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A Review: Nanosponge Drug Delivery System

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Abstract: ***The nanosponge drug delivery system has emerged as a revolutionary approach in pharmaceutical nanotechnology, offering significant improvements in drug solubility, stability, and bioavailability. These porous, nano-sized carriers (typically ranging from 10–1000 nm) are composed of hyper-cross-linked polymers such as cyclodextrins, polyesters, or polyamales, forming a three-dimensional network capable of entrapping both hydrophobic and hydrophilic drugs. Their unique structural properties enable controlled, sustained, and targeted drug release, minimizing side effects and enhancing therapeutic efficacy. Nanosponges are particularly advantageous for poorly water-soluble drugs (BCS Class II & IV), protecting them from chemical degradation, enzymatic hydrolysis, and pH variations. They can be engineered for various administration routes, including oral, topical, transdermal, ocular, and pulmonary delivery. Recent advancements explore stimuli-responsive nanosponges that release drugs in response to pH, temperature, or enzymes, as well as hybrid nanosponges combined with liposomes or nanoparticles for multifunctional applications. This review comprehensively discusses the fabrication techniques (e.g., emulsion solvent diffusion, ultrasound-assisted synthesis), characterization methods (DLS, SEM, BET analysis), and biomedical applications (cancer therapy, antiviral delivery, protein encapsulation). Despite their potential, challenges such as scalability, long-term toxicity, and regulatory approval remain. Future research focuses on personalized nanosponge formulations and clinical translation, paving the way for next-generation drug delivery systems.***

Keywords: ***Nanosponge drug delivery, Cyclodextrin-based nanosponges, Controlled drug release, Enhanced drug solubility, Stimuli-responsive nanocarriers, Targeted drug delivery, Poorly water-soluble drugs, Biocompatible polymers***

I. INTRODUCTION

The rapid advancements in nanotechnology have revolutionized drug delivery systems, with nanosponges emerging as a promising approach to overcome the limitations of conventional formulations [1]. These nanostructured, porous carriers exhibit a unique three-dimensional network capable of encapsulating a wide range of therapeutic agents, including hydrophobic drugs, proteins, and genetic material [2]. Nanosponges are typically composed of cross-linked polymers, with cyclodextrins being the most extensively studied due to their biocompatibility and ability to form inclusion complexes [3]. By modulating their porosity and surface properties, nanosponges can achieve controlled and sustained drug release, enhancing therapeutic efficacy while minimizing adverse effects [4].

One of the key challenges in pharmaceutical sciences is the poor aqueous solubility of many active compounds, which restricts their bioavailability and clinical utility [5]. Nanosponges address this issue by providing a high drug-loading capacity and improving dissolution rates [6]. Additionally, their versatile structure allows for surface functionalization, enabling targeted delivery to specific tissues such as tumors or inflamed sites [7]. Recent studies have also explored stimuli-responsive nanosponges that release payloads in response to pH, temperature, or enzymatic triggers, further optimizing drug delivery precision [8].

Beyond solubility enhancement, nanosponges offer protection against drug degradation from light, oxidation, and enzymatic breakdown, making them suitable for sensitive biologics [9]. Their applications span cancer therapy, antimicrobial delivery, wound healing, and neurological disorders, demonstrating broad biomedical potential [10].

However, challenges such as large-scale production, stability, and regulatory hurdles must be addressed to facilitate clinical translation [11]. This review comprehensively examines the fabrication, characterization, mechanisms, and therapeutic applications of nanosponge-based drug delivery systems, highlighting recent innovations and future directions in the field [12].

II. COMPOSITION IN NANOSPONGES

Nanosponges are primarily composed of three key components: polymers, cross-linkers, and active pharmaceutical ingredients (APIs), along with solvents that facilitate their formation. The most widely used polymers include cyclodextrins (α, β, and γ), which form a hydrophobic cavity capable of entrapping drug molecules, enhancing solubility and stability[13] Other synthetic and natural polymers such as polyvinyl alcohol (PVA), ethyl cellulose, poly (lactic-co-glycolic acid) (PLGA), and polyurethanes are also employed to improve structural integrity and drug-loading efficiency.[14]

Cross-linking agents play a crucial role in forming the porous, sponge-like architecture of nanosponges. Commonly used cross-linkers include diphenyl carbonate (DPC), carbonyl diimidazole (CDI), and pyromellitic anhydride, which react with hydroxyl groups of cyclodextrins or other polymers to create a stable three-dimensional network.[15] The degree of cross-linking influences drug release kinetics, with higher cross-linking densities resulting in slower, more sustained release profiles.[16]

