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Review Article

DEVELOPMENT OF MICROSPONGES FOR TOPICAL FORMULATION: A REVIEW

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Microsponges are advanced, highly porous polymeric microspheres designed for controlled and sustained topical drug delivery. Their unique sponge-like architecture allows high drug loading capacity, localized delivery, and prolonged release of active pharmaceutical ingredients, minimizing systemic absorption and reducing adverse effects. This review provides comprehensive guidance on the development of microsponge-based topical formulations, covering formulation strategies, preparation techniques, and critical characterization parameters. The advantages of microsponges in enhancing drug stability, improving therapeutic efficacy, and reducing skin irritation are discussed. Various fabrication methods, including quasi-emulsion solvent diffusion and suspension polymerization, are evaluated for their scalability and suitability in industrial applications. The review also highlights emerging frontiers such as stimuli-responsive release systems and hybrid nanoscale combinations aimed at enhancing targeted delivery and skin penetration. Furthermore, regulatory considerations, safety assessments, and recent clinical advancements are addressed. This article serves as an essential reference for researchers and formulators aiming to harness microsponge technology for innovative and effective topical therapies.

Keywords: Controlled release, Sustained release, Polymer microspheres, Nanotechnology, Dermatological applications, Stimuli-responsive delivery

INTRODUCTION

The concept of microsponge technology was first introduced by Won in 1987, with the initial patents assigned to Advanced Polymer Systems. Microsponges are highly porous, polymer-based microspheres characterized by an intricate network of interconnected voids, typically ranging in size from 5 to 300 µm. These unique carriers are capable of encapsulating a wide spectrum of bioactive compounds, including emollients, essential oils, fragrances, sunscreens, antimicrobial agents, antifungals, and anti-inflammatory drugs, making them particularly suitable for topical delivery applications. Once incorporated into dosage forms such as creams, gels, lotions, or powders, microsponges provide multiple therapeutic and cosmetic benefits. Their non-collapsible, sponge-like structures enable controlled and sustained release of active ingredients through the porous surface. Depending on the particle size, the total pore length may extend up to 10 feet per particle, with a pore volume reaching 1 ml/gm. Release of the entrapped active substances can be time-dependent or triggered by external stimuli such as rubbing, changes in pH, or skin temperature. One of the key

advantages of microsponges is their exceptionally high entrapment capacity, allowing them to incorporate nearly three times their own weight of active agents. This sets them apart from conventional delivery systems. Additionally, the technology ensures that the drug remains localized in the epidermis, thereby minimizing systemic absorption and reducing the likelihood of systemic side effects. [1, 2]

The main rationale for developing microsponge systems lies in the limitations of conventional topical formulations, which usually provide high concentrations of actives with only short-term efficacy. Such fluctuations can result in alternating cycles of overmedication and under medication, often accompanied by adverse reactions like irritation or rashes. By contrast, microsponges facilitate a steady, prolonged release, maintaining therapeutic efficacy while reducing irritation and enhancing tolerability. Due to their ability to absorb skin secretions, microsponges are also effective in reducing oiliness and imparting a matte appearance to the skin. They consist of minute, inert, and non-biodegradable polymeric spheres that remain confined to the superficial layers of the skin, gradually releasing the drug in response to the skin's needs. This property prevents unnecessary accumulation of active ingredients in deeper skin layers and reduces the risk of irritation from potent agents such as retinoids or benzoyl peroxide. [3-6]

Functionally resembling true sponges, each microsphere is composed of an immense network of interconnected poreswithin a rigid and stable structure. The drug release primarily follows diffusion-controlled mechanisms, enabling prolonged therapeutic effects, improved safety, and enhanced patient compliance. Currently, Microsponge Delivery System (MDS) technology has found widespread application in cosmetics, sunscreens, over-the-counter skincare products, and prescription dermatological formulations. Its ability to combine efficacy, controlled release, and reduced side effects makes it a promising tool in the development of novel dermatological and cosmetic therapies. [7, 8]

