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MICROSPONGES OF DICLOFENAC SODIUM

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ABSTRACT

For controlled administration of diclofenac sodium to the skin in this investigation, ethyl cellulose-facilitated microsponges were created using the two fold emulsification approach (also known as the quasi emulsion technique). By using ethyl cellulose as a polymer and a quasiemulsion solvent diffusion technique, the microsponges formulations were created. Fourier Transform Infra-Red (FTIR) spectroscopy was used to determine the drug's compatibility with formulation ingredients.

We looked at the microsponges' surface shape, particle size, production yield, and drug entrapment effectiveness. Using scanning electron microscopy, the microsponges' shape and surface morphology were studied. The porous, spherical form of the microsponges was discovered using scanning electron microscopy.In all variations, SEM images showed that the microsponges were spherical; however, at larger ratios, drug crystals were seen on the microsponge surface.

Consequently, though in ascending sequence due to the rise in polymer concentration, beyond a certain concentration, it was noticed that when the ratio of drug to polymer rose, the particle size. The gel's pH was determined to have an average pH. The drug content of various formulations, the spredibility of gel-containing microsponges, exhibiting good spreading characteristics, and the cumulative release of the formulations. The viscosity of the formulation was analysed by Brookfield viscometer.

KEY WORDS: Quasi Emulsion Technique, Sodium Diclofenac, Fourier Transform Infrared (FTIR),Scanning Electron Microscopy(SEM), Microsponge Delivery System (MDS).

INTRODUCTION

Microsponges: Microsponges are small, spherical particles that resemble sponges and are made up of a high number of interconnected spaces inside a non-collapsible framework.Spherical particles with a size range of 5 to 300 m are known as microsponges.

Sodium Diclofenac: Diclofenac is a pain-relieving medicine. It is used to treat pain, swelling, stiffness, and joint pain in conditions like rheumatoid arthritis, osteoarthritis, and acute musculoskeletal injuries. It is commonly used in back pain, shoulder pain, neck pain, sprains, and spasms.

Class: NSAID's- Non-Selective COX 1&2 Inhibitors (acetic acid).

The health care system is significantly impacted by microsponge delivery systems (MDS) that may precisely regulate release rates or direct medications to a particular bodily spot. The dermatological drug delivery solutions can use the microsponge drug delivery technology widely. But MDS also broadens the scope of its application in RNAi silencing, bone and tissue engineering, oral medication delivery, and disease detection. The proposed effort entails the creation and assessment of a Diclofenac sodium microsponge formulation employing a quasi-emulsion technique using ethyl cellulose as the polymer.Finally, the gel containing the improved Diclofenac sodium microsponges is applied to the skin tissue as a transdermal drug delivery system. Consequently, in the current work, anaimed to create synthetic polymer-based controlled release microsponges to reduce frequent dosing, extend the pharmacological action, and hence boost patient compliance.

