REVIEW ARTICLE

Engineering Microsponge Gel Systems for 6Enhanced Topical Bioavailability: A Comprehensive Review

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Abstract

Microsponge gel medication delivery system is the most effective, advanced approach in cutaneous or dermal drug release mechanism as it can release the drug relatively slowly. Microsponges have highly small porous polymer particles of size up to 300 µm, which can retain both water-soluble and oil-soluble drugs in it. Mixing the micro sponges with gel acts as the tiny storage pool of medicament that releases gradually on application on skin. This kind of dosage form shows a steady drug level on site of action and improves the stability of the formulation and reduce irritation feel compared to traditional or conventional products. This review explains the help us in understanding the basic design of formulation of micro sponge gels, its drug release behavior, and where these are commonly used and therapeutic applications in dermatological-related issues, pain management like in, Rheumatoid artitis and cosmetic formulations. There are various methodological approaches like Quasi-emulsion solvent diffusion method, suspension polymerization, emulsion-based methods and these methods are outlined by focusing on their impact on particle characterizes and performance. These microsponge gels provide some advantages over traditional topical dosages, such as better safety, patient convenience, which make them more suitable for dermatological pain relief and cosmetic applications.

Key words: Controlled drug release, microsponge system, porous polymer microsponges, skin drug delivery, topical gel formulation

INTRODUCTION

Topical drug delivery system is mostly used in skin-related problems and other local issues because these gels are easy to apply and have more patient adherence. Another major benefit is that it decreases the penetration of the drug into the blood circulation instead, it completely shows the effect only at the site of action and eliminates the unwanted side effect this also can avoid the overdose issues, which may lead to serious adverse effects.[1] However, traditional medications have some disadvantages and drawbacks, such as few of this kind of gels have a fast drug release pattern, low retention on skin, few cause skin irritation based on the skin type (any formulations applied in the skin should be used only on a dermatologist prescription), and sometimes instability of the active pharmaceutical ingredient. To bypass these issues, microsponge technology is developed, which is an enhanced drug delivery system.[2] As Figures 1 and 2 describe, these Microsponges are tiny, micro-sized, porous polymeric particles that hold and entraps the drug molecule in its matrix due to this kind of sponge-like cross-linked network which can hold the therapeutic drug and release slowly.[3] This complex design enables more drug loading capacity and release behavior by controlled diffusion rate over an extended period of time. Based on the use and need, microsponges can be incorporated in different formations like gels, creams, tablets, capsules and other ocular or mucosal preparation. In all of these formulations microsponge-based gels are more suitable for topical use as they have easy spreading, give a comfortable feel and less irritation.[4] The

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mixing of microsponges in a gel base acts as tiny reservoirs that will release the drug gradually. The release can also be influenced by different factors such as temperature, pH and style of application on skin.[5] The manner of sustain release promotes in maintaining the consistent drug level at the site of application. Along with this micro sponge system protects the encapsulation from environmental deterioration, enhances the formulation stability and shelf life.[6] Various techniques have been used for the preparation of microsponges, including quasi-emulsion solvent diffusion, liquid–liquid suspension polymerization, and emulsion-based approaches. Picking up a suitable polymer type (polymers like Eudragit RS100, ethyl cellulose, polystyrene, PHEMA), preparation technique, and formulation parameters plays a crucial role in determining particle size, porosity, drug-entrapment efficiency, and release behavior, and shelf life.[7] Due to these advantages, microsponge-based gel formulations have emerged as a versatile and effective method for controlled topical drug delivery in pharmaceutical and cosmetic applications.[8]

