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Formulation and Evaluation of Framycetin Sulphate Microsponge Loaded Topical Gel For The Treatment of WOUND Healing

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ABSTRACT

Wounds are majorly caused by physical disruption of the outermost protective layer of the body, which consists of the skin. The main aim of the present study is to prepare and evaluate drug loaded microsponge gel for the treatment of wounds. Microsponge are polymeric porous structure, whose sizes range between 5 and 300 µm in diameter, consisting of interconnected voids inside a non-collapsible structure. Framycetin sulphate microsponges were prepared by w/o/w emulsion solvent diffusion method. Here, Eudragit RS100 polymer was dissolved in dichloromethane to form the organic phase. Drug was dispersed in xanthan gum solution which was thenpoured into the organic phase and was emulsified with the help of surfactant to form primary emulsion. This emulsion was then poured into the external phase containing PVA solution and surfactant to form w/o/w emulsion. The optimum size of microsponges were found to be around 177.38µm in the F8 batch and percentage yield was found to be 93.67% The formulated optimized microsponge loaded gel was clear and transparent having a smooth texture with good aesthetic appeal. The pH of the gel was 7.2 which is appropriate for application on the injured skin surface. The viscosity of the gel was optimum for topical application having a viscosity of 38470 cps. The gel was studied for spreadability properties which indicated that the gel can easily spread on the skin surface. The in vitro release studies showed that the there was no release in the beginning 0.5 hours. After 1 hour 1.45% drug was released from the formulation into the donor compartment. A steady drug release was seen for the next 3 hours with a concentration of 6.26%. The concentration remained the same after 2 hours and againincreased with a concentration of 15.90%. This indicates that the drug release was verynegligible after 24 hours, which is desired as the drug will remain on the skin surface without much penetration into the skin. The antibacterial studies revealed the antibacterial effect of framycetin sulphate microsponge loaded topical gel. The optimized gel was compared to the marketed formulation of soframycin cream (Sanofi Aventis). The antibacterial effect of optimized gel was closely similar to the marketed formulation. The developed microsponge loaded gel was seen to be effective against combating thebacteria and thus preventing the infection. The study delivers future insights for developing controlled release microsponge based gels for healing skin related disorders

Keywords: Framycetin Sulphate, Wound Healing, Microsponge Topical Gel, Bacillus subtilis, Bacillus pumilis.

INTRODUCTION

A wound can be described as any damage to the skin that compromises with its protective function. The basic role of normal, undamaged skin is to prevent it from bacterial invasion. Thesebacteria are normally present on the skin surface and the skin prevents it from invadingand colonizing the skin

tissues. When the skin is injured, it is exposed to the external environment with loss of skin integrity, providing a moist, warm and conductive environment for the bacterial colonization. The bacterial population will be influencedby various factors like wound type, location, depth, level of tissue perfusion and host response. In case of clean, surgical wounds, the microbial count is expected to be minimum but can be influenced by presence of foreign