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# Nanosponges: A Novel Class of Drug Delivery System

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## Abstract

Achieving effective targeted drug delivery systems has been an aspiration for quite some time, but this goal has often been hindered by the intricate chemistry involved in creating new systems. The development of nanosponges represents a significant advancement in addressing these challenges. Nanosponges are nanoscale porous carriers comparable in size to certain viruses, capable of containing a diverse range of drugs. Traditional topical drug delivery systems encounter numerous issues such as limited permeability, skin irritation, and allergic reactions. The newly developed colloidal system known as nanosponges has the potential to mitigate these concerns. These tiny sponges, measuring between 250 nm and 1 μm, have cavities that can be filled with various drugs. They improve solubility, enhance bioavailability, decrease side effects, and alter drug release. Nanosponge-based drug delivery systems have emerged as one of the most promising approaches in pharmaceutical sciences.

Keywords: Nanosponge, Minuscule, Topical Delivery, Colloidal System, Bioavailability.

## Introduction

Medical researchers have long faced challenges in achieving targeted drug delivery, i.e., delivering therapeutic agents to the desired site of action and regulate their release to prevent overdoses. These issues may be resolved by the creation of novel, intricate molecules known as nanosponges. A wide range of chemicals can be contained in nanosponges, a novel class of materials composed of minuscule particles having cavities that are only a few nanometers wide. Both lipophilic and hydrophilic compounds can be carried by these particles, which can also increase the solubility of molecules that are weakly soluble in water [1]. The rise of new and intricate molecules known as nanosponges holds promise for addressing these issues. Nanosponges represent a novel category of materials consisting of tiny particles with cavities measuring just a few nanometers, which can encapsulate a wide range of substances. These particles can transport both lipophilic and hydrophilic compounds and enhance the solubility of molecules that are poorly water-soluble [2].

The nanosponge is roughly the size of a virus and has a “backbone” (a scaffold structure) made of naturally degradable polyester. The long polyester strands are combined in solution with small molecules known as cross-linkers, which have an affinity for specific parts of the polyester. They “cross-link” segments of polyester to create a spherical shape with several pockets (or cavities) for drug storage. The polyester is reliably biodegradable, so as it

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breaks down in the body, the medicine can be delivered on a predictable timetable [3]. Their unique properties, such as high surface area, tunable porosity, chemical stability and biocompatibility, make them ideal candidates for advanced drug delivery applications.

## Historical Background and Development

The development of Nanosponges is closely linked to the evolution of nanotechnology and polymer science:

- **1960s-1970s: Foundation of Controlled Drug Delivery:** The concept of controlled drug release began during this time. Focusing on improving therapeutic efficiency and reducing dosing frequency, early systems included polymers and reservoir-based delivery devices
- **1980s: Emergence of cyclodextrins:** Cyclodextrins were introduced as drug carriers due to their ability to form inclusion complexes with hydrophobic drugs. This marked an important step towards improving drug solubility and stability [26].
- **1990s: Crosslinked Cyclodextrin Polymers:** Researchers began developing crosslinked cyclodextrin networks which led to the formation of porous structures resembling nanosponges. These materials showed enhanced drug encapsulation capacity.
- **Early 2000s: Introduction of Nanosponges:** The term nanosponges was introduced when scientists developed the nanoporous structures capable of trapping and releasing drugs in a controlled manner. This system was initially explored for topical drug delivery and later expanded to oral and parenteral routes [27].
- **2010-2015: Expansion in Pharmaceutical Applications:** During this period, nanosponges gained attention for
  - Cancer drug delivery
  - Solubility enhancement for poorly soluble drugs
  - Targeted delivery system

  Researchers demonstrated improved therapeutic outcomes and reduced toxicity
- **2016-Present: Advanced and Smart Nanosponges:** Recent developments include stimuli responsive nanosponges, DNA-based and biomimetic nanosponges, Application in antiviral therapy toxin removal and environmental remediation. Nano sponges are now being chemically explored in precision medicine and nanomedicine, showing significant clinical potential [28].