Microsponge Drug Delivery Systems are patented, polymer-based carriers that appear as minute, sponge-like spherical particles ranging from 5 to 300 μm in diameter (Fig. 1). These microspheres possess a highly porous architecture, with surface areas between 20–500 m^2/g and pore volumes of 0.1–0.3 cm^3/g, which can be tailored during formulation. The defining feature of microsponges is their non-collapsible, interconnected porous structure, which makes them mechanically stable, chemically inert, and resistant to shear forces. Owing to these

characteristics, they can be conveniently incorporated into a variety of topical dosage forms, such as powders, lotions, and creams. Designed to achieve controlled and efficient drug delivery at minimal doses, microsponges not only improve the stability of active pharmaceutical ingredients (APIs) but also reduce undesirable side effects and allow for modification of drug release profiles.Drug release from microsponges is typically triggered by external stimuli, including mechanical pressure or rubbing, variations in skin temperature, changes in pH, or solubility shifts. This controlled release ensures that the active ingredient is available only when and where needed, enhancing therapeutic efficacy while minimizing irritation. [9-11]

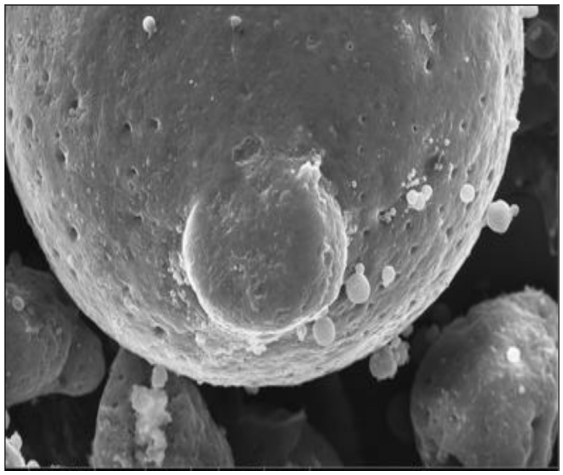

Figure 1: Microsponge[12]

Microsponges for Topical Delivery

The effectiveness of a drug applied topically depends on two sequential processes: initially, the drug must be released from its formulation base and reach the skin surface, and subsequently, it must penetrate the skin barrier to reach the intended site of action. These processes are strongly influenced by the physicochemical properties of the drug, the nature of the formulation vehicle, and the characteristics of the skin barrier. Among these, the stratum corneum is recognized as the primary obstacle to percutaneous absorption. [13, 14]

Transdermal drug delivery systems (TDDS) have been designed to exploit the skin as a route for systemic drug administration, offering improved efficacy and safety for several therapeutic agents. However, TDS is unsuitable when the therapeutic target is the skin itself. For such cases, research has focused on achieving controlled drug release to the epidermis, ensuring that the drug remains localized at the site of action while minimizing systemic absorption.

Conventional topical formulations, such as ointments, present several limitations. They are often greasy, sticky, and aesthetically undesirable, which negatively affects patient compliance. Moreover, due to their inefficient delivery, these systems require higher drug concentrations to achieve therapeutic effects, frequently leading to irritation or hypersensitivity

