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MICROSPONGES FOR DERMATOLOGICAL PURPOSE

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ABSTRACT

Microsponges are innovative porous microspheres designed to enhance topical drug delivery by improving the controlled release and minimizing side effects. Their unique structure consists of a porous, sponge-like network that can encapsulate active pharmaceutical ingredients (APIs). This encapsulation allows for sustained and targeted release of drugs at the application site, making microsponges particularly useful in dermatology, cosmetics, and transdermal therapies. The fabrication of microsponges typically involves processes such as solvent evaporation, polymerization, or quasi-emulsion solvent diffusion, resulting in particles ranging from 10 to 25 micrometers. These microspheres have a high surface area and pore volume, which facilitate the efficient loading of APIs and their controlled diffusion out of the sponge matrix. Moreover, their porous nature ensures minimal drug wastage and improved stability of sensitive compounds. The advantages of microsponges in topical applications include enhanced drug stability, reduced systemic absorption, and prolonged residence time on the skin. This leads to improved therapeutic efficacy and patient compliance. Additionally, microsponges can be incorporated into various topical formulations such as gels, creams, and lotions, providing versatile delivery options. Overall, microsponges represent a promising approach for topical drug delivery, offering controlled release, targeted action, and improved safety profiles. Their potential extends across various dermatological treatments, making them a significant advancement in pharmaceutical and cosmetic sciences.

Keywords: Tropical skincare, Controlled release , Encapsulation, Biocompatibility.

INTRODUCTION

Delivery of drug is the method of administering of a drug to attain a therapeutic outcome in human or animals. For many decades the acute and longlasting illness are cured with pharmaceutical dosage form like tablet, pills, capsules, ointments, creams, liquids, injectable, suppositories, and gels, which are considered as conventional dosage forms.

Conventional transdermal uses of gels are to discharge the drug upon application, leads to accumulation and irritation of drug in layers of the skin. The active moiety can be applied directly to the skin, either in a substantially pure form or dispersed in liquid vehicle. Such direct application of active moiety leads to rapid evaporation of volatile active substance, extensively pure active form can often lead to unexpected increase in active moiety in the blood plasma levels, causes serious adverse reactions, such as allergic reactions and toxicity. The adverse reaction can be reduced by dilution of the drug in an appropriate liquid carrier, and moreover, further dilution of drug resultant in reduction of the effectiveness of the final product. Therefore, precaution should be taken during dilution of drug, which may show sub therapeutic effect. For this above reason, it would be desirable to optimize the composition, so that the drug could be accomplished of providing prolonged delivery of finished products, while application of drug to the skin. Desirably, these delivery systems could control toxicity of active substance. Due to enzymatic degradation, and poor design module fails to reach systemic circulation for certain period of time, which 2 frequently results in poor patient compliance this problem can be overwhelmed by design of novel drug delivery systems.

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Recently new approaches in the novel drug delivery systems introduced are

Oral Drug Delivery System (DDS)
Mucosal DDS Nasal DDS
Parenteral DDS
Vaginal DDS
Intrauterine DDS
Ocular DDS
Transdermal DDS

Among the various delivery systems, transdermal delivery of drugs is suitable for anti-inflammatory action which can increases bioavailability, decreases side effects, by pass hepatic first pass metabolism, and desirably shows local action.

TOPICAL DELIVERY Topical delivery includes two basic types External topical delivery on to the skin (spread, sprayed, or dispersed) Internal topical that are intended to apply on the mucosal membranes. Several advanced modules were developed and adopted for delivering directly to the systemic circulation by transdermal drug delivery system (TDDS) using the skin as an effective surface area for entry. TDS has enhanced the efficacy of many 3 drugs that are administered through skin with safety. For sustained and local action of drugs on that skin and dermis, no efficient carrier system has been developed. Application of topically applied drugs can causes many problems such as unappealing, oiliness, tackiness, that results into lack of poor patient compliance. The high concentration of drug is required for its low efficiency of delivery system, and results into irritation, allergic reactions. Thus the

necessity for prolonging to maximize amount of time for active ingredient to present either on superficial layer of the skin or deeper layers, while attempting to minimizing its transdermal penetration into the body.

