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#### **Review Article**

# **Microsponges: A Novel Drug Delivery For Dermatological Application**

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#### ABSTRACT

A microsponge's delivery system is a highly cross-linked, porous, polymeric microsphere system composed of porous microspheres capable of entrapping and releasing chemicals into the skin over time. This delivery system offers extended release, lower discomfort, better tolerance, and improved thermal, physical, and chemical stability. Microsponges are created using a variety of processes, such as suspension polymerization in a liquid-liquid system and emulsion systems. Microsponges can trap a variety of medications and can be utilized in cream, powder, gel, or lotion formulations. The delivery mechanism of microsponges solves the drawbacks of topical preparations, which include offensive odor, greasiness, and skin irritation, as well as their inability to enter the systemic circulation. Microsponge's formulations are compatible with the majority of vehicles and ingredients and stable throughout a pH range of 1 to 11. They are also stable at temperatures as high as 130°C. The current review provides an overview of microsponge technology, including its synthesis, characterisation, benefits, assessment, and drug delivery system release mechanism. It also includes information on marketed products and the most recent findings about microsponges.

#### **INTRODUCTION**

The initial patents for Won's 1987 invention, Microsponges technology, were awarded to Advanced Polymer System, Inc. This business developed several iterations of the technique, which were subsequently applied to pharmaceutical prescriptions and over-the-counter (OTC) items in addition to cosmetics. Currently, Cardinal Health, Inc. is the owner of a license to use this technology for topical applications..(1)A proprietary system of highly cross-linked, porous polymeric microspheres known as the Microsponge Delivery System (MDS) has the

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ability to entrap and release a broad range of active ingredients at a regulated rate [2].The effectiveness of drugs applied topically may be enhanced by this method. This is a new method of releasing topical medications gradually. It uses microporous beads with active chemicals inside that have a diameter of 10 to 25 microns. Particles created by their high degree of cross-linking are insoluble, inert, and robust enough to survive the high shear that is commonly employed in the manufacturing of creams, gels, lotions, and powders. Their capacity to "load" or adsorb a significant amount of active materials into the particle and onto its surface sets them apart [2, 3].



#### Fig 1: Classification of Noval Approaches for Ache Treatment.

The Microsponge Delivery Device (MDS) is a patented polymeric device comprised of porous microspheres. These tiny spherical particles, resembling sponges, feature interconnecting gaps and a porous surface, allowing for the controlled release of active substances. Microsponges range in diameter from  $5-300\mu m$ , with a typical  $25\mu m$  sphere containing up to 250000 pores and an inner pore structure comparable to 10 feet in length. This results in a total pore capacity of around 1 m l/g, allowing for substantial drug retention



Fig 2: Highly porous Structure of Microsponges.

#### Characteristics

Characteristics of Materials that is Entrapped in Microsponges [5-9]:

Potential characteristics of microsponge medication delivery devices.

- 1. Microsponges work well with the variety of ingredients.
- 2. Microsponges have a high entrapment efficiency.

- 3. Microsponges are evaluated based on their free-flowing qualities.
- 4. Microsponges maintain acceptable stability at high temperatures (up to 130°C) and pH ranges from1 to 11.
- 5. Microsponges' small pore size (0.25 μm) prevents bacteria penetration, eliminating the need for sterilization preservative.
- 6. Microsponges are hypoallergenic, irritant free,nonmutaganic and non toxic.



7. Microsponges may absorb up to six times their weight in oil without drying. [7]

# Benefit of Microsponge drug delivery system

- 1. Increased formula flexibility.
- 2. Enhanced thermal, physical and chemical flexibility.
- 3. Flexibility in developing nivel product forms.
- 4. Microsponge systems are not irritating, mutagenic, allergic, or toxic.[8]

- 5. Improved product performance.
- 6. Extended release.
- 7. Reduced irritation, resulting in increases patient compliance.
- 8. Effective product elegance.
- 9. Improved oil control, as it can absirb oil upto six times its weight without drying.





# Characteristics of actives moieties that is entrapped into Microsponges

- a. Active compounds entrapped in microsponge can then be added to a variety of products, including creams, gels, powders, lotions and soap.
- b. Specific considerations are used when creating the vehicle in order to attain the appropriate product qualities.
- c. It should be either completely miscible in monomer or capable of becoming miscible by adding a modest amount of a water immiscible solvent.
- d. It should be inert to monomers and not raise the mixture's viscosity during the formulation.
- e. It should be insoluble in water or only slightly soluble [10].
- f. It should not collapse the spherical structure of the microsponges.

