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REVIEW ARTICLE **OPEN ACCESS**

An Updated Review on Formulation and Evaluation of Microsponge

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ABSTRACT

Microsponges delivery system contain of porous microspheres of polymeric delivery systems. They are minute in size sponge-like circular particles with a bulky porous surface. They may improve stability, reduce side effects and transform drug release satisfactorily. Microsponge Systems are based on microscopic, polymer-based microspheres that can suspend or entrap a wide variety of substances, and then can be incorporated into a formulated product such as a gel, cream, liquid or powder. Microsponge and Nanosponge delivery System was firstly developed for topical delivery of drugs can also be used for controlled oral delivery of drugs using water soluble and bioerodible polymers. Microsponge delivery system (MDS) can entrap wide range of drugs and then release them onto the skin over a time by difussion mechanism to the skin. It is a unique technology for the controlled release of topical agents and consists of nano or micro porous beads loaded with active agent.

Keywords: *Microsponges, Controlled release, Porous microspheres, Solvent Diffusion Method, Quasi-Emulsion Method.*

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INTRODUCTION:

The microsponges Delivery system (Microsponge drug delivery system) is a patented polymeric system consisting of porous microspheres. They are tiny sponge like spherical particles that consist of a myriad of interconnecting voids within a noncollapsible structure with a large porous surface through which active ingredient are released in a controlled manner. The size of the microsponge's ranges from 5-300µm in diameter and a typical 25µm sphere can have up to 250000 pores and an internal pore structure equivalent to 10 feet in length, providing a total pore volume of about 1ml/g for extensive drug retention. The drug delivery technology landscape has become highly competitive and rapidly evolving. More and more developments in delivery systems are being integrated to optimize the efficacy and cost-effectiveness of the therapy.[1]

They are highly cross-linked, porous, polymeric microspheres that can entrap wide range of actives and then release them with desired rate. This system is useful for the improvement of performance of topically applied drug. It is a unique technology for the controlled release of topical agents and consists of micro porous beads, typically 10-25 microns in diameter, loaded with active agent.Amicrosponge delivery system (MDS) is highly cross linked, patented, porous, polymeric microspheres that acquire the flexibility to entrap a wide variety of active ingredients such as emollients, fragrances, sunscreens, essential oils, anti-infective, anti-fungal and antiinflammatory agents etc and are used as a topical carrier system.[2]

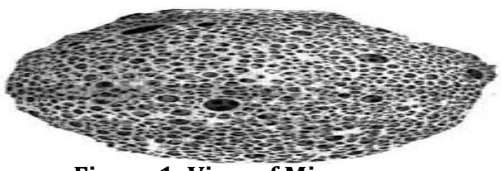

Figure 1: **View of Microsponge**

Defining Microsponges:

The Microsponge Delivery System (MDS) is a patented polymeric system consisting of porous microspheres. They are tiny sponge like spherical particles that consist of a myriad of interconnecting voids within a noncollapsible structure with a large porous surface through which active ingredient are released in a controlled manner.The size of the microsponges ranges from 5300µm in diameter and a typical 25µm sphere can have up to 250000 pores and an internal pore structure equivalent to 10 feet in length, providing a total pore volume of about 1ml/g for extensive drug retention. The surface can be varied from 20 to 500 m2/g and pore volume range from 0.1 to 0.3cm3/g.

Advantages of Microsponge Delivery System :

- MDS can improve bioavailability of the drugs. [8]
- It can also improve efficacy in treatment.
- They have better thermal, physical and chemical stability.
- Liquids can be converted in to powders improving material processing.
- It provides continuous action up to 12 hours i.e. extended release.
- These are non-irritating, non-mutagenic, nonallergenic and non-toxic.