The active pharmaceutical ingredient (API) is encapsulated within the nanosponge matrix, either by inclusion complexation (for cyclodextrin-based nanosponges) or physical entrapment (for polymer-based nanosponges).[17] Both hydrophobic and hydrophilic drugs can be incorporated, making nanosponges versatile for various therapeutic applications. Additionally, co-solvents such as dimethylformamide (DMF) and dimethyl sulfoxide (DMSO) are often used during synthesis to ensure proper polymer dissolution and homogeneous drug distribution.[18]

Recent advancements have introduced surface-modified nanosponges, where targeting ligands (e.g., folic acid, antibodies) or stealth coatings (e.g., polyethylene glycol, PEG) are attached to enhance site-specific delivery and prolong circulation time.[19] The choice of materials depends on the desired drug release profile, biocompatibility, and intended route of administration.

III. METHOD OF PREPARATION

The preparation of nanosponges involves various techniques to achieve a highly porous, cross-linked polymeric structure capable of efficient drug encapsulation. The most commonly used methods include emulsion solvent diffusion, ultrasound-assisted synthesis, solvent method, and quasi-emulsion solvent diffusion, each offering distinct advantages in terms of particle size control, drug loading efficiency, and scalability.

1) Emulsion Solvent Diffusion Method The emulsion solvent diffusion technique is widely employed for nanosponge fabrication due to its simplicity and reproducibility. In this method, the polymer (e.g., cyclodextrin) and drug are dissolved in a water-miscible organic solvent (e.g., ethanol or acetone). This solution is then emulsified in an aqueous phase containing a stabilizer (e.g., polyvinyl alcohol) under mechanical stirring or homogenization. The organic solvent diffuses into the aqueous phase, leading to polymer precipitation and the formation of nanosponges. The resulting particles are collected via centrifugation or filtration, followed by lyophilization to obtain a dry powder. [20]
2) Ultrasound-Assisted Synthesis Ultrasound-assisted synthesis enhances the cross-linking efficiency and reduces particle size through cavitation effects. In this approach, cyclodextrin and a cross-linker (e.g., diphenyl carbonate) are dispersed in a solvent, and ultrasonic waves are applied to facilitate rapid and uniform polymerization. The high-energy sonication breaks down aggregates, resulting in smaller, more homogeneous nanosponges with improved drug-loading capacity. This method is particularly useful for thermolabile drugs, as it operates at lower temperatures compared to conventional heating methods. [21]
3) Solvent Method (Direct Cross-Linking) The solvent method involves direct cross-linking of cyclodextrins with a bifunctional agent (e.g., carbonyl diimidazole or pyromellitic anhydride) in a controlled solvent system (e.g., dimethylformamide or dimethyl sulfoxide). The reaction is typically carried out under reflux conditions with continuous stirring to ensure uniform cross-linking. The resulting nanosponge network is then purified via dialysis or repeated washing to remove unreacted reagents. This method allows precise control over porosity and drug release kinetics. [22]
4) Quasi-Emulsion Solvent Diffusion This technique is particularly useful for hydrophobic drugs, as it improves encapsulation efficiency. The drug and polymer are dissolved in a partially water-miscible solvent (e.g., ethyl acetate), which is then emulsified in an aqueous phase. As the solvent diffuses out, nanosponges precipitate, entrapping the drug within their matrix. The process is optimized by adjusting stirring speed, temperature, and surfactant concentration to achieve desired particle characteristics. [23]

IV. CHARACTERIZATION OF NANOSPONGES

The characterization of nanosponges is crucial to ensure their physicochemical properties, drug-loading efficiency, and release kinetics align with therapeutic requirements. Various analytical techniques are employed to evaluate these parameters. Particle size and zeta potential are determined using dynamic light scattering (DLS), which provides insights into the hydrodynamic diameter and colloidal stability of nanosponges in suspension [24]. A narrow size distribution (typically 100–500 nm) is desirable for optimal drug delivery, while a zeta potential above ±30 mV indicates good stability by preventing aggregation [25]. Scanning electron microscopy (SEM) and transmission electron microscopy (TEM) are used to examine the morphology and porosity of nanosponges, revealing their sponge-like, highly porous structure [26].