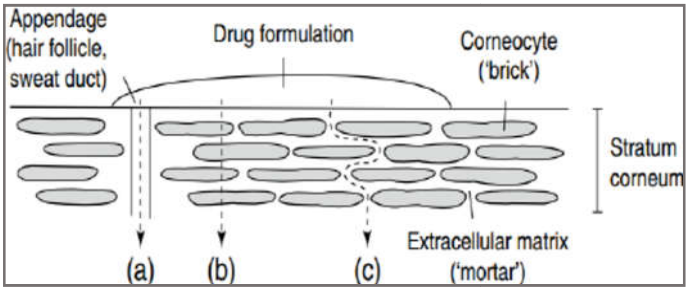

FIG: 1 Trans Appendgeal of Skin

Drug permeation pathways in the skin (stratum corneum shown): (a) the appendageal route, (b) the transcellular route, and (c) the tortuous extracellular route. The transcellular and intercellular routes constitute the transepidermal pathway.

Delivering the drug from dosage form into the epidermis remains localized at that region, and allow drug enter into the blood with limited amount, it means of controlling side effects that are related to drugs. The need for delivery systems is to shows its action either on the skin or deeper layers of the skin, the drug molecule can penetrate by three potential ways into the layers of the skin as shown in FIG: 1 Trans Appendgeal of Skin 4

There are three possible ways that drug molecules can pass through stratum corneum.

Transfollicular route.

Transcellular route.

Intercellular route.

Carrier systems for drug delivery, often called drug delivery vehicles or systems, are crucial tools in pharmaceuticals designed to transport drugs to specific sites within the body.

The primary goals of using these carrier systems are to:

- **Enhance drug efficacy** by concentrating the drug at the target site.
- **Minimize side effects** by limiting exposure of healthy tissues to the drug.
- **Improve drug stability** and prevent premature degradation.
- **Increase the bioavailability** of drugs, especially those with poor water solubility.
- **Achieve controlled or sustained release** of the drug over a prolonged period.

Common Types of Drug Carrier Systems:

Many of these carriers operate at the nanoscale (nanocarriers), offering advantages like better tissue penetration and targeted delivery.

1. **Liposomes:**

- Spherical vesicles made of one or more lipid bilayers that enclose an aqueous core.
- Can encapsulate both **hydrophilic** (in the core) and **hydrophobic** (in the bilayer) drugs.
- Widely used in cancer therapy (e.g., Doxil) and vaccine delivery.

2. **Nanoparticles (Polymeric, Lipid, or Metal-based):**

- Tiny particles typically 1 to 1000 nanometers in size.
- Can be made from various materials (polymers, lipids, metals).
- Their small size allows them to penetrate tissues and cells more effectively, making them ideal for targeted therapies.

3. **Micelles (Polymeric Micelles):**

- Self-assembling structures formed by amphiphilic (having both hydrophilic and hydrophobic parts) molecules in aqueous solution.
- Characterized by a **hydrophobic core** that encapsulates water-insoluble drugs, and a hydrophilic shell that provides stability in water.
- Used to improve the solubility of hydrophobic drugs.

4. **Dendrimers:**

- Highly branched, globular, nanoscale polymers with a precise and defined structure.
- Drugs can be encapsulated within their core or attached to their surface.
- Explored for targeted delivery and gene therapy.

5. **Microspheres:**

- Hollow, micron-sized carriers, often formed from polymers.
- They encapsulate the active drug, and release is often controlled by drug diffusion through the structure or by the degradation of the sphere's material.

6. **Cyclodextrins:**

- Cyclic oligosaccharides with a hydrophobic inner cavity and a hydrophilic outer surface.
- Form inclusion complexes with drug molecules, enhancing drug solubility and stability.

MICROSPONGE: AN APPROACH FOR TOPICAL DELIVERY

Microsponge Technology In recent years, micro particular drug delivery system has shown a great interest in the pharmaceutical area to improve novel microsponge based drug delivery systems, in order to adapt release behaviour of the drugs by incorporation into a carrier system. This can alter the therapeutic index, duration of the activity of drugs, and its therapeutic efficacy, with reduction of side effects. Carrier technology in the microparticulate system adopted to solve the problems related to above challenges to achieve targeted and sustained release of drugs. Each microsponge comprises of interconnecting voids spaces, inside a non-collapsible structure, with large porous surface area. Microsponges belongs to polymeric delivery systems consisting of porous nature surrounded to microspheres, that can protect by entrapping wide range of active ingredients such as, anti-infective, anti-fungal, and anti-inflammatory agents. The microsponge technology was developed by Won in 1987, and the original patents were assigned to advanced polymer systems. (Barry BW *et al.,* 2001).

