



## Microsponges: Emerging Porous Carrier for Advanced Drug Delivery

Dr. Daisy Chella Kumari S\*, Ahrsiya Noorin M<sup>1</sup>, Nivethitha RJ<sup>1</sup>, Dr. Devi Damayanthi R<sup>2</sup>, Deepika P<sup>1</sup>, Diven B Chajjer<sup>1</sup>

\*Associate Professor, Department of Pharmaceutics, College of Pharmacy, Madras Medical College, Chennai-600003, India

<sup>1</sup>Department of Pharmaceutics, College of Pharmacy, Madras Medical College, Chennai-600003, India

<sup>2</sup>Associate Professor, Department of Pharmaceutics, College of Pharmacy, Madras Medical College, Chennai-600003, India  
Affiliated to The Tamil Nadu Dr. M.G.R. Medical University, Guindy, Chennai-600032 India.

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### ABSTRACT:

Microsponges are porous polymeric microspheres (5-300  $\mu\text{m}$ ) and they are commonly used in advanced drug delivery systems. They enhance compliance rates in the patient, minimize skin irritation and increase drug stability, which makes them very appropriate in the topical and dermatological use. Their application in delivering oral, targeted and site-specific drugs in regard to attaining improved therapeutic results has also been covered in recent studies. They tend to be non-toxic, non-irritating, non-allergic, and non-mutagenic in nature and also have self-sterilizing property. Variations of quasi-emulsion solvent diffusion and liquid-to-liquid suspension polymerizations can be used to prepare microsponges. They have various biomedical applications such as; bone substitutes, anticancer drug delivery, and controlled and sustained release targeted therapy systems.

**Keywords:** External delivery of drugs, microsponges, porous polymeric carriers, novel drug delivery systems, and quasi-emulsion and solvent dispersion

### INTRODUCTION:

Over the last few years, the improved knowledge about drug pharmacokinetics and pharmacodynamics has facilitated such rational approach towards effective drug delivery system design. Any therapeutic agent that can be used more safely and effectively with an improved delivery system provides pharmaceutical companies with strong marketing opportunities, along with better treatment of various human diseases.

Ideal drug delivery system is developed to achieve delivery of a preset dosage of the drug to the intended site at the correct timing and rate based on the physiological requirements of the body. Conventional formulations are unable to control drug release kinetics or specifically direct drugs to the intended site.

New drug delivery technologies have a number of benefits over traditional multidose therapy. The novel drug delivery system (NDDS) is a carrier that transports the necessary dose of medication to the site of action and ensures drug levels of therapeutics are sustained over a prolonged duration. This is critical since drugs delivered in physiological fluids and non-target tissues tend to demand higher doses than those required in that of target cells and this may cause severe side effects in the process of drug delivery.<sup>1</sup>

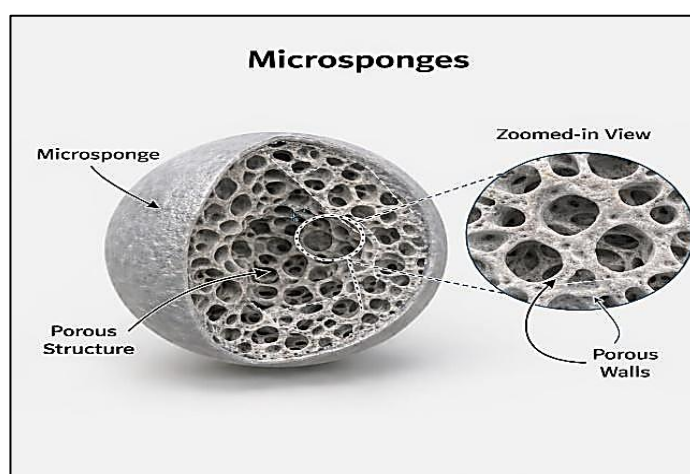
Modern tendencies indicate that microparticulate drug delivery systems are ideally suited to oral formulations that possess controlled or delayed release, short gastric residence time, minimum risk of dose dumping, and flexible blending in order to obtain various release patterns. Drug release of microparticles is influenced by several factors such as the quantity of drug loaded and the carrier used in formulating the drug particles. Hence, the possibilities of developing new oral controlled and sustained release preparations with the help of the microparticulate drug delivery technologies are great, which opens more possibilities in advancing the pharmaceutical side in the future.

