

FORMULATION AND EVALUATION OF MICROSPONGES LOADED GEL FOR TOPICAL DELIVERY

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Abstract—The present research focuses on the formulation and evaluation of a microsphere-based topical gel containing Karanjin for the treatment of skin conditions such as psoriasis. Microspheres were prepared using the quasi-emulsion solvent diffusion technique with ethyl cellulose and polyvinyl alcohol as key polymers. The formulated microspheres were characterized in terms of particle size, production yield, and encapsulation efficiency. The optimized microsphere formulation was incorporated into a Carbopol 940-based gel and evaluated for physical properties including pH, viscosity, spreadability, and drug content. In vitro, diffusion studies and release kinetics were conducted using a Franz diffusion cell, and the formulation followed Korsmeyer-Peppas release behaviour. The optimized gel demonstrated sustained drug release, good stability, and effective potential for topical delivery. The study concludes that the microsphere-loaded gel system provides a promising approach for enhanced therapeutic efficacy and controlled release of Karanjin through the skin.

Index Terms—Microspheres, Psoriasis, Topical Drug Delivery, Controlled Release, Gel Formulation, Quasi-emulsion Solvent Diffusion.

I. INTRODUCTION

A Microspheres Delivery System (MDS) is a porous polymeric system made of microspheres that entrap active ingredients and release them into the skin over time in response to triggers. Traditional topical formulations often achieve systemic effects rather than local action [1-3], but microsphere technology improves drug residence time in the dermis and epidermis, enhancing the efficacy of topical agents. [4] MDS utilizes delayed-release technology through porous microspheres with a large surface area, resulting in improved stability and controlled drug release. This system addresses common issues with topical applications, such as greasiness, stickiness, and the loss of active ingredients, which can lead to poor patient compliance. [5] Overall, the microsphere delivery system offers a more effective way to administer topical drugs. These microspheres can be integrated into various formulations, including creams, gels, moisturizers, and powders, improving both safety and aesthetic appeal [6]

Psoriasis is a chronic skin condition marked by scaling and inflammation, appearing in thick, red patches covered with silvery scales. Its inflexibility can range from localized areas to wide content and is allowed to be inheritable, told by environmental factors, affecting 1- 3% of people worldwide. [7] The vulnerable system plays a crucial part, with hyperactive T cells inaptly driving skin inflammation. This accelerates skin cell growth, leading to their accumulation on the face rather than normal development, contributing to the formation of lesions. [8]

The present study aims to develop and evaluate a microsphere-based topical gel formulation of Karanjin for sustained dermal drug delivery. Employing a quasi-emulsion solvent diffusion technique, microspheres were prepared using ethyl cellulose and polyvinyl alcohol and further incorporated into a Carbopol 940-based gel. A systematic approach was used to optimize key formulation parameters, such as polymer concentrations, to achieve desirable physicochemical characteristics. The study evaluated the drug content, encapsulation efficiency, particle size, zeta potential, in vitro diffusion behavior, and stability profile of the final gel formulation, with the goal of enhancing localized drug delivery and patient compliance in the management of dermatological conditions.

II. MATERIAL AND METHOD

MATERIAL

Karanjin was purchased from Yucca Enterprises, Mumbai, Ethyl cellulose and Dichloromethane were obtained from Pallav chemical and solvent, and Tarapur, Polyvinyl alcohol, Carbopol 940, and Triethanolamine were obtained from S.D. Fine chemicals, Mumbai.

METHOD [9, 10]**Preparation of karanjin microsponges**

Karanjin microsponges were fabricated using the quasi-emulsion solvent diffusion method. In this system, Karanjin was added to an organic internal phase conforming to ethyl cellulose dissolved in dichloromethane (DCM). DCM serves as an effective solvent for dissolving both the drug and the polymer. Next, the internal phase was added dropwise into a thirsty result containing polyvinyl alcohol (PVA), which was stirred at 1000 rpm using a glamorous stirrer for 2 hours. As DCM was removed from the response medium, microsponges formed. The performing microsponges were also filtered, washed with distilled water, and dried at room temperature. Several parameters were set up to affect the drug of the microsponges. Thus, the optimization of karanjin-loaded microsponges was achieved by varying the concentration of ethyl cellulose (300 mg, 600 mg, and 900 mg) and PVA (50 mg, 75 mg, and 100 mg).

PREFORMULATION STUDIES OF KARANJIN**Characterization of Karanjin**

Organoleptic characters Karanjin was tested for organoleptic characters similar to colour, odour, taste, and texture. The results are shown in Table 3.