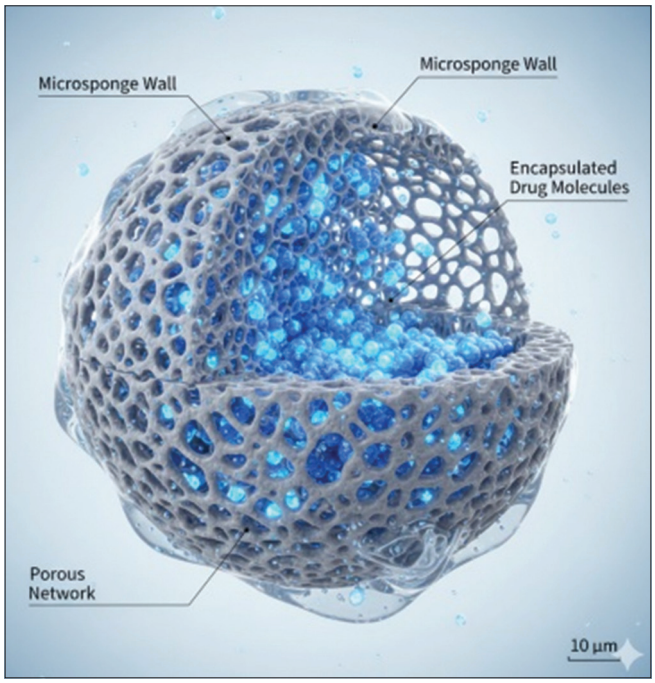

Figure 1: Basic structure of microsponge

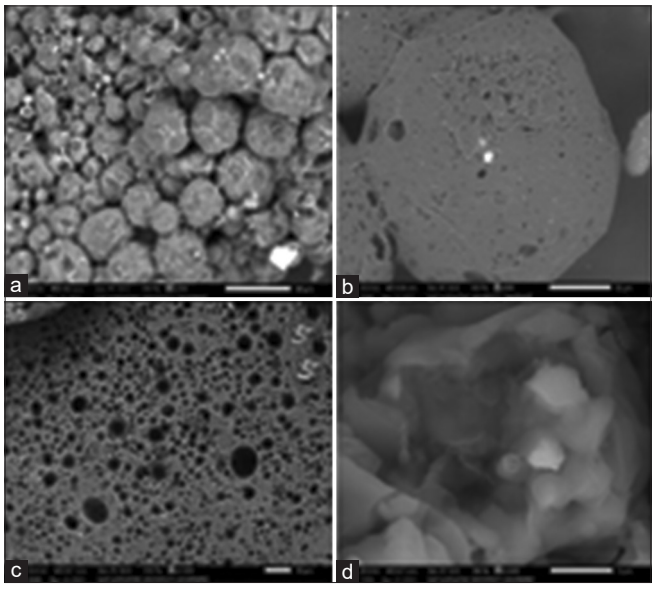

Figure 2: (a-d) Microscopic view of microsponge

Topical applications where localized, controlled release is preferred are the main uses for microsponge gels. Common indications and applications consist of:

- For musculoskeletal pain, local analgesics and anti-inflammatory medications (non-steroidal anti-inflammatory drug, local anesthetics) are used.
- Cosmetic uses, such as sunscreens, sebum-regulating agents, and prolonged fragrance release.
- New applications where extended contact and less irritation are advantageous include ocular, intranasal, and mucosal delivery.[9]

MECHANISM OF ACTION OF MICROSPONGE GEL

On topical application, micro sponge-loaded gels form a uniform thin translucent layer over the skin or mucosal surface, in which the active drug remains primarily entrapped within the porous polymeric micro spheres distributed throughout the gel matrix. These microsponges function as a microscopic pool that prevents the immediate release of the encapsulated drug and gradually diffuses from the porous microsponge into the cutaneous layers, as shown in Figure 3, thereby avoiding sudden spikes in concentration peaks commonly associated with conventional dosage forms.[10]

Drug release from microsponge gels occurs primarily through a diffusion-controlled process. On gel comes into contact with the physiological stimuli, the drug gradually moves from the internal porous network of the microsponges into the surrounding gel phase and further penetrates into the skin. Viscosity of the gel base plays a vital role in altering drug release. External conditions such as body temperature, local pH, hydration level, skin health, Injuries on skin, and storage conditions of gel and mechanical actions such as Scrubbing or massage can further enhance drug diffusion from the micro sponge matrix. This responsive release behavioral pattern allows the formulation to adapt to physiological conditions at