Characteristics of Microsponges:

- Microsponge formulations are compatible with most vehicles and ingredients;
- Microsponge formulations are self sterilizing as their average pore size is 0.25µm where bacteria cannot penetrate;
- Microsponge formulations have higher payload (50 to 60%), still free flowing and can be cost effective. [9,10]
- Microsponge formulations are stable at the temperature up to 130oC;
- Microsponge formulations are stable over range of pH 1 to 11;

Method of Preparation of Microsponges:

1) Liquid-Liquid suspension polymerization

In this Liquid-liquid suspension polymerization method, the porous microspheres are prepared by suspension polymerization method in liquid-liquid systems. In their preparation, the monomers are first dissolved along with active ingredients in a suitable solvent solution of monomer and are then dispersed in the aqueous phase, which consist of additives (surfactant, suspending agents, etc.). The polymerization is then initiated by adding catalyst or by increasing 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.

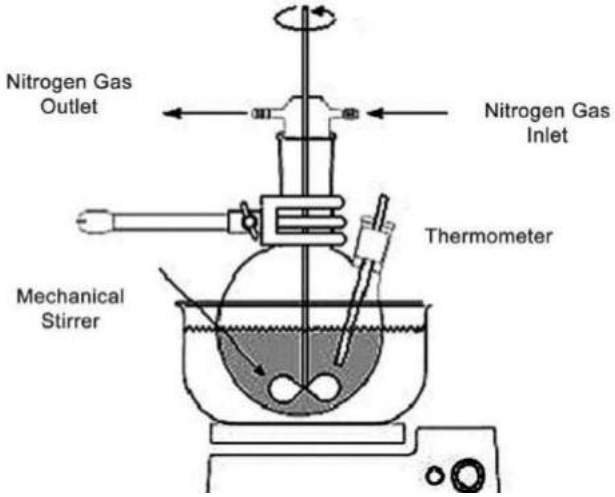

Fig 2: Reaction vessel for microsponge preparation by liquid-liquid suspension polymerization

2) Quasi-emulsion solvent diffusion:

In this Quasi-emulsion solvent diffusion method that is two steps process where the microsponges can prepared by quasiemulsion solvent diffusion method using the different polymer amounts. To prepare the inner phase, Eudragit RS 100 was dissolved in ethyl alcohol. Then, drug can be then added to solution and dissolved under ultrasonication at 35oC. The inner phase was poured into the PVA solution in water (outer phase). Following 60 min of stirring, the mixture is filtered to separate the microsponges. The microsponges are dried in an air-heated oven at 40°c for 12 Hr and weighed to determine production yield (PY). (17, 18, 19)

