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GASTRORETENTIVE SUPERPOROUS HYDROGEL TABLETS OF DEXLANSOPRAZOLE

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ABSTRACT: Superporous hydrogels (SPHs) were developed to retain the drug in the gastric medium. These systems swell very rapidly in the stomach and maintain their integrity for longer time even in the acidic environment of stomach, while releasing the pharmaceutical active ingredient. The present work focuses on concept of development of superporous hydrogel tablets of Dexlansoprazole, their comparativeness to the marketed delayed release dosage forms. The aim of this study was to prepare Gastroretentive dosage form based on SPH using Dexlansoprazole, a proton pump inhibitor as a model drug for swelling & prolonged drug release characteristics in acidic pH. The formulation is based on preparation of third generation SPHs with three different polymers, 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 characterization studies for SPH were performed by measurement of apparent density, porosity, swelling studies, mechanical strength, scanning electron microscopy (SEM) and FT-IR. All formulations were evaluated for stability, drug content, and kinetic drug release & *in-vitro* drug release profile. It was concluded that the proposed gastroretentive drug delivery system based on SPHs is promising for stomach specific delivery of Dexlansoprazole.

INTRODUCTION: Hydrogels have long been established in this field to control the release of a drug from a conventional solid dose formulation. It gradually swells in the aqueous medium and controls drug release by both diffusion and erosion. These types of hydrogels are non-crosslinked and ultimately dissolve over time in the presence of sufficient water or the swelling medium^{1, 2}. Superporous hydrogels (SPHs) are porous hydrophilic crosslinked structures with the ability of absorbing aqueous fluids up to a few hundred times their own weight. Maximum swelling is generally reached in a fraction of a minute with SPHs having average pores of 200 nm in size³.

In the preparation of SPHs certain ingredients, including initiators, crosslinkers, foam stabilizers, foaming aids and foaming agents, are added into a water-diluted monomer. The foaming of SPHs is then driven by the interaction of acids and carbonates. For instance, acetic, acrylic and hydrochloric acids are commonly used with sodium, potassium and ammonium carbonates. Since the acid-carbonate interaction is only effective in aqueous media, the solution technique is the preferred method of polymerization in the preparation of SPHs^{4,5,9}.

The third generation superporous hydrogels are the SPH hybrid (wherein a water-soluble counterpart, a hybrid agent is employed)⁵. Depending on the agent type and its associated treatment, various third generation SPHs can be created, ranging from high modulus to highly elastic and rubbery (in their water-swollen states). Water-soluble hydrocolloids, including sodium alginate, sodium carboxymethyl cellulose, pectin and chitosan, have been used

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alone or in combination as the preferred hybrid agents. Overall, these third generation SPHs are elastic superporous hydrogels having enhanced mechanical properties⁵⁻¹¹.

Dexlansoprazole is a proton pump inhibitor used as an antiulcer drug in the treatment and maintenance of healing of duodenal or gastric ulcers, erosive and reflux esophagitis, NSAID-induced ulcer, Zollinger-Ellison syndrome, and Barrett's esophagus^{12, 13}. It lasts longer than lansoprazole, to which it is chemically related, and needs to be taken less often, making it possible to better control gastric acid. It is active against *Helicobacter pylori* with a bioavailability of 80% or more and protein binding of 97%. Its half life is 1-1.5 hrs with poor absorption may be because of degradation and poor solubility¹³. The solubility and absorption can be improved with an increase in the gastric residence time. Superporous hydrogels are a good alternative for providing gastroretentive drug delivery systems for therapeutic management of peptic ulcer¹⁴.

MATERIALS & METHODS: Dexlansoprazole was obtained as gift sample from MSN Laboratories Pvt Ltd, Hyderabad. Sugar Spheres were obtained from Arun Pharma Pvt Ltd. chitosan from Central Institute of Fisheries Technology, Kochi, India. Sodium alginate, Pectin, Formaldehyde, Sodium bicarbonate, Microcrystalline cellulose, Magnesium stearate were obtained from SD fine chemicals Mumbai.

Preparation of drug loaded SPHs: Hydrocolloid 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, 0.2 ml of formaldehyde solution (10% w/w of the dry weight of chitosan) was mixed. Further, 0.2 ml of tween 80 was added and mixed thoroughly followed by 50 mg of sodium bicarbonate. The prepared mixture was stirred well and kept aside overnight.

10 ml of 0.1 N HCL was taken. To this 20 mg of drug and 100 mg of superporous hydrogel were added and mixed for 1 h at 50°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 40°C for 24h, finally powdered and stored in a well closed container¹⁵⁻¹⁸. Different formulations are shown in **Table 1**.