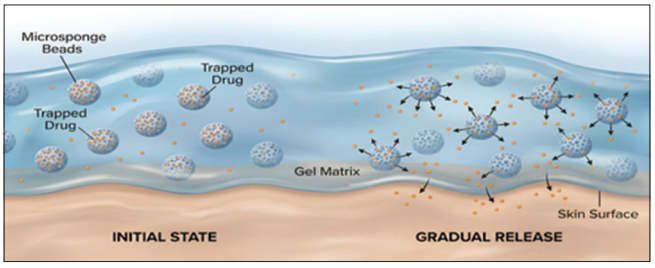

Figure 3: Release of drug into the skin

the target location.[11] Because microsponge gels release the drug slowly, they can maintain a sufficient medicament on application for a longer duration. This not only improves the overall therapeutic effect but also helps in reducing irritation, limiting systemic absorption, and lowering the chances of side effects.[12]

RECENT ADVANCEMENTS IN GELS CONTAINING MICROSPONGES

- Engineered polymer systems: Use of biodegradable and stimuli-sensitive polymers to facilitate environment- triggered release.
- Hybrid systems: Layering microsponges with liposome or incorporating nanoparticles into the porous structure to create multi-model release.
- Mucoadhesive and permeation-modulating gels: Combination of microsponges and mucoadhesive polymers to optimize residence time on mucosal surfaces.[13]

LIMITATIONS AND CHALLENGES

Although microsponge gels offer several advantages, they also have some limitations:

- Drug loading issues: Some drugs are difficult to incorporate into the microsponge structure or may not remain stable inside it.
- Incomplete or uncontrolled release: Improper optimization of the formulation may lead to the quick release of the drug at the beginning (burst release) or may not release sufficiently over time.
- Safety and regulatory concerns: In some instances, non-biodegradable polymers or residual chemicals from the preparation process may be present, which may raise safety concerns and require extensive testing before approval of the drug.[14]

ADVANTAGES OF MICROSPONGE GELS

Microsponge gels offer some advantages, especially in skin treatments. One of the main benefits is their ability to release the drug slowly and gradually over a longer period of time, which helps in maintaining the therapeutic effect and lowering of frequent application of drug. This makes the treatment more convenient and comfortable to the patients. They also protect the drug from early degradation, which improves its chemical and physical stability and increases shelf life. Another advantage is their pleasant feel on the skin. Microsponge gels are light, non-greasy and absorb excess oil and sweat, and give a smooth feel after application. Microsponge gels can carry both water-soluble and lipid-soluble drugs and help in the preparation wide range of formulations.[15]

DISADVANTAGES OF MICROSPONGE GELS

Even though these Microsponge gels are an advanced form of topical formulations, they have some limitations. The microsponge gel preparation process is slightly difficult, sensitive and requires specialized equipment, which will increase the expenses and complications are arised in large-scale production. Preparation of microsponge gel takes a longer period of time, as several factors should be maintained accurately for consistency and quality. Suboptimal formulation may cause problems as sudden drug release (dose dumping) or instability. The choice of polymer also plays a major impact on how much drug can be loaded and released. In some cases, certain polymers may cause mild skin irritation or sensitivity based on the type of skin of the patient. Due to these factors, the overall cost and complexity of production can make microsponge gels less affordable than traditional gel-based formulations.[16]

IDEAL PROPERTIES OF MICROSPONGE GELS

Microsponge gels should be non-toxic and biocompatible. They should be chemically and physically stable, and should possess high drug loading efficiency and should provide controlled and sustained drug release. On application, it should be non-irritant and non-allergenic, suitable pH for skin application. They should allow localized drug delivery at the site of action. Microsponge gels should have adequate porosity for drug release and compatible with both hydrophilic and lipophilic drugs. Microsponge gels should show reproducible drug release profiles.[17]

METHOD OF PREPARATIONS

Microsponge gels were prepared using two-step process, first preparing the microsponges next incorporating them into a gel base, such as carpool. The most common method used is his technique is commonly employed technique for the formulation Quasi-emulsion solvent diffusion method. These methods work well for controlled drug release for topical applications.[18]