The surface area and pore size distribution are analyzed using Brunauer-Emmett-Teller (BET) nitrogen adsorption-desorption, which confirms the high surface area (often >100 m^2/g) essential for efficient drug loading [27].

Differential scanning calorimetry (DSC) and thermogravimetric analysis (TGA) assess the thermal stability and crystallinity of nanosponges, ensuring that the drug remains stable within the polymer matrix [28]. X-ray diffraction (XRD) helps determine whether the encapsulated drug exists in an amorphous or crystalline state, which influences dissolution rates [29].

Drug loading and encapsulation efficiency are quantified using UV-Visible spectroscopy or high-performance liquid chromatography (HPLC), ensuring optimal therapeutic payload [30]. In vitro drug release studies in simulated physiological conditions (e.g., PBS at pH 7.4 or gastric fluid at pH 1.2) help predict the release kinetics, which can be modulated for immediate, sustained, or stimuli-triggered delivery [31]. Additionally, Fourier-transform infrared spectroscopy (FTIR) confirms the absence of undesirable chemical interactions between the drug and polymer [32]. Collectively, these characterization techniques ensure that nanosponges meet the necessary criteria for efficacy, safety, and scalability in drug delivery applications.

V. ADVANTAGES OF NANOSPONGES

1) Enhanced Drug Solubility and Bioavailability: Nanosponges can encapsulate poorly water-soluble drugs (BCS Class II and IV), significantly improving their solubility and dissolution rates. This property is particularly beneficial for drugs with low oral bioavailability, such as curcumin and paclitaxel [33].
2) Controlled and Sustained Drug Release: The porous, three-dimensional structure of nanosponges allows for tunable drug release kinetics, reducing dosing frequency and minimizing peak-and-valley plasma drug concentrations [34].
3) Protection of Labile Drugs: Nanosponges shield sensitive drugs (e.g., proteins, peptides, and nucleic acids) from degradation due to light, pH variations, or enzymatic activity, thereby enhancing stability [35].
4) Targeted Drug Delivery: Surface-modified nanosponges can be functionalized with ligands (e.g., folic acid, antibodies) for active targeting to specific tissues, such as tumors or inflamed sites, reducing off-target effects [36].
5) Biocompatibility and Low Toxicity: Since many nanosponges are made from biodegradable polymers like cyclodextrins and polyesters, they exhibit excellent biocompatibility and minimal systemic toxicity [37].
6) Versatility in Drug Loading: Nanosponges can encapsulate a wide range of therapeutics, including small molecules, proteins, genes, and even gases (e.g., oxygen for wound healing) [38].
7) Improved Topical and Transdermal Delivery: Their nano-sized structure enhances skin permeation, making them ideal for dermatological applications, such as antifungal and anti-inflammatory treatments [39].
8) Stimuli-Responsive Release: Advanced nanosponges can be engineered to respond to specific triggers (e.g., pH, temperature, or enzymes), enabling site-specific drug release in conditions like cancer or infections [40].

VI. APPLICATIONS IN DRUG DELIVERY

Nanosponges have demonstrated remarkable potential in various drug delivery applications due to their unique structural and functional properties. One of the most promising applications is in cancer therapy, where nanosponges improve the delivery of chemotherapeutic agents such as paclitaxel and doxorubicin. Their ability to encapsulate hydrophobic drugs enhances solubility, while surface modifications with targeting ligands (e.g., folic acid or antibodies) enable tumor-specific delivery, reducing systemic toxicity and improving therapeutic efficacy [41]. Additionally, stimuli-responsive nanosponges that release drugs in response to the acidic tumor microenvironment or overexpressed enzymes further enhance precision in cancer treatment [42].

In topical and transdermal drug delivery, nanosponges enhance skin permeation and retention of drugs such as antifungals (e.g., clotrimazole) and anti-inflammatory agents (e.g., dexamethasone). Their porous structure allows for sustained release, minimizing irritation and improving patient compliance [43]. For oral drug delivery, nanosponges overcome the challenges of poor bioavailability associated with BCS Class II and IV drugs. Studies have shown improved absorption of drugs like curcumin and resveratrol, attributed to prolonged gastrointestinal retention and protection from enzymatic degradation [44].

