



Nanosponges: A Novel Class of Drug Delivery System

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ABSTRACT

Nanosponges are a novel class of materials consisting of microscopic sponge-like structures with narrow cavities that are a few nanometers in diameter. Nanosponges are solid porous particles that can load drugs and other active chemicals into their nanocavity. They can be topical, parenteral, oral, or inhaled. Nanosponges, which are about the size of viruses, can hold many drugs. These tiny sponges can move through the body until they reach the target, stick to the surface, and release the medication in a controlled and predictable manner. Recent interest in these materials stems from their potential in medication delivery, cancer therapy, and other biomedical sectors. Polymers, copolymers, and cross-linkers can be used to manufacture nanosponges with therapeutically tuned characteristics. They improve bioavailability, solubility, and sustained release of weakly water-soluble medicines. Nanosponges can also target cancer cells and deliver medications selectively. Nanosponges are diverse platforms for drug delivery and other biomedical applications, as shown in this review.

Keywords: Targeted drug delivery system, Bioavailability, nanosponges, cyclodextrin, Nanotechnology.

1. INTRODUCTION

Insoluble solid porous materials with typical nanometric porosity and absorption characteristics with complexation qualities are referred to as nanosponges. Both organic and inorganic substances are used in its synthesis¹. Nano sponges are a family of materials consisting of microscopic sponge-like structures with narrow cavities that are a few nanometers in diameter, with an average diameter of less than 1µm. They create a spherical shape with several chambers where the medicine can be kept by cross-linking the polyester segments. A variety of substances can be used to fill the tiny spaces². A revolutionary type of material consisting of tiny particles with new chambers just a few nanometers across, nanosponge can contain a wide variety of compounds³. Because the polyester is reliably biodegradable, the medicine can be released on a predetermined timetable as it breaks down in the body⁴. A wide range of medications that are insoluble on their own are entrapped by the voids, which encapsulate them in the matrix and increase their bioavailability⁵.

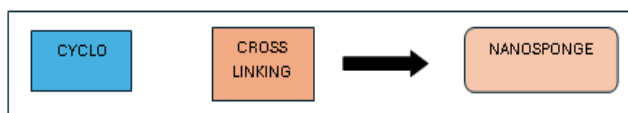


Figure 1: Formation of Nanosponges¹⁸

Nanosponge is a novel class of material made up of tiny particles with a hollow that is only a few nanometers wide. Many kinds of materials can be used to fill these little cavities⁶. A new class of nanoparticles, typically derived from natural sources, are represented by these nanosponges⁷. In addition to increasing the release rate and improving the drug's bioavailability, nanosponges can solubilize poorly water-soluble drugs⁸. For prolonged

release, skin retention, less toxicity, decreased variability in medication absorption, and improved patient compliance, a nanosponge could be placed topically. They can improve the effectiveness of medications in addition to lessening discomfort⁹. Additionally, nanosponges can be tailored to match certain therapeutic needs thanks to their adjustable pore size, surface charge, and degradation kinetics¹⁰. Nanosponges resemble a three-dimensional structure or network¹¹. Although the Nanosponge medication delivery system was first only used topically, it is now possible to administer Nanosponges orally or intravenously (IV) in the twenty-first century¹². It has been reported that the poor water solubility and gastrointestinal degradation of drug result in an extremely low oral bioavailability. Novel drug delivery strategies must be investigated to maximize Drug's therapeutic potential¹³.

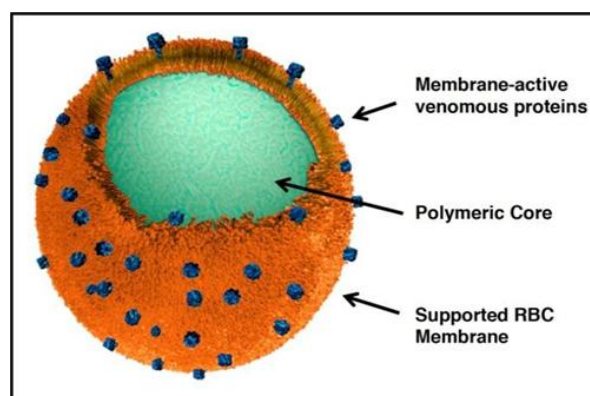


Figure 2: Structure of Nanosponges²⁶

Nanosponges have a number of alluring advantages, including minimal toxicity, excellent biocompatibility, and biodegradability¹⁴. Nanotechnology makes it feasible to create drugs with sizes in the nanoscale range, increasing their efficacy in a variety of dosage formats¹⁵. The goal of