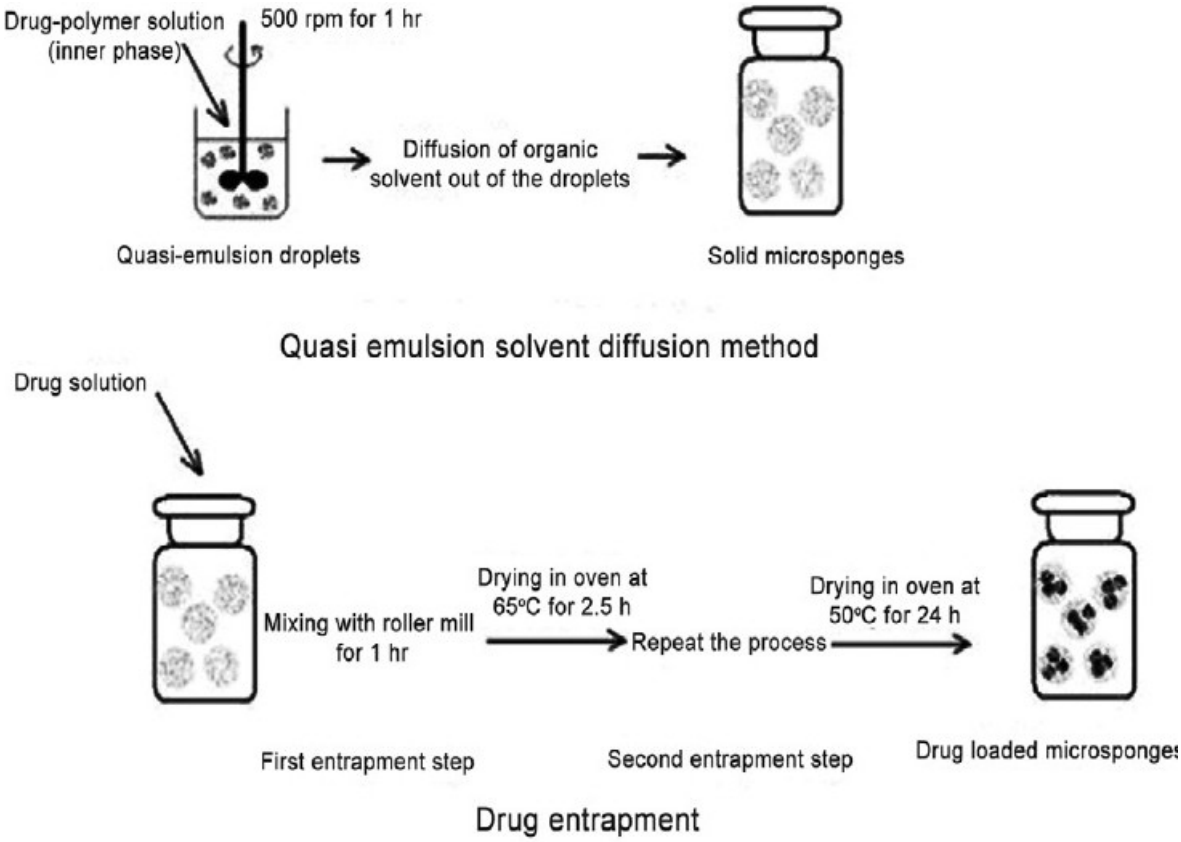

Fig 3: Method of quasi-emulsion solvent diffusion

Safety Consideration: -

Safety studies of microsponges can be established by:

- Eye irritation studies in rabbits.
- Skin irritation studies in rabbits.
- Mutagenicity in bacteria.
- Oral toxicity studies in rats.
- Allergenicity in guinea pigs. [16]

Drug Release Mechanism: -

Microsponges can be intended to release given amount of active ingredients over time in response to one or more following external triggers i.e. pressure, temperature change and solubility etc which are described as follows

1. Temperature change: At room temperature, few entrapped active ingredients can be too viscous to flow suddenly from microsponges onto the skin. With increase in skin temperature, flow rate is also increased and therefore release is also enhanced.
2. Pressure: Rubbing or pressure applied can release the active ingredient from microsponges onto skin.
3. Solubility: Microsponges loaded with water miscible ingredients like antiseptics and anti perspirants will release the ingredient in the presence of water. The release can also be activated by diffusion but taking into consideration, the partition coefficient of the ingredient between the microsponges and the external. [17]

Evaluation Parameters of Micro Sponges:

1. Particle size (Microscopy)

The most widely used procedures to visualize microparticles are conventional light microscopy (LM) and scanning electron microscopy (SEM). Both can be used to determine the shape and outer structure of microparticles. LM provides a control over coating parameters in case of double walled microparticles. The microparticles structures can be visualized before and after coating and the change can be measured microscopically. SEM provides higher resolution in contrast to the LM. SEM allows investigations of the microparticles surfaces and after particles are cross-sectioned, it can also be used for the investigation of double walled systems. Conflocal fluorescence microscopy is used for the structure characterization of multiple walled microparticles. Laser light scattering and multi size coulter counter other than

instrumental methods, which can be used for the characterization of size, shape and morphology of the microparticles (microsponges). [18]

2. Morphology and surface topography of microsponges

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 (SEM). SEM of a fractured microsponge particle can also be taken to illustrate its ultra structure. [19]