Melting point analysis [11]

The melting point of Karanjin was determined using the capillary tube system. In this system, a double-end opened capillary tube was taken, and one end was sealed using direct heat. Also, the drug was filled into the capillary tube before fitting it into the melting point outfit. The metamorphosis of solid-state medicine patches into the liquid state was noted, and the corresponding temperature at which this solid-to-liquid metamorphosis passed was also noted.

Fourier transform infrared spectroscopy [12]

The drug sample and drug-exciipient fusions from the expression were chosen for the study. The fragment was created by compressing the samples using potassium chloride. The fragment was scrutinized between 4000- 400 cm^{-1} in a SHIMADZU FTIR (IR Affinity1) spectrophotometer.

UV spectrophotometric method

Preparation of standard stock result 100 mg of karanjin was counted directly and dissolved in an admixture of phosphate buffer (pH 7.4) and methanol (at a rate of 70:30) in a 100 ML volumetric beaker. This was sonicated for 10 twinkles, and the volume was made up to the mark with the same result. The attention of this standard stock result (A) was 1000 $\mu\text{g}/\text{ml}$. From the below result, take 1 ml and adulterate up to 10 ml to gain a primary stock result which is 100 $\mu\text{g}/\text{ml}$.

Determination of λ_{max}

10 $\mu\text{g}/\text{ml}$ result of karanjin was prepared in phosphate buffer pH 7.4. This result was further scrutinized in the range of 200- 400 nm using a UV-visible spectrophotometer.

Preparation of standard estimation curve of karanjin in phosphate buffer (pH 7.4) and methanol (at a rate of 70:30)

From a result having an attention of 100 $\mu\text{g}/\text{ml}$, aliquots of 0.5, 1.0, 1.5, 2.0, and 2.5 ml were pipetted out into a 10 ml volumetric beaker. The volume was made up to the mark with buffer result to get the final attention of 5, 10, 15, 20, and 25 $\mu\text{g}/\text{ml}$. A graph of absorbance versus attention was colluded. It shows a straight line, meaning the estimation wind obeys Beer's law.

Formulation of microsponges**Table 1: Formulation of karanjin microsponges**

Batch	Karanjin (mg)	Ethyl Cellulose (mg)	PVA (mg)	DCM (ml)	Water (ml)
F1	100	600	75	10	100
F2	100	600	100	10	100
F3	100	300	75	10	100
F4	100	300	50	10	100
F5	100	600	50	10	100
F6	100	900	75	10	100
F7	100	300	100	10	100
F8	100	900	100	10	100
F9	100	900	50	10	100

CHARACTERIZATION OF MICROSPONGES**Microscopy [13]**

Motic digital microscopy can be used to study the morphology of set microsponges by placing them on a glass slide at room temperature. Fractured microsp sponge patches can also be examined to illustrate their ultrastructure. Karanjin-loaded microsp sponge morphology was observed using a Motic Digital Microscope at a 10x ideal, with an exaggeration of 2048 x 1536.

Production yield [14]

The percentage yield of the microsponges can be determined by calculating the original weight of the raw accoutrements and the final weight of the microsponges attained.

$$\text{Production yield} = \frac{\text{Practical mass of microsponges}}{\text{Polymer} + \text{Drug}} \times 100$$

Encapsulation efficiency [15]

A precisely counted quantum of medicine-loaded microsponges (10 mg) was crushed using a mortar and pestle with phosphate buffer and methanol at a 70:30 ratio. The admixture was also transferred to a volumetric beaker, and the volume was made up to 10 ml using the same buffer-methanol solution. The sample was sonicated for 15 minutes to ensure the complete dissolution of the medicine. After sonication, 1 ml of the sample was withdrawn and further adulterated up to 10 ml with phosphate buffer and methanol. The absorbance of the result was measured at 298 nm against a blank using the phosphate buffer. The Encapsulation effectiveness for all batches was calculated using the ensuing expression.

$$\text{Encapsulation effectiveness} = M_{\text{act}} / M_{\text{the}} \times 100$$

Where,

M_{act} = actual drug content in the counted volume of microsponges

M_{The} = Theoretical drug content in microspoonge

Particle size analysis [16]

Particle size analysis of set microsponges was carried out by using a Motic digital microscope particle size analyzer (B1), advanced series. Microsponges were dispersed on the slide before running the sample in the instrument, to ensure that the light scattering signal and particle size were measured, which is within the instrument's perceptivity range.

Zeta Potential [17]

Zeta potential is an index of flyspeck face charge and flyspeck stability. Patches won't cleave to each other if the value of zeta eventuality is above 30 or below 30 mV. Zeta size A Zeta sizer was used to determine the flyspeck size distribution of the given samples. Malvern software was used to assay the intensity distribution data of patches of different size ranges, and a graphical representation was attained. The peak on the graph indicates the size of the utmost patches present In the sample.

