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A novel approach on microsponge

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Abstract
Microsponge can be utilized successfully in topical drug delivery systems to retain dosage forms on skin by offering a site-specific drug delivery method and increasing the time between doses. Additionally, it can be used for the regulated release of medications and the delivery of medications specifically for the colon using bio erodible polymers. It is believed that the components are trapped by microsponge drug delivery systems, which reduces systemic exposure, boosts stability, and restricts local cutaneous reactions. Better elegance and flexibility in the formulation. The delivery technique using microsponges solves the issue. The systemic circulation is not reached by topical drugs, which also have a number of disadvantages such an unpleasant odour, greasiness, and skin irritation. Most vehicles and components are compatible with microsponge formulations. In addition to remain constant between pH values of 1 to 11. Also stable at temperatures as high as 1300c. The Synthesis, Characterization, Configurable Parameters and MDS Release Mechanism of the Microsponge Technology are described in the current review.

Keywords: Microsponge, site-specific drug, dosage forms

Introduction
The oral route is the most practical and popular way to administer medication. Drugs with a rapid half-life and simple gastric absorption are eliminated swiftly through blood circulation. Orally controlled release formulations, which release medication gradually into the digestive system and aid in maintaining steady medication concentration in the serum for a longer period of time, have been created to prevent these issues. The oral method of medication administration is widely used. Due to their frequent, simple, appropriate administration with accurate dosage, self-medication, pain evasion, and most significantly patient compliance, up to 50-60% of oral solid dosage forms are popular. Tablets and capsules are the most admired solid dose forms; they can be used for a wide variety of innovative medicine delivery mechanisms such microsponges, nano sponges, microspheres, and nano spheres.
Microspheres can be produced using certain methods. Due to its suitability for many medications used in topical therapy for skin infections and illnesses, microsponge technology may therefore be a fascinating alternative option for FLZ encapsulation. Many cutting-edge drug carrier systems have been developed recently to increase the bioavailability, sustained, and controlled release of drugs. These systems include liposomes and niosomes, hydrogels, organo gels, FLZ hydrogels, polymeric mucoadhesive films, and poly microspheres. They also maintain localized effects and enhance drug accumulation in different skin strata. Due of liposomes' stability problems up to now, a variety of complications have come up. Additionally, nothing extensive and satisfactory.
Microsponges are small spheres that can absorb skin secretions to lessen skin shine and oiliness. Spherical particles made up of groups of even smaller spheres can hold four times as much skin secretions as they weigh. These products often come in the traditional forms of creams, gels, or lotions and have a reasonably large amount of active chemicals. Recently, their utility for oral medication delivery has also been studied. This page offers succinct details on the numerous facets of the construction, evolution, uses, and prospects for microsponges. The purpose of this paper is to provide an overview of the extensive research that has been done and the numerous career prospects that exist in the field of microsponges.

Defining microsponges [3]
The Microsponge Delivery Device is a patented polymeric system comprised of porous microspheres (MDS). The active substances are administered in a controlled manner through these tiny, spherical, sponge-like particles' wide porous surface. The building cannot collapse. A typical 25-mm sphere has an internal pore structure that is 10 feet long and up to

250000 holes, giving it a total pore volume of about 1 ml/g for significant drug retention. The diameter of the microsponges varies from 5 to 300 m. Pore volume varies between 0.1 and 0.3 cm 3 / g, and surface might be anywhere from 20 to 500 m 2 / g. Because of this, each microsponge has a huge reservoir that can accommodate as much active agent as it weighs.

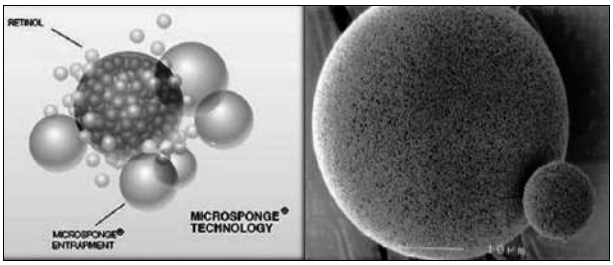


Fig 1: A typical diagram of Microsponge

Drug explored in micrsponge drug delivery system [4]

- Paracetamol
- Ibuorofen
- Fluconazole
- Benzoyl Peroxide
- Ketoprofen
- Dicyclomine
- Flubiprofen
- Ketoconazole
- Tretinoin
- Trolamine
- Retinol
- Salicylic acid