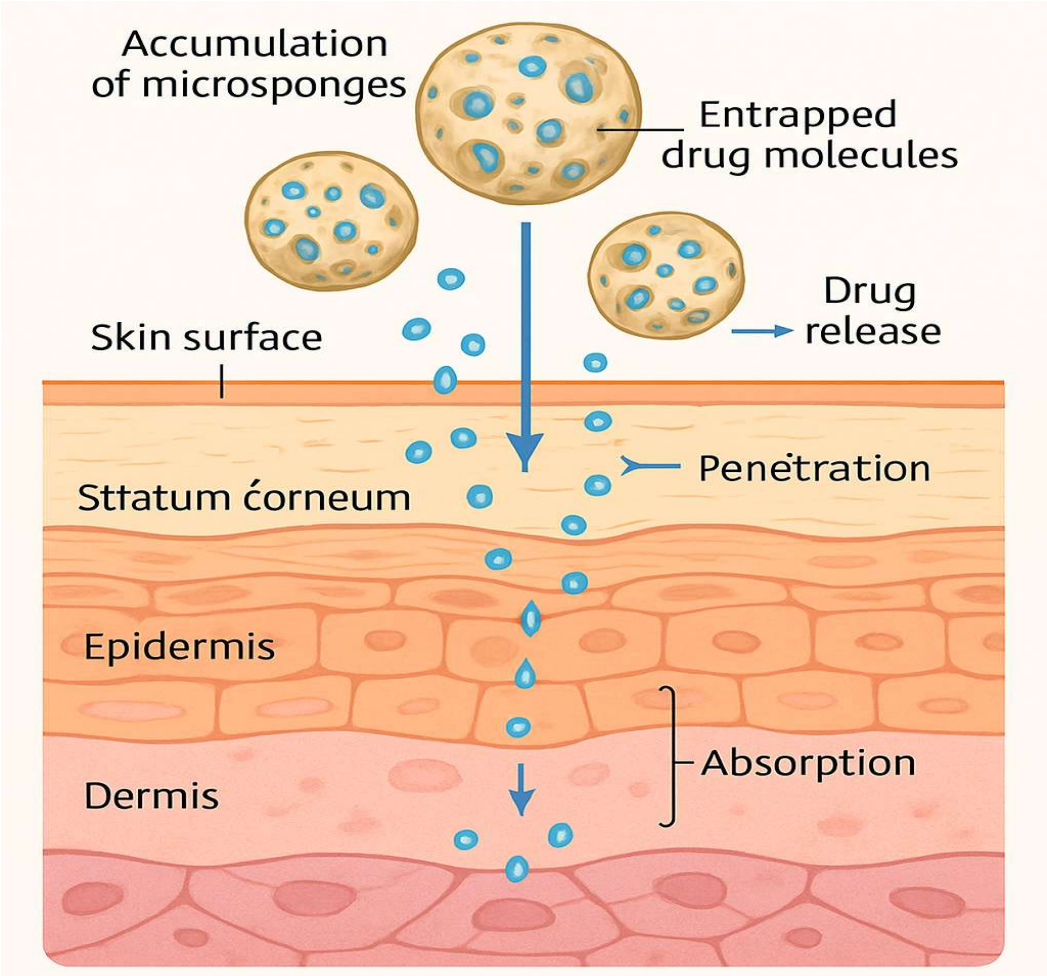

Figure 2: Mechanisms of drug release from topical microsponges[19]

reactions. Other drawbacks include uncontrolled evaporation of actives, unpleasant odors, and possible incompatibility between drugs and excipients. This highlights the need for advanced systems capable of prolonging drug residence time on the skin surface or within the epidermis, while reducing deeper transdermal penetration.

Traditional topical formulations generally act only on the outermost skin layers, where they release the active drug rapidly, creating a concentrated film that is quickly absorbed. This often leads to excessive accumulation of drug in the epidermis and dermis, increasing the risk of irritation. Incorporating drugs into microsponge delivery systems provides a solution to this problem by enabling controlled and sustained release, thereby reducing irritation while preserving therapeutic efficacy. As illustrated in Figure2, microsponges release drugs through multiple mechanisms such as diffusion, pore-controlled

release, and surface desorption, ensuring a steady and localized delivery profile. These polymer-based, porous microspheres possess a stable, sponge-like structure with interconnected channels, allowing entrapment of a wide variety of active substances. Furthermore, they can be formulated into diverse dosage forms, including creams, gels, lotions, liquids, and powders, with fabrication parameters tailored to optimize release behavior, therapeutic outcomes, and formulation compatibility. [15-18]

Characteristics of microsponges

- **pH Stability –** Microsponge formulations remain stable across a broad pH range (1–11).
- **Thermal Stability –** They can withstand temperatures up to 130 °C without losing integrity.
- **Compatibility –** They are compatible with most pharmaceutical vehicles and excipients.
- **Self-Sterilizing Nature –** Due to their average pore size of about 0.25 µm, bacteria cannot penetrate, making the system inherently self-sterilizing.
- **High Payload Capacity –** They can incorporate a relatively high drug payload (50–60%) while maintaining a free-flowing nature, making them efficient and cost-effective.[20, 21]

Advantages of Microsponges in Topical Formulation

- **Controlled and sustained drug release:** Microsponges provide prolonged and gradual release of the active ingredient, which helps maintain effective drug levels over time and reduces dosing frequency. This improves therapeutic efficacy and patient compliance.
- **Reduced side effects and irritation:** By controlling the release and limiting excessive local concentration of the drug, microsponges minimize skin irritation and other side effects commonly seen with conventional topical formulations.
- **Enhanced stability and shelf life:** Microsponges can protect active ingredients from degradation by environmental factors such as light, heat, and oxygen, enhancing the stability of the formulation.
- **Improved drug penetration:** The porous structure of microsponges allows better adherence to the skin and improved penetration of the drug into different layers of the skin, increasing bioavailability.
- **Versatility in formulation:** Microsponges can be incorporated into diverse topical forms such as creams, gels, lotions, and powders, and are compatible with a wide range of active compounds.