Morphology determination by scanning electron microscopy (SEM) [17]

Scanning electron microscopy (SEM) was utilized to assess the morphology of the set microsponges. SEM characterizes bitsy samples down to flyspeck sizes of 10- 10 to 10- 12 grams. The sample was placed in a vacated chamber and scrutinized with an electron ray, which produced images and essential data. The microsponges were set up to be globular and invariant, with no medicine chargers on the face. The shape of the microsponges influences their face area and dissolution rate in a dissolution terrain.

Differential scanning calorimetry [17]

Differential scanning calorimetry (DSC) study estimated the thermal geste and thermo tropic characteristics of the medicine and optimised expression F8). A 2.0 mg sample was sealed in an aluminium visage and hotted at 10 °C/ min from 40- 400 °C under a nitrogen atmosphere (10 ml/ min), yielding a thermogram from the regard SW 12.10 thermal analyser.

Preparation of karanjin-loaded microspoonge gel [18]

A gel of karanjin-loaded microspoonge was prepared under moderate stirring. Carbopol 940 was added to an admixture of water and glycerin. Parabens and edentate disodium were dissolved in water and mixed with the previous admixture. After that, this admixture was neutralized by adding Triethanolamine with gentle mixing. Eventually, Karanjin microsponges (original to 0.1 w/ w of Karanjin) were incorporated to gain homogenous karanjin microspoonge-loaded gels.

Table 2: Displays Karanjin microspoonge gel compositions.

SR. NO	INGREDIENT	QUANTITY
1	Microsponges (mg)	Equivalent to 50 mg of Karanjin
2	Carbopol 940 (%)	0.5
3	Glycerin (g)	2.5
4	Triethanolamine	q.s
5	Methylparaben (mg)	90
6	Propyl paraben (mg)	10
7	EDTA (mg)	25
8	Distilled water (ml)	Up to 50

EVALUATION OF MICROSPONGES LOADED GEL**Visual Examination**

The set gel expression of microsponges was audited visually for their colour, texture, and appearance. Results are reported in Table 6.

pH dimension [19]

The pH of the gel expression was determined by using a digital pH cadence. One gram of gel was dissolved in 100 mL of distilled water and stored for two hours. The dimension of the pH of the expression was done. Results are reported in Table 6.

Spreadability study [20]

A weight volume of 0.5 g gel was placed within a circle of 1 cm periphery-marked on a glass plate over which an alternate glass plate was placed. A weight of 500 g was allowed to rest on the upper glass plate for 5 min. The increase in the periphery due to the spreading of glass was noted. The spreadability of expression was done in triplet, and the mean value was calculated.

$$\text{Spreadability} = M.L / T$$

Where,

M – Weight tied to an upper glass slide,

L – Length of the glass slide,

T – Time taken to separate slides

Viscosity measurement [21]

The viscosity of the different gel phrasings was determined using a Brookfield viscometer with spindle no. 4 at 100 rpm at a temperature of 25 °C. The density of the optimized expression was determined as similar without dilution using a Brookfield Viscometer Model- LVDV-E. The Brookfield Viscometer consists of a mug, which is stationary, and a spindle which is rotating. Different-sized rotating spindles are used and immersed in the test material. For liquids with low density, large-sized spindles(large periphery and face area) are used, while for advanced-density liquids, small spindles (small periphery and face area) are used. Rotate the spindle in the microspunge gel till we get a constant dial reading on the display of the viscometer. This procedure is repeated three times for reproducible results. Results are reported in Table 6.

Drug content [22]

1gm of karanjin-loaded microspunge gel was directly counted and dissolved using methanol. Sonicated for 10- 15 min and made up to the mark in a 100 ml volumetric beaker with methanol. From this, 10 ml was pipetted out and thinned 100 ml with methanol, and the final dilution was made using distilled water to get attention within Beer's range. The absorbance was measured by a UV spectrophotometer (Dynamica, Halo DB-20) at 298 nm against a Blank gel treated in the same manner as the sample. Results are reported in Table 6.

In vitro drug diffusion tests [23]

A perpendicular Franz diffusion cell with a force capacity of 9.5 mL was used for in vitro release examinations. Between the chambers of the prolixity cell, an egg membrane with an effective prolixity area of 2.54 cm² was fitted. The receptor medium was composed of an admixture of water and methanol (50:50, v/ v), and it was kept at 32 ± 0.1 °C and swirled constantly. Each expression importing 1g of microspunge-grounded gel was placed on the patron side. 2 mL of the sample was taken from the receiver fluid and replaced with an equal volume of fresh receiver fluid at predefined time intervals. Collected samples were assayed by a 298 UV- Vis spectrophotometer after a suitable dilution. Results are reported in Table 7.