Characteristics of microsponge [3]

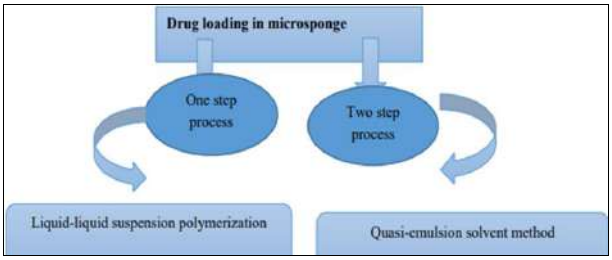
When these are put to the skin, the microsponge gradually releases its active substance with excellent efficacy and minimum irritability on a timer mode and in reaction to stimuli like rubbing, temperature, and pH influence, among others.

The following are characteristics of microsponges:

1. Microsponge compositions maintain their stability from pH 1 to 11.
2. Microsponge formulas are stable up to 1300C in temperature.
3. The majority of vehicles and components are suitable with microsponge compositions.
4. Because bacteria cannot enter the pores of microsponge formulations with an average pore size of 0.25 m, they are self-sterilizing.
5. Entrapment in microsponge compositions can reach up to 50% to 60%.
6. Cost-effective and free-flowing microsponge compositions are available.
7. The fact that the microsponge particles themselves are too big to easily permeate into the skin adds to the safety of these microsponge materials by preventing the negative effects of the microsponge adjuvants.
8. Even for the mass market application of cosmetics, where the cost of the components is crucial, microsponges formulations can be economically viable.
9. Microsponges have a 6x weight capacity for oil absorption without drying.
10. It offers extended release with sustained activity for up to 12 hours.
11. They are more flexible in their formulations.

Preparation of Microsponge [5, 6]

Depending on the physio-chemical characteristics of the drug to be loaded, loading can be done in microsponges in one step or two steps. Drugs that are generally inert nonpolar substances will produce porogens, which are porous structures. Porogen medication is locked in a one-step process so that it neither prevents polymerization nor is activated by it and is Stable to free radicals.



Suspension of liquids in liquids Polymerization

In liquid-liquid systems, the suspension polymerization process is used to create porous microspheres. In order to prepare them, the monomers are first mixed with the active components in a suitable monomer solvent solution, and then the aqueous phase, which contains the additives, is added (surfactant, suspending agents, etc.). Then, the catalyst is added, the temperature is raised, or irradiation is used to start the polymerization.

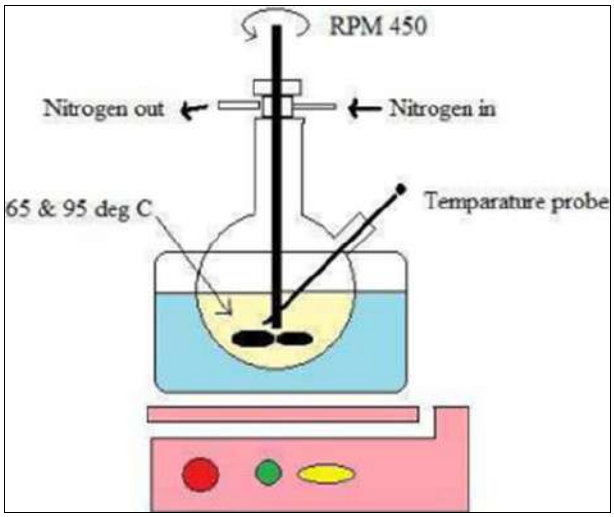
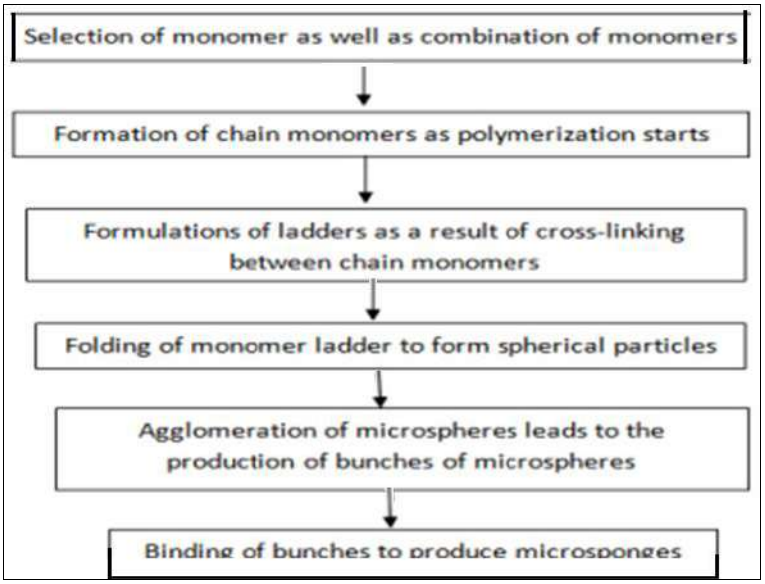