STRUCTURE OF MICROSPONGES

The microsponges size can be varied from 5-300 µm in diameter, although the microsponge sphere can have upto 2,50,000 pores, this results in a larger surface area to diffuse the drug from each microsponge. The microsponge particles are relatively larger than skin pores as they can't go into the skin, rather they are entrapped in tiny hooks and stay in the layers of the skin there slow release of entrapped drug takes place, this adds a point of safety to these microsponge by preventing bacterial contamination and bacterial cannot enter into the pores of the microsponges. (Bhatia M *et al.,* 2018)

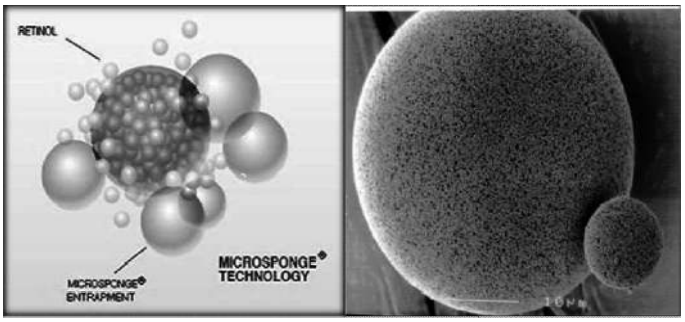

Fig no 2: Typical Structure of Microsponges

In general, the release of drug from topical formulation over an extended period of time is difficult, the vehicles process high concentration of drug for effective therapy because of their low efficiency in designing the module, resulting in devoid of allergic reactions and irritation, and upholding efficacy. Their high grade of cross linking result in particles that are insoluble, inert of sufficient strength to stand up to the high shear and stress, commonly used in manufacturing of creams, lotion, and powder. (Bichave A *et al.,* 2015). The Typical structure of microsponges shown in Fig .2. Their characteristic feature is the capacity to adsorb an active material into the particles and on its surface. Its capacity for entrapment is up to three times of its weight. (Chaudhary H *et al.,* 2013).

Table No: 1 Drugs Delivered using Microsponges

Drug	Category
Antifungal	Terbinafine
Anti-bacterial	Mupirocin
Anti-inflammatory	Ibuprofen
Antiviral	Acyclovir
Anti-cholinergic	Dicyclomine
Anti-pyretic	Paracetamol
Anti-acne treatment	Benzoyl peroxide

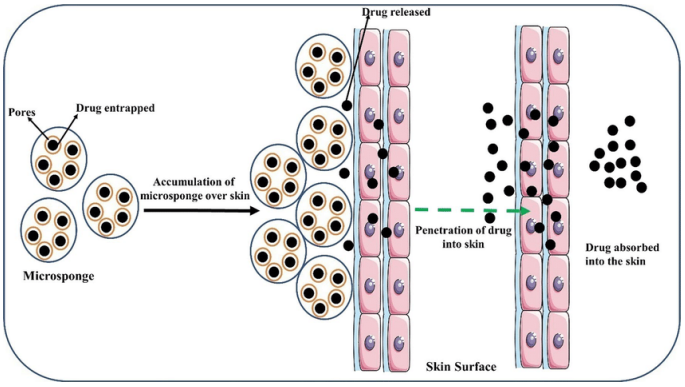

Fig no 3: Mechanisms of drug release from topical microsponges

MECHANISM OF ACTION OF TYPICAL MICROSPONGES

The selected drug is added to the continuous vehicle as its solubility is merely soluble. The microsponges have an effective porous nature where the drug is allowed to move in and out from the pores of the microparticles and into the vehicle until the equal concentration is achieved. When the vehicle becomes saturated with the microsponge then the diffusion is stopped. Due to this typical property of the formulated microsponges are applied superficially to the skin, the active drug that is there in the vehicle will be absorbed first into the skin where continuous vehicle can deliver the initial dose and followed by prolonged release. For that initial therapy, the vehicle should be treated with the drug, when the drug is released into the vehicle from the microsponges. As, microsponges are scattered into the vehicle, it delivers the drug to diffuse out. The mechanism of drug release from microsponges shown in **Fig 3.**

POLYMERS USED IN MICROSPONGE PREPARATION Usually monomers like styrene, di vinyl benzene, ethyl vinyl benzene and methyl methacrylate are engaged in liquid-liquid suspension polymerization technique. Where Eudragit RS-100 and carbopol are employed for quasi emulsification technique. Eudragit polymers are copolymers synthesis from esters of acrylic and methacrylic aids, whose physicochemical properties are recognized by functional groups. Eudragit RS100 polymer are obtainable in a wide range of various physical forms. Eudragit RS100 is employed for quasi emulsification technique . External phase consists of eudragit RS 100, ethyl cellulose, in organic solvent and internal phase includes polyvinyl alcohol in water.