In vitro medicine release kinetic study [24]

To determine the medicine release medium and to compare the release profile differences among microspunge gel phrasings, the data obtained from the medicine released quantum and time were used. The medicine release kinetics was analysed with fine models like Zero order, First order, Higuchi matrix, and Hixson-Crowell and Korsmeyer- Peppas models. Several kinetic models have been proposed to describe the release characteristics of a medicine from the matrix. The three parameters were used to study the release medium, i.e. release rate constant(k), correlation measure(R), and release exponent(n), and determine the stylish fit model for optimised expression.

Stability testing [23]

Expression MG8 was subordinated to stability studies according to ICH guidelines. The phrasings were covered for over 6 months at 40 ± 2 % / 75 ± 5. At 1, 2, 3, 4, 5, and 6 months, the appearance, pH, medicine content, and medicine release of the gel were estimated.

III. RESULTS AND DISCUSSION**Preformulation studies of Karanjin****Characterisation of Karanjin**

Organoleptic characters: The organoleptic characterisation of Karanjin was performed. The results are as follows:

Table 3: Organoleptic characters of karanjin

Sr. No.	Organoleptic characters	Result
1	Colour	White to off-white
2	Odour	Disagreeable
3	Taste	Bitter
4	Texture	Needle-shaped Crystalline solid

From the above result of organoleptic characterisation of karanjin, it was observed that all the organoleptic characteristics like colour, odour, taste, and texture.

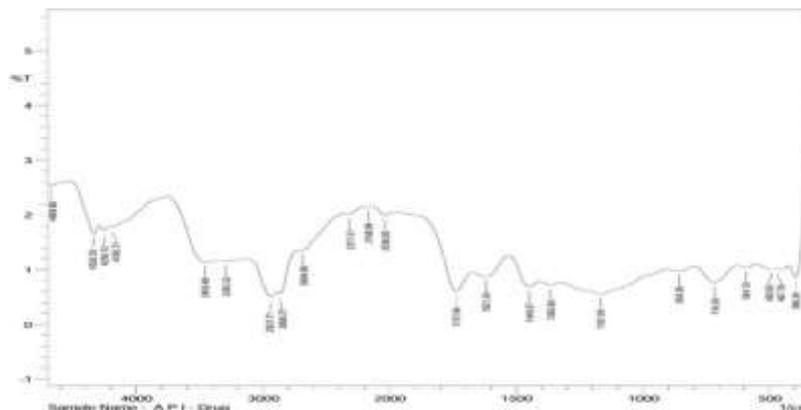
Melting Point Determination

The melting point of the Karanjin was found to be 156^oC to 158^oC °C, which is within the reported range of 156^oC-161^oC. This temperature complies with the purity of the drug sample.

Drug-Excipient Compatibility Study

Fourier transform-infrared spectroscopy

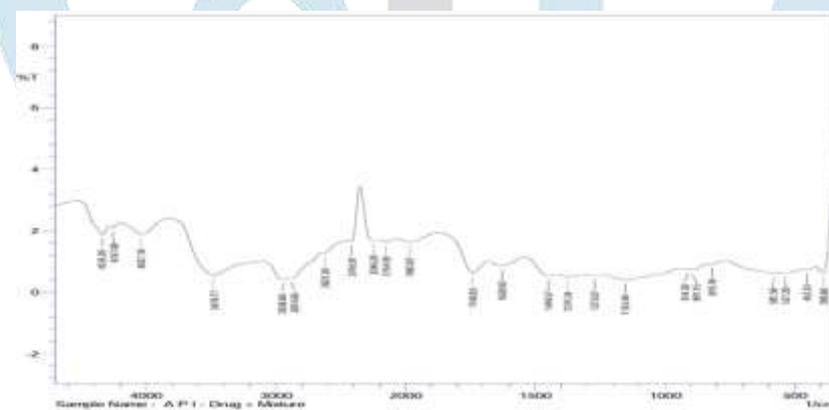
FT-IR spectrum of Karanjin



Graph 1: FTIR Spectrum of Pure API (karanjin)

Fourier transform infrared spectroscopy for drug-excipient interaction study:

Fourier transform infrared spectroscopy for medicine- excipients interaction study. The possible interaction between the medicine and polymer was studied by FT-IR spectroscopy. There was no considerable change in the positions of characteristic immersion bands and bonds of colourful functional groups present in the medicine. This observation easily suggests that the karanjin shows no prominent change in its characteristics, indeed in its physical admixture. The results of FTIR gamuts indicated the commerce between medicine and polymer. It showed that karanjin was compatible with other polymers (Ethyl cellulose and PVA) they are shown below.