Fig 2: Reaction vessel for Microsponge [7]

As a result of the polymerization process, a reservoir-style system with a spherical structure continues to develop. The solvent is eliminated following the polymerization process, leaving the spherical-shaped porous microspheres, also known as microsponges. The numerous methods needed to prepare microsponges are outlined as follows in Scheme 1:



Scheme 1: Steps in the preparation of microsponges

Method for solvent diffusion using a quasi-emulsion

(Top down approach) This procedure necessitates the development of two separate phases: an inner phase and an external phase, much like emulsions. The outer phase of the aqueous polyvinyl alcohol (PVA) solution is applied to the inner phase of the drug-polymer mixture created in an extremely volatile solvent, such as ethanol, acetone, or dichloromethane, with vigorous stirring. Different emulsion globules emerge as a result of stirring. Then, the solvent is extracted from these globules, producing hard, insoluble micro particles also referred to as microsponges. After thorough stirring, the mixture is filtered to remove the microsponges before being dried. After 10 to 12 hours at 40 °C in an air-heated oven, weigh the dried microsponges.

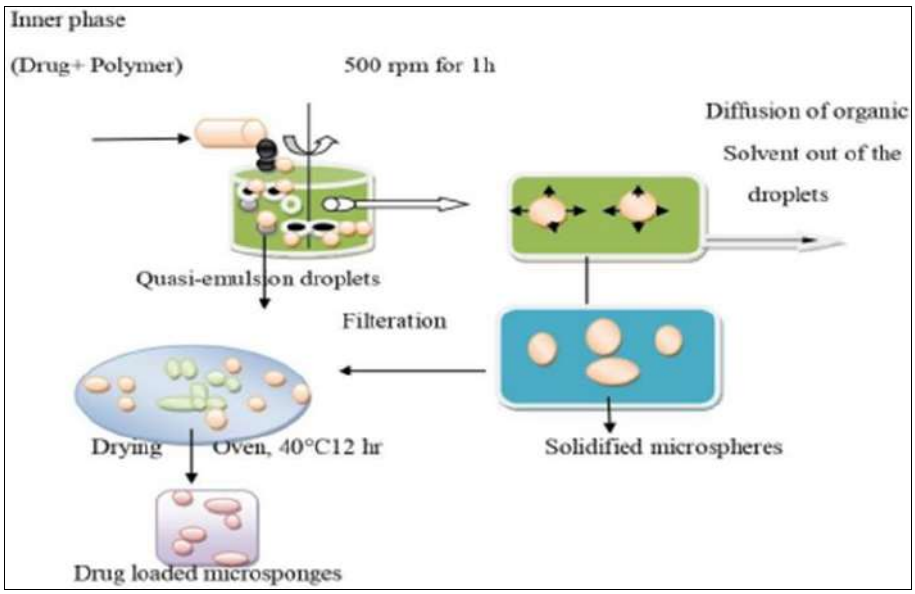


Fig 3: Quasi- Emulsion solvent diffusion method

Evaluation of microsponges [7, 8]

Particle size Determination

Laser light diffraction or other appropriate techniques can be used to analyse the particle size of loaded and unloaded microsponges. The average of the measured value over all formulations can be used to express the value (d50). The percentage of cumulative drug release from microsponges with various particle sizes is plotted against time to examine the impact of particle size on drug release. Particles between 10 and 25 m are employed in the final topical formulation since particles bigger than 30 m can have a gritty appearance.

Scanning electron microscopy

A scanning electron microscope can be used to confirm the surface morphology of the processed microsponges after they have been palladium-gold plated in argon environment at standard ambient temperature (SEM). The ultra-structure of the microsponge can also be described using SEM of damaged microsponge particles.