- **Minimized systemic absorption:** Microsponges restrict drug absorption primarily to the targeted skin area, reducing systemic exposure and toxicity.
- **Self-sterilizing property and safety:** Microsponges are generally non-toxic, non-irritant, non-mutagenic, and non-allergenic, making them safe for topical use.
- **Overcome limitations of conventional formulations:** Unlike ointments which may be greasy and poorly tolerated, and liposomes which may suffer stability issues, microsponges offer stable, non-greasy, and cosmetically acceptable formulations without preservatives.[22-24]

Methods of Microsponge Preparation

Several techniques are employed for the development of microsponge-based drug delivery systems. These include:

Lyophilization Method

The lyophilization technique is employed to convert microspheres into porous structures. In this method, microspheres are first dispersed in a chitosan hydrochloride solution and then subjected to freeze-drying. The rapid removal of solvent during lyophilization creates pores within the microspheres. This approach is simple, efficient, and allows quick production of microsponges. However, due to the rapid solvent removal, the resulting microparticles may appear fractured or shrunken. [25, 26]

Addition of Porogen Method

In this approach, the internal aqueous phase of the water-in-oil-in-water (w/o/w) emulsion is substituted with a porogen such as hydrogen peroxide or sodium bicarbonate. The porogen is uniformly dispersed within the polymeric solution, creating a stable dispersion framework that is subsequently re-emulsified into a polyvinyl alcohol (PVA)–containing aqueous phase. Following the addition of an initiator, the organic solvent is removed from the w/o/w system, resulting in the formation of microparticles. Incorporation of hydrogen peroxide as the porogen produces a porous structure characterized by evenly distributed and interconnected pores, typically ranging from 5 to 20 µm in size. Although the architecture may be susceptible to some structural fragility, it ensures a regular and consistent porous network. [27, 28]

Liquid–Liquid Suspension Polymerization Technique

In this method, microsponges are produced in a single step by dispersing drug–monomer solutions into an aqueous phase containing surfactants or dispersants, followed by polymerization induced by catalysts, heat, or radiation. The process yields porous reservoir systems with surface openings, capable of entrapping drugs such as antifungals, anti-acne, and anti-inflammatory agents. For

polymerization-sensitive drugs, a two-step process using a porogen is employed, with the drug incorporated later under mild conditions. While the technique allows flexible drug loading, limitations include lower loading efficiency, potential entrapment of residual monomers/solvents, and the need for two-step processes for thermolabile compounds. [29]

Quasi-Emulsion Solvent Diffusion Method

The quasi-emulsion solvent diffusion technique is one of the most widely employed methods for preparing microsponges. In this process, an internal organic phase—comprising polymer, solvent (such as ethyl alcohol or trichloromethane), and a plasticizer like triethyl citrate—is dispersed into an external aqueous phase containing polyvinyl alcohol (PVA). The system is emulsified under constant stirring, followed by filtration, washing, and drying to obtain the final microsponges.This method offers several advantages, including the production of spherical particles, high drug loading capacity, minimal solvent residue, and the ability to control particle size by modifying stirring conditions. Additionally, the drug remains protected from environmental exposure during preparation. However, certain limitations exist, such as the risk of residual monomer or solvent entrapment, variability in structural uniformity, slow monomer reactions, and reduced efficiency for thermosensitive drugs that may require a two-step process. [30-32]

Water-in-Oil-in-Water (w/o/w) Emulsion Solvent Diffusion Method

The w/o/w emulsion solvent diffusion method is a simple and widely used technique for preparing biodegradable porous microspheres. In this method, the internal aqueous phase containing an emulsifying agent (such as span, polyethyleneimine, or xanthan gum) is dispersed within an organic polymeric solution to form a water-in-oil (w/o) emulsion. This is subsequently dispersed into an external aqueous phase containing polyvinyl alcohol (PVA), resulting in a double emulsion system.The method is advantageous for its ability to encapsulate both water-soluble and water-insoluble compounds. However, the use of water-insoluble surfactants can leave residues within the microsponge matrix, which may limit its applicability. [33, 34]