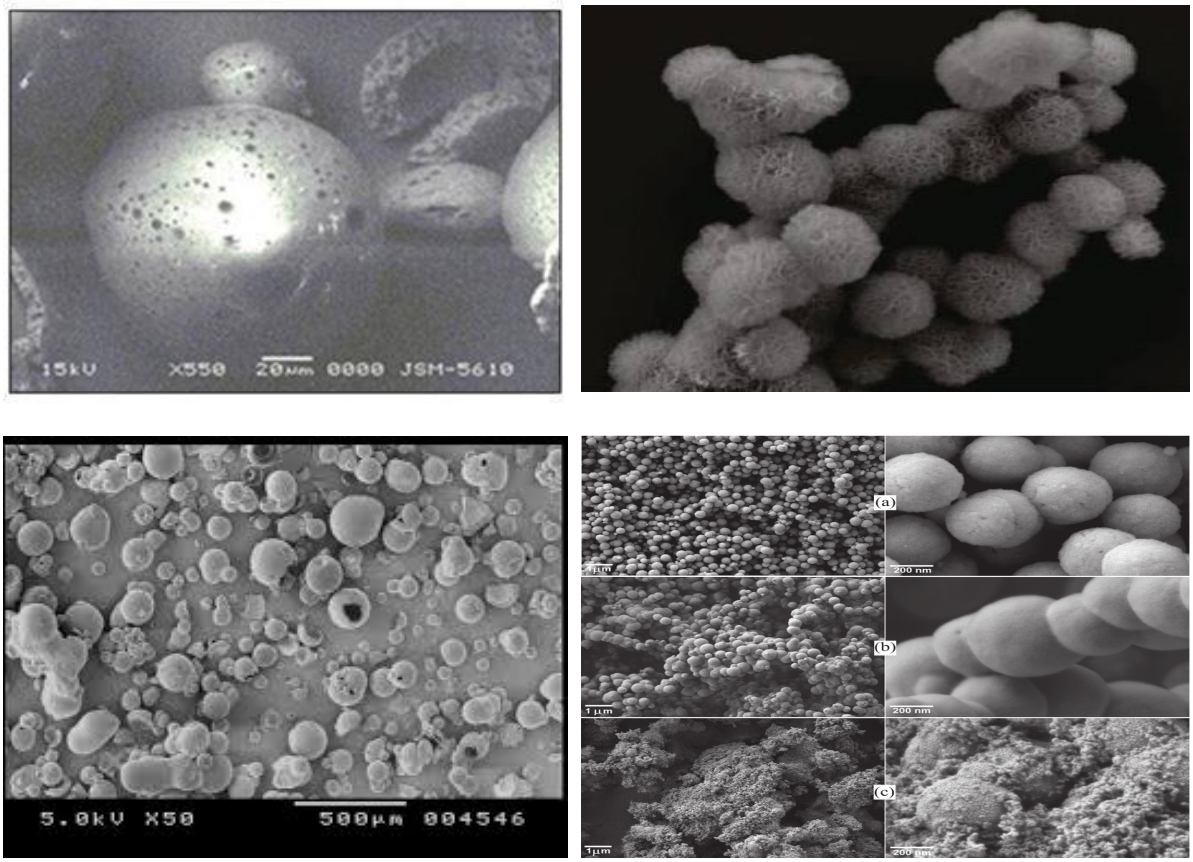

Fig 4. SEM photographs of microsponge formulations at different magnification.

3) Determination of loading efficiency and production yield: [22]

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

$$\text{Loading efficiency} = \frac{\text{Actual Drug Content in Microsponges}}{\text{Theortical Drug Content}} \times 100$$

$$\text{Production yield} = \frac{\text{Practical Mass of Microsponges}}{\text{Theoretical Mass (Polymer + Drug)}} \times 100$$

4) Compatibility studies:

Compatibility of drug with reaction adjuncts can be studied by thin layer chromatography (TLC) and Fourier Transform Infra-red spectroscopy (FT-IR). Effect of polymerization on crystallinity of the drug can be studied by powder X-ray diffraction (XRD) and Differential Scanning Colorimetry (DSC). For DSC approximately 5 mg samples can be accurately weighed into aluminum pans and sealed and can be run at a heating rate of 15 C/min over a temperature range 25–430°C in atmosphere of nitrogen. [21]

5) Resiliency (viscoelastic properties):

Resiliency (viscoelastic properties) of microsponges can be modified to produce beadlets that is softer or firmer according to the needs of the final formulation. Increased cross-linking tends to slow down the rate of release. [22]