FORMULATION CONSIDERATION Following considerations are taken into brief explanation in order to achieve desired finished product. The solubility of drugs must be limited in the vehicle; otherwise the encapsulation is major problem. Formulation of microsponges much be integrated more than 10 to 12 % w/w to escape cosmetic problem. Optimizations of polymer are studied to incorporate desired concentration levels of active into the microsponges to attain required release for given period.

METHOD OF PREPARATION OF MICROSPONGES Based on the preparation of microsponges, this is divided in to two ways,

1) One stage process or liquid-liquid suspension polymerization
2) Two stages process or quasi-emulsion diffusion

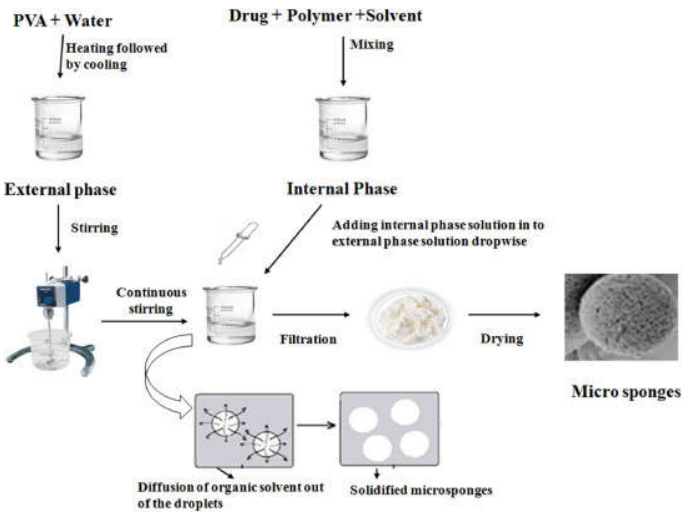

Fig no 4: Method of preparation of Microsponges

EFFECT OF STIRRING RATE IN THE FORMATION ON THE PHYSICAL PROPERTIES OF MICROSPONGES As the stirring rate has influence on size of the microsponges are obtained. Increase the stirring rate decrease the production yield but the drug content increased as stirring rate is increasing. This is due to the turbulence produced within the external phase due to which polymer gets detected at the paddle region and production yield gets reduced.

APPLICATION MICROSPONGE

The microsponge system has a wide range of applications in various therapeutic areas due to its unique properties of controlled and targeted drug delivery. Some of the key applications include:

1. Dermatology: Microsponges are extensively used in topical formulations for treating skin conditions such as acne, dermatitis, psoriasis, and fungal infections. They enhance drug penetration, provide sustained release, and reduce skin irritation by controlling the rate of drug release.
2. Anti-inflammatory and Analgesic Therapy: Microsponges can deliver anti-inflammatory agents like hydrocortisone, minimizing systemic absorption and side effects while maintaining therapeutic efficacy over prolonged periods.
3. Antiseptics and Antibacterial Agents: Incorporation of antimicrobial agents into microsponges improves stability, prolongs antimicrobial activity, and reduces the frequency of application, which is beneficial in wound care and infection prevention.
4. Cosmetic and Dermatological Products: Microsponges are used in sunscreens, anti-aging creams, and other skincare products to deliver active ingredients efficiently, improve product stability, and provide a matte finish by controlling oil release.
5. Controlled Release of Drugs: They are employed in transdermal patches and topical gels to achieve sustained drug release, thereby enhancing patient compliance and therapeutic outcomes.
6. Vaccine Delivery: Emerging research explores microsponges for delivering vaccines or immunomodulators through the skin, aiming for non-invasive immunization strategies.

BENEFITS OVER CONVENTIONAL FORMULATION

Conventional formulations of topical applied drugs are executed to shows its action on the outer stratum of the skin. Such finished products release their drug upon presentation, creating a extremely concentrated layer of drug that is quickly absorbed. When compare to the modify release system microsponge can prevent unnecessary accumulation of active agent within the layers of the skin. Actually, the microsponge system can diminish the irritation of the drugs without reducing their therapy.

BENEFITS OVER MICROENCAPSULATION AND LIPOSOMES

Liposome suffer from lower encapsulation efficiency, difficult in formulation design, limited chemical and microbial stability. It has ability to stay stable at pH of 1 to 11, and withstands temperature up to 130 °C, compatible with most continuous phase, due to presence of pores it is self-sterilizing as average pore size is 0.25 µm where small bacteria cannot penetrate into the carrier system.