Oil-in-Oil (o/o) Emulsion Solvent Diffusion Method

In this approach, a volatile organic solvent (e.g., dichloromethane) serves as the internal phase, while a fixed oil (such as mineral or corn oil) combined with an organic solvent forms the external phase. Polymers like polylactic glycolic acid (PLGA) are commonly employed. The internal phase is slowly introduced into the external dispersion medium under continuous stirring until the solvent evaporates, leading to microsponge formation.This method has been

successfully applied to prepare hydroxyzine HCl-loaded microsponges using Eudragit RS-100, with acetone as the solvent and liquid paraffin as the continuous phase. Its key advantage lies in the absence of surfactant residues in the final product. However, the reliance on organic solvents and the necessity to completely remove alcohol traces are major limitations. [35]

Vibrating Orifice Aerosol Generator (VOAG) Method

The VOAG method was originally used for producing lipid bilayered mesoporous silica particles. In this process, a hydro-ethanolic solution of tetraethyl orthosilicate is refluxed with diluted HCl to form a precursor stock solution, which is then diluted with a surfactant-containing solvent. The mixture is passed through a vibrating orifice to generate uniform microdroplets. Upon solvent evaporation and deposition, porous microsponge structures are obtained.The technique allows precise control of particle size and uniformity; however, it is relatively complex and equipment-intensive. [36]

Ultrasound-Assisted Production Method

This method is a modification of liquid–liquid suspension polymerization, where β-cyclodextrin acts as a monomer and diphenyl carbonate as the cross-linking agent. The reaction mixture is heated and sonicated to regulate microparticle size, followed by cooling, pulverization, and sequential washing with water and ethanol.The resulting cross-linked cyclodextrin-based sponges demonstrate high reproducibility and efficient drug loading, without residual solvent contamination. Nonetheless, a significant drawback is the possible retention of cross-linking agent residues, which may pose safety concerns. [37]

Electrohydrodynamic Atomization (EHDA) Method

The EHDA method involves preparing porous microspheres by electrospraying a chitosan solution containing air bubbles generated through ultrasonication. The bubble suspension is passed through a steel capillary using a syringe pump, where electrostatic forces atomize the solution. Process parameters such as applied voltage and solution flow rate are optimized to maintain stable cone-jet spraying. The resulting microspheres are cross-linked using sodium hydroxide.This technique enables precise control over microsponge particle and pore size, with potential for combining therapeutic molecules within the matrix. However, it requires significant expertise to maintain stable electrospraying conditions, and process scalability remains a challenge. [38]

Characterization and Evaluation Parameters

The key parameters involved in assessing microsponge systems are illustrated in Figure 3 below.