Quasi-emulsion solvent diffusion method

When developing microsponges, using various polymers are used to enhance drug-release sensitivity. This method involves two distinct phases: the internal phase (Dispersed phase) and the external phase (Continuous phase). Dispersed phase comprises a polymer such as Eudragit RS-100, which is a cationic, non-biodegradable polymer with low permeability. An increase in polymer concentration is generally associated with improved drug entrapment efficiency. The polymer

is solubilized in an appropriate solvent, and the mixture is maintained approximately 35°C. Ultrasonication is employed to ensure uniform dispersion and proper dissolution of the components.[19]

The continuous phase is made of water, and PVA functions as a stabilizer. The dispersed phase is slowly introduced into the continuous phase under continuous stirring. Blending is continued for about 1 h to facilitate solvent diffusion and microsponge formation. The resulting microsponges are then isolated by a filtration technique there solvent in evaporated for around 12 h.[19]

Preparation of gel microsponge: The gel base is formulated by slowly adding Carbopol in water with gentle stirring and followed by adequate hydration tie to ensure complete swelling. After full hydration, the Carbopol is neutralized to form a smooth, uniform gel. This well-formed gel base then provides a stable medium for incorporating the dried microsponges.[19]

Liquid-liquid suspension polymerization

In this technique, the monomer is first blended with a non-polar ingredient and then dissolved into an aqueous solvent containing surfactants and dispersing agents to form a stable suspension macro molecule formation starts on the addition of a catalyst under controlled temp conditions to facilitate polymerisation and solvent diffusion, which leads to the gradual formation of spherical polymer particles. Once polymerization is complete, the solvent is removed, resulting in porous, sponge-like microspheres known as microsponges.[20]

It involves different steps as follows:

i. Select the monomer or a combination of monomers and dissolve them along with the active ingredient in an organic solvent to form the organic phase
ii. Prepare the aqueous phase by mixing water with surfactants and dispersing agents to stabilize the suspension.
iii. Slowly add the organic phase into the aqueous phase while stirring continuously to create a stable suspension of monomer droplets in the water. This initiates polymerisation by increasing the ambient temperature, causing the monomer to link together, form cross linked ladder structure and fold into round, spherical micro particles.
iv. Filter the content and dry to get porous microsponges with a uniform microspherical, highly porous structure, ready for a drug delivery system
v. Microsponges are incorporated into a gel by dispersing the prepared microsponges evenly into a gel base, such as Carbopol, with gentle stirring to form a smooth and uniform microsponge-loaded gel. The pH of the gel is then adjusted to ensure proper consistency and stability for topical application.[20]

Oil-in-oil emulsion solvent diffusion

In the method, microsponges are formulated by volatile organic solvents as interphase. During this process, this inner phase is gradually added dropwise into the dispersion medium on continuous stirring at 800 rpm for 60–90 min. Now, adding the solution in a slow manner initiates pore formation, which helps in the formation of micropores. The addition of hydrogen peroxide or sodium bicarbonate to the polymer solution creates pores in the microsponge. This porous surface holds the drug in it and gradually release on administration.[21,22]

Electrodynamic atomization

Electrohydrodynamic atomization uses a high-voltage electric field to create fine charge jets from a polymer-drug solution that break into porous microsponge particles as the solvent evaporates. This technique produces uniform solvent – efficient microsponges ideal for lab-scale controlled release gels with heat-sensitive drugs.[23,24]

Marketed formulations

There are a few marketed formulations available in the market using the above methods that are mentioned in Table 1.

EVALUATION OF MICROSPONGE GEL

Actual drug content and encapsulation efficiency.

A 10 mg of ovendried microsponge was crushed, and then a small portion of phosphate buffer of PH 7.4 is admixed and keep a side over a day. Thereafter, dilute stepwise with the same buffer and filter with Whatman filter paper. The final solution was analysed at 261nm using ultraviolet spectrophotometer.[25] The drug content and entrapment efficiency were calculated by a formula,

$$\text{Entrapment Efficiency} = \frac{\text{Actual drug}}{\text{Theoritical drug}} \times 100$$

Visual inspection

The gel microsponge formulation was examined visually to observe color, texture and appearance. It is for assess quickly the quality and consistency of the gel.[26]

Spreadability studies

The gel should possess easy spreading on the skin or effected area. It is known as spreadability, and it is important because to determine how well gel spreads affects how well it works.