Microparticulate delivery system is also considered a highly proven system to target drugs to specific locations and keep the levels of drug required without serious side effects. Microparticles are tiny solids or liquid droplets held in natural or synthetic polymeric shells of different thickness and permeability that regulates the release rate of the active component. They are normally 0.1  $\mu\text{m}$  to 200  $\mu\text{m}$  in diameter. Microparticles are one of the popular drug delivery systems currently being used due to their advantages which

include enhanced bioavailability, decreased frequency of dosing, controlled release in therapeutic range and reduced levels of toxicity. One of the key advantages of microparticulate system is that it is both possible to achieve both long-term release of a drug, as well as a controlled release of a drug, using synthetic or natural rate-controlling polymer.<sup>2</sup>

### MICROSPONGES:

Microsponges are polymeric delivery systems made up of porous microspheres that can entrap a variety of active compounds and have particle sizes ranging from 5 to 300  $\mu\text{m}$ . It is a tiny spherical particle that resemble sponges and are made up of numerous interconnected voids inside a structure that is non collapsible and has a huge porous surface. Their unique structure shields active pharmaceutical ingredients (APIs) against environmental deterioration while enabling controlled release. This technology is particularly useful in addressing issues like instability, poor solubility, and frequent dosage requirements that are present in conventional drug delivery systems.<sup>3</sup>



The skin cannot penetrate the microsponge particles, which are tiny, inert spheres. Instead, they get stored in the minute-sized pores in the skin and then release the drug trapped, whenever the skin needs it. The microsponge system is useful in preventing over-accumulation in the dermis and epidermis. Microsponge technology can reduce irritation by active drugs with no decrease in drug efficacy. When washing or cleansing, the empty spheres are dislodged out of the skin.

In microsponge delivery technology, these properties are introduced together to create a new generation of safely and extremely effective therapeutics. They typically occur as creams, gels, or lotions that include a non-low concentration of active ingredients. Microsponges have extensive applications in sunscreens, cosmetics, over-the-counter and prescription skin care preparations. It has a delivery system in the form of polymeric beads that forms a porous net and contains active ingredients and can release therapeutic agents in a controlled manner.

The porous character of these particles can be shielding against light, heat, and pH, which may adversely affect active substances, and enhances therapeutic effect and patient outcome. Their design enables release of drugs over a long period in a gradual, controlled way. This is especially applicable to drugs with a small therapeutic index, where the dose is supposed to be taken regularly. The rate of the release can be carefully regulated by modifying size and surface properties of the pore to realize the intended therapeutic outcome. Microsponges can also enhance patient compliance over regular drug delivery systems particularly in patients undergoing a long-term regime or patients with complicated pharmacologic regimens.<sup>4</sup>

Microsponges have shown great promise in numerous therapeutic uses. They are also capable of effectively entrapping hydrophilic and hydrophobic drugs, and hence delivery of a large variety of pharmacologically active agents is possible. Moreover, these particles can be formulated readily to various dosage forms based upon the necessary application. Microsponge system has also been demonstrated to increase the dissolution rate of drugs with low aqueous solubility in oral delivery as the microsponge system entraps the poorly aqueous soluble drugs in its porous structure. Because of the very small pores the drug is essentially turned into microscopic particles and the greater number of surface area dramatically enhances the solubilization rate. Microsponge system can also increase residence time of drugs in both small and large intestines in another way which is an important advantage because it increases absorption of the drug, as well as overall bioavailability.<sup>5</sup>



## HISTORY:

In 1987, Won invented the microsp sponge technique, and Advanced Polymer Systems, Inc. was the first to patent the technique. This corporation also trusted a number of versions of the technique and utilized them in over-the-counter (OTC), prescription drug, and cosmetic merchandise. Currently, the Cardinal Health, Inc. has the license to utilize this technology in topical preparations.<sup>6</sup>

## CHARACTERISTICS:

Microsponges can withstand pH values between 1 and 11. It is resistant to temperatures as high as 130°C. They are highly effective at trapping up to 50%–60%. It has good skin-absorbing properties. It is resistant to moisture attack and has a longer half-life. They are non-toxic, non-allergic, non-mutagenic, and non-irritating.<sup>7</sup>

## ADVANTAGES OF A MICROSPONGE BASED DELIVERY SYSTEM:

Microsponge drug delivery systems are a type of drug delivery technology with several advantages in the pharmaceutical and cosmetics sectors. Here are a few of the main benefits:

- 1. Controlled Release:** Drugs can be encapsulated in porous microspheres called microsponges. They enable the medicine to be released gradually and under control over a long period of time. This controlled release lessens the need for frequent doses, minimises negative effects, and keeps the drug concentration in the bloodstream steady.
- 2. Better Drug Stability:** Drugs can be shielded by microsponges from deterioration brought on by heat, light, or chemical interactions. This improved stability will ensure that the medication stays effective for extended periods of time and increase the shelf life of pharmaceutical products.
- 3. Reduce Side Effects:** By lowering the drugs peak blood concentrations, controlled drug release can lessen side effects and increase patient compliance. Additionally, it aids in preventing the adverse effects linked to elevated drug levels.
- 4. Targeted Delivery:** By utilising microsponges designed to release the medication at particular places, drugs can be administered to particular parts of the body. This is especially helpful for medications that must be administered to a specific organ or tissue.
- 5. Improved Bioavailability:** Some drugs are poorly soluble, which may restrict how well the body absorbs them. Because microsponges disperse the medicine in a form that is easier to absorb, they can increase drug solubility and bioavailability.
- 6. Decreased Dosage Frequency:** Patients usually require fewer doses of medication due to the continued release properties of microsponges. Overall therapy results and patient compliance could both benefit from this.
- 7. Versatility:** Microsponges work with a range of medications, including both hydrophobic and hydrophilic substances. Additionally, they can be used for parenteral, oral, or topical medication administration.
- 8. Less Irritation:** By controlling their release and minimising direct skin contact, microsponges in topical formulations might help lessen skin irritation brought on by specific medications.
- 9. Tailored Release Profiles:** Depending on the drug's therapeutic requirements, microsponges can be made to provide release profiles, such as zero-order, first-order, or pulsatile release.
- 10. Compatibility:** Microsponges are generally biocompatible and can be incorporated into a variety of pharmacological dosage forms, including creams, gels, lotions, and oral capsules.
- 11. Long-Lasting benefits:** Long-lasting therapeutic benefits can result from the extended release of pharmaceuticals from microsponges, which makes them appropriate for therapies that need to act continuously or for chronic illnesses.
- 12. Better Patient Compliance:** Microsponge drug delivery devices can improve patient satisfaction and treatment compliance by lowering the frequency of drug administration and minimising side effects.<sup>8</sup>



## FACTORS INFLUENCING THE DRUG'S RELEASE FROM MICROSPONGES:

It is highly advised that the active ingredients in microsp sponge entrapment must be soluble enough in the vehicle used such that formulation can administer an adequate loading dose to the drug prior to exit of the microsp sponge. This could be done by balancing the carrier system and the polymer matrix. The other method of reducing unwanted drug leaching is to form a free and entrapped polymerized porous microsp sponge vehicle that forms a pre-saturated system. The diffusion and external forces like pH, friction, or temperature can also influence the rate of drug release with the partition coefficient between the polymer and the vehicle along with the diffusion coefficient. In general, various aspects might affect the release of drugs through the microsp sponge system such as formulation properties and the environment.

### Temperature:

The viscousness of some encapsulated materials might not allow them to be stuck out of microsp sponges into the skin quickly at room temperature. The kind of sponge increases the temperature of the skin which increases the flow rate and improves and increases speed of drug delivery in the process of microsp sponge.

### Pressure:

Microsp sponges can be rubbed or pressed onto the skin to deliver the active chemical. The strength of the microsp sponges determines how much is released.

### Solubility:

Microsp sponges of substances such as antiseptics and deodorants leak their contents when they come in contact with water. Its release is primarily through diffusion, which is dependent on the partition coefficient between the microsp sponges and the external medium.

### pH:

By altering the microsp sponge's covering, the pH-based release of the active can be triggered.<sup>9</sup>

## FEATURES OF MOIETY ENTRAPPED IN MICROSPONGE:

It should be fully miscible in the monomer or made so using a small amount of water-insoluble solvent.

It must be almost insoluble or insoluble in water.

It should be inactive against monomers and other formulation excipients.

The vehicle must contain no more than 10–12% w/w microsp sponges in order to minimise the solubility of active compounds and avoid cosmetic issues. If not, the vehicle will run out of microsp sponges before applying them.

Microsp sponges' spherical structure shouldn't crumble. Its active ingredient payload and polymer structure of the microsp sponges will need to be tweaked to achieve an appropriate rate of release within the given time.

It should be stable when in contact with a polymerisation catalyst.<sup>10</sup>

## METHODS FOR PREPARATION OF MICROSPONGES:

### Polymerisation of liquid-liquid suspensions:

In this process, the active components and monomers are dissolved in an appropriate solvent and components of an aqueous phase like surfactants and suspending agents are added. Both heat and a catalyst initiate polymerization to create structures of spherical reservoirs. Lastly, to form porous microspheres, the solvent is taken off. Two-step processing is applied when it is important that much attention be given to the conditions of polymerization of the drug, when a functional molecule fills the porogen.