## Chemicals Used in Synthesis of Nanosponges

The drug candidates intended for encapsulation within NS must possess certain characteristics. The drug's molecular weight must fall within the range of 100 to 400 daltons. Drug molecules must consist of fewer than five fused rings. The drug's melting point must be below 250°C [4]. In addition to the drug, other necessary chemicals for synthesizing NS are listed in Table 1 [5-7]. The selection of polymer in the formulation can influence the performance of NS. The polymer must be chosen based on the needed drug release and type of drug to be encapsulated. CD-based NSs can also be produced by creating covalent bonds between the CDs and a particular multifunctional agent referred to as a crosslinker (Table 2) [8]. Cross-linkers are selected according to the structural characteristics of the polymer and the drug intended for the formulation.


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**Table 1:** Different chemicals used for synthesis of nanosponges [5-7].

| Material | Examples |
|---|---|
| Polymers | Hyper cross-linked polystyrene, CDs and its derivatives like methyl $\beta$-cyclodextrin ($\beta$-CD), alkyloxy carbonyl CDs, 2-hydroxy propyl $\beta$-CDs, Eudragit, Ethyl Cellulose, Pluronic F-68 (Poloxamer 188), Pluronic F-127 (Poloxamer 407) |
| Copolymers | Ethyl cellulose, poly (valero lactone-allylvalero lactone) and poly (valero lactone-allyl valero lactone oxepanedione), polyvinyl alcohol (PVA), hydroxypropyl methylcellulose (HPMC) |
| Cross-linkers | Diphenyl carbonate, di-aryl carbonates, di-isocyanates, acetic acid, pyromellitic anhydride, carbonyl di-imidazole, glutaraldehyde, epichloridrine, carboxylic acid di-anhydrides, 2,2-bis (acrylamidos), dichloromethane |
| Aprotic solvents | Methanol, ethanol, dimethylacetamide, dimethyl sulphoxide, dimethylformamide |

**Table 2:** Different crosslinkers used in the synthesis of cross linker based nanosponges [8].

| Types of CD based NSs | Cross-linkers |
|---|---|
| Carbonate | Carbonyls: diphenyl carbonate (DPC); 1,1'-carbonyl diimidazole (CDI); dimethyl carbonate (DMC) and triphosgene |
| Carbamate | Diisocyanates: 1,6-hexamethylene diisocyanate (HDI); methylene diphenyl diisocyanate (MDI), toluene 2,4-diisocyanate (TDI) and toluene 2,6-diisocyanate |
| Ester | Dianhydrides: pyromellitic dianhydride (PMA); ethylenediaminetetraacetic acid dianhydride (EDTA), Epiclon-B-4400; dialcohol 2-hydroxyethyl disulfide (2-HEDS) can be use together with PMA to introduce disulfide bonds Carboxylic acids: citric acid (CA) and 2,6-naphthalene dicarboxylic acid (NDCA) |
| Ether | Epoxides: epichlorohydrin; 1,4-butanediol diglycidylether (BDE); E-51 epoxy resin |
| Polyamidoamine | 2,2'-bis(acrylamido)acetic acid and its polyamidoamine derivates (PAA) formed by reaction with amines (such as 2-methylpiperazine) |
| Polyamine | Polyamines: 1,6-hexanediamine (am6), 1,8-octanediamine, 1,12-dodecanediamine (am12) |

## Synthesis of Nanosponges

- **Solvent method:** Combine the polymer with an appropriate solvent, specifically a polar aprotic solvent such as dimethylformamide or dimethylsulfoxide. Next, introduce this mixture to an excess of the cross-linker, ideally using a crosslinker/polymer molar ratio between 4 and 16. Conduct the reaction at temperatures between 10°C and the reflux temperature of the solvent, for durations of 1 to 48 hours. The preferred crosslinkers are carbonyl compounds like dimethyl carbonate and carbonyl diimidazole [9]. Once the reaction has finished, permit the solution to reach room temperature. Next, introduce the


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product into a significant excess of bidistilled water and retrieve the product through vacuum filtration. Afterwards, purify the product by extended soxhlet extraction with ethanol. Eliminate moisture from the product under vacuum and process it in a mechanical mill to achieve a uniform powder [10].