- g. It should be stable in contact with the polymerization catalyst as well as under polymerization conditions.
- h. The solubility of actives in the vehicle should be controlled.
- i. If not, the vehicles will exhaust the microsponges prior to application.
- j. To avoid esthetic issues, only 10 to 12% w/w microsponges should be used in the car.
- k. Optimize the payload and polymer design of microsponges to achieve the desired release rate over a specific time period [11].

# Applications of Microsponge Systems

# 1. Topical agents:-

are widely used in cosmetics and dermatological treatments. However, they are associated with significant skin irritancy, particularly in sensitive people. This irritation has been linked to the fast release and subsequent buildup of the active components in topical treatments. The use of microsponge delivery technology allows for the regulated release of active chemicals onto the skin. Several microsphere-based topical medicines have been tested for safety and efficacy for cosmetic objectives as well as the treatment of dermatological problems, and they are currently available in the United States. These compositions include benzoyl peroxide, tretinoic acid, HQ with retinol, and 5-FU. Topical agent formulations using the Microsponge drug delivery system technology have shown little or no irritation in patients with acne, photodamaged skin. hyperpigmentation, or AK, without sacrificing efficacy [12].

# 2. Oral Delivery:-

The microsponge system in oral medication delivery accelerates the solubilization of weakly water soluble medicines by trapping them in the system's pores. Because these holes are so small, the medicine is effectively reduced to minute particles, and the increased surface area significantly increases the rate of solubilization. A microsponge system allows active components to remain in a safe environment while providing regulated delivery of oral medication to the lower gastrointestinal (GI) tract, where it is released when exposed to certain enzymes in the colon. If this strategy is effective, it will open up whole new possibilities for the Microsponge medication delivery system. It has been demonstrated that the microsponge system improves the solubilization of poorly soluble medicines by entrapping them in its pores [13].

### 3. Bone replacements:-

Pre-polymerized polymethylmethacrylate and liquid methylmethacrylate monomer powders were mixed with two aqueous dispersions of atricalcium phosphate (a-TCP) grains and calciumdeficient hydroxyapatite (CDHA) powders to create bone substitutes. The resulting composites appeared porous. The resultant composites' osteoconductivity and osteoconductivity were assessed in vivo using rabbit implantation. Inside the pores containing the inorganic particles, new trabecular bone formed. The material created has good biocompatibility, osteointegration rate, and osteogenetic features [14].

### 4. Cardiovascular:-

Microsponge technology for cardiovascular Biodegradable engineering. materials with autologous cell seeding necessitate a complex and invasive method that increases the risk of biodegradable graft infection. А material incorporating collagen microsponge for the regeneration of autologous vascular tissue has been produced. This material's potential to expedite in-situ cellularization with autologous endothelium and smooth muscle cells was with evaluated both and without precellularization. Poly (lactic-coglycolic acid), a biodegradable scaffold, was combined with collagen microsponge to create a vascular patch material. Histological analysis revealed the creation of an endothelial cell monolayer, a parallel alignment of smooth muscle cells, and a repaired vessel wall containing elastin and collagen fibers. After 6 months, the patch's cellular and extracellular components reached levels comparable to natural tissue. This patch shows potential as a bioengineered material for facilitating in situ cellularization and autologous tissue regeneration during cardiovascular surgery [15].





Fig 4 : Application of Microsponges Drug Delivery System

# 5. Micro-sponges for biopharmaceutical delivery

The microsponge delivery system is used for both the delivery of biopharmaceuticals and tissue engineering. Dai 2010 et al created 3D scaffold hybrid constructions that combine the benefits of natural type I collagen and synthetic PLGA knitted mesh. The collagen microsponges promoted cell seeding and tissue development, while the mechanically robust PLGA mesh acted as a skeleton. The scaffolds were separated into three groups: a) Thin: collagen microsponge formed in the PLGA mesh's interstices; b) Semi: collagen microsponge formed on one side of the PLGA mesh; c) Sandwich: collagen sponge formed on both sides of the PLGA mesh (16). Afrasim M et al. (2016) successfully developed a polymeric microsponge-based Fluconazole system using a quasi-emulsion solvent diffusion method for continuous topical delivery over an extended period of time in order to reduce application frequency, hypersensitivity reactions associated with the conventional marketed formulation, and improve bioavailability and safety. The implemented process was found to be simple, reproducible, and quick, resulting in the creation of highly porous, spherical microsponges with good flow. Different drug polymer ratios had a significant impact on drug content, encapsulation efficiency, particle size, and drug release. The F1 gel formulation with FLZ loaded microsponges was chosen for further study due to its superiority