6. Drug release kinetics:

The dissolution profile of each formulation have been subjected to various models such as Zero order kinetics (percentage drug release against time), First order kinetics (log percentage drug unreleased against time), Higuchi (percentage drug released against square root of time) and Korsemeyer Peppas (log percent drug released against log of time) were applied to assess the kinetics of drug release from prepared microsponges. [23-25]

Table 1: Applications of microsponges with respect to their advantages. [27]

Sr. no	Applications	Advantages
1.	Anti-acne Eg. Benzoyl peroxide	Maintained efficacy with decreased skin irritation and sensitization
2.	Sunscreens	Long lasting product efficacy, with improved protection against sunburns and sun related injuries even at elevated concentrations and with reduced irritancy and sensitization
3.	Antipruritics	Extended and improved activity
4.	Skin depigmenting agents Eg. hydroquinone	Improved stabilization against oxidation with improved efficacy and aesthetic appeal.
5.	Anti-dandruffs Eg.Zinc pyrithione,selenium sulphide	Reduced unpleasant odour with lowered irritation with extended safety and efficacy.

List of Marketed Products Based on Microsponges. [27-29]

Microsponge delivery System	Drug	Disease
Tablets	Indomethacine Paracetamol Meloxicam Chlorpheniramine maleate Fenofibrate Ketoprofen	Inflammation Anti-pyretic Hay Fever Muscoskeletal pain Gout Arthritis
Implants	Poly(DL-lactic-co-glycolic acid)	Skin tissue engineering
Grafts	Poly(lactic-co-glycolic acid)	Cardiovascular surgery
Creams	Hydroquinone and Retinol	Melanoma
Gels	Benzyl peroxide Mupirocin Flucanazole Acyclovir Hydroxyzine HCL Terbinafine HCL	Inflammation Anti-acne Treatment Viral infection Urticaria and atopic dermatitis Anti-fungal
Lotions	Benzoyl peroxide	Anti-acne treatment
Injection	Basic fibroblast growth factor	Growth factor

Table 2 : List of Marketed Products Based on Microsponges

UPDATED RESEARCH ABOUT MICROSPONGES:

1) Formulation and Evaluation of Microsponge Drug Delivery System Using Indomethacin

Formulated Indomethacin Microsponges by using Eudragit RS 100, pH independent release polymer and PVA, stabilizer or emulsifier. Microsponges by quasi emulsion solvent diffusion method by changing drug polymer ratio (3:1, 4; 1, 5:1) and process was optimized. In- Vitro dissolution study indicated that the release of Indomethacin varied according to the concentration of matrix forming polymer.

2) Preparation and Evaluation of Microsponge Loaded Controlled Release Topical Gel of Acyclovir Sodium

Microsponge formulation was prepared as gel in carpool and studied for pH, viscosity, spreadability, drug content, invitro release. The Microsponge formulation gel, showed viscosity 206.72 pa.sspreadability of 11.75g cm/s and drug content of 92.37%. A Microsponge acyclovir sodium gel formulations showed an appropriate drug release profile.

3) Formulation and Evaluation of Microsponges for Topical Drug Delivery of Mupirocin

Formulated Mupirocin Microsponges by using an emulsion solvent diffusion method. Mupirocin microsponges were then incorporated into a vanishing cream base for release studies. It was shown that the drug: polymer ratio, stirring rate, volume of external and internal phase influenced the particle size and drug release behavior of microsponges.

4) Formulation and Evaluation of Optimized Oxybenzone Microsponge Gel for Topical Delivery

Formulated Oxybenzone loaded microsponge gel for enhanced sun protection factor with reduced toxicity. Microsponge for topical delivery of oxybenzone by quasi emulsion solvent diffusion method. The effects of ethyl cellulose and dichloromethane were optimized by the 3^2 factorial designs. The optimized

microsponges were dispersed into the hydro gel and further evaluated. It also showed the enhanced sun protection factor compared to the marketed preparation with reduced irritation and toxicity.