Graph 2: FTIR Spectrum of Physical Mixture of API and Excipient

Spectrometric Analysis

Determination of λ_{max} of karanjin in Phosphate buffer (pH 7.4) and methanol (at a rate of 70:30)

The maximum absorbance of the karanjin was studied and set up to be 298 nm.

Standard Calibration curve of karanjin in Phosphate buffer (pH 7.4) and methanol (at a rate of 70:30)

The UV-visible spectrophotometric system was used to assay karanjin. The absorbance of the medicine in the Phosphate buffer pH. 7.4 and methanol (at a rate of 70:30) were measured at 298 nm. A working standard within the range of 5- 35 $\mu\text{g}/\text{ml}$ was prepared by periodical dilution of stock results (100 $\mu\text{g}/\text{ml}$) with phosphate buffer (pH 7.4) and Methanol. Standard estimation of wind revealed that Beer's law was adhered to throughout the attention range 5- 35 $\mu\text{g}/\text{ml}$. The direct regression equation of absorbance was set up to be $y = 0.0055 x + 0.0543$, with the correlation measure of $R^2 = 0.9908$.

Evaluation of Drug-Loaded Microsponges

Microscopy



Fig 1: Microscopic image of Karanjin Microsponges

Determination of product yield

The product yield of all batches ranged from 57.5 % to 88.7 %. It was set up that product yield was greatly affected by the medicine polymer rate as well as by the attention of polyvinyl alcohol. It was indicated that adding polymer attention increased product yield.

Encapsulation efficiency

In the study of medicine ruse effectiveness, F1 shows $66.85\% \pm 0.83\%$ EE, F2 shows $74.3\% \pm 0.56\%$ EE, F3 shows $54.8\% \pm 0.27\%$ EE, F4 shows $49.7\% \pm 0.80\%$ EE, F5 shows $60.71\% \pm 0.65\%$ EE, F6 shows $75.4\% \pm 0.39\%$ EE, F7 shows $57.4\% \pm 0.40\% \pm 0.28\%$ EE, F8 shows $81.3\% \pm 0.28\%$ EE, F9 shows $69.1\% \pm 0.89\%$ EE from this study, The F8 batch was optimized batch. In this study of medicine ruse effectiveness, the medicine and polymer were greatly affected. The polymer attention dropped the ruse effectiveness, and advanced polymer attention increased the ruse effectiveness. The ruse effectiveness also depends on the medicine-polymer commerce. The high solubility of the polymer in organic detergent, dropped ruse effectiveness, and the low solubility of the polymer in organic detergent, increased ruse effectiveness.

Table 4: Evaluation of batches (F1-F9) percentage yield, encapsulation efficiency.

Formulation	Percentage yield (%)	Encapsulation Efficiency (%)
F1	72.1±0.92	66.85±0.83
F2	77.7±0.64	74.3±0.56
F3	60.0±0.54	54.8±0.27
F4	57.5±1.03	49.7±0.80
F5	67.8±0.34	60.71±0.65
F6	83.9±0.40	75.4±0.39
F7	65.8±0.52	57.4±0.40
F8	88.7±0.62	81.3±0.28
F9	79.1±0.84	69.1±0.89

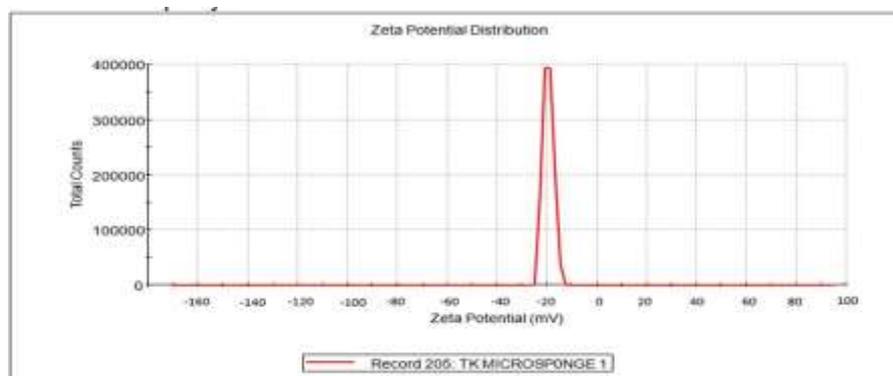
*n=3

Particle Size Analysis of microsponges

Particle Size Analysis of Microsponges As per the literature, the mean particle size of microsponges should lie in the range of 5- 350 μm . In the present work, the average particle size of karanjin-loaded microsponges ranged from $12.76 \pm 1.26 \mu\text{m}$ to $70.38 \pm 0.98 \mu\text{m}$. The mean particle size was significantly increased by adding polymer.