in physiochemical characterization, production drug content, entrapment efficiency, vield. morphology, surface topography, intact particle percent, and particle size. The results of the invitro drug release investigation revealed that the zero order models had the highest regression values, and the F1 formulation was found to be more effective for extended drug release (85.38% at 8 h) than the conventionally marketed formulation. The in-vitro antifungal assessment and stability investigation yielded encouraging findings. Thus, the microsponge-based delivery method created and evaluated in the current study appears to be promising for the eradication of face fungus, candidiasis, and a variety of other fungal illnesses, as well as practical applications in pharmaceuticals and cosmeceuticals.[17] Barde P. (2015) concluded that microsponges containing Terbinafine HCl were synthesized utilizing the quassi-emulsion solvent diffusion process using Eudragit RSPO as a polymer. The resulting microsponges formulation was refined and tested further. The concentrations of the polymer Eudragit RSPO and stabilizing agent PVA were shown to alter the particle size and drug content of the microsponges that formed. The production yield, loading efficiency, surface morphology, and particle size were all analyzed. Scanning electron microscopy was used to analyze the surface morphology of microsponges, particularly their pore structure. Microparticles were mixed into Carbopol 934 gel basis and tested for penetration



in a Franz diffusion cell. Scanning electron microscopy revealed that microsponges have microporous surfaces. Drug release was found in compared to the marketed formulation. The current work aimed to design, develop, and evaluate a microsponge-incorporated gel for topical medication administration of Terbinafine HCl with extended release. The internal phase consists of a mixture of Eudragit RSPO and medication in DCM. The exterior phase consisted of a PVA solution in water. Terbinafine HCl is easily inactivated by the stomach environment, resulting in gastrointestinal symptoms such as diarrhoea, nausea, abdominal discomfort, and vomiting. The optimal formulation. F4 was integrated into gels, which were tested for physical properties and demonstrated extended release for up to 12 hours. Stability experiments at room temperature revealed no significant changes in homogeneity, pH, spreadability, extrudability, viscosity, drug content, or in-vitro release after three months. As a result, it was determined that the improved microsponges could be mixed into gel for topical antifungal applications. [18] Yadav P. et al. (2014) stated that skin must withstand a variety of external traumas such as wounds, burns, blisters, and irritation, as well as topical diseases such as psoriasis, vitilago, cancer, and herpes. Drug delivery systems such as vesicles, microspheres, transdermal patches, nanoemulsions, microemulsions, and microsponges are superior to traditional methods due to their ability to bypass systemic circulation and target specific sites. Microsponges are tiny spherical particles that resemble sponges and have a wide porous surface. They allow controlled release. Herpes simplex is a viral disease that manifests in two forms: Herpes labialis and Herpes keratitis, which affect the lips and the epidermal layer of the skin, respectively. Conventional formulations used for treating herpes have several problems, such as discomfort, rashes, frequency of dose, and low absorption. To address these microsponge-loaded limitations, topical formulations of Acyclovir herbal gel and medicated lipstick were developed. The quasi emulsion solvent diffusion approach was used to create Acyclovir controlled release formulations placed onto microsponge. Particle size, manufacturing yield, and entrapment efficiency were all measured for the suggested Acyclovirloaded microsponges formulations. Scanning electron microscopy validated the porous structure of microsponges. Following evaluation, the most optimized batch was used in carbopol, aloe gel, and lipstick bases. The physical properties of microsponge-loaded herbal gel and lipstick were examined. In vitro release investigations utilizing diffusion cells found that drug release followed the Korsemeyer-Peppas paradigm. Acyclovircontaining microsponges were made utilizing a quasi-emulsion solvent diffusion process with ethyl cellulose and PVA. [19]

#### **PREPARATION OF MICROSPONGE:**

Drug loading in microsponges can occur in two ways: one-step or two-step processes, as outlined in liquid-liquid suspension polymerization and quasi emulsion solvent diffusion techniques, which are based on the physicochemical properties of the drug to be loaded.

