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**Review Article**

# Super Porous Hydrogel Based Drug Delivery System: A Review

Navneet Kumar Verma[1*], Asheesh Kumar Singh[1], Vikas Yadav[1], Prashant Singh[1], Ankur Yadav[1], Shiwani Jaiswal[1]

[1]Buddha Institute of Pharmacy, GIDA, Gorakhpur, Affiliated To Dr. APJ Abdul Kalam Technical University Lucknow, UP. India

***Corresponding Author**
Navneet Kumar Verma

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**Abstract:** Superporous hydrogels (SPHs) is originally developed as a novel drug delivery system to retain drugs in the gastric medium by instant swelling on water absorption through open porous structure and maintain their integrity in that harsh environment. These materials can be synthesized to respond to a number of physiological stimuli present in the body, such as PH, ionic strength, temperature. Hydrogels are a unique class of three dimensional cross-linked polymeric networks that can hold a large fraction of aqueous solvents and biological fluids within their structures. Nowadays, hydrogels have attracted a growing interest of many scientists in different fields of research. Intelligent hydrogels have found a significant role in a wide variety of applications such as drug delivery systems, tissue engineering, optics, diagnostics and imaging. The purpose of this paper is to present a brief review on the basis concept of hydrogels, the description about classification, synthesis methods, stimulation situations, relevant mechanisms, and applications. It also involved technologies adopted for hydrogel production together with process design implications, block diagrams, and optimized conditions of the preparation process. An innovated category of recent generations of hydrogel materials was also presented in some details. The formulations obeyed Higuchi and Korsmeyer- Peppas kinetics of drug release. For further confirmation, the data were fitted to the Kopcha model to get the evidence of drug release by the combination of diffusion-controlled and chain relaxation–swelling mechanism. However, the diffusion mechanism predominated the process leading to quasi diffusion and anomalous diffusion mechanism.

**Keywords:** Hydrogel, Preparation, Processing, Types of hydrogels, Preparation methods, Applications.

## INTRODUCTION

Super porous hydrogels (SPHs) basically developed initially create as a novel drug delivery system to absorb and continue to hold the drugs in the gastric medium which allows absorption in stomach and upper part of the gastrointestinal tract. These systems get swollen in the stomach instantly and in the harsh stomach environment they maintain their integrity, while the pharmaceutical active ingredient is being released. Oral controlled drug delivery system release drug from the systems predictably and reproducibly to achieve better bioavailability of basic drugs that have poor solubility at higher pH as well as drugs that have short elimination half- lives. A major drawback encountered with oral formulations is the inability to increase their retention time in the stomach and the proximal part of the small intestine. Many methods have been developed to prolong the residence time of drugs in the stomach. Different approaches to improve the gastric residence include dosage forms like mucoadhesive or bioadhesive systems, high-density systems, magnetic systems, superporous hydrogels, raft forming systems, low- density systems, and floating ion exchange resins [1]. Among these, superporous hydrogel system is one of the challenging approaches.Hydrogels are cross-linked hydrophilic polymers with a network structure consisting of acidic, basic, or neutral monomers, and they have the ability to absorb large amounts of water. The swelling properties of hydrogels are closely related to so many factors like the elasticity of the network, thepresence of hydrophilic functional groups (such as -OH, -COOH, -CONH2, -SO3H) in the polymer chains, the extent of cross-linking, and porosity of the polymer. Hydrogel swells in water with some mechanical strength, but their swelling index and mechanical strength are not so enough to exhibit fast swelling properties [2]. Such slow swelling is beneficial for many applications, but there are many situations where a fast swelling polymer is more desirable. Therefore, a new generation of hydrogels that swell by absorbing water very rapidly, has been developed. Examples of this new generation are superporous hydrogel, which swells to an equilibrium size in a short period of time [3]. 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 [4, 5]. 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 mm in size [6]. 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 [7-9]. Hydrogel drug delivery is most commonly used in the US market despite of more than 100 prescription drugs. Although this is a water soluble polymer, it shows gel properties when wide open to an aqueous environment. HPMC is used in tablet form to resist the release of drug over a longer time with different degrees of substitutions. HPMC is enabled to function as a controlled delivery system in two features. First, it is hydrophilic due to its hydroxyl propyl contents. Second, the HPMC chains are in a compressed form in a tablet, which prevents them from a fast dissolution in the aqueous environment. These two features provide gelling properties such as those found in a chemically cross-linked hydrogel. Even though there isn't no chemical cross-linking in the HPMC structure; the pressure applied during tablet preparation supplies enough entanglement and barrier for the retarded polymer dissolution.

## GASTRO RETENTIVE DRUG DELIVERY SYSTEM

The most easy and preferred means of any drug delivery to the system is oral administration. Recent inclining interest in pharmaceutical field about controlled release of drug delivery through oral route have been an achievement in improving curing advantages, such as ease of dosing administration, patient compliance and formulation flexibility [10]. Drugs which are removed immediately from the systemic circulation and are easily absorbed from gastrointestinal tract (GIT) also have short lives. Suitable curing activity can be achieved by periodic dosing of drugs. Releasing the drug slowly into the gastrointestinal tract (GIT) by oral sustained-controlled release and these formulations are an attempt to avoid this limitation and maintain drug in the systemic circulation for a long time. Such a drug would be remained and release it in the stomach controlled manner so that drug could be continuously.supplying to the absorption sites in the gastrointestinal tract (GIT). There are mainly two adversities that drug delivery system suffers: the short gastric retention time (GRT) and unpredictable short gastric emptying time (GET), which can also result to incomplete drug release from the dosage in the absorption zone (stomach or upper part of small intestine) which leads to diminished efficacy of administered dose [11]. It is desirable to achieve a prolong gastric residence time by the drug delivery to formulate a site-specific orally administered controlled release dosage. Prolonged gastric retention increases bioavailability and improves the solubility of the drug in a high pH environment [12]. It also increases the drug release duration, reduces drug waste. Prolonged gastric retention time (GRT) in the stomach could be advantageous for local action in the upper part of the small intestine e.g. treatment of peptic ulcer etc. It is an approach extends gastric residence time, by targeting site-specific drug release in the upper gastrointestinal tract (GIT) for local or systemic effects. Gastro retentive dosage forms extend the gastric retention time (GRT) for extended periods. In the past, several gastro retentive drug delivery approaches were designed and developed, including: high density (sinking) systems that is retained in the bottom of the stomach, low density (floating) systems that causes buoyancy in gastric fluid [13], mucoadhesive systems that causes bioadhesion to stomach mucosa, unfoldable, extendible, or swellable systems which limits emptying of the dosage forms through the pyloric sphincter of stomach, superporous hydrogel systems, magnetic systems etc.

## SUPERPOROUS HYDROGELS (SPH)

A superporous hydrogel is a 3-dimensional network of a hydrophilic polymer that absorbs water in large amount in a short period of time due to the presence of interconnected microscopic pores . SPHs are a new type of hydrogel that have numerous super size pores inside them [14] and the swelling occurs by capillary wetting but rarely by diffusion. Certain ingredients, including initiators, cross linkers, foam stabilizers, foaming aids and foaming agents, are added into monomer diluted water in the preparation of SPHs. Superporous hydrogel do not have only fast swelling, but also properties like slipperiness, biodegradability biocompatibility, high swelling capacity, high mechanical strength, and stability in acidic condition of the stomach. Thereby, they swell completely within minutes regardless of their size due to absorption of water by capillary force rather than by simple absorption. Second generation superporous hydrogels composites are developed which has fast swelling, medium swelling ratio and improved mechanical properties, while third generation superporous hydrogel hybrid possess high elastic properties [15]. Gastric retention devices will be most beneficial for local action of drugs in the stomach, e.g. antacids and antibiotics for bacteria based ulcers or drugs that are required be absorbed primarily in the stomach.

### Various generations of Superporous hydrogel

There are three different generations of superporous hydrogel.

1. First generation superporous hydrogel

2. Second generation superporous hydrogel
3. Third generation superporous hydrogel

**First Generation Superporous Hydrogel**

These are also described as Conventional SPH (CSPH) with having fast swelling kinetics and super absorbent properties16. Monomers used for the preparation of CSPH Monomers include vinyl monomers like acrylamide, ionic monomer like salt of sulfopropylacrylate potassium, acrylic acid etc. Alcohol preserves the porous structure of SPH. The dried CSPHs so formed have poor mechanical strength. Conventional superporous hydrogel cannot withstand for long time in hostile gastric environment like gastric contraction, enzymatic degradation and gastric fluid content.

**Second Generation Superporous Hydrogel**

These are also referred as superporous hydrogel composites (SPHC) due to use of composite agents in their preparation. SPHC were prepared with some modification in CSPH17. These second generation superporous hydrogel possesses good mechanical strength as compared too conventional one but the SPH composites are still brittle in nature and cannot tolerate the stress for prolonged period of time and fractured. Composite agents used include Cross-linked sodium carboxy methylcellulose (Ac-Di-Sol), Carbopol, Polyvinyl alcohol (PVA). Cross-linked sodium starch glycolate (Primojel) and Cross-linked polyvinylpyrrolidone (crospovidone).

**Third Generation SPH**

Superporous hydrogel of third generation possess excellent mechanical strength. Their excellent mechanical properties are due to use of hybrid agents that provide elastic characteristics to these superporous hydrogel18. Due to these elastic and rubbery characteristics SPH hybrid can tolerate stress condition for more period of time. Hybrid agents used in third generation superporous hydrogel includes Sodium alginate, sodium carboxymethyl cellulose and chitosan which possess good ionogelation properties.

**PREPARATION OF SUPERPOROUS HYDROGEL (SPH)**

Superporous hydrogel can be prepared by following methods:

- Porosigens Technique
- Phase separation Technique
- Cross linking Technique
- Gas blowing Technique

**Drug Loading into Superporous Hydrogel**

Drug is loaded into this superporous hydrogel delivery system by using any of two techniques.

- Drug loading into superporous hydrogel reservoir devices
- Drug loading into superporous hydrogel polymers

**Drug loading into superporous hydrogel reservoir devices**

Whole superporous hydrogel can act as reservoir devices for the different drug delivery systems like controlled release mini tablets or microparticles.

**Two types of drug delivery systems have been designed:**

- Core inside shuttle system
- Core attached to surface of shuttle system

Both systems are consisting of two components named as a core and a conveyor system. Drug blend with appropriate excipients is termed as core and conveyor is made up of SPH and SPHC19.

**Core inside the shuttle system**

In this system, core is prepared in two different forms viz. micro particles and gross mass. For micro particles preparation, the drug is dispersed in melted polymers like PEG 6000 and then whole mixture is cooled to get gross mass. This gross mass is crushed and sieved and used as core material. SPHC is work as the body of the conveyor system because of having good mechanical strength and SPH is used as the cap of the conveyor system because of its high swelling ratio. A hole is made inside SPHC in its swollen state by use of borer, as the core has to be incorporated inside SPHC. The SPHC is then dried by either at ambient temperature or by reduced pressure at 60°C. This is called as the body of conveyor which is capped by piece of SPH.

**Core attached to surface of shuttle system**

In this system, core is in the form of small tablets which are prepared by dispersing the drug in melted polymer like PEG 6000 and sieving which were mixed with lubricant and compressed into tablets using single punch machine.

The conveyor made up of only SPHC in which two holes were made on counter side instead of one as in previous approach. The core material (mini tablet) was put inside the holes by using bio-adhesive glue i.e. (cyanoacrylate). The polymer swells when it comes in contact with gastric fluids and the size of holes is enlarged. The glue helps to keep the dosage forms at the site of drug absorption. The whole assembly is kept into gelatin capsule shells of size 000.

**Drug loading into Superporous hydrogel polymers**

The amount of water used for full swelling of hydrogel is determined. Then, drug solution in determined amount of water is prepared and weighed amount of hydrogel is placed in drug solution to suck up the drug solution. After 20 min, completely swollen polymers loaded with drug are placed in oven at 30°C for drying overnight [20].

**Drying of Superporous Hydrogel**

Superporous hydrogel are dried under two different conditions. Under Condition I, drying of swollen superporous hydrogel are carried out by keeping under blowing warm air (60 °C) in an oven for a day. Under Condition II, firstly absolute ethanol (5–10 ml) is used to dehydrate the swollen superporous hydrogel. After this initial dehydration step, superporous hydrogel are dehydrated further by placing them in 50 mL of absolute ethanol several times to ensure complete replacement of the water by ethanol. During the dehydration process, the soft and flexible superporous hydrogel convert into hard and brittle form. After the dehydration is completed, the excess ethanol in dehydrated superporous hydrogel is removed by draining using paper towel. Then the superporous hydrogel are dried in an oven at 55°C for a day [21].

**Evaluation parameters of Superporous hydrogel**

**Swelling Studies**

**Swelling time**

This is an important characteristic of superporous hydrogel. Time of swelling of hydrogel was determined by putting hydrogel in swelling media and time was noted upto equilibrium swelling. Swelling ratio Firstly, hydrogel was fully dried and then keep in excess of swelling medium. At predetermined time hydrogel was taken out from the media and weighed. The swelling ratio was determined as:

$Qs=Ws-Wd/Wd^{x}100$

Where,
Qs - Swelling ratio,
Ws - Weight of hydrogel in swollen state
Wd - Weight of dried hydrogel.

**Density Measurement**

After drying, superporous hydrogel lose their cylindrical shape and hence it is difficult to measure their volume directly. Thus solvent displacement method is used to determine the density of SPH which represents the apparent density of SPHs. A hydrophobic solvent hexane can be used for this purpose because it is not absorbed by the SPH. By using forceps, the pre-weighed SPH immersed in hexane in graduated cylindrical. Initial volume of hexane was noted and the increase in volume was also noted. Density was calculated as:

**Density** = MSPH / VSPH

Where,
MSPH: Mass of SPH
VSPH: Volume of SPH

**Porosity measurement**

Porosity is an important parameter that affects swelling ratio, mechanical strength and drug release profile. For determination of porosity, dried SPH was kept in hexane overnight and weight was taken after excess hexane on the surface was blotted.

The porosity was calculated as
Porosity = VP/VT

Where

VP (VT-VSPH) is the pore volume of SPH and VT is the total volume of SPH. Total volume of SPHC can be measured from its dimensions, as it is cylindrical in shape.

**Measurement of Gelation Kinetics**

As the polymerization reaction proceeded, the viscosity continuously increased until the full network structure (gel structure) was formed. The gelation time was defined as a period of time for gel formation following addition of glyoxal and measured by a simple tilting method after adjustment of pH to 5.0 with acetic acid. It was determined by the duration of time taken by the reactant mixture to become viscous and the viscous solution no longer descended in the tilted tube position [22].

**Mechanical properties**

Mechanical properties or compressibility of SPH is determined to measure the strength of SPH to withstand at gastric fluid pressure. Chen *et al*., described the method 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 (23).

**Determination of Drug Content**

A weight of SPH containing drug in 100 ml volumetric flask was treated with about 10 ml hydrochloric acid solution of pH 1.2 mixed well and made up to volume [24]. The mixture was filtered and drug content was determined using UV-VIS spectrophotometer [25].

**Fourier transform infrared (FTIR) spectroscopy**

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

**7.9 Scanning electron microscopy**

The dried SPH were used for scanning electron microscopy (SEM) studies to determine the morphology of the dried samples (Fig 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) [26].

**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 [27].

**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 is the weight of the dried hydrogel

Ws the weight of the fully swollen hydrogel,

Wp the weight of the hydrogel at various exposure times.

**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[29]. 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 [30].

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

**In vitro release studies**

In vitro drug release from the superporous hydrogels was evaluated in triplicate at 37±0.5o C using a United States Pharmacopoeia (USP) Dissolution Test Apparatus Type 2 (paddle method) at a rotation speed of 50 rpm in 900 ml of 0.1M HCl (pH 1.2 buffer) for 6 h [31]. At regular time intervals, 10 ml 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 [32].

**APPLICATIONS OF SUPER POROUS HYDROGEL**

SPHs were generally proposed as gastric retention devices. However, SPHs may be tailor- made for applications other than gastric retention in the pharmaceutical and biomedical industries.

**Chemoembolization and occlusion devices**

Chemoembolization is a combined method of embolization and chemotherapy [33]. Embolization has been used for cancer treatment by restricting the oxygen supply to the growing tumours. This method could be combined with chemotherapeutic agents to achieve local delivery and low systemic toxicity. A chemotherapeutic agent and an anti-angiogenic agent could be loaded into SPHs for chemoembolization therapy. The strong SPHs would likely be better candidates for this application as they fit better in the blood vessels and provide better blocking [34].

**SPH-based gastroretentive platforms**

Evaluated the feasibility of chitosan and gly- col chitosan hydrogels for the gastric retention application. They prepared the hydrogels after optimizing the gelation and foaming kinetics in different acidic conditions [35]. They concluded that glycol chitosan hydrogels offer better swelling properties over the chitosan alone. Moreover, the hydrogel swelling property was found significantly dependent on the foaming/ drying method, pH and crosslink density. The kinetics of the SPH degradation has also been studied in the simulated gas- tric fluid (SGF).

**Gastric Retention drug delivery / Devices**

There has been a multitude of approaches using well-established principles to prevent the dosage form from exiting the pylorus during gastric emptying over few decades. Gastric retention devices may be extremely useful for the delivery of many drugs. Such devices would be most beneficial for drugs that act locally in the stomach (e.g., antacids and antibiotics for bacteria-based ulcers), or for those drugs that are primarily absorbed in the stomach. For drugs that have a narrow absorption window (i.e., mainly absorbed from the proximal small intestine), such as For drugs that are absorbed rapidly from the gastrointestinal tract, bioavailability could be improved by a slow release from the stomach. Gastric retention devices can further be used for drugs that are poorly soluble in an alkaline pH medium or for drugs that degrade in the colon (e.g., metoprolol). Prolonged gastric retention, however, is not desirable for all drugs. Gastric retention is not desirable for aspirin and non- steroidal anti-inflammatory drugs, or for drugs that are unstable in acidic pH. In addition, for those drugs that are primarily absorbed in the colon, a longer gastric retention may not be necessary because the time spent in the colon can sustain blood levels for up to 24 h [36].

**Peptide drug delivery**

Till recent, delivery of proteins and peptides through injections have been the common mean of their administration because of their poor oral bioavailability. However oral route is the most preferred route because of ease of administration and patient acceptance. Designing and formulating a polypeptide drug delivery through the gastro intestinal tract has been a persistent challenge because of their unfavorable physicochemical properties, which includes enzymatic degradation, poor membrane permeability and large molecular size. Superporous hydrogels have been used in the development of peptide delivery systems via oral administration. SPH have the tendency to increase their volume by 200 fold. Such volume increase allowed the gels to mechanically stick to the intestinal gut wall and deliver the incorporated drug directly to the gut wall [19].

**Fast dissolving tablet**

Fast dissolving tablets (FDTs) are meant for dissolve or disintegrate in the mouth in the absence of additional water for easy administration of active pharmaceutical ingredients. FDTs are solid unit dosage forms, which disintegrate or dissolve rapidly in the mouth without chewing and water. This is useful particularly for children and elderly patients. There are three different methods to formulate the fast dissolving tablet including freeze drying, sublimation and direct

compression. In first two methods, tablets are prepared that are intend to dissolve within 5-15 seconds but these methods are very expensive and tablets prepared from these method possess poor mechanical strength. But the direct compression method involves addition of fine particles of SPH to the granulation or powder formulation. The SPH microparticles within the tablet core expedite water absorption by an increased wicking mechanism. Tablets prepared by direct compression in the presence of SPH microparticles disintegrate in less than 10 seconds [37, 38].

## CONCLUSION

Super porous hydrogels (SPHs) are recent advancement in gastro retentive drug delivery system (GRDDS) which also includes intragastric floating system (low density system), mucoadhesive system, high density system and swellable system. These systems should instantly swell in the stomach and maintain their integrity in the harsh stomach environment, while releasing the pharmaceutical active ingredient. Hydrogel has the capacity to hold water and medicament in them due to cross linked structure. This features support formulation of pharmaceutical products in the form of hydrogel. Due to the ability of holding water they can hold and retain wound exudates. Gelatine and sodium alginate based hydrogels when applied have the ability to cover and protect the wound from bacterial infection. Hydrogel a kind of revolutionary advancement since last few years in the field of Pharmaceutical and Biomedical products manufacturing. It supports as a tool for Novel drug delivery system in various system. Few limitations are there such as low mechanical strength. Superporous hydrogels are a new class of hydrogel materials that swell to larger size regardless to their size and serves as a promising device for gastro-retentive delivery. Different generations of SPHs are investigated successfully for gastric retention. The network structure and possibility of rearrangements of hydrophobic/hydrophilic domains during swelling process, including entanglements and crystalline regions make these polymers water insoluble. A successful oral drug delivery platform that uses SPHs is expected to meet certain criteria including safety, effectiveness, desirable drug loading and release, feasible manufacturing as well as minimum interactions with gastric contents.

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