5) Microsponge Based Drug Delivery System for Augmented Gastroparesis Therapy: Formulation Development and Evaluation

Developed a microsponge based novel dosage form for sustained delivery of domperidone. Quasi-emulsion solvent diffusion method by using Eudragit RS-100 with various drug–polymer ratios for the preparation of microsponges. It was found that there were no chemical interactions between drugs and polymers used as per DSC and FTIR results. SEM micrographs revealed that microsponges were spherical in shape with porous surface, and had 104 ± 0.22 _m mean particle size. The microsponges were then loaded in capsules followed by in vitro drug release study.

7) Development and Characterization of Valacyclovir Loaded Microsponges

The formulated microsponges by emulsion solvent diffusion method and optimize for various formulation parameters. The formulation were characterized in terms of particle size, drug entrapment efficiency (DEE), scanning electron microscopy (SEM), differential scanning calorimetry (DSC) and zeta potential measurement. The drug release from the microsponge-loaded gel was studied by modified Franz diffusion cell. The microsponge gel formulations showed an appropriate drug release profile. SEM Analysis confirmed spherical shape of microsponges.

8) Formation and Evaluation of Famotidine Floating Microsponges

Famotidine floating microsponges are prepared to improve site-specific absorption of drug for peptic ulcer treatment. Modified quasi emulsion solvent diffusion method was used to formulate microsponges. Different concentration of Eudragit S100 and polyvinyl alcohol were used and the prepared microsponges were evaluated for % entrapment efficiency, % buoyancy and % cumulative drug release. It was found that the % entrapment efficiency was 88.3%, % buoyancy was 76.4% and % cumulative drug release was 86.9% for formulation. This study presents a new approach based on floating ability of microsponges for treatment of ulcer.

9) Formulation and evaluation of microsponge gel for Topical Delivery of Antifungal Drug

Formulated and evaluated microsponges by quasi-emulsion solvent diffusion method by using polymer Eudragit S100 and Eudragit L-100. All the formulated microsponges were subjected for various evaluation parameters such as production yield, encapsulation efficiency, particle size analysis and in vitro drug release study. The optimized microsponge formulation was further formulated as gel formulation for topical delivery. Prepared gel was evaluated for physical parameters like pH, spreadability, viscosity, drug content and in vitro diffusion study and compared with the marketed formulation. The Fourier transform infrared radiation measurement (FTIR) and Differential scanning calorimetry (DSC) of drug and Excipient confirm compatibility.

10) Development and Evaluation of Terbinafine Hydrochloride Polymeric Microsponges for Topical Drug Delivery

Formulated Microsponges of ethyl cellulose containing terbinafine hydrochloride by quasi emulsion solvent diffusion method. Morphology of obtained microsponges was revealed by scanning electron microscope and was found to be porous and spherical. Optimized formulation of microsponge was dispersed in Carbopol gel and evaluated for drug content, pH, viscosity and in vitro drug release. Release of drug was found to be sustained through microsponge gel as compared to marketed product and pure drug gel.

11) A Research on Formulation and Evaluation of Microsponge Loaded in Topical Gel of Ritonavir

Formulated Microsponges loaded with Ritonavir by using Emulsion solvent diffusion with nine different proportions of polymer. The developed microsponges were analyzed for particle size, production yield, entrapment efficiency and drug content. Scanning electron microscopic images of microsponges revealed that they are spherical in shape and contain pores. Microsponge were then incorporated in to 1% carbopol gel and evaluated for pH, viscosity, and spreadability and diffusion study. Thus, the formulated microsponges based gel of Ritonavir would be a promising alternative to conventional therapy for safer and efficient treatment of various skin disorders.

12) Tolnaftate Microsponges Embedded Biocompatible Gels for Controlled and Effective Antidermatophytic Activity

Formulated Tolnaftate microsponges by quasi-emulsion solvent diffusion technique applying biocompatible polymers Eudragit RL100 and Eudragit RS100. Formulated Microsponges were embedded in Carbopol 934 and HPMC to attain controlled topically effective formulation and their physical parameters like viscosity, pH, spreadability, the in-vitro drug release kinetics were evaluated. Drug-Excipient compatibility was performed by FTIR and TGA. FESEM analysis revealed micro size microsponges with numerous pores present over their surface.