Zeta potential and zeta sizer

The zeta implicit graph plot showed a peak at $21.5 \pm 0.35 \text{ mv}$, of F8 expression, which meant that most of the microspunge patches in the expression had this charge, showing that the patches had an affinity for each other.



Graph 3: Result of Graphical Presentation of Zeta Potential Distribution

Table 5: Result of Karanjin base microsponges particle size and zeta sizer

Formulation batches	Particle size (μm)	Zeta Potential (Mv)
1	28.19 \pm 1.23	-13.3 \pm 0.82
2	31.36\pm0.87	-14.8\pm0.76
3	16.96 \pm 1.07	-9.23 \pm 0.45
4	12.76 \pm 1.26	-8.45 \pm 1.75
5	23.50 \pm 2.33	-11 \pm 1.87
6	38.42 \pm 1.64	-18.4 \pm 1.36
7	19.87 \pm 2.03	-10 \pm 0.98
8	70.38\pm0.98	-21.5\pm0.35
9	31.65 \pm 1.06	-16.9 \pm 1.25

*n=3

SEM (Scanning Electron Microscopy)

The representative SEM photographs of the microsp sponge formulations F8 are shown in Figure 2 SEM images showed the microsponges were spherical and devoid of aggregation. Therefore, they would easily disperse into the gel formation.

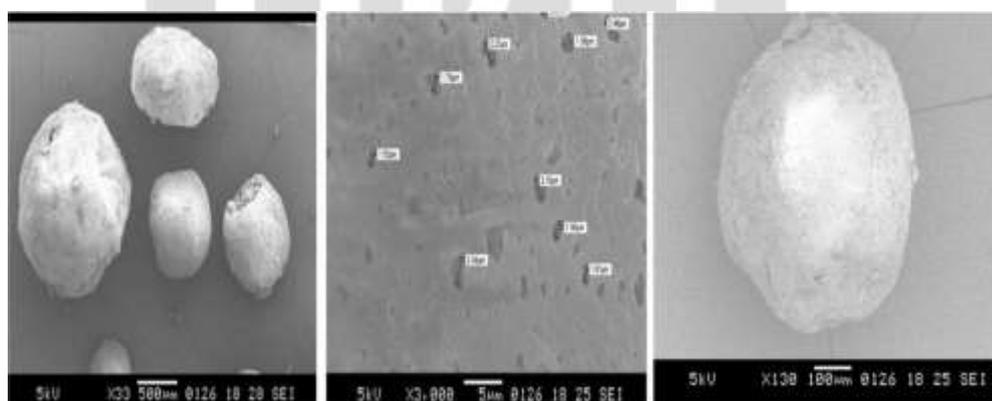
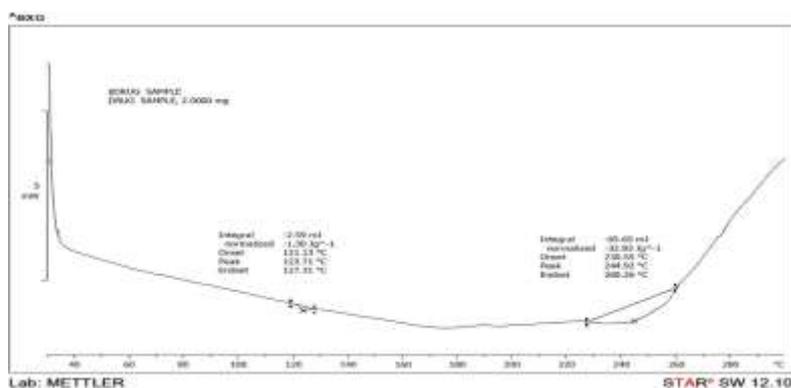


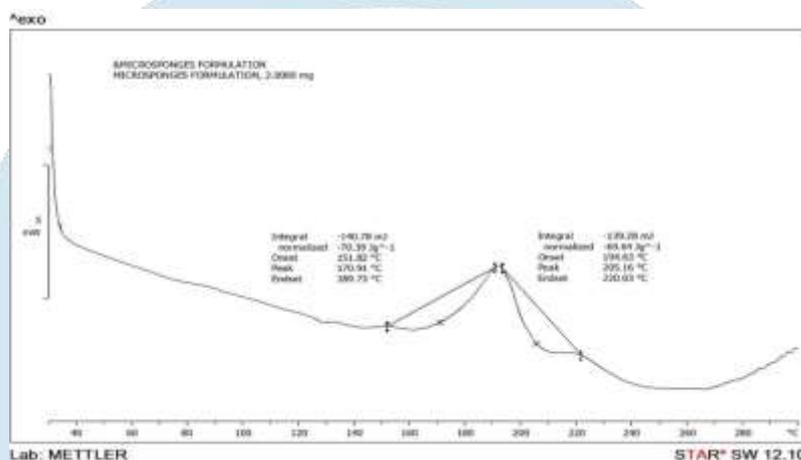
Fig 2: SEM image of F8 batch Karanjin Microsponges