Determination of loading efficiency

The following equation can be used to compute the loading efficiency (%) of the microsponges: Eq.

$$\text{Loading efficiency} = \frac{\text{Actual Drug Content in Microsponge}}{\text{Therotical Drug Content}} \quad (1)$$

Determination of production yield

By precisely quantifying the initial weight of the raw materials and the final weight of the microsponge produced, the production yield of the micro particles can be ascertained.

$$\text{Production Yeild(PY)} = \frac{\text{Practical Mass of Microsponges}}{\text{Therotical Mass}} \times 100 \quad (2)$$

Determining true density

The true density of microsponges can be assessed using an ultra-pycnometer under helium gas and is determined by taking the mean of several measurements.

Studies on compatibility

Thin-layer FT-IR and chromatography can be used to examine the compatibility of a medicine with reaction adjuncts (TLC). The impact of polymerization on the drug's crystallinity is examined using X-ray diffraction (XRD) and differential scanning calorimetry (DSC) techniques.

Polymer/monomer composition

The drug release from microspheres is governed by elements such microsphere size, drug loading, and polymer composition. The partition coefficient of the entrapped drug between the vehicle and the microsponge system can be affected by the polymer composition of the microsponges drug delivery system. This has a direct impact on the release rate of the entrapped drug. To examine drug release from microsponge structures with different polymer compositions, plot cumulative percent drug release against Time.

Characterization of pore structure

Pore volume and diameter play a key role in determining the extent and time frame of an active ingredient's efficacy, according to a description of pore structure. The movement of active substances from microsponges into the vehicle in which the material is disseminated is also influenced by pore diameter. To investigate the relationship between pore volume and diameter and the rate of drug release from microsponges, mercury intrusion porosimetry can be used.

Mercury intrusion porosimetry can be used to determine the porosity parameters of microsponges, including the intrusion-extrusion isotherms, pore size distribution, total pore surface area, average pore diameters, interstitial void volume, percent porosity, shape and morphology of the pores, bulk, and apparent density.

With the help of the Washburn equation, the pore diameter of microsponges can be determined.

$$D = \frac{-4\gamma\cos\theta}{P} \quad (3)$$

The contact angle (130o), the mercury's surface tension (485 dyn cm 1), the pore diameter (m), and the pressure (P) (psia). Equation was used to compute the total pore area.

$$A_{tot} = \frac{1}{\gamma\cos\theta}\int_0^{V_{tot}} P\,dV \quad (4)$$

Where,

P is the pressure in psia, V is the volume of the intrusion (in mL g1), and Vtot is the total intrusion volume (in mL g1).

Using equation, the average pore diameter (Dm) was determined.

$$D_m = \frac{4V_{tot}}{A_{tot}} \quad (5)$$

Equation was used to calculate the microsponges' envelope (bulk) density (se).

$$\rho_{se} = \frac{W_s}{V_p - V_{Hg}} \quad (6)$$

Where,

Vp is the volume of an empty penetrometer (mL); Ws is the weight of the microsponge sample (g); and VHg is the volume of mercury (mL).

Using equation, the absolute (skeletal) density (sa) of microsponges was determined.

$$\rho_{sa} = \frac{W_s}{V_{se} - V_{tot}} \quad (7)$$

Where,

Vse equals the penetrometer's volume minus the mercury's volume (mL).

Finally, using equation, it was possible to determine the sample's percent porosity.

$$\text{Porosity (\%)} = \left(1 - \frac{\rho_{se}}{\rho_{sa}}\right) X\ 100 \quad (8)$$

The intrusion-extrusion profiles of mercury in the microsponges, as described by Orr, can be used to identify the pore morphology.

Resiliency [9]

According to the demands of the final formulation, microsponges' resilience (viscoelastic characteristics) can be altered to produce bead lets that are either softer or stiffer. The rate of release is typically slowed down by increased cross linking. In order to study and improve the resilience of microsponges, release will be taken into account as a function of cross-linking throughout time.

Dissolution Studies [12]

The dissolving profile of microsponges can be investigated using the dissolution apparatus (USP XXIII) and a modified basket consisting of 5 m stainless steel mesh. 150 rpm is the spinning speed. The dissolution medium is selected while taking the actives' solubility into consideration in order to attain sink conditions. Samples from the dissolution media may be subjected to suitable analytical techniques throughout time.