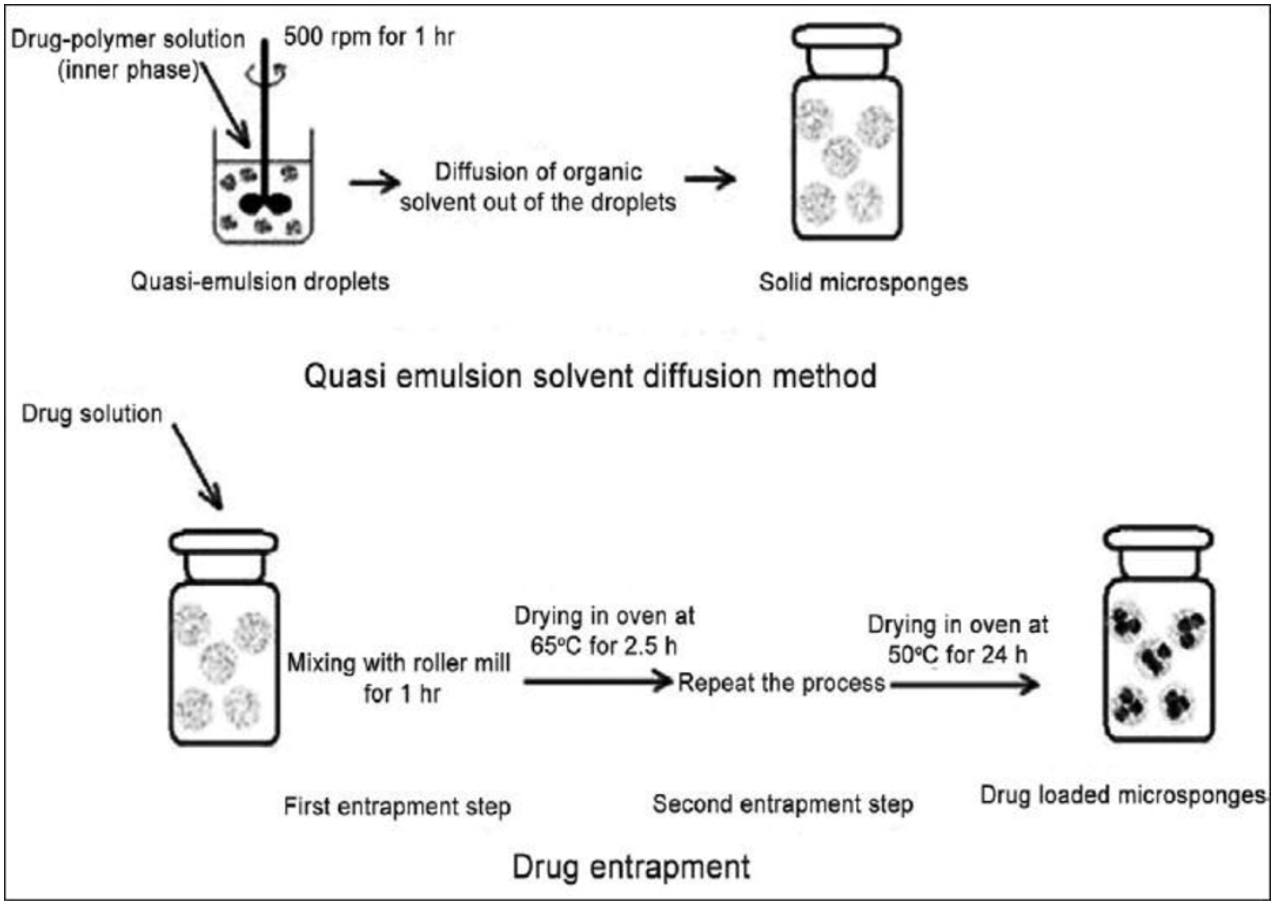

Fig 1: Image Showing Quasi-emulsion solvent diffusion method set up.

Microsponge Preparation Process

According to the formula in table No. 1, quasi-emulsion solvent diffusion method was used to create microsponges containing diclofenac sodium and ethyl cellulose.internal phase and external phase, which are two distinct phases that are comparable to emulsions, are formed in a quasi-emulsion. Details regarding the prepared formulations are provided in Table No. 1

1. The internal phase of a drug-polymer solution prepared in dichloromethane, a volatile solvent, with a 1: different ratio (10 ml).
2. After that, it was vigorously stirred into the exterior phase's aqueous 5% (5 mg/100 ml water) polyvinyl alcohol (PVA) solution before being added.
3. Glycerol (1-2 ml), which was added at an adequateamount in order to facilitate plasticity. Stirring lead to the formation of discrete emulsion globules called quasiemulsion globules.
4. The stirring was continued upto 6 hrs till the insoluble,rigid microparticles i.e. microsponges is formed.
5. Then it was filtered to separate the microsponges.
6. The microsponges were then dried in an air heated oven

Table 1: Table revealing the master formula for microsponges formulation

S.NO.	INGREDIENT (mg/ml/gm)	M1	M2	M3	M4	M5	M6
1	**Diclofenac sodium**	1	1	1	1	1	1
2	**Ethyl cellulose**	1	2	3	4	5	6
3	**Polyvinyl alcohol**	500	500	500	500	500	500
4	**Dichloromethane**	10	10	10	10	10	10
5	**Glycerol**	1	1	1	1	1	1
6	**Water**	100	100	100	100	100	100
7	**Drug:polymer**	1:1	1:2	1:3	1:4	1:5	1:6

2.2 Making Diclofenac Sodium Microsponge Gel the formula for making Diclofenac Sodium gel is found in table number 2.

TABLE 2: Table revealing the master formula for gel formulation

S.NO.	INGREDIENT	QUANTITY(MG/ML)
1	Carbopol 934 P	35
2	Triethanolamine	2
3	Methyl paraben	3
4	Propyl paraben	1
5	Distilled water	q.s

A distinct spread of carbopolwas made with gentle agitation in water.

1. With moderate agitation, a transparent carbopol dispersion (35 mg) is made in water (q.s).
2. The usage of Triethanolamine (1-2 drops) to neutralise theformulation, followed by preservatives to stop the growth of microorganisms, methyl paraben (3 mg) and propyl paraben (1 mg) were added.
3. Water was then used to keep the volume constant. Ultrasonication was used to degas the produced gel.

A) Microsponges' particle size analysis

By using optical microscope to measure the microsponge's particle size, it was discovered that the microsponges were all of the same size. As the concentration of polymer increases, the average particle size of all formulations increases from 28.7 m to 45.9 m, but after a certain concentration, it was found that the particle size reduced as the ratio of drug to polymer rose. This may be the result of the relatively lower amount of polymer accessible per microsponge with high drug to polymer ratios.

B) Scanning electron microscopy morphology analysis (SEM)

The produced microsponges' morphology was studied using scanning electron microscopy (SEM). The appearance and size of microscopic specimens with particle sizes as small as 10 to 12 grammes can be characterised by SEM.A controlled pattern of electron beam scanning was performed on the sample inside an evacuated chamber. Various physical phenomena are created when the electron beam interacts with the specimen; when these phenomena are detected, images are created and essential details about the specimens are revealed.