Nanosponges also show promise in ocular and pulmonary drug delivery, where conventional formulations face rapid clearance and low bioavailability. By encapsulating drugs such as timolol (for glaucoma) or budesonide (for asthma), nanosponges prolong drug residence time and reduce dosing frequency [45]. Furthermore, their application in protein and peptide delivery addresses stability issues, as nanosponges shield biologics from enzymatic degradation while facilitating controlled release. Insulin-loaded nanosponges, for instance, have demonstrated enhanced stability and prolonged hypoglycemic effects in diabetic models [46].

Emerging research explores antiviral applications, particularly in neutralizing viruses such as SARS-CoV-2. Nanosponges coated with cell membranes act as decoys, binding to viral particles and inhibiting infection, offering a novel therapeutic strategy [47]. With continued advancements, nanosponges are poised to revolutionize drug delivery across multiple therapeutic areas.

VII. RECENT ADVANCES

1) Stimuli-Responsive Nanosponges Researchers have designed smart nanosponges that release drugs in response to specific biological triggers, such as pH, temperature, or enzymes. For instance, pH-sensitive nanosponges loaded with anticancer drugs (e.g., doxorubicin) exhibit controlled release in the acidic tumor microenvironment, minimizing off-target effects [48]. Similarly, temperature-responsive nanosponges have been explored for localized hyperthermia therapy in cancer treatment [49].
2) Hybrid Nanosponge Systems Combining nanosponges with other nanocarriers, such as liposomes, polymeric nanoparticles, or metallic nanoparticles, has led to multifunctional drug delivery platforms. Hybrid nanosponges improve drug-loading capacity, stability, and targeting efficiency. For example, gold nanoparticle-conjugated nanosponges have been used for photothermal therapy and imaging-guided drug delivery [50].
3) Antiviral and Antibacterial Applications Nanosponges have been investigated as antiviral agents, particularly against enveloped viruses like SARS-CoV-2. These nanosponges mimic host cell membranes, binding to viral particles and neutralizing them before infection occurs [51]. Additionally, antibiotic-loaded nanosponges have shown enhanced efficacy against drug-resistant bacterial strains due to improved biofilm penetration [52].
4) Gene and Protein Delivery Nanosponges are being explored for the delivery of biologics, including siRNA, mRNA, and therapeutic proteins. Their porous structure protects nucleic acids from enzymatic degradation while facilitating controlled release. A recent study demonstrated successful siRNA delivery using cyclodextrin-based nanosponges for gene silencing in cancer cells [53].
5) 3D-Printed Nanosponge Scaffolds for Tissue Engineering Incorporating nanosponges into 3D-printed scaffolds has enabled sustained drug release in regenerative medicine. These scaffolds promote tissue repair while delivering growth factors or anti-inflammatory agents in a controlled manner [54].
6) Enhanced Brain Targeting Surface-modified nanosponges (e.g., with transferrin or TAT peptides) have improved blood-brain barrier (BBB) penetration, enabling targeted drug delivery for neurological disorders such as Alzheimer's and glioblastoma [55].

VIII. CHALLENGES & FUTURE PERSPECTIVES

Despite the significant potential of nanosponges in drug delivery, several challenges hinder their widespread clinical adoption. One major obstacle is the difficulty in scaling up production from laboratory to industrial levels, as maintaining consistent particle size, drug loading efficiency, and stability during large-scale manufacturing remains complex. Additionally, regulatory hurdles pose a significant barrier, as nanosponge-based formulations require rigorous safety and efficacy evaluations before approval by agencies such as the FDA or EMA. Long-term toxicity studies are also limited, raising concerns about biocompatibility and biodegradation over extended periods.[56]

Future research should focus on optimizing nanosponge formulations to improve reproducibility and cost-effectiveness. Advances in stimuli-responsive nanosponges (e.g., pH-, temperature-, or enzyme-triggered release) could enhance precision medicine applications, particularly in cancer therapy and infectious diseases. Another promising direction is the development of hybrid nanosponges, integrating them with other nanocarriers (e.g., liposomes, metallic nanoparticles) for multifunctional drug delivery. Furthermore, personalized nanomedicine approaches could leverage nanosponges for patient-specific treatments, particularly in chronic diseases requiring controlled drug release.[57]

To facilitate clinical translation, collaborative efforts between academia, pharmaceutical industries, and regulatory bodies are essential. Standardized protocols for characterization, in vivo testing, and quality control must be established to ensure reproducibility.[58] Additionally, exploring green chemistry approaches for nanosponge synthesis could address environmental and toxicity concerns.[59] With continued innovation, nanosponges could revolutionize drug delivery, offering targeted, efficient, and safer therapeutic options for diverse medical conditions.