Procedure for the preparation of superporous hydrogel tablets: 20 mg drug equivalent of drug loaded SPHs, microcrystalline cellulose and PVP (5% w/v solution), except magnesium stearate were weighed accurately 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 obtaining a uniform blend, it was passed through sieve no 60. The prepared powder blend was compressed into tablets.

TABLE 1: FORMULATIONS WITH HYDROCOLLOID POLYMER-SUPERPOROUS HYDROGEL.

Ingredients (% w/w)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Chitosan	2	---	---	3	---	---	4	---	---
Pectin	---	2	---	---	3	---	---	4	---
Sodium alginate	---	---	2	---	---	3	---	---	4
Poly Vinyl Alcohol	4	4	4	4	4	4	4	4	4
Formaldehyde	10	10	10	10	10	10	10	10	10
Tween 80	0.2ml								
Sodium Bicarbonate	50 mg								
Dexlansoprazole	20 mg								

Swelling studies: Completely dried superporous hydrogel was weighed and then immersed in excess of 0.1 N HCL. At various time intervals, the hydrogel was removed from the solution, blotted to remove excess of medium and then weighed¹⁶⁻¹⁸. Swelling ratio was calculated according to the following equation:

$$Q = (M_s - M_d) / M_d$$

Where, Q is the swelling ratio, Ms the mass in the swollen state and M the mass in the dried state.

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:

$$\text{Porosity} = (M_2 - M_1) / \rho V$$

Where, M_1 and M_2 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 hydrogel¹⁶⁻¹⁸.

Determination of void fraction: The void fraction was calculated by the following equation:

Void Fraction = Dimensional volume of the hydrogel / Total volume of pores

The void fraction inside superporous hydrogels was determined by immersing the hydrogels in 0.1 N HCl up to equilibrium swelling. The dimensions of the swollen hydrogels were measured and thereby dimensional volume was determined. In the meantime, the amount of absorbed buffer into the hydrogels was determined by subtracting the weight of dried SPHs from the weight of swollen SPHs and the resulting values were assigned as the total volume of pores in the SPHs¹⁶⁻¹⁸.

Water retention capacity: The following equation was used to determine the water retention capacity (WR_t) as a function of time:

$$WR_t = (W_p - W_d) / (W_s - W_d)$$

Where, W_d is the weight of the dried SPHs, W_s is the weight of the fully swollen SPHs (after exposure for 1 day), and W_p is the weight of the SPHs after exposure time of 6 hours. For determination of the water-retention capacity of the SPHs at 37°C, the water loss of the fully swollen polymer was determined by gravimetry¹⁶⁻¹⁸.

Mechanical Properties: The tensile strength (T) of superporous hydrogel formulations, which is a measure of the stress necessary to cause diametral fracture of the compact, was determined from the mean data obtained from the hardness test carried out on the SPHs ($n = 3$) using the Monsanto hardness tester. The T values were computed from equation below,

$$T = 2 P / \pi D t$$

Where, P is the load applied on the SPH that causes tensile fracture of the SPH of diameter, D, and t is the SPH thickness^{19, 20}.

Determination of drug content: A weight of superporous hydrogel containing 5 mg of drug in 100 ml volumetric flask was treated with about 10 ml 0.1 N HCl of pH 1.2 mixed well and made up to volume. The mixture was filtered and drug content was determined using UV-Vis spectrophotometer at 286 nm.

FT-IR spectroscopy: FT-IR spectroscopy was employed to ascertain the compatibility between the drug and the polymers. It was also used to investigate the chemical structure of the synthesized SPHs. The FTIR spectrum was recorded over the range of 400–4000 cm^{-1} using KBr pellet method by Fourier-Transform Infrared (FT-IR) spectrophotometer, (Bruker- Alpha-T-1020).

Scanning electron microscopy: The dried superporous hydrogels were used for scanning electron microscopy (SEM) studies to determine the morphology of the dried samples. 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).

Precompression characterization: Powder blend of Dexamethasone 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 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 Pharmacopoeia (IP) 2010²¹.

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 Roche friabilator (Electrolab, Mumbai, India) as per IP 2010.

Porosity of superporous hydrogels depends on the amount of crosslinking agent. It increases with decrease in hydrocolloid polymer to crosslinking agent ratio. This is due to the incorporation of the higher crosslink density within the polymer structure leading to the decrease in the occupied volume. 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 in the amount of uptake of water into the structure, resulting in decrease in the swelling ratio.