It was noted that there were no drug crystals on the surface of the microsponges, which were uniformly spherical. In spherical microsponges, surface area and surface area per unit weight are influenced by the shape of the microsponges. In a dissolution environment, the dissolution rate may be impacted by the particles' irregular shapes.

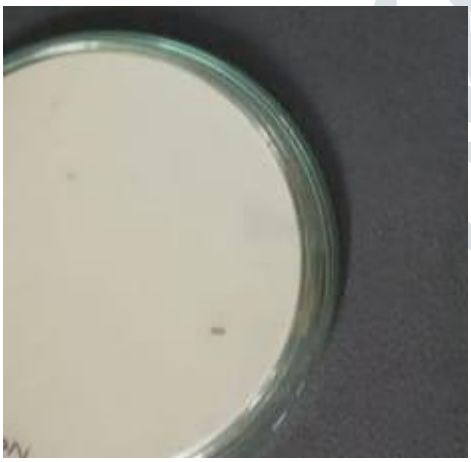

Fig 1: Image Showing Showing highly porosity of theMicrosponges at 451 KX

Fig 2: Image Showing Microsponge structure at 249x

C) Percentage yield

It is calculated to know about the efficiency of any method,thus it helps in selection of appropriate method of production.After the preparation of formulations the Practical yield was calculated as microsponges recovered from each preparationin relation to the sum of starting material (Theoretical yield).

It can be calculated using following formula.

Percentage yield = Practical yield × 100

Theoretical yield (drug + polymer)

The loss of product was due to the formation of someagglomerates and polymer adherence to the container as aresult of a viscous nature of slurry. It is calculated to knowabout the efficiency of any method, thus it helps in selection ofappropriate method of production and in this experiment,it isrevealed that with increase in polymer ratio the percent yieldalso increase.

D) Drug content

The drug content was determined by using phosphate buffer(pH 7.4) with the help of UV- spectrophotometer by dissolvingthe formulation in phosphate buffer for 24 hrs and then thesample was taken and analysed in UV- spectrophotometer.

E) Test of spredibility

Manually weighing and spreading a precise amount of gel over a surface to test the spreadability of the gelafter some time, scraped the aforementioned gel off the skin, weighed. It was determined how much gel was spread on the skin by deducting the final amount of gel from the initial amount.

F) pH Measurement

After being prepared, the pH of the Microsponge gel was assessed. A digital pH metre was used to determine the gel's pH.

G) Measurement of viscosity

An analysis of the formulation's viscosity using a Brookfield viscometer with spindle no. 7 at 50 revolutions per minute showed that the viscosity also rises with an increase in polymer content.

H) In vitro diffusion studies using KC cell.

In vitro release studies was performed using KC cell diffusionapparatus at 37 °C. The release medium is selected, whileconsidering solubility of active ingredients to ensure sinkconditions. Sample aliquots were withdrawn from the mediumand analyzed by the suitable analytical method at regularintervals of time. Egg membrane was fitted at the donor side ofthe cell and predetermined amount of formulation wasmounted on the membrane. The receptor medium iscontinuously stirred at and thermostated with a circulatingjacket. Samples are withdrawn at different time intervals andanalyzed using suitable method of assay.

I)Surface morphology:

Using an ion coater, gold was vacuum-coated onto the microspheres at high voltage (800–1500V).

Samples were scanned with an electron microscope.

J) Micromeritic characteristics:

An optical microscope was used to measure the average particle size of the microspheres. By measuring the angle of repose, tapped density, and bulk density7, the flow parameters and packing qualities were examined.

Conclusion

The quasi-emulsion approach was used to create the microsponges.It was assessed for its various aspects, revealingnumerous intriguing outcomes for effective preparation of the microsponges. Check the particles size, percentage yield, drug content, spreadibility, pH, viscosity. All these parameters are optimised range for preparing a controlled release dosage form so showing and optimised formulation.

Fourier transformation infrared (FTIR) spectroscopy analysis indicated the chemically stable, the chemical stability and amorphous nature of the drug in these microsponges were shown by FTIR spectroscopy investigations. The spherical form of the microsponges was captured on SEM images.in all its forms. Higher ratios, however, led to the presence of drug crystals on the microsponge surface. With the findings of the many evaluation criteria revealed, it is concluded that the microsponges-based delivery system has developed into a highly competitive, rapidly evolving technology.the controlled release of topical medicines and is used for oral as well as biopharmaceutical medication delivery. Microporous beads are filled with the active ingredient.

The drug encapsulation was significantly influenced by the formulation variable drug-polymer ratio. The results of this investigation demonstrate the effectiveness of microspheres in delaying the release of drugs.

The health care system is significantly impacted by microsponge delivery systems' ability to precisely control release rates or direct medications to specific body sites. The active ingredient of a microsponge delivery system can be released both on a timer and in reaction to external stimuli.

As a result, microsponge has a lot of potential and is a rapidly developing topic that needs to be investigated. A considerable portion is made up of microsponges because of their small size and effective carrier properties.

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