Differential Scanning Calorimetry (DSC) thermogram:

Differential Scanning Calorimetry (DSC) thermogram the thermal behavior of the pure medicine and the microsponges expression was estimated using Differential Scanning Calorimetry (DSC). The DSC thermogram of the pure medicine showed a sharp endothermic peak at 123.71 °C, indicating its liquid nature. In discrepancy, the microsp sponge's expression showed broad peaks at 170.91 °C and 205.16 °C, with a sense of the medicine's melting peak. The results are shown below. The exposure of the medicine's melting peak in the microsp sponge expression suggests successful encapsulation and possible conversion of the medicine from crystalline to unformed form. This indicates effective dissipation within the polymer matrix.



Graph 4: DSC thermogram of karanjin (API)



Graph 5: DSC thermogram of F8 formulation

EVALUATION OF KARANJIN MICROSPONGE GEL:

Visual Examination

The set gel formulations of karanjin microsponges were audited visually for their colour, texture, and appearance. All set phrasings were pearl white, thick medications with a smooth texture.



Fig 3 Microsponges gel

pH measurement

The pH value of all set phrasings was set up to be in the range of 6.8 ± 0.03 , which was considered to be respectable to avoid the threat of vexation upon operation to the skin. The pH of all the phrasings was set up to be 6.8 depicted in the table. The more hydrogen ions present, the lower the pH; again, the smaller the hydrogen ions, the more advanced the pH.

Spreadability Study

The values of spreadability indicated that the gel was fluently spreadable by a small amount of shear. The spreadability of microsponge gel (MG8) was set up to be 41.99 g Cm/ sec, indicating that the spreadability of drug-loaded microsponge hydrogel was good. In the expression, the MG8 batch spreadability is good. The lower the density, the lesser its spreadability, and the more advanced the density, the lower its spreadability.

Viscosity Studies

The viscosity studies for microsponge phrasings were carried out. Viscosity is an expression of the resistance of a fluid. The more advanced the resistance, the lesser the viscosity; and the lower the resistance, the lower the viscosity. The resistance offered by the fluid to flow freely.

Drug Content Studies

Drug content studies for microsponge phrasings were carried out. The medicine content of MG2 and MG8 phrasings is shown in the table the drug content of the expression showed that the drug was slightly distributed in the hydrogels. From the below result, microsponge gel (MG8) has advanced medicine content, i.e., $78.3 \pm 0.21\%$. The medicine content analysis revealed that batch MG8 displayed an advanced

medicine content (78.3 ± 0.21) compared to batch MG2 (71.2 ± 0.34). This advanced medicine ruse in MG8 may be attributed to the optimized rate of polymer attention, particularly the ethyl cellulose and PVA combination, which handed a more effective matrix structure for recapitulating the medicine.

Table 6: Result of microsponges gel, Visual Inspection, pH measurement, Spreadability Study, Viscosity Studies, %Drug Content.

Formulation of microsphere gel	Visual Inspection	pH measurement	Spreadability Study (g Cm/ sec)	Viscosity Studies (mPa.s)	Drug Content Studies (%)
MG2	Pearl White	7.1 ± 0.02	34.79 ± 0.045	6875.9 ± 0.0198	71.2 ± 0.34
MG8	Peral white	6.8 ± 0.03	41.99 ± 0.026	6571.8 ± 0.0157	78.3 ± 0.21

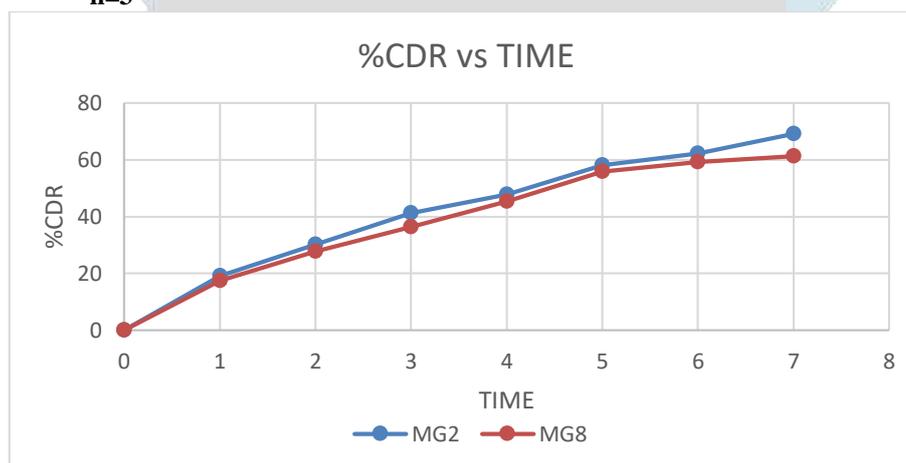
*n=3

In-Vitro Drug Diffusion study: The cumulative percent drug diffusion for formulation batch MG8. The MG8 batch was more than the other batches, showing $61 \pm 0.50\%$. These results are shown in Table 7.