13) Studies on Formulation and Characterization of Topical Emulgel Containing Microsponges of Mefenamic Acid

Formulated & characterized the microsponge of mefenamic acid microsponges by quasi-emulsion method. Preformulation studies by FTIR, revealed no interaction between pure drug and the different polymers used. The prepared microsponges were characterized for their production yield, drug content, mean particle size & entrapment efficiency, Effect of formulation variable was studied. The microsponge containing 0.5 gm of poly vinyl alcohol, 0.6 gm of ethyl cellulose and 5ml ethanol good were compared to the other formulation prepared. The best microsponges in cooperated into emulgel. The topical emulgel was evaluated for their organoleptic characters, viscosity, spreadability, drug content and drug release studies.

14) Preparation and Characterization of Itraconazole Microsponges Using Eudragit RSPO and Study the Effect of Stirring on the Formation of Microsponges

Formulated Microsponges containing Itraconazole by using quasi-emulsion solvent diffusion method at different stirring rate i.e. 500, 800, 1000, 1200 and 1500rpm. Particle size of prepared microsponge was observed in the range of 78.43 to 23.18 µm. Scanning electron microscopy revealed the porous, spherical nature of the microsponges. The production yield, entrapment efficiency, and drug content were found to be 80.88%, 84.53% and 82.89%. As drug polymer ratio increased, Production yield, drug content and entrapment efficiency was found to be increased while drug: polymer ratio has reverse effect on particle size, as drug: polymer ratio increase, particle size decreases.

Recent Advances in Microsponge Drug Delivery System:

Various advances were made by modifying the methods to form nanosponges, nanoferrosponges and porous microbeads. β-CD nanosponges were also developed that can be used for hydrophobic as well as hydrophilic drugs, in contrast to polymeric micro or nanosponges. These advanced systems were studied for oral administration of dexamethasone, flurbiprofen, doxorubicin hydrochloride, itraconazole and serum albumin as model drug. These nanosponges were developed by cross-linking the β-CD molecule by reacting the β-CD with diphenyl carbonate. Some researchers also observed the nanosponges as good carrier for the delivery of gases. Researchers also observed that incorporating a cytotoxic in a nanosponge carrier system can increase the potency of the drug suggesting that these carriers can be potentially used for targeting the cancerous cells [30]. Nanoferrosponge, a novel approach constituted the self-performing carriers having better penetration to the targeted site due to the external magnetic trigger which enforces the carriers to penetrate to the deeper tissue and then causing the removal of magnetic material from the particle leaving a porous system [31]. Due to the improved characteristics of porous microspheres, process was developed to produce the porous micro beads. This method (High internal phase emulsion, HIPE) consisted of the monomer containing continuous oil phase, cross linking agent and aqueous internal phase [32]. They also observed an improved stability of RNA and the relatively effective encapsulation process of siRNA. The approach could lead to novel therapeutic routes.[33]

FUTURE PROSPECTS

Microsponge drug delivery system holds a promising opportunity in various pharmaceutical applications in the upcoming future as it has unique properties like enhanced product performance and elegancy, extended release, improved drug release profile, reduced irritation, improved physical, chemical and thermal stability which makes it flexible to develop novel product forms. The real challenge in future is the development of the delivery system for the oral peptide delivery by varying ratio of polymers. The use of bioerodible and biodegradable polymers for the drug delivery is enabling it for the safe delivery of the active material. As these porous systems have also been studied for the drug delivery through pulmonary route which shows that these system can show effective drug release even in the scarce of the dissolution fluid thus colon is an effectivesite for targeting for drug release. These carriers also require to be developed for alternative drug administration routes like parenteral and pulmonary route. These particles can also be used as the cell culture media and thus can also be employed for stem cell culture and cellular regeneration in the body. Due to their elegance, these carrier systems have also found their application in cosmetics. These developments enabled researchers to utilize them variably. These novelties in formulation also open new ways for drug deliver. [34]

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