± 0.145	0.560 ± 0.271	0.472 ± 0.033	14.50 ± 0.18	1.14 ± 0.12
7	F7	32.16 ± 0.642	0.555 ± 0.326	0.400 ± 0.091	15.98 ± 0.78	1.14 ± 0.02
8	F8	34.19 ± 0.162	0.555 ± 0.118	0.444 ± 0.031	15.28 ± 0.27	1.19 ± 0.03
9	F9	33.35 ± 0.550	0.539 ± 0.173	0.421 ± 0.038	14.05 ± 0.23	1.18 ± 0.12

Table No.4: Post-Compression parameters of all SPHS tablets

S.No	Formulations	Hardness (kg/cm2)	Friability (%)	Wt. uniformity (%)	Drug content (%)
1	F1	4.6 ± 0.13	0.501 ± 0.040	1.030 ± 0.005	98.97 ± 0.88
2	F2	4.6 ± 0.19	0.504 ±1.150	0.987 ± 0.180	100.1 ± 0.83
3	F3	4.8 ± 0.21	0.603 ±0.150	1.009 ± 0.009	99.72 ± 0.87
4	F4	4.5 ± 0.11	0.571±0.910	1.009 ± 0.016	95.8 ± 0.64
5	F5	4.0 ± 0.63	0.521±1.000	0.987 ± 0.034	99.42 ± 0.80
6	F6	4.4 ± 0.30	0.460±0.610	0.987 ± 0.190	92.98 ± 0.50
7	F7	4.9 ± 0.26	0.502±0.201	0.966 ± 0.024	96.80 ± 0.68
8	F8	3.4 ± 0.16	0.602±0.310	1.030 ± 0.061	94.90 ± 0.51
9	F9	3.5 ± 0.18	0.704±0.123	1.009 ± 0.003	98.85 ± 0.24

Table No.5: *In-vitro* drug release studies

S.No	Sampling time(hr)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	0	0	0	0	0	0	0	0	0	0
2	2	16.13 ±0.42	16.01 ±0.30	13.98 ±0.50	15.08 ±1.30	13.02 ±1.54	12.02 ±2.17	10.08 ±1.30	7.02 ±1.50	6.02 ±2.16
3	4	37.13 ±0.52	36.45 ±0.65	35.72 ±0.47	36.34 ±1.14	34.28 ±2.10	31.28 ±1.95	18.34 ±1.14	15.28 ±2.10	13.28 ±1.95
4	6	55.43 ±0.43	52.01 ±0.56	50.81 ±0.80	53.69 ±1.25	48.04 ±1.01	44.85 ±1.07	28.69 ±1.22	22.04 ±1.01	18.85 ±1.90
5	8	71.90 ±1.01	68.01 ±0.47	65.76 ±0.94	66.44 ±1.33	62.16 ±0.81	57.09 ±1.01	36.44 ±1.30	28.16 ±0.81	26.09 ±1.21
6	10	87.13 ±0.54	85.51 ±0.81	78.88 ±0.91	75.50 ±1.58	73.28 ±1.09	68.23 ±1.04	52.50 ±1.51	37.28 ±1.09	35.23 ±1.01
7	12	92.99 ±1.02	94.71 ±0.30	97.65 ±0.66	87.33 ±1.69	85.11 ±0.91	82.55 ±1.08	67.33 ±1.60	58.11 ±0.91	54.55 ±1.01

Table No.6: Drug release kinetics studies

S.No	Formulations	Zero order		First order		Higuchi	Korsemeyer	Mechanism of release
		K	R2	K	R2	R2	R2	N
1	F8 Non-fickian	9.234	0.980	0.092	0.949	0.956	0.952	0.804