Table 7: Result of %CDR OF selected microsponges formulation

Time in hr.	%CDR	
	MG2	MG8
0	0	0
1	19.18 ± 0.35	17.45 ± 0.75
2	30.12 ± 0.49	27.81 ± 0.98
3	41.18 ± 0.78	36.36 ± 0.61
4	47.9 ± 0.65	45.45 ± 0.40
5	58.12 ± 0.38	55.8 ± 0.83
6	62.3 ± 0.78	59.18 ± 0.94
7	69.2 ± 0.85	61.3 ± 0.50

*n=3



Graph 6: % Cumulative Drug Diffused VS. Time of gel

Discussion

MG2 showed a faster and more complete release, reaching $69.2 \pm 0.85\%$ by the 7 hours. In contrast, MG8 exhibited a more controlled and sustained release, reaching $61.3 \pm 0.50\%$ at 7 hours.

This sustained release behavior in MG8 can be attributed to a denser microsphere matrix, likely due to higher concentrations of ethyl cellulose, which is hydrophobic and slows down drug diffusion. Meanwhile, MG2, with a relatively lower polymer content, allowed for quicker hydration and drug diffusion, resulting in a faster release. Drug release from microsponges was due to the porous nature of microsponges. Porosity can influence the apparent diffusion coefficient of the drug, which can ultimately change the drug release. At a higher level of ethyl cellulose viscous phase, coarsening time gets prolonged, and larger pores are formed that hold the drug release from microsponges.

These findings confirm that batch MG8 offers a more sustained and controlled drug release, which is preferable for prolonged therapeutic action, while MG2 may be suitable for applications requiring a quicker onset of action.

Drug release kinetic study of optimized formulation MG8:

To evaluate the drug release behavior of the optimized microsp sponge gel formulation, the *in vitro* drug diffusion data were fitted to various kinetic models, including Zero-order, First-order, Higuchi, and Korsmeyer–Peppas models. The selection of the most appropriate model was based on the correlation coefficient (R^2) and the release exponent (n) obtained from each model. Among the tested models, the Korsmeyer–Peppas model exhibited the highest correlation coefficient ($R^2 = 0.9927$), indicating the best fit for the release data. The release exponent (n) was calculated to be approximately 0.82, which corresponds to anomalous (non-Fickian) transport, suggesting a combination of diffusion and polymer matrix relaxation mechanisms. This result confirms that the drug release from the microsp sponge gel is sustained and controlled, governed by both diffusion and erosion processes. Therefore, the Korsmeyer–Peppas model was identified as the most suitable kinetic model for describing the release behavior of the microsp sponge-based gel formulation.

Stability Studies

The optimized batch MG8 was subjected to stability studies. The results are as follows

Table 8: Stability data of optimized batch MG8

Sr.No	Period parameter	0 days	30 days
1	pH.	6.8±0.05	6.7±0.08
2	Drug content %	78.6±0.24	77.6±0.24
3	<i>In vitro</i> diffusion study %	61.3±0.75	61.4±0.90

The result of stability studies showed that there were no significant changes in the pH, Drug content, and *in-vitro* diffusion study of gel, after storing at a room temperature of 40±2°/75±5%. Relative humidity for 1 month.

IV. CONCLUSION

The present study successfully developed a Karanjin-loaded microsp sponge gel for topical application using the quasi-emulsion solvent diffusion system. Among all the formulations, batch F8 and its corresponding gel MG8 were set up to be optimised grounded on particle size, entrapment efficiency, drug content, and sustained medicine release. The set microsp sponge-based gel demonstrated excellent physicochemical properties, including applicable pH, spreadability, density, and medicine content, which are essential for effective topical delivery.

In vitro diffusion studies verified that the micro sponge gel provided sustained release of the medicine, reducing the need for frequent operation. The drug release followed Korsmeyer–Peppas kinetics, indicating a controlled release medium involving both diffusion and polymer erosion. Stability studies further verified that the expression remained stable over time without significant changes in medicine content or release geste.

Overall, the study concluded that microsp sponge technology offers a promising and effective strategy for enhancing the topical delivery of Karanjin. This approach can potentially improve remedial issues, patient compliance, and minimise side goods, making it suitable for the treatment of skin diseases similar to psoriasis.

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