- **Nanosponge prepared from hyper crosslinked cyclodextrin :** Nanosponges can be prepared by both melt and solvent methods. In the melt method, cyclodextrins are mixed with a crosslinker and heated at 100 °C for 5 h under magnetic stirring. After cooling, the product is washed to remove unreacted materials and purified. In the solvent method, the crosslinker is dissolved in a polar aprotic solvent such as DMF or DMSO and reacted with the polymer at 10 °C to the solvent's boiling point for 1–48 h. The crosslinker-to-polymer ratio is optimized to obtain the desired product. The resulting nanosponges are recovered by precipitation in bidistilled water, followed by vacuum filtration and Soxhlet extraction for purification [11,12].
- **Ultarsound Assisted synthesis**: In this approach, nanosponges are produced by reacting polymers with cross-linking agents without the use of a solvent and through the application of sonication. The resulting nanosponges from this process will be spherical and consistent in size [13]. Combine the polymer and the cross-linker in a specified molar ratio within a flask. Immerse the flask in an ultrasonic bath filled with water and heat it to 90°C. Sonicate the blend for 5 hours. After sonication, let the mixture cool and then break the product into rough pieces. Rinse the product with water to eliminate any unreacted polymer, followed by purification through extended soxhlet extraction using ethanol. Dry the resulting product in a vacuum and store it at 25°C until needed for further applications [13].

## Aspects Affecting Formation of Nanosponges

- **Type of polymer:** The kind of polymer utilized can affect both the development and the effectiveness of nanosponges.
- **Type of drug:** Drug molecules intended for complexation with nanosponges should possess specific attributes outlined below [14].

1. A molecular weight ranging from 100 to 400

ii. The drug molecule should contain fewer than five condensed rings

iii. Water solubility must be under 10 mg/mL

iv. The substance should have a melting point lower than 250°C.

- **Temperature:** Alterations in temperature can influence the complexation of Drug/Nanosponge. Typically, a rise in temperature leads to a reduction in the magnitude of the apparent stability constant for the Drug/Nanosponge complex, which may be attributed to a possible decrease in the interactions between the drug and the nanosome, such as van der Waals forces and hydrophobic interactions, as the temperature increases [15].

- **Method of preparation:** The way the drug is loaded into the nanosponge can influence the complexation between the drug and the nanosponge. Nevertheless,


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the success of a particular method is contingent upon the characteristics of both the drug and the polymer; often, freeze drying has proven to be the most efficient method for drug complexation [16].

- **Degree of Substitution**: The ability of the nanosponge to form complexes could be significantly influenced by the type, quantity, and placement of the substituents on the parent molecule [17].

## Characterisation of Nanosponges

Inclusion complexes created between the drug and nanosponges can be analyzed using the following techniques.

1. **Thermo-analytical methods:** Thermo-analytical techniques assess whether the drug substance experiences any alterations before the thermal degradation of the nanosponge. Alterations in the drug substance could involve melting, evaporation, decomposition, oxidation, or polymorph transitions. These changes in the drug substance suggest the formation of complexes. The thermogram obtained from DTA and DSC can reveal broadening, shifting, the emergence of new peaks, or the disappearance of existing peaks. Additionally, changes in weight loss can further indicate the formation of inclusion complexes [18].
2. **Microscopy Studies:** Scanning Electron Microscopy (SEM) and Transmission Electron Microscopy (TEM) are techniques that can be utilized to examine the microscopic characteristics of the drug, nanosponges, and the end product (the drug/nanosponge complex). The variations in the crystallization states of the raw materials compared to the final product observed under the electron microscope suggest the creation of inclusion complexes [19].
3. **X-ray diffraction and single-crystal X-ray structure analysis:** X-ray diffraction (XRD) is widely used to confirm inclusion complex formation in the solid state. The diffraction pattern of a drug-nanosponge complex differs from that of the pure drug, nanosponge, or their physical mixture, indicating successful complexation. Changes such as the appearance of new peaks, disappearance or shifting of existing peaks, and alterations in crystallinity provide evidence of drug encapsulation within the nanosponge matrix. Additionally, single-crystal X-ray analysis can be employed to determine the inclusion structure and the precise host-guest interactions between the drug and nanosponge molecules [20].
4. **Solubility Studies:** The phase solubility method established by Higuchi and Connors is the most commonly utilized technique for investigating inclusion complexation, analyzing how a nanosponge influences drug solubility. Phase solubility diagrams reveal the extent of complexation [21,22].
5. **InfraRed Spectroscopy:** Infrared spectroscopy is employed to assess the relationship between nanosponges and drug molecules in their solid form. Changes in nanosponges' bands typically remain minimal when a complex is formed, and if less than 25% of the guest molecules are encapsulated in the complex, the bands associated with the included portions of the guest molecules can be easily obscured by the bands present in the nanosponges' spectrum. This technique is typically not effective for identifying inclusion complexes and is not as clear as other methods [23]. The use of Infra-red spectroscopy is restricted to drugs that possess specific characteristic bands, like carbonyl or sulfonyl groups. Infrared spectral analysis provides insights into the participation of hydrogen in different functional groups. This typically results in a downward shift of the absorbance bands, increases in intensity, and broadening of the bands due to the stretching vibrations of the groups that form hydrogen bonds. Within this context, hydrogen bonding at the hydroxyl group leads to the most significant shift in the stretching vibration band [24].