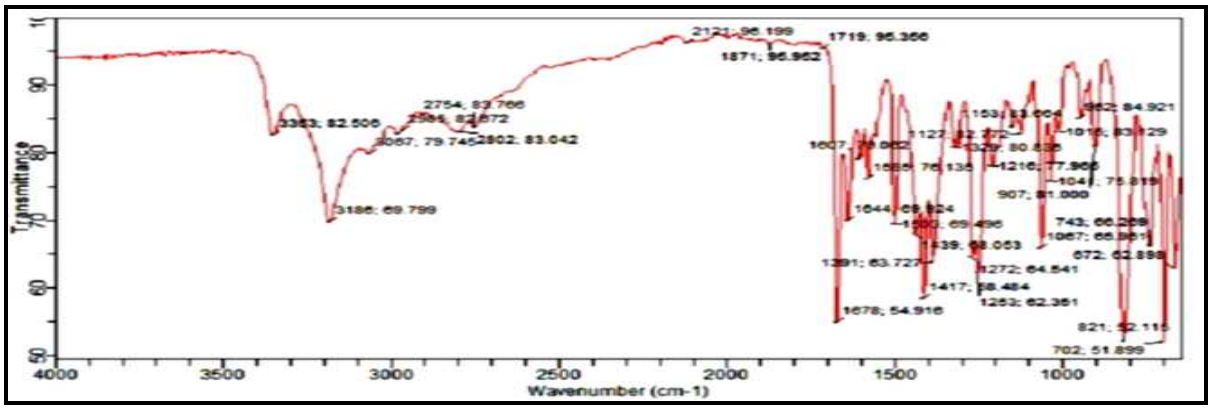

Figure No.1: FTIR of Labetalol HCl

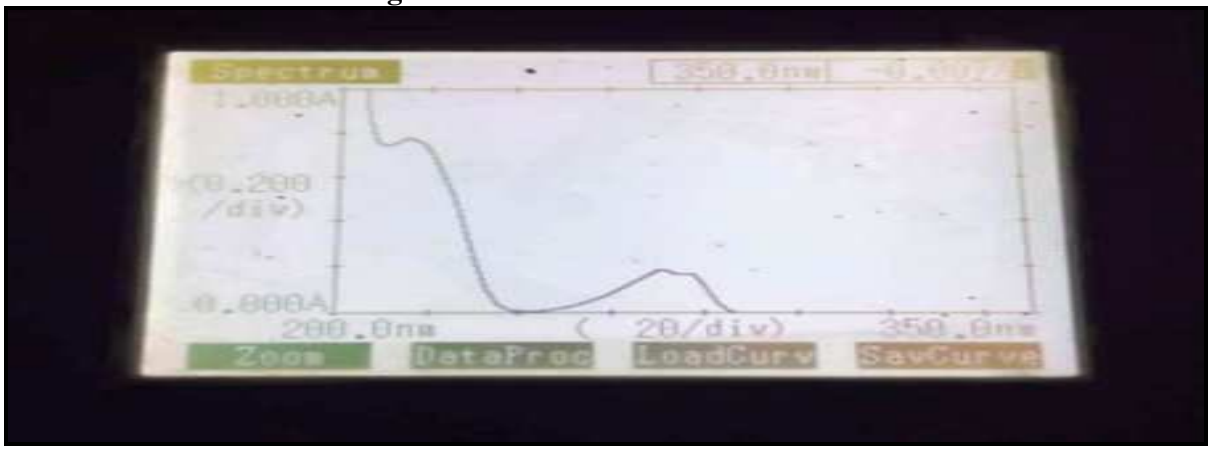

Figure No.2: Spectrum of Drug in 0.1 N HCl

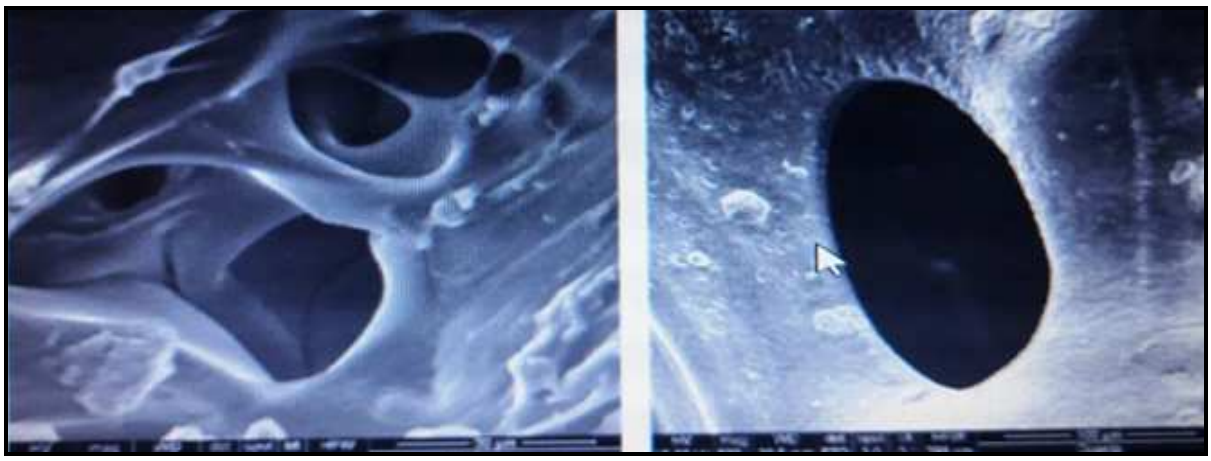

Figure No.3: Scanning electron micrographs of SPHS of chitosan (F8)

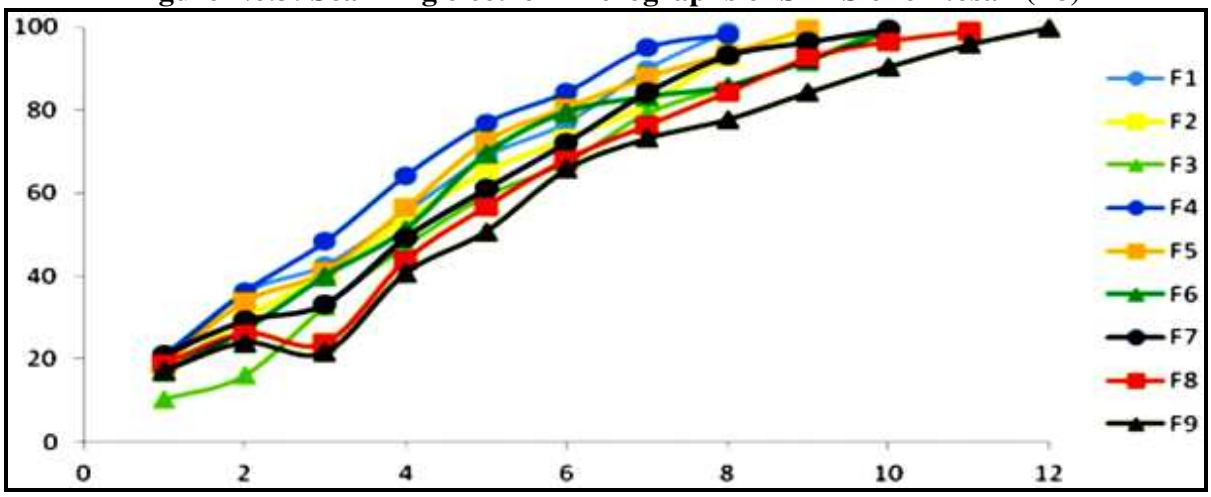

Figure No.4: % Cumulative drug release vs. time graph of all formulations

CONCLUSION

There results conclusively demonstrate that superporous hydrogel tablets of Labetalol hcl were effectively prepared with desired properties. The superporous hydrogel tablets of Labetalol hcl were prepared by direct compression method. The directly compressed formulations exhibited better *in-vitro* drug release profiles if compared to the marked delayed release tablets of labetalol hcl. The Formulation F8 prepare by direct compression containing SPH of chitosan cross linked with formaldehyde exhibited good swelling index as well as mechanical strength with maximum rate of drug release. The formulation was thus considered as the optimized formulation. The prepared tablet formulations of F8 revealed good pre-compression as well as post-compression properties as per prescribed limits of IP 2010. Thus, formulated superporous hydrogel tablets of labetalol hcl offer a superior alternative over conventional marketed dosage forms in regards to localized action and sustained release of drugs.

ACKNOWLEDGEMENT

The authors wish to express their sincere gratitude to Kailash Institute of Pharmacy and Management, GIDA, Gorakhpur, Uttar Pradesh, India for providing necessary facilities to carry out this research work.

CONFLICT OF INTEREST

We declare that we have no conflict of interest.

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