BENEFITS OVER OINTMENTS these are often aesthetically unattractive, oiliness, tackiness etc. that frequently results into poor patient compliance. These continuous phase (vehicles) need high concentrations of drugs for therapy because of their low ability in delivery system chosen, ultimately results into allergic reactions. moreover, the disadvantage of topical formulation has uncontrolled evaporation of active ingredient likely continuous phase has incompatibility with the drug. Microsponge system has the ability to uphold the active ingredient for a maximum period either on the superficial layer of the skin or within the layers, while limiting its entry into transdermal.

12 The recent technologies in microsponges drug delivery system are made by modifying the method to form β-CD microsponges that can be used for highly hydrophobic drugs, for oral administration of BCS class II drugs. Future predictions of microsponge drug delivery system holds a unique opportunity in various pharmaceutical applications in the forthcoming future as it, has distinctive properties to develop novel product forms

RECOMMENDATIONS

Microsponge technology is widely used in dermatology for delivering active ingredients in a controlled and sustained manner. Here are some recommended microsponge formulations for dermatological purposes:

1. Acne Treatments

Clindamycin Microsponge Gel: Provides sustained release of clindamycin for acne vulgaris.
Salicylic Acid Microsponge Formulation: Helps in deep pore cleansing and reduces acne breakouts.

2. Anti-aging and Skin Brightening

Retinol Microsponge Cream: Ensures controlled release of retinol, minimizing irritation.
Vitamin C Microsponge Serum: Enhances stability and prolonged delivery of vitamin C for skin brightening.

3. Anti-itch and Anti-inflammatory

Hydrocortisone Microsponge Lotion: Provides sustained anti-inflammatory effects with reduced side effects.

4. Sun Protection

Zinc Oxide Microsponge Sunscreen: Offers controlled release of zinc oxide for long-lasting sun protection.

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CONCULSION

The goal of cosmetic chemists and dermatologists is to create customised goods and new technologies. Improved knowledge of skin physiology, including its structure and function, can lead to the development of novel cosmetic and dermatological formulations. Additionally, in order to successfully implement this novel method in drug delivery, the pharmaceutical formulator needs to have a solid understanding of the physicochemical characteristics of the medicines and polymers utilised. Without further optimisation, addition of polymers to the existing formulations will seldom result in acceptable outcome. Microsponge based delivery systems have been one of the key technologies investigated in the last few years. These systems display a strong rationale for cosmetic and dermal applications, in order to enhance the therapeutic performance of active molecules, with improved patient compliance. According to Li *et al.,* the microsponge delivery method may improve paeonol penetration while reducing transdermal penetration of the active molecule. This should increase the active molecule's bioavailability in the skin and minimise adverse effects while treating skin conditions. A extended active period for the medication in topical treatment is also possible due to microsponges' ability to prolong the drug's residency in the skin and permit prolonged drug release for up to 12 hours. These properties ascertain that MDS could be a promising platform for a new generation of dermatological and cosmetic treatments. However, further research is required to examine these features because the method of drug penetration and the degree of

drug distribution in the stratum corneum, epidermis, and dermis layers of skin are still in their infancy. The scientific literature suggests that microsponge technology is an essential instrument for both the industrial creation of new cosmetic items and scientific study based on this system. Microsponges are currently being utilised, or are being proposed for use in the future, as carriers of dermatological and cosmetic active ingredients in commercial formulations. In order to create safe topical goods using new technology for both medical and cosmetic objectives and assist in cost-effectively communicating these benefits to consumers, researchers, regulators, and manufacturers should collaborate to take a scientific approach. Although, topical application for cosmetic and dermal benefits is associated with the advantage of reduced systemic side effects, certain drugs have the potential to induce problems like local irritation. Microsponges for topical delivery have overcome this obstacle to a great extent. Furthermore, these facilitate controlled release of potentially irritating molecules with better therapeutic delivery, resulting in improved adherence of patients to topical treatment. These microcarriers are also harmless since the microsponge particles are too big to be absorbed via the skin. More thorough research on the safety profile of these porous microparticles is necessary for the system's effectiveness because there are still some unresolved, potentially murky areas pertaining to their toxicity and biocompatibility. Fascinatingly, a sharp rise in dermatological and cosmetic goods based on microsponge technology is anticipated in the near future.

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