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6. **Thin Layer Chromatography:** In Thin Layer Chromatography, the Rf values of a drug molecule significantly decrease, aiding in the identification of the formation of complexes between the drug and the nanosponge [25].
7. **Loading Efficiency:** The loading efficiency of nanosponges can be assessed by quantitatively measuring the amount of drug incorporated into nanosponges using UV spectrophotometry and HPLC techniques.

***Figure 1:*** *Overview of analytical techniques utilized for the physicochemical characterization of nanosponge inclusion complexes.*

## Physicochemical Characterisation of Nanosponges

1. **Particle size determination** By regulating particle size during polymerization, it will be possible to achieve free-flowing powders with appealing aesthetic qualities. The analysis of particle size for both loaded and unloaded nanosponges will be conducted using laser light diffractometry or a Malvern Zeta sizer. The cumulative percentage of drug release from nanosponges with varying particle sizes will be graphed against time to examine the influence of particle size on drug release. Particles exceeding 30 micrometers can create a gritty texture; therefore, particles sized between 10 and 25 micrometers are preferred for the final topical formulation [26].
2. **Determination of loading efficiency and production yield** The efficiency of drug loading in the prepared nanosponge is assessed by deducting the unentrapped drug from the overall quantity of drug. The efficiency of drug entrapment will be evaluated by isolating the unentrapped drug through an appropriate analytical method. Techniques such as gel filtration, dialysis, and ultra- centrifugation are employed for the separation of unentrapped drug.

**The loading efficiency is calculated using the formula:** Loading efficiency = (Actual drug content in nanosponge / Theoretical drug content) × 100. The production yield of the nanosponge can be calculated by precisely measuring the initial weight of the raw materials and the final weight of the produced nanosponge.

Production yield = Actual mass of nanosponge / Theoretical mass (drug + polymer) × 100

3. **Porosity**: A porosity analysis is conducted to evaluate the extent of nanochannels and nanocavities present. The porosity of nanosponges is measured using a helium pycnometer, as helium gas can infiltrate both inter- and intra-particular channels in materials. The actual volume of the material is established through the helium displacement method. Due to their porous characteristics, nanosponges display greater porosity than the original polymer utilized to create the system. The percentage of porosity is represented by the equation [27]:

%Porosity = (Bulk volume - True volume) / Bulk volume × 100.

4. **Swelling and water uptake:**To assess water absorption in swellable polymers such as polyamidoamine nanosponges, the nanosponges should be immersed in an aqueous solution. The swelling and water absorption can be computed using the equations [8][13]. % Swelling = Measurement on the cylinder at a designated time / Initial measurement before immersion × 100.

% Water uptake = Mass of the hydrogel after 72 hours / Initial mass of the dry polymer × 100.

5. **Resiliency (Viscoelastic properties)** : The flexibility of sponges can be adjusted to create beadlets that are either softer or firmer based on the final formulation's requirements. A higher degree of crosslinking generally reduces the speed of release. Therefore, the resilience of sponges will be


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analyzed and fine-tuned according to the specifications by treating the release as a variable dependent on cross-linking.