Thus, the production of microsp sponges with the help of this technique consists of the following steps:

1. The choice of one monomer or several monomers together.



2. Monomer chains will form as a result of polymerisation.
3. When the monomeric chains cross-link, ladders will be formed.
4. To produce spherical particles, the ladder will be folded.
5. Clusters of microspheres will form as a result of microsphere aggregation.
6. Additionally, bunches will result in the development of microsponges.<sup>11</sup>

#### **Quasi-emulsion solvent diffusion:**

polymer. The inner layer is made using Eudragit RS 100 dissolved in ethanol, the drug is added and sonicated at 35°C. This step is then combined with an aqueous PVA solution (outer phase) and stirred through the phase by 60 minutes. The microsponges that appear are filtered, dried at 40°C over 12 hours and weighted to find out production yield (PY).<sup>12</sup>

#### **Ultrasound-assisted production:**

The process is a modification of liquid-liquid suspension polymerization to manufacture MDS with the use of beta cyclodextrin monomer and diphenyl carbonate as a cross-linking agent. The paste is heated sonicated to maintain the size of the particle and cooled, reduced to a fine powder and washed with distilled water and ethanol. Nevertheless, it is not good at eliminating toxic residues of cross-linking agents.<sup>13</sup>

#### **Diffusion of Water in Oil in Water (W/O/W) Emulsion Solvent:**

Formation of water in oil emulsion by using an inner water phase and organic polymer solution with emulsifiers (span, polyethyleneimine, and stearyl amine) gives rise to this technique which produces biodegradable porous microspheres. This is dispersed then into an external aqueous PVA solution to form a double emulsion. It has been able to capture soluble and insoluble drugs, such as proteins and other heat-sensitive substances.<sup>14</sup>

#### **Addition of Porogen:**

This method substitutes internal emulsions with porogens such as hydrogen peroxide or sodium bicarbonate, dissolved in a polymer solution to create one-phase system. It is then resettled in aqueous PVA phase and then an initiator is added and the organic solvent is evaporated to create microparticles. The hydrogen peroxide forms uniformly distributed, interconnected pores 5-20 mm.<sup>15</sup>

### **EVALUATION OF MICROSPONGES:**

#### **Particle size Analysis:**

Particle size and size distribution are usually evaluated using an optical or electron microscope. The surface and stability of the formulation are greatly influenced by the particle size. The particle sizes of loaded and unloaded microsponges are usually examined using laser light diffractometry. To investigate the impact of particle size on drug release from microsponges, cumulative percentages of the release of active ingredients from the vehicle of the various particles are plotted versus time.<sup>16</sup>

#### **Determination of loading efficiency and production yield:**

The loading efficiency (%) of the Microsponges can be calculated according to the following equation:

$$\% \text{Loading efficiency} = \frac{\text{Actual drug content in microsponges}}{\text{Theoretical drug content}} \times 100$$

The production yield of the microparticles can be determined by calculating accurately the initial weight of the raw materials and last weight of the SPM obtained.<sup>17</sup>

$$\% \text{Production yield} = \frac{\text{Production yield} \times 100}{\text{Theoretical mass (polymer + drug)}}$$



### **Resilience (viscoelasticity properties):**

Microsponge resilience could be varied to make soft or hard beadlets as needed. An augmented cross-linking has the general effect of slowing down the rate of drug release.<sup>18</sup>

### **Morphology and surface topography:**

Morphology and surface topography are studied through photon correlation spectroscopy (PCS), scanning electron microscopy (SEM) and transmission electron microscopy (TEM). SEM is widely used, in which microsponges are coated with gold palladium in an argon atmosphere at room temperature, and then analyzed.<sup>19</sup>

### **Compatibility Analysis:**

Drug compatibility with formulation ingredients is measured using the thin layer chromatography (TLC) and fourier transform infrared spectroscopy (FT-IR). Differential scanning calorimetry (DSC) and powder X-ray diffraction (XRD) measure the alterations in crystallinity of a drug after polymerization. In the case of DSC, samples of 5 mg are placed in aluminum pans and heated at a rate of 15 °C/min, at a temperature of 25°C to 430°C under a nitrogen atmosphere.<sup>20</sup>

### **In-vitro Release Studies:**

The release of microsponge is studied with the help of a USP XXIII dissolution apparatus having a modified 5 µm stainless steel mesh basket. It operates at 150 rpm and 37°C. The medium used to dissolve the drug is based on the solubility of the drug to sustain sink conditions. Sampling is done periodically and the results are examined with a UV spectrophotometer.<sup>21</sup>

### **Polymer/monomer composition:**

Polymer composition needs to be studied in order to determine release rate of microsponge. It impacts the partition coefficient between the drug and microsponge system influencing the release. This is tested by the cumulative drug release percentage verses time.<sup>22</sup>

## **APPLICATION OF MICROSPONGES**

Microsponges are used in a variety of applications primarily topical but are also recently applied as oral delivery.