# 1. Liquid-liquid suspension polymerization: (20,21,22)

Porous microspheres are created in liquid-liquid systems using the suspension polymerization process. In their preparation, the monomers are first dissolved in an appropriate monomer solvent solution, followed by dispersion in an aqueous phase containing additives (surfactants, suspending agents, etc.). The polymerization process is then launched by adding catalyst, raising temperature, or irradiation.

The various steps involves in the preparation of microsponges are summarized as



- Selection of monomer or combination of monomers
- Formation of chain monomers as polymerization begins.
- Formations of ladders as a result of cross linking between chain monomers
- Folding of monomer ladder to form spherical particles- Agglomeration of microspheres, which give rise to formation of bunches of microspheres.
- Binding of bunches to form microsponges.



Fig 5: Reaction vessel for microsponge preparation by liquid-liquid suspension polymerization

#### 2. Quasi-emulsion solvent diffusion: (23,24,25)

This Quasi-emulsion solvent diffusion method is a two-step approach that allows microsponges to be created using various polymer quantities. To produce the inner phase, Eudragit RS 100 was dissolved in ethyl alcohol. The medicine can then be added to the solution and dissolved using ultrasonication at 35oC. The inner phase was added to the PVA solution in water (outer phase). After 60 minutes of stirring, the mixture is filtered to remove the microsponges. The microsponges are dried in an air-heated oven at 40°C for 12 hours and weighed to measure the production yield (PY). **RELEASE MECHANISMS [32-37]:** Microsponges can be designed to release given amount of active ingredients over time in response

amount of active ingredients over time in response to one or more external triggers.

#### **Temperature change:**

Some entrapped actives may be too viscous at room temperature to flow spontaneously from microsponges to the skin. Increased skin warmth might cause an increase in flow rate, resulting in release 8. Viscous sunscreens, for example, were shown to release more from microsponges when exposed to greater temperatures; hence, a sunscreen would only be released from a microsponge when exposed to the sun's heat.



Figure 6: Release mechanism of active ingredient from microsponges

#### **Pressure:**

The microsponge system releases the entrapped substance, and rubbing or applying pressure can cause active ingredients to be released onto the skin. The amount emitted is determined by the sponge's specific features. The microsponge most suited for a given application can be optimized by altering the material and process variables. When compared to mineral oil microcapsules, mineral oil microsponge had a significantly greater softening effect. Emolliency lasted substantially longer in microsponge systems. pH-triggered systems. Modifying the microsponge's covering can trigger the active's pH-based release. This has numerous uses in drug delivery. Solubility When exposed to water, microsponges containing water-soluble chemicals such as antiperspirants and antiseptics release the component. The release can also be triggered via diffusion, which takes into account the ingredient's partition coefficient between the microsponges and the surrounding system. Microsponges with sustained release capabilities can also be produced. Physical and chemical properties of entrapped actives are some of the aspects to consider while developing such formulations. Particle size, pore properties, resilience, and monomer compositions can all be programmable regarded parameters, and microsponges can be constructed to release specific amounts of actives in response to one or more external triggers such as pressure, temperature, and active solubility.

### LIMITATIONS [32]

Both procedures often use organic solvents as porogens, which constitute an environmental risk as well as a safety risk because some are very inflammable.Furthermore, traces of residual monomers have been detected in the Bottom-Up technique, which may be poisonous and dangerous to human health. While the constraints appear to be substantial, they can be easily addressed by implementing effective quality control procedures and post-manufacture cleaning, as well as good uniformity of the various operations.

# **EVALUATION OF MICROSPONGE:**

#### 1. Particle size determination: [33]

Laser light diffractometry or any other suitable methods are using to Particle size analysis of loaded and unloaded microsponges. The values can be expressed for all formulations, size range. Cumulative percentage drug release from microsponges of different particle size will be plotted against time to study effect of particle size on drug release. Particles larger than 30  $\mu$ m can impart gritty feeling and hence particles of sizes between 10 and 25 $\mu$ m are preferred to use in final topical formulation.

#### 2. Scanning electron microscope study: [34]

For morphology and surface topography, prepared microsponges can be coated with gold palladium under an argon atmosphere at room temperature and then the surface morphology of the microsponges can be studied by scanning electron microscopy (SME). SEM of a fractured microsponge's particle can be taken its ultra structure.