IX. CONCLUSION

Nanosponges represent a breakthrough in drug delivery, offering improved drug stability, bioavailability, and targeted release. With ongoing research, they hold immense potential for treating various diseases, including cancer, infections, and neurological disorders. Future advancements in polymer science and nanotechnology will further expand their applications.

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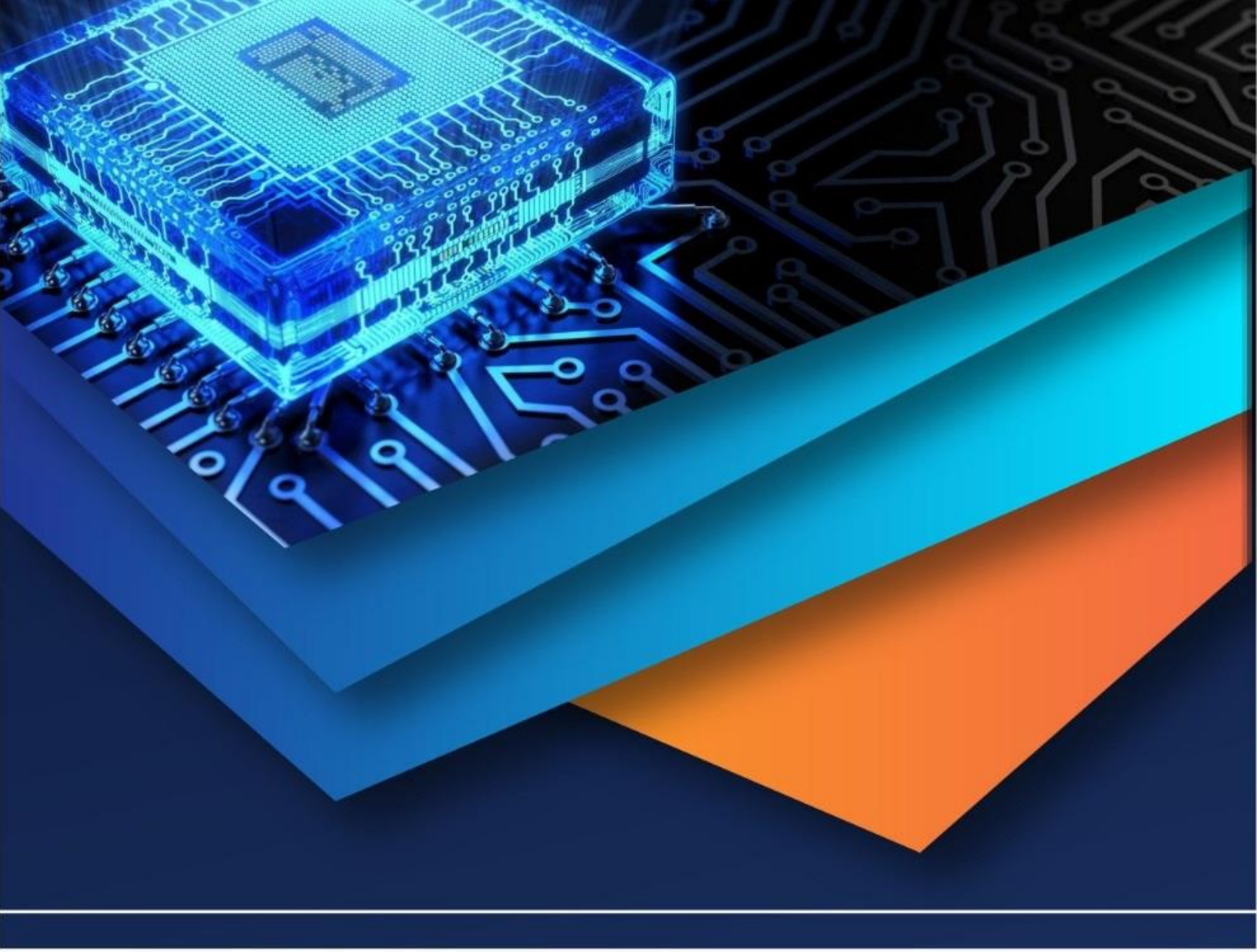

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