6. **In vitro release studies**: The dissolution profile of Nanosponge can be investigated using the dissolution apparatus USP XXIII, equipped with a modified basket made of 5m stainless steel mesh. The rotation speed is set at 150 rpm. The dissolution medium is chosen based on the solubility of the active ingredients to maintain sink conditions. Samples taken from the dissolution medium can be evaluated using an appropriate analytical technique. The dissolution apparatus USP XXIII, along with the modified basket made of 5m stainless steel mesh, is employed for this analysis. The speed of rotation is maintained at 150 rpm. The selection of the dissolution medium is made with the solubility of the active compounds in mind to ensure sink conditions. Samples from the dissolution medium can be analyzed using a suitable analytical method [28].

## Advantages of Nanosponges [29-31]

1. This technology allows for the encapsulation of ingredients and minimizes side effects.
2. Enhanced stability, greater elegance, and improved formulation versatility.
3. These formulations maintain stability across a pH range of 1 to 11.
4. These formulations remain stable at temperatures of up to 1300C.
5. These formulations work well with most vehicles and ingredients.

## Applications of Nanosponges

1. Nanosponges are utilized for drug delivery due to their nanoporous design, which allows them to effectively transport water-insoluble medications (specifically class-II drugs according to the Biopharmaceutical Classification System ).
2. Nanosponges have a solid structure and can be developed into various dosage forms, including Oral, Parenteral, Topical, or Inhalation routes. Drugs with sizes in the nanoscale range can be produced thanks to nanotechnology, boosting their effectiveness in a range of dosage forms [32].
3. The nanosponge delivery system is an innovative technology designed for the controlled release of topical agents, enabling prolonged drug release and retention on the skin. Local anesthetics, antifungal agents, and antibiotics are examples of drugs that can be easily formulated using topical nanosponges. When active ingredients penetrate the skin, they can cause rashes or more severe side effects. In contrast, this technology provides a steady and uniform rate of release, minimizing irritation while ensuring effectiveness. A diverse range of substances can be included in a formulated product such as gels, lotions, creams, ointments, liquids, or powders [33].
4. Econazole nitrate is an antifungal medication used topically to alleviate symptoms of superficial candidiasis, dermatophytosis, versicolor, and skin infections, and it is available in forms such as cream, ointment, lotion, and solution. When applied to the skin, the absorption of econazole nitrate is minimal, necessitating a high concentration of active ingredients for effective treatment Therefore, Nanosponge formulations of econazole nitrate were created


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using the emulsion solvent diffusion technique, and these Nanosponges were incorporated into a hydrogel to serve as a local depot for prolonged drug release [34].

5. Numerous industrial processes involving chemical transformations face operational challenges. Non-specific reactions often result in poor yields, and the necessity to operate at elevated temperatures and pressures leads to significant energy consumption and substantial cooling water demands in the downstream processes. However, these issues can be eliminated or greatly minimized by utilizing enzymes as biocatalysts. These enzymes function under mild reaction conditions, exhibit rapid reaction rates, and demonstrate high specificity. They positively impact the environment by lowering energy usage and minimizing pollutant generation. The catalytic effectiveness of an enzyme primarily relies on the proper orientation of its active site [35].
6. The nanosponge system contains pores that enhance the solubilisation rate of poorly soluble drugs by capturing them within these pores. The nanoscale size significantly expands the surface area, which further accelerates the solubilisation process.

## Conclusion

Nanosponge are colloidal carriers at the nanoscale, allowing them to easily penetrate the skin. Their tiny size and porous structure enable them to bind poorly soluble medications within their matrix, enhancing the bioavailability of these drugs and improving their solubility. Composed of nano-sized polymeric spheres, nanosponges can suspend or entrap a diverse range of substances, which can then be incorporated into various formulated products such as gels, lotions, creams, ointments, liquids, or powders. This innovative technology allows for the entrapment of ingredients, leading to minimized side effects, better stability, enhanced appeal, and increased formulation versatility. Nanosponges can be effectively utilized in topical drug delivery systems, ensuring the dosage form remains on the skin, as well as for oral drug delivery through bioerodible polymers, particularly for targeted colon delivery and controlled release, thereby improving patient adherence with site-specific drug administration and extended dosage intervals. These nanosponges can accommodate both lipophilic and hydrophilic drugs and release them in a controlled and predictable manner at the desired location.

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