nanotechnology is to manipulate the tiniest atom and molecular formations. Nanoparticles and nanosponges have connections to colloidal chemistry, physics, biology, medicine, pharmacy, and engineering¹⁶. Usually made from natural derivatives, nanosponges are a novel type of nanoparticle¹⁷. They are nontoxic, porous, and insoluble in organic solvents and water, which sets them apart from other nanoparticles¹⁸.

1.1 Advantages: ^{14,19,20,21,22}

- This method lowers negative effects, improves the solubility of poorly soluble medications, and traps components.
- Enhanced flexibility in formulation, enhanced elegance, and improved stability.
- These formulations exhibit stability across the pH range of 1 to 11.
- At temperatures as high as 1300C, these compositions remain stable.
- Biodegradable.
- Drug molecules should be released in a predictable way.
- These can be economical and free-flowing.
- These formulations alter the drug's release.
- They make poorly soluble drugs more soluble.
- Cost-effective and Free-Flowing: Nanosponges are cost-effective, which increases their appeal for a variety of applications, and they have free-flowing properties, which make them useful for drug delivery.
- Nanosponges have exceptional stability in terms of their thermal, physical, and chemical characteristics, which makes them a dependable option for drug delivery systems.
- The body may eliminate toxins and poisons with the help of nanosponges.
- This novel method can be applied to entrap active ingredients while reducing harmful effects and increasing stability.

1.2 Disadvantages ^{23,24,25,30}

- NSPs can only include small therapeutic molecules
- Their primary constraint is the possibility of dose dumping.
- They depend on the drug molecules' loading capacity.
- They only contain tiny molecules no large molecules are present.
- They may be crystalline in character.

1.3 Characteristic Features of Nanosponges ^{27,28,29,33}

- The size of nanosponges varies, and the cavities' polarity can be altered.
- Nanosponges of a specific size can be created by varying the ratio of cross-linker to polymer.
- They can be either crystalline or paracrystalline, depending on their manufacturing process.
- When complexing with pharmaceuticals, the crystal structure of the nanosponges is crucial.
- Both hydrophilic and lipophilic medicines can be entrapped by them.
- It provides customized distribution for BCS class II and IV medications, which include poor permeability and low solubility.
- A large variety of substances can be delivered effectively with the aid of the three-dimensional scaffold.
- For target drug delivery, nanosponge preparations come in topical, parenteral, oral, and inhalation forms.
- Their nature is non-mutagenic and non-immunogenic.
- The degree of crystallization of the medication determines its loading capacity.
- Numerous drug loading capacities can be demonstrated using paracrystalline nanosponges.
- They are porous, non-toxic particles that can tolerate temperatures of up to 300 degrees Celsius and are insoluble in most organic solvents.
- Their three-dimensional structure allows for the imaging, transportation, and selective release of different objects.
- They can remove organic impurities from water.

2. MATERIALS USED IN THE PREPARATION OF NANOSPONGES: ^{31,37}

Nano sponges are created using a variety of polymers, copolymers, and cross-linkers.

A. Polymers: Cyclodextrins and their derivatives, such as Alkyloxy carbonyl Cyclodextrins, Methyl β -Cyclodextrins, and Hydroxy Propyl β -Cyclodextrins; hypercross-linked polystyrenes.

B. Copolymers: Polyvinyl alcohol, Ethyl Cellulose, and Poly Lactone Poly Valero.

C. Crosslinkers: Diaryl carbonates, carboxylic acid dianhydrides, dichloromethane, and carbonyl diimidazoles are examples of crosslinkers. Pyromellitic anhydride, epichloridine, glutaraldehyde, diisocyanates, diphenyl carbonate, and 2,2-bis acetic acid.