Kinetics of Release

To determine the drug release mechanism and analyse the variations in release patterns among microsponges, the drug released amount versus time was used. The release data were evaluated using the following mathematical models:

$$Q = k_1 t^n \text{ OR } Q = \log k_1 + n \log t \quad (1)$$

Where,
Q represents the amount of the drug released at time (h),
N specifies the release mechanism through a diffusion exponent, and k1 is a constant describing the drug-polymer interaction.
Kinetic parameters n and k1 were determined by plotting the log Q versus log t data and calculating the slope and intercept. The data was also subjected to Eq. 1, which may be regarded as simple, for comparison's sake.

$$Q = k_{2t}^{0.5} + C \quad (2)$$

With K2 shown as a root time dissolution rate constant and C as a constant, the above equation for release data dependent on the square root of time would result in a straight line release profile.

Mechanism of drug release
A microsponge can be created to release a predetermined amount of active substances over time in response to one or more external triggers by properly manipulating the aforementioned programmable parameters.

Temperature change
Few encapsulated active substances can be too viscous at room temperature to flow abruptly from microsponges onto the skin. The rate of flow also increases with an increase in skin warmth, which improves release.

Pressure
The active component from microsponges can be released onto skin by rubbing or applying pressure.

Solubility [10]
When there is water present, microsponges containing water-soluble compounds such as antiseptics and deodorants release the component. Diffusion can also be used to activate the release, but it must take into account how evenly the substance is distributed between the microsponges and the external system.

Mechanism of Microsponge [12]
Since the micros pongic particles don't have a continuous membrane, they have an open structure that allows the active substance to pass freely in and out. The vehicle's active component will be absorbed by the skin.
Following this, the stratum corneum's surface-retained microspongic particles continue to distribute the medication to the skin over time through a sustained release. The mode of action emphasizes the value of transporting vehicles; if the active ingredient is more soluble in the vehicle during formulation, the completed product will not be able to provide the intended effect of progressive release.

Therefore, it becomes vital to create a vehicle with a low solubilizing power when creating a microsponge with an entrapped medication.

Release mechanism of microsponge
The following factors affect how quickly a microsponge releases its active ingredients:

Pressure
For topical preparations of microsponges, pressure or rubbing might cause the medication to be released onto the skin.

Solubility
Water soluble component; when there is water present, microsponges release the medication.

Change in temperature
If the medicine incorporated into the microsponge is too viscous to flow over the skin, the flow and release rate are accelerated by raising the skin's temperature. Franz - diffusion cells are used to analyse medication release.

Systems that depend on pH
pH triggered release can be achieved by coating microsponges.

Advantages of microsponge drug delivery systems [11]
- Improved product functionality.
- Extension of allow to leave.
- Reduce irritability, which improves patient compliance.
- Enhanced product class.
- Better oil control due to its ability to absorb up to six times its weight in oil without drying.
- Makes room for innovative product formats.
- Enhances the effectiveness of treatment.
- More quickly confirm the cure or control.
- Enhance condition management.
- Enhance the bioavailability of identical medicines.
- The freedom to create new product formats.
- Non-toxic, non-allergenic, non-mutagenic, and non-irritating.
- Enhances thermal, physical, and chemical stability.
- Permits the inclusion of immiscible goods.
- Facilitates the transformation of liquids into powders, for example.

Applications of microsponges [1, 14]
Topical prescription, over-the-counter, and personal care products' safety, efficacy, and cosmetic quality are improved by using microsponge delivery systems. There are several applications for microsponges. It is usually used topically, though oral use has increased recently. Due to its high loading capacity and capability for prolonged release, it has been mentioned in several patents that it can be employed as excipients. It provides the formulator with a variety of options for creating pharmaceutical and cosmetic products. Microsponges are created to effectively administer a pharmaceutical active component at the lowest amount possible, as well as to improve stability, lessen adverse effects, and alter drug release. Numerous moisturizers, specialist rejuvenative treatments, and sunscreens are examples of over-the-counter goods that use the microsponge drug delivery technology.

The three main methods that products now in development or on the market use Topical Microsponge systems are as follows:

1. As containers for absorbing undesired elements, such as excessive skin oils.
2. As reservoirs releasing active compounds over time.
3. As closed containers that keep substances far enough from the skin to have only surface effects.