### **In oral administration:**

Despite being safe and practical, oral delivery has limitations such as high first-pass metabolism and low half-life of the drugs which are rapidly excreted. Thus, different microsponge formulations are created to deliver orally in a controlled and targeted manner.

The technology of microsponges increases the rate at which hydrophobic medications dissolve by trapping them in pores. A larger surface area accelerates the rate of solubilisation for small particles. Ibuprofen microsponges were developed for regulated drug distribution by modifying the intraparticle density of eudragit RS. The dry impact mixing process is used to create powder-coated microsponges of chlorpheniramine maleate for extended release.<sup>23</sup>

### **Microsponges for tissue engineering and bone replacement:**

The microsponges of bone and tissue engineering were made by incorporating the calcium hydroxyapatite, tricalcium phosphate, and prepolymerized polymethyl methacrylate with methyl methacrylate monomer. The porous composites that were formed served as microsponges. Basic fibroblast growth factor (bFGF) conjugated to a collagen sponge displayed dose-dependent angiogenicity in mice, when subcutaneously introduced. The significant increase in blood flow that the collagen microsponges containing bFGF produced in the mouse's ischaemic hind leg would never have been possible with bolus administration of bFGF.<sup>24</sup>

### **Long-lasting coloured cosmetics:**

Colours trapped in microsponges are used in a number of coloured cosmetic items, including lipsticks and rouge. As mentioned above, microsponges help to increase covering power and promote uniform spreading. Therefore, coloured cosmetics made with microsponges would be very advanced.<sup>25</sup>



### Targeting colon-specific medications to treat rheumatoid arthritis:

The Microsponge 5640 system was used to deliver Flurbiprofen controlled. In vitro experiments revealed that colon-specific tablets released the drug after 8 hours, the same time as the proximal colon is reached. The pore-plugging occurred upon enzyme stimulation, which enhanced the release of drugs after 8 hours and generated an altered release profile.<sup>26</sup>

### Anti-glaucoma:

The quasi-emulsion solvent diffusion technique was used to obtain stable acetazolamide microsponges. Ex vivo experiments demonstrated that in-situ gel preparations are useful topical ocular delivery in the treatment of glaucoma, and have less systemic side effects than when delivered orally.<sup>27</sup>

### Anti-cancer:

A microsponge-5-fluorouracil gel is applied to treat skin cancers and has better skin deposition and less skin irritation. Increased surface area and volume of pore were observed in BET analysis. The optimized formula was superior in thixotropic and textural characteristics over the commercial cream and enhanced skin deposition by 5.5 times and greatly decreased in vivo irritation.

Therefore, compared to the existing formulation, the new microsponge-based formulation appears to be a feasible alternative with improved topical administration of 5-FU.<sup>28</sup>

### Burn wound therapy:

A water-in-oil-in-water quasi-emulsion solvent diffusion method was used to prepare silver sulfadiazine-loaded microsponges. They were included in a gel scaffold without influencing antibacterial activity, which increases drug efficacy by decreasing cytotoxicity to fibroblasts and keratinocytes. Microsponges enhance delivery to the sites of burns with minimal damage of the host cells.<sup>29</sup>

### FUTURE PROSPECTS:

Microsponge drug delivery system has a high potential in the pharmaceutical industry because of the ability to release drugs at a controlled rate, lower irritation, enhance stability, and the varieties of forms in which it can be formulated. Future problems involve creating oral peptide delivery with varying polymers ratios. Their porous structure is also beneficial to pulmonary, parenteral, and other alternative routes of delivery. Microsponges can also have additional applications in stem cell culture, tissue regeneration and cosmetic products, which provide new opportunities in drug delivery and biomedical applications.<sup>30</sup>

### CONCLUSION:

The delivery system of the microsponge allows the release of the macroporous beads to be regulated, decreases side effects, but has no impact on the therapeutic efficacy. Entrapment of drugs increases stability, elegance, and flexibility of formulation. It enhances the experience in disease treatment and provides topical site-specific, sustained delivery. It also has the ability to enable oral and colon-targeted controlled delivery with bioerodible polymers. Overall, the use of microsponge systems is expected to become important in drug delivery matrices in several therapeutic uses.<sup>31</sup>

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