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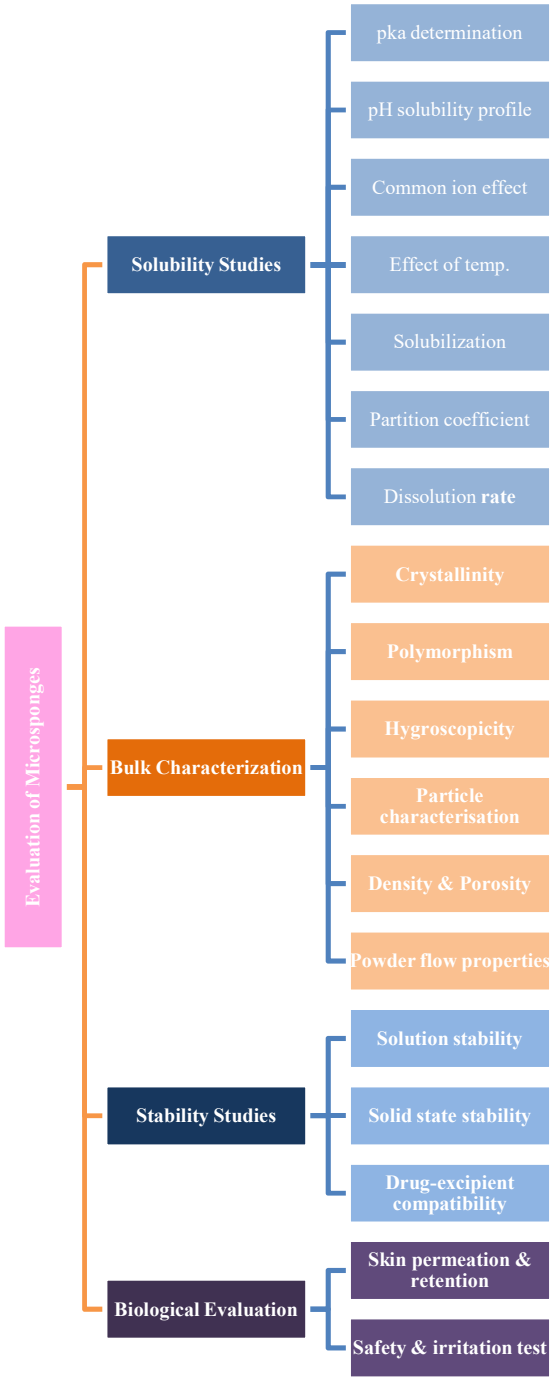

Figure 3:Characterization and Evaluation of Microsponges[39]

Applications of Microsponges in Topical Drug Delivery

Microsponges have gained significant attention for their ability to improve drug delivery, reduce side effects, and enhance patient compliance. Their porous, polymeric structure allows for controlled release, site-specific delivery, and minimized systemic exposure. Key applications include:

- **Acne Treatment:** Microsponges enhance the delivery of anti-acne agents such as benzoyl peroxide, tretinoin, and fluconazole, providing sustained release, reduced skin irritation, and improved efficacy.
- **Dermatological Disorders:** Used for psoriasis, eczema, dandruff, alopecia, sunburn, hyperhidrosis, and skin cancer treatment by localized drug delivery minimizing systemic absorption and side effects.
- **Cosmetic and Skin Care Products:** Incorporated in anti-aging creams, sunscreens, deodorants, antiperspirants due to controlled release of active ingredients and oil absorption capacity.
- **Topical Analgesics and Anti-inflammatories:** Microsponges deliver analgesic and anti-inflammatory drugs with improved patient compliance and reduced dosing frequency.
- **Enhanced Drug Stability and Reduced Side Effects:** The porous nature protects drugs from degradation and allows lower doses with fewer adverse reactions.
- **Formulation Flexibility:** Microsponges can be incorporated into gels, creams, lotions, powders, and liquids, suitable for various skin types and conditions. [40-42]

Conclusion and Future Perspectives

Microsponges have emerged as a versatile and innovative drug delivery system, effectively addressing limitations of conventional topical formulations. Their porous, polymeric microsphere structure allows efficient drug encapsulation, controlled prolonged release, and enhanced stability, significantly reducing skin irritation and systemic side effects. This unique mechanism improves therapeutic efficacy and patient compliance across various dermatological and cosmetic applications.Successful development of microsponge-based topical formulations requires meticulous optimization of formulation variables such as polymer type, drug-to-polymer ratio, emulsifier content, and process parameters. Advanced manufacturing techniques, including quasi-emulsion solvent diffusion and suspension polymerization, facilitate scalable, reproducible production with precise control over particle size and drug release profiles.Comprehensive characterization and rigorous evaluation—encompassing physicochemical analysis, in vitro drug release, stability testing, skin permeation

studies, and safety assessments—are essential to ensure product quality, efficacy, and regulatory compliance.

Future directions include integration of stimuli-responsive polymers for on-demand drug release triggered by environmental factors (e.g., pH, temperature), and combining microsponges with nanotechnology or bioactive ligands to enhance skin penetration and target specificity. Addressing challenges in scale-up, long-term safety, and in vivo validation through interdisciplinary collaboration will be crucial to translate microsponge technology to clinical and commercial success.

In conclusion, microsponges offer a robust, adaptable platform with considerable potential to revolutionize topical drug delivery by merging controlled release, safety, and formulation flexibility, paving the way for next-generation dermatological therapies.

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