Kinetics of swelling is important because of the gel barrier formed with water permeation. Swelling is also a vital factor to ensure floating^{23, 24}. The swelling ratio was in the range 40.00 ± 0.12 to 74.50 ± 0.20 . F6 formulation is having higher swelling index. The reason for higher swelling ratio value can be 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 could be the reason for more water uptake by formulation from F4, F8 and F9 as shown in the **Table 2**.

Mechanical strength was measured in terms of tensile strength i.e, the measure of stress required to fracture the piece of formed SPH. To make the third generation superporous hydrogels for their effective applications, appropriate mechanical strength is necessary. The results as shown in the **Table 2** indicate that increase in amount of crosslinking agent increased the stress required for fracture, thus increasing the mechanical stability. The presence of PVA increased the overall 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 withstand pressure. Compared to other hydrocolloid polymers, sodium alginate gave most strong SPHs. SEM studies revealed highly porous structure of Superporous hydrogels of F9 as shown in the **Fig.2**.

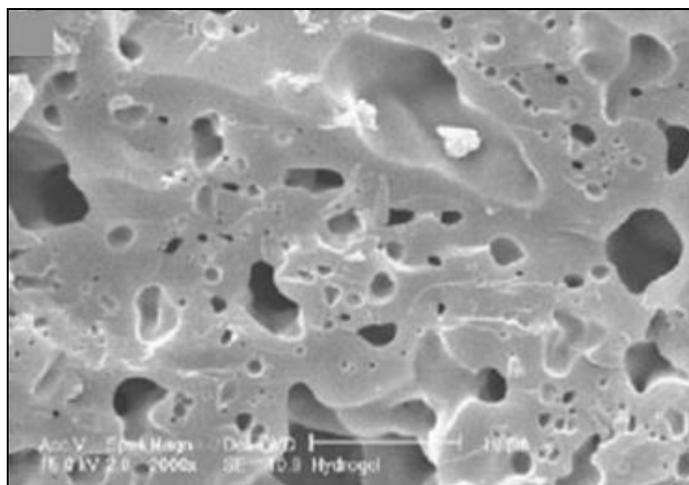


FIG. 2: SCANNING ELECTRON MICROGRAPHS OF SPHS OF SODIUM ALGINATE (F9). The magnification of the micrographs is $\times 200$, and the scale bar indicates 10 μm .

TABLE 3: PRE-COMPRESSION PARAMETERS OF ALL SPHS FORMULATIONS:

Formulations	Angle of repose	Bulk density (gm/ml)	Tapped density (gm/ml)	Carr's Index	Hausner's Ratio
F1	32.31 ± 0.512	0.533 ± 0.033	0.407 ± 0.013	14.18 ± 0.19	1.16 ± 0.11
F2	33.39 ± 0.739	0.537 ± 0.008	0.418 ± 0.017	14.13 ± 0.41	1.16 ± 0.45
F3	34.36 ± 0.629	0.541 ± 0.421	0.454 ± 0.121	14.11 ± 0.32	1.17 ± 0.19
F4	32.38 ± 0.321	0.532 ± 0.296	0.399 ± 0.073	15.03 ± 0.84	1.18 ± 0.02
F5	33.07 ± 0.631	0.539 ± 0.583	0.407 ± 0.066	14.05 ± 0.71	1.16 ± 0.07
F6	31.38 ± 0.145	0.559 ± 0.271	0.471 ± 0.033	13.50 ± 0.18	1.13 ± 0.12
F7	31.16 ± 0.642	0.554 ± 0.326	0.399 ± 0.091	14.98 ± 0.78	1.13 ± 0.02
F8	32.35 ± 0.550	0.538 ± 0.173	0.422 ± 0.038	13.05 ± 0.23	1.17 ± 0.12
F9	33.19 ± 0.162	0.554 ± 0.118	0.443 ± 0.031	14.28 ± 0.27	1.18 ± 0.03

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 3**. Good flow of powder blends ensures content uniformity and dose precision of tablets.

TABLE 4: POST-COMPRESSION PARAMETERS OF ALL SPHS TABLETS

Formulations	Hardness (kg/cm ²)	Friability (%)	Wt. uniformity (%)	Drug content (%)
F1	4.6 ± 0.13	0.501 ± 0.040	1.030 ± 0.005	98.97 ± 0.88
F2	4.6 ± 0.19	0.504 ± 1.150	0.987 ± 0.180	100.1 ± 0.83
F3	4.8 ± 0.21	0.603 ± 0.150	1.009 ± 0.009	99.72 ± 0.87
F4	4.5 ± 0.11	0.571 ± 0.910	1.009 ± 0.016	95.8 ± 0.64
F5	4.0 ± 0.63	0.521 ± 1.000	0.987 ± 0.034	99.42 ± 0.80
F6	4.4 ± 0.30	0.460 ± 0.610	0.987 ± 0.190	92.98 ± 0.50
F7	4.9 ± 0.26	0.502 ± 0.201	0.966 ± 0.024	96.80 ± 0.68
F8	3.4 ± 0.16	0.602 ± 0.310	1.030 ± 0.061	94.90 ± 0.51
F9	3.5 ± 0.18	0.704 ± 0.123	1.009 ± 0.003	98.85 ± 0.24

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 4**.