3. MECHANISM OF DRUG RELEASE FROM NANOSPONGE:

Since the nanosponges are open and contain pores on their surface, meaning that there isn't a continuous membrane around them, the active ingredient is given to the vehicle in an encapsulated form. The active ingredient that is encapsulated can freely flow from the particles into the vehicle until the vehicle reaches saturation and equilibrium is reached. The active ingredient's carrier becomes unsaturated when the product is applied to the skin, upsetting the balance. Until the vehicle has either dried out or absorbed, the active will begin to move from the sponge particle into the vehicle and then from the vehicle to the skin. The release of active substances into the skin persists for a considerable amount of time even after the stratum corneum, the skin's surface, has been stripped of the nanosponge particles³⁴.

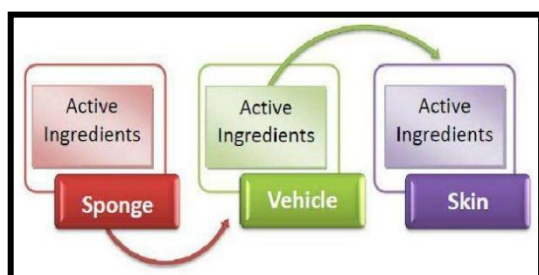


Figure-3: Mechanism of Topical use of drug release from nanosponge³⁵.

3.1 Mechanism of Parenteral use of drug release from nanosponges:

When the nanosponge formulation is placed within the rat vein in the presence of a non-ionizing light source, such as broadband light, lasers, or LEDs in the visible or infrared range. To modify the biological function of cells, Energy is produced from metabolic energy. Cancer cells then grow when the medication is delivered into the tumor cell. T-cells and lymphocytes infiltrate cancer cells. An invasive technique called tumor ablation is used to treat lung, kidney, liver, and bone tumors. To attain cytotoxic levels in the heart or cool tissue, thermal energy is utilized. Eventually, tumor cells die. In the presence of nanosponge uptake, the formulation binds to receptors and causes cell death. The drug is loaded into nanosponge.

4. METHOD OF PREPARATION OF NANOSPONGES:

Nano sponges are prepared depending on type of delivery systems.

4.1 Thermal Decomposition Method Materials:

often employs precursors such as metal alkoxides in conjunction with ceramic or metallic nanosponges.

Method of Preparation:

- Precursor Preparation: The metal precursor is made into a solution.

- Thermal Decomposition: The precursor breaks down and porous structures are formed when the solution is heated to high temperatures.
- Purification and Drying After washing the product to get rid of any leftover residue, it is dried³².

4.2 Quasi-emulsion solvent diffusion:

The nanosponges are made utilizing a quasi-emulsion solvent diffusion process with varying polymer proportions. Eudragit RS100 is manufactured by dissolving it in an appropriate solvent to form the inner phase. After that, the medication is added to the mixture and dissolved at 35 °c using ultrasonication. To separate the nanosponges, filter the mixture after adding the inner phase to the PVA solution in water and stirring for an hour. For 12 hours, the nanosponges are dried at 40°c in an air-heated oven³³.

4.3 Emulsion solvent diffusion method:

Organic and aqueous phases are used in this method. The aqueous phase consists of the PVA and organic phase include the drug and polymer. The drug and polymer are mixed with the organic solvents and it is added slowly to the aqueous phase and stirred for 2 hours or more. The Nano sponges are collected, filtered, washed and dried at room temperature or dried in an oven at 40°c for 24 hrs. Finally, products are stored in the vacuum desiccator to ensure the removal of residual solvent³⁶.

4.4 Ultra-sound assisted synthesis:

In a flask without a solvent, polymers are designed to react with crosslinkers. The flask is submerged in a water-filled, 90°C ultrasonic bath, and the mixture is sonicated for five hours³⁸.