Microsponge for topical delivery

The Microsponge systems are built on tiny, polymer-based microspheres that can bind, suspend, or entrap a wide range of chemicals. These microspheres can then be added to a designed product, like a gel, cream, liquid, or powder.

A single Microsponge has a diameter of less than one thousandth of an inch and is as small as a talcum powder particle. Each microsphere, like a real sponge, is made up of countless interconnected gaps inside a non-collapsible structure that can take in a variety of chemicals.

Typically, the outer surface is porous, allowing for the regulated flow of materials into and out of the sphere. Polymers that are physiologically inert make up microsponge systems. The polymers are non-irritating, non-mutagenic, non-allergenic, non-toxic, and biodegradable, according to extensive safety investigations.

The result is that they cannot be broken down or converted into other compounds by the human body.

Microsponge for oral delivery

By trapping ineffectively water-soluble pharmaceuticals in the pores of the microsponge system, it has been demonstrated that the microsponge system speeds up the rate of solubilization of such drugs in oral applications. As a result of the drug being effectively reduced to microscopic particles due to the tiny size of these pores, the rate of solubilization is significantly accelerated by the large increase in surface area.

As an illustration, Eudragit RS, an acrylic polymer, allows for the regulated oral delivery of ibuprofen microsponges by varying the intra-particle density. Chlorpheniramine maleate sustained release formulation for oral medication delivery employing powder-coated microsponges made using the dry impact mixing method.

Microsponge for Bone and Tissue Engineering

Pre-polymerized poly methyl methacrylate and liquid methyl methacrylate monomer powders were combined with two aqueous dispersions of tri-calcium phosphate grains and calcium deficient hydroxyapatite powders to create bone-substitute compounds. The finished composites functioned as microsponges and seemed porous.

Basic fibroblast growth factor (bFGF), which was included in a collagen sponge sheet, was sustained released in the mouse sub cutis in response to the sponge matrix's biodegradation and shown local angiogenic activity in a dose-dependent manner. Microsponges are mostly utilized for topical administration, while they have lately been used for oral administration and the delivery of biopharmaceuticals.

Microsponges for Biopharmaceuticals Delivery [7]

Both the delivery of biopharmaceuticals and tissue engineering utilize the microsponge delivery system (MDS). There have been developed hybrid 3D scaffolds that benefit from both type I collagen and PLGA knitted mesh.

The collagen microsponges encouraged cell seeding and tissue growth, while the mechanically strong PLGA mesh served as a skeleton.

Collagen microsponge can be generated in three different ways:

1. Thinly (in the PLGA mesh's gaps),
2. Semi-opaquely (on one side),
3. Sandwich-style (on both sides).

For 2, 4, and 8 weeks, bovine chondrocytes were grown in the scaffolds and subcutaneously implanted into naked mice.

All transplants demonstrated homogenous cell distribution, significant cartilaginous ECM deposition, and typical chondrocyte morphology. In comparison to the Thin group, the Semi and Sandwich groups synthesized significantly more GAGs per DNA and expressed more type II collagen and aggrecan mRNA.

Young's modulus demonstrated that the synthetic cartilage has a mechanical strength of 54.8 49.3% and a stiffness of 68.8 62.7% in Semi and Sandwich, respectively, when compared to real articular cartilage.

These scaffolds could be used in tissue engineering 43 to produce articular cartilage with varying thickness. Iwai *et al*. developed a biodegradable graft material that incorporated collagen microsponge and permitted the regeneration to overcome these problems.

Poly (lactic-co-glycolic acid) was used as a biodegradable scaffold and coupled with collagen microsponge to generate a vascular patch material. Poly (lactic-co-glycolic acid) collagen patches, either with or without autologous vascular cellularization, were used to patch the canine pulmonary artery trunk.

Two and six months after the implantation, histology and biochemistry were evaluated. Both groups' poly (lactic-coglycolic acid) scaffolds were about entirely absorbed, but neither group developed thrombus.

The histologic findings showed the formation of an endothelial cell monolayer, parallel alignment of smooth muscle cells, and repair of the arterial wall with elastin and collagen fibers.

The cellular and extracellular components of the patch have reached sizes similar to those of normal tissues after six months.

This patch has potential for use in cardiovascular surgery as a bioengineered material since it promotes in-situ cellularization and the regrowth of autologous tissue. 3D biodegradable porous scaffolds are crucial for tissue engineering.