TABLE 5: IN-VITRO DRUG RELEASE STUDIES:

Time (hrs)	Cumulative % drug release								
	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	10.62	16.89	10.36	15.83	18.97	16.88	14.12	18.76	17.19
2	35.84	29.82	16.07	36.24	33.86	26.97	29.24	26.12	23.93
3	42.58	40.15	32.69	48.29	41.02	39.96	33.26	23.73	21.58
4	55.38	53.39	47.23	64.19	56.29	51.18	49.26	43.75	40.69
5	68.77	65.03	59.29	76.87	72.39	69.39	61.02	56.72	50.76
6	76.95	72.90	67.38	84.39	80.49	79.46	72.14	68.09	65.68
7	89.93	81.23	79.14	95.01	87.8	83.14	84.20	76.29	73.18
8	98.96	92.84	85.69	98.12	93.47	85.64	93.08	84.22	77.76
9		98.58	92.19		99.39	91.83	96.37	92.48	84.28
10			100.02			98.80	99.53	96.49	90.45
11								98.9	95.83
12									99.89

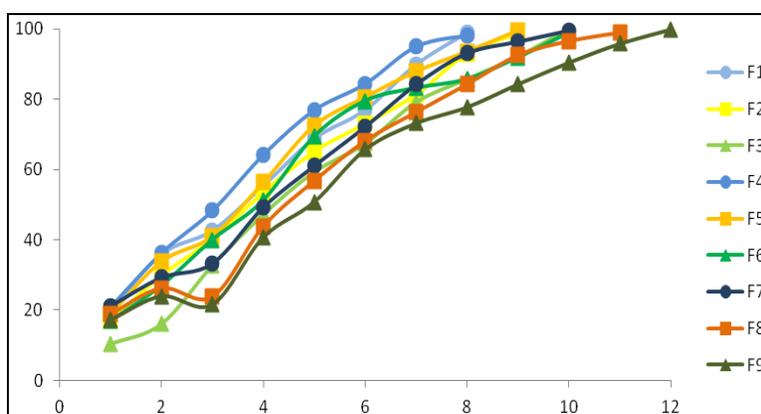


FIG. 3: %CUMULATIVE DRUG RELEASE VS. TIME GRAPH OF ALL FORMULATIONS

TABLE 6: DRUG RELEASE KINETICS STUDIES

Formulations	Zero order		First order		Higuchi	Korsmeyer		Mechanism of release
	K	R ²	K	R ²	R ²	R ²	n	
F1	11.218	0.996	0.093	0.928	0.984	0.994	0.769	Non-fickian diffusion
F2	10.292	0.992	0.088	0.904	0.993	0.813	0.999	Case -II
F3	10.355	0.982	0.103	0.858	0.989	1.047	0.980	Case -II
F4	11.379	0.976	0.090	0.890	0.993	0.995	0.768	Non-fickian
F5	10.304	0.973	0.084	0.888	0.988	0.991	0.774	Non-fickian
F6	10.702	0.980	0.092	0.899	0.986	0.992	0.846	Non-fickian
F7	10.288	0.986	0.085	0.954	0.964	0.964	0.752	Non-fickian
F8	9.777	0.974	0.092	0.934	0.942	0.914	0.795	Non-fickian
F9	9.234	0.980	0.092	0.949	0.956	0.952	0.804	Non-fickian

The *in-vitro* dissolution study was performed for all formulations and the results are shown in **Table 5** and **Fig. 3**. *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, F9 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 release²⁵. The results of linear regression analysis including rate constants and regression coefficients are summarized in **Table 6**.

The F9 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.

CONCLUSION: There results conclusively demonstrate that superporous hydrogel tablets of Dexlansoprazole were effectively prepared with desired properties. The superporous hydrogel

tablets of Dexlansoprazole 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 Dexlansoprazole. The Formulation F9 prepare by direct compression containing SPH of sodium alginate 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 F9 revealed good pre-compression as well as post-compression properties as per prescribed limits of IP 2010.

Thus, formulated superporous hydrogel tablets of Dexlansoprazole offer a superior alternative over conventional marketed dosage forms in regards to localized action and sustained release of drugs.

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