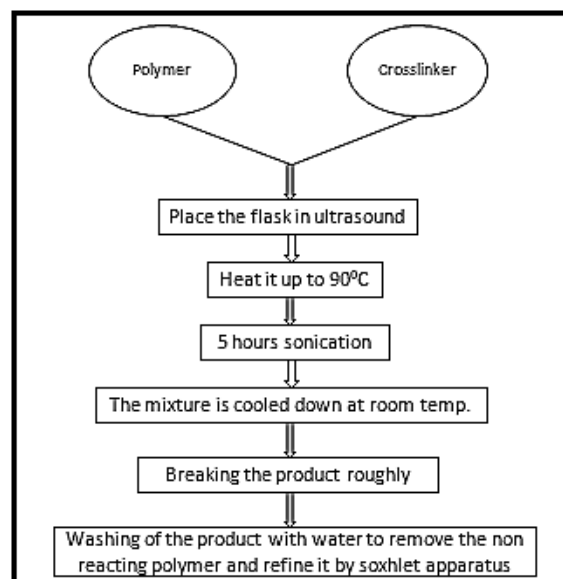


Figure 3: Flow diagram for the preparation of nanosponges by ultrasound-assisted method³⁸.

4.5 Hyper cross-linked beta cyclodextrins:

Crosslinking various cyclodextrin forms results in nanosponges with a carbonyl as a crosslinker. To make

them, cyclodextrin is combined with a cross-linker, such as diphenyl carbonate diisocyanates ³⁹.

4.6 Solvent method:

In Solvent Technique mix the polymer with polar aprotic solvents such as dimethylformamide and dimethyl sulfoxide to create nanosponges. A 1:4 crosslinker was added to this mixture. For 1 to 48 hours, the aforementioned reaction was carried out at a temperature of 10° to reflux the solvent's temperature. The product of the reaction is now add to bi-distilled water when the solution has cooled to room temperature. By filtering it under vacuum, the product is recovered. To get the finished product, the material is next dried and purified using Soxhlet extraction with ethanol ⁴⁰.

4.7 Nanosponges prepared from hyper cross-linked cyclodextrins:

The crosslinker and CDs are melted together in the melt process. After all the materials are thoroughly mixed, they are put in a 250 ml flask that was heated to 100°C. The reaction is then allowed to run for 5 hours while being stirred magnetically. After allowing the reaction mixture to cool and breaking down the resultant product, the unreacted excipients and byproducts are removed by repeatedly washing it with the appropriate solvents. The solvent technique eliminates the need for melting and dissolves the crosslinker in solvents such as dimethylformamide or dimethyl sulfoxide. Typically, the polymer is combined with an appropriate solvent especially a polar aprotic solvent and then added to an excess of the crosslinker. By altering the crosslinker/polymer molar ratio, the process is optimized. For 1 to 48 hours, the reaction is conducted at temperatures between 10°C and the solvent's reflux temperature. The carbonyl compounds diphenyl carbonate, dimethyl carbonate, or carbonyl diimidazole are the preferred crosslinkers for this process. The cooled solution is mixed with a significant amount of bi-distilled water to create the final product. Filtration under vacuum is used to recover the product, and prolonged Soxhlet extraction is used to further purify it ⁴².

5. CLASSIFICATION OF NANOSPONGES: ⁴¹

Various organic or inorganic materials are used to create nanosponges. Nanosponges are categorized into 5 kinds based on the type of material utilized in their synthesis.

- 5.1 Nanosponges based on cyclodextrin.
- 5.2 Nanosponges of hypercross-linked polystyrene.
- 5.3 Metallic nanosponges covered with carbon.
- 5.4 Nanosponges based on metal oxides, such as titanium.
- 5.5 Nanosponges made of silicon.

6. FACTORS AFFECTING FORMULATION OF NANOSPONGE:

6.1 Degree of substitution: The kind, amount, and location of the substituent on the parent molecule may have a

significant impact on the nanosponges capacity for complexation ⁴⁰.

6.2 Preparation method: The loading of the drug into the nanosponge formulation may affect the complexation. The kind of drug and polymer may influence the complexation. In several cases, freeze drying has been shown to be a more effective method for pharmacological complexation ⁴¹.