Table 1: Marketed formulations on microsponge gels

S. No.	Branded name	Manufacture name	Active ingredient	Formulation type	Application
1	Clozole gel 15 g	Psyco Remedies	Fluconazole	Gel	Antifungal infection treatment
2	Neobenz	Skin Medica	Benzoyl peroxide	Microsponge cream	Acne
3	Terbinafine HCl Gel (Exp)	In development	Terbinafine HCl	Experimental gel	Fungal infections
4	Luliconazole Gel (Exp)	In development	Luliconazole	Experimental gel	Fungal infections
5	Retina-A micro	Ortho-MeNeil	Tretinoin	cream	Acne vulgaris
6	Oxybenzone Gel	In development	Oxybenzone	Experimental gel	Sun protection
7	Betamethasone	GlaxoSmithKline/ Schering-Plough	Betamethasone	Controlled- release gel	Skin anti-inflammatory gel
8	Lactrex 12% moisturizing cream	SDR Pharmaceuticals Pvt. Ltd., India	Ammonium lactate	Cream	Moisturizier.

To determine spreadability, a glass slide is fixed on a wooden block with a pulley at one end. 1 g of gel is placed on the slide, and the other is placed on top to sandwich the gel. The excess gel was scrapped off from the edges, a 20 g weight is then tight to upper slide, and the time elapsed of two slides to get separated is recorded. Spreadability is inversely proportional to the time required for spreading.[27,28]

Spreadability is calculated using the formula:

$$S = M \times L/T$$

Where
S: Spreading ability
M: Mass used,
L: Displacement of the slide moves,
T: Time taken for the slides to separate.

Determination of production yield

In micro sponge formulations, it is evaluated using the mass of starting raw materials and the end weight of microsponges.[29]

$$\text{Production yield\%} = \frac{\text{Practical mass of microsponge}}{\text{Theoritical mass } (\text{drug+polymer})} \times 100$$

Motic digital microscopy

To determine the shape, size and topographical features, the formulated microsponges were mounted on a clean glass slide at room temperature to study surface morphology by a motic digital microscope (B1 advanced series).

For better understanding, a broken microsponge particle was also observed under microscope. The samples were observed using a ×10 objective lens, and the images are captured at a magnification power of 2048 × 1536.[30,31]

Differential scanning calorimetry (DSC)

Thermal analytical study was determined to confirm that if there was any evidence of interaction among the drugs and other ingredients used in the microsponge formulation. The thermogram of microsponge was analysed by the DSC instrument. Standard Indium was used to measure accurate thermal condition and heat measurement.[32] The microsponge powder was placed in pan made of aluminum and maintained temp at a constant rate of 10°C/min under the temperature of 30°C–300°C under a nitrogen atmosphere flowing at 20 mL/min.[33,34]

Fourier transform infrared spectroscopy (FTIR)

The chemical structure of microsponge was observed using (FTIR - Shimadzu) with KBr pellet method. FTIR spectra were recorded for microsponge formulation eudragit s-100, eudragit- L100, Carbopol 934 over the wavenumber range of 4000–4000 cm^{-1}.[35,36]

Particle size analysis

For prepared microsponges, particle size analysis was measured by applying the Motic digital microscope particle size analyzer.[34] Microsponges were uniformly distributed on a glass slide to obtain a light scattering signal within the sensitivity limits of the instrument for exact measurements.[37,38]

pH measurement

To determine whether the solution was suitable for application, the pH was measured. 1 g of gel was mixed in 100 mL of laboratory-grade water and stand for 2 h. The pH of the solution was measured confirming its suitability for topical delivery.[39,40]

CONCLUSION

In the summary, microsponge gels offer a great, effective, and versatile platform for advanced drug delivery, ensuring controlled and extended drug release that improves the efficacy of treatment by entrapping the API in a porous matrix or network. This system helps in overcoming the problems of conventional formulations like erratic absorption, skin allergy, chemical instability, and need for higher drug concentration. Even though there are some drawback like complex procedural method and achieving consistency through the process. On further optimization of this drug delivery system has a great potential to play a major role in improving the transdermal drug delivery system by means of improving patient adherence, ensuring safety, lowering irritations, and showing the most effective therapeutic action.

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