# **3.** Determination of loading efficiency and production yield: [35]

The loading efficiency (%) of the microsponges can be calculated according to the following equation.

#### Loading efficiency = Actual Drug Content in Microsponge ×100 Theortical Drug Content

#### 4. Production yield:

The production yield of the micro particles can be determined by calculating accurately the initial weight of the raw materials and the last weight of the microsponge obtained.

**Production Yield (PY) = Practical Mass of** 

Microsponges × 100 Theortical Mass Theoretical mass (Polymer+drug).

#### 5. Determination of true density:



The true density of Microsponges can be measured using an ultra-pycnometer under helium gas and is calculated from a mean of repeated determinations.

### 6. Compatibility studies: [36]

Compatibility of drug with reaction adjuncts can be studied by thin layer chromatography (TLC) and Fourier Transform Infrared spectroscopy (FT-IR). Effect of polymerization on crystallinity of the drug can be studied by powder X-ray diffraction (XRD) and Differential Scanning Calorimetry (DSC).

# 7. Polymer/monomer composition: [37]

Factors such as microsphere size, drug loading, and polymer composition govern the drug release from microspheres. Polymer composition of the MDS can affect partition coefficient of the entrapped drug between the vehicle and the microsponge system and hence have direct influence on the release rate of entrapped drug. Release of drug from microsponge systems of different polymer compositions can be studied by plotting cumulative % drug release against time.

# SAFETY CONSIDERATION [38,39,40]

Skin irritation studies in rabbits: The scores for erythema totalled for intact and abraded skin for all rabbits at 24 and 72 hr. The primary irritation index was calculated based on the sum of the scored reactions divided by 24 (two scoring intervals multiplied by two test parameters multiplied by six rabbits). Anti-inflammatory activity by ear edema measurement: Experiments reported in this study were performed after approval by the Animal Ethics Committee of our College and were carried out in accordance with the CPCSA guidelines Anti-inflammatory activity was done by Male Swiss mice (25-35 g) housed at 22±2 °C under a 12 hr light/12-hr dark cycle and with access to food and water, which were performed during the light phase of the cycle. The animals were allowed to acclimate to the laboratory for at least 2 hr before testing and were

used only once. Oedema was induced in the right ear by topical application of 0.1mg/ear of croton oil dissolved in 20µL of acetone. In house gels of FA containing free, entrapped drug and marketed gel were applied topically simultaneously with the croton oil. Ear thickness was measured before and 6 hr after the induction of inflammation using a digital vernier caliper and reported Primary Eye Irritation Study (Unwashed Eyes) Test substance is instilled into one eye of each of 6 rabbits (unwashed eyes), The cornea, iris, and conjunctiva tissue of the treated eyes are graded for irritation effects at 1, 24, 48 and 72 hr after instillation. Observation period may be extended for up to 21 days to evaluate the reversibility of the effects observed. Other evaluation studies are Oral toxicity studiesin rats, Mutagenicity in bacteria, allergenicity in guinea pigs, Compatibility studies by (TLC) thin layer chromatography

# **CONCLUSION:**

A novel technique for the controlled release of macroporous beads containing an active ingredient that may lessen adverse effects without sacrificing therapeutic efficiency is the microsponge delivery system. Entrapment of components is provided by the microsponge drug delivery method, which is thought to help with less side effects, increased stability, increased elegance, and increased formulation flexibility. Furthermore, a plethora of studies has verified that microsponge systems are non-toxic, non-mutagenic, non-irritating, and nonallergic. At the moment, sunscreens, prescription medications, over-the-counter skin care products, and cosmetics all use this technology. A greater understanding of how various diseases are healed could result from the use of this type of drug delivery technology. When used in topical medication delivery systems, microsponge can effectively maintain dosage forms on the skin by providing a site-specific drug delivery system and increasing the interval between doses. It can also be used to administer medication orally by



employing bioerodible polymers, particularly for controlled release drug delivery systems and transport to the colon. By injecting the active pharmaceutical ingredient into the macroporosity beads using the microsponge delivery technology of a controlled release mechanism, side effects are reduced and therapeutic efficacy is increased. Microsponge can be employed effectively in topical medicine administration systems by providing a method for site-specific medication delivery and improving the time between doses, to keep dosage forms on the skin. Hence, the microsponge-based drug delivery technology is likely to become a valuable drug delivery matrix substance for various therapeutic applications in the future.

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