Using pre-prepared ice particles as the porogen material, the freeze-drying and porogen leaching processes were coupled to create porous scaffolds constructed of synthetic biodegradable polymers. Researchers have developed hybrid porous sponges that are biodegradable and comprised of collagen and synthetic polymer.

Mixing synthetic polymer sponges with collagen microsponges.

The collagen microsponges were made using the pores of synthetic polymer sponges. Hybrid sponges made of inorganic hydroxyapatite, synthetic polymer, and collagen were produced by coating the collagen microsponges in the

synthetic polymer-collagen sponges with hydroxyapatite particles.

The hydroxyapatite and collagen are utilized to encourage cell contact and assist cell seeding, whereas the synthetic polymer sponge was used as a mechanical skeleton to help mould these hybrid sponges into desirable forms and contributed good mechanical strength and handling.

Application of microsponge system [13]

Sr. No.	Active agents	Applications
1.	Anti-inflammatory e.g. Hydrocortisone	Skin allergic response and dermatoses.
2.	Anti-dandruffs e.g. zinc pyrithione, selenium sulphide	Reduced unpleasant odor with reduced irritation with extended efficacy and safety.
3.	Skin de pigmenting agents e.g. hydroquinone	Improved stabilization against oxidation.
4.	Anti-fun gals	Sustained release of actives.
5.	Anti-acne e.g. Benzoyl peroxide	Maintained efficacy with reduced skin irritation and sensitization.
6.	Antipruritics	Extended and improved activity.
7.	Sunscreens	Long lasting product efficacy with improved protection against sunburns and sun related injuries even at elevated concentration and with reduced irritancy and sensitization.
8.	Rubefacients	Prolonged activity with reduced irritancy, greasiness and odor.

Optimum values for microsponge formulation [13]

Sr. No.	Specification	Optimum value
1	Drug and polymer ratio	1:1, 1:2, 1:3, 2:1, 3:1
2	Amount of drug (mg)	100-300
3	Polyvinyl alcohol (mg)	100
4	Inner phase solvent (ml)	Ethyl alcohol
5	Amount of inner phase solvent	10
6	Amount of water in outer phase (ml)	100
7	Temperature of inner phase	25°C
8	Types of process	Magnetic stirrer & Bath sonicater
9	Magnetic stirrer speed	100 rpm

Future prospect [14]

Microsponge drug delivery system holds a promising opportunity in a variety of pharmaceutical applications in the near future due to its unique qualities like improved product performance and elegance, extended release, improved drug release profile, reduced irritation, improved physical, chemical, and thermal stability that make it flexible to develop novel product forms. The main difficulty in the future will be to develop a delivery technique for oral peptide delivery employing different polymer ratios. The use of bioerodible and biodegradable polymers in drug delivery allows for the safe diffusion of the active component. The capacity of these porous structures to display efficient medication release even in the rarest of rare situations has also been explored for drug delivery via the pulmonary route.

Because the colon absorbs fluid, it is a good location for the release of medications. Additionally, these carriers must be developed for parenteral and pulmonary medication delivery. Since they can also be utilized as the media for cell culture, these particles can be used for stem cell cultivation and cellular regeneration in the body. Due to their elegance, these carrier systems have been utilized in cosmetics. Researchers could now employ them in new ways as a result of these modifications. Additionally, these formulation advances offer fresh drug delivery options.

Conclusion

Using the microsponge delivery technology of a controlled release method, the active pharmaceutical ingredient is injected into the macro porosity beads, which begins to lessen adverse effects while increasing therapeutic efficacy. Microsponge can be utilized successfully in topical medication delivery systems to retain dosage forms on the skin by offering a site-specific drug delivery system and extending the time between doses. In especially for controlled release drug delivery systems and distribution to the colon, it can also be utilized to give medications orally using bio erodible polymers. Using the microsponge delivery technology of a controlled release method, the active pharmaceutical ingredient is injected into the macro porosity beads, which begins to lessen adverse effects while increasing therapeutic efficacy. By offering a mechanism for site-specific medication delivery and enhancing the time between doses, to retain dose forms on the skin, microsponge can be used efficiently in topical medication delivery systems. In especially for controlled release drug delivery systems and distribution to the colon, it can also be utilized to give medications orally using bio erodible polymers. This needs to be looked into with the majority of future study inquiries.

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