6.3 Temperature: Variations in temperature may impact the development of the drug-nanosponge combination. The apparent stability constant of the drug nanosponge complex generally diminishes as the temperature rises. This could be because as the temperature rises, drug nanosponge contact forces such hydrophobic and Vander Waal interactions decrease ⁴⁰.

6.4 Polymer type: The kind of polymer utilized can affect both the creation and functionality of nanosponges. The cavity size of nanosponges should be appropriate for complexation in order to hold a medication molecule of a specific size ⁴².

6.5 Drug Loading into Nanosponges: Drug delivery nanosponges should undergo pretreatment to achieve a mean particle size of less than 500 nm. To prevent aggregates, nanosponges are sonicated while suspended in water, and the suspension is subsequently centrifuged to extract the colloidal fraction. After separating the supernatant, the sample is freeze-dried. Another method involves making an aqueous suspension of nanosponges and dispersing an excess of medication in it while stirring continuously for the precise amount of time needed for complexation. Following complexation, centrifugation are used to separate the complexed and uncomplexed drugs. Then, either solvent evaporation or freeze drying are used to create solid crystals of nanosponges. The way that nanosponges complex with drugs is greatly influenced by their crystal structure ⁴³.

7. EVALUATION OF NANOSPONGES: ^{42,43,44,45}

Inclusion complexes formed between the drug and nanosponges can be characterized by following methods:

7.1 Solubility Studies: The phase solubility method, as outlined by Higuchi and Connors, is the most popular technique for studying inclusion complexes. It looks at how a nanosponge affects a drug's solubility. Phase solubility diagrams show the complexation level. Changes in the visitor's solubility are plotted against the concentration of cyclodextrin in solubility experiments. Complex formation in solution is indicated if the solubility of a potential guest increases as the concentration of cyclodextrin increases. To determine the impact of multi-component complexation on medication solubility and to analyse the drug's pH solubilization profile, solubility studies were conducted.

7.2 Thin Layer Chromatography: The Rf values of a drug molecule significantly decrease in Thin Layer Chromatography, which aids in determining the complex formation between the drug and nanosponge.



7.3 Resiliency: When required for the final formulation, the viscoelastic characteristics of sponges are altered to make beadlets that are harder and softer. Increased cross-linking tends to slow down the rate of release. By releasing the cross-linking function over time, resilience is examined in accordance with requirements.

7.4 Dissolution tests: The dissolution profile of nanosponges is determined using a dissolution apparatus USP that rotates at a speed of about 150 rpm and has a modified basket made of 5 ml stainless steel mesh. To guarantee sink conditions, the right dissolution medium is taken, and the solubility of the active ingredients is considered. For the sample form dissolution media, appropriate analytical techniques are applied.

7.5 Zeta Potential: Surface charge is measured by zeta potential. An extra electrode in the particle size apparatus are used to measure it. Zeta potential meters and laser Doppler anemometry are also useful.

8. APPLICATIONS OF NANOSPONGES:

8.1 Nanosponges for drug delivery: Water-insoluble medications can be effectively transported by nanosponges due to their nanoporous nature. These complexes can be used to turn liquids into solids, mask off offensive odours, and speed up the rate at which medications dissolve, become more soluble, and remain stable ⁴³.

8.2 Delivery of protein and peptides: Most protein medications are poorly absorbed across biological membranes due to their large molecular size, hydrophilic character, degree of ionization, high surface charge, chemical and enzymatic instability, and low permeability through mucous membranes. Following intravenous administration, protein molecules may be rapidly eliminated from the circulation, attach to plasma proteins, and be susceptible to proteolytic enzymes. Bioavailability is the problem with oral delivery. The development of proteins depends on their long-term stability. Proteins can, however, reversibly denature during lyophilization and thereafter acquire conformations that differ significantly from their native ones ⁴⁴.

8.3 Antiviral application: Nanosponges are administered via the pulmonary and nasal routes. Targeting viruses like influenza and rhinovirus that can cause RTI, it offers selectivity in delivering antiviral drugs via RNA to the lungs or nasal pathway using nanocarriers. Saquinavir and zidovudine are two medications that are utilized as nanocarriers ⁴⁵.

8.4 As absorbent in treating poison in blood: By absorbing the toxin, nanosponges can be employed to eliminate the harmful chemical from our blood. The toxins can be absorbed by injecting the nanosponges into the bloodstream. The nanosponge, which resembles a red blood cell in the bloodstream, deceives poisons into attacking it before absorbing them. The type of poison determines how many molecules of the toxin each nanosponge can absorb ⁴⁶.

8.5 Gaseous encapsulation: CD Carbonates based on NSs have been used to create enclosure complexes with carbon dioxide, oxygen, and 1 methylcyclopropene. Numerous biomedical applications can benefit from carbon dioxide and oxygen complexation, as NSs containing oxygen can efficiently supply hypoxic areas. The nanosponge were investigated as a gas transporter with controlled oxygen release because of their extremely porous structure. They have the potential to be a useful instrument for absorbing these gasses in the future. It has been discovered that alpha, β -, or gamma-CD can effectively trap O₂ over an extended period. These kinds of nanosponge can release oxygen with or without ultrasonography. However, an in vitro release study's findings indicate that ultrasonic enhances O₂ entry and liberation into cells ⁴⁷.

8.6 Transporter of enzymes, biocatalysts, proteins, vaccines and antibodies: Nanosponges are effective carriers for adsorbing macromolecules, proteins, enzymes, and antibodies, among other substances. Applying enzymes using nanosponge as a transporter can increase their usefulness, performance, and temperature range of activity.[48] Proteins and other macromolecules can be readily transported to nanosponge by adsorbing or encapsulating in them. When NS-based proteins, such as bovine serum albumin, form a compound with swell-capable poly amidoamine nanosponge, protein stability can be greatly increased ⁴⁹.

8.7 Cyclodextrin Nanosponges in Drug Discovery: Even at very low concentrations, cyclodextrin-based nanosponges can interact with organic molecules very strongly and extract them from water. By carefully combining polymer and cross linker, the same idea can be applied to remove bitter elements from grapefruit juice. With the aid of size exclusion chromatography, micro porous hypercross-linked nanosponges have been widely employed in the selective separation of inorganic electrolytes. Peptide fractionalization for proteomic applications will be greatly aided by the multi-dimensional nanosponge. Gases such as carbon dioxide and oxygen can be transported via nanosponges ⁵⁰.

8.8 Solubility Enhancement: Nanosponges provide a solution for drugs that have a very low solubility in water. Dispersing medications within the nanosponge structure enhances the dissolution process, which leads to an increase in apparent solubility ⁵¹.

8.9 Cancer Therapy: Nanosponges have become an essential element in the targeting of specific sites in cancer therapy. They address the challenges associated with a variety of nanocarriers, such as solid lipid nanoparticles, nanostructured lipid carriers, inorganic nanoparticles, polymeric nanoparticles and erythrocyte ghosts, in conventional drug delivery systems. Hydrophilic and hydrophobic medications can be allowed by nanosponges ⁵¹.

8.10 Other applications of Nanosponges: Even at very low concentrations, cyclodextrin-based nanosponges can firmly



bind and remove organic molecules from water. When polymer and crosslinker are combined selectively to remove bitter components from grapefruit juice, the same idea may be helpful. Peptide fractionalization can be aided by 3D-dimensional nanosponges for proteomic applications. Nanosponges could be employed as a means of transporting gases like carbon dioxide and oxygen²².

CONCLUSION

Nanosponges have emerged as a promising platform for drug delivery and other biomedical applications. Their unique properties, such as tunable pore size, surface charge, and degradation kinetics, make them an attractive option for delivering therapeutic agents in a controlled and targeted manner. The ability of nanosponges to improve the solubility of poorly water-soluble drugs, enhance bioavailability, and provide sustained release of therapeutic agents has significant implications for the treatment of various diseases, including cancer. Further research is needed to fully explore the potential of nanosponges and to develop standardized protocols for their synthesis and characterization. However, the existing evidence suggests that nanosponges have the potential to revolutionize the field of drug delivery and provide new opportunities for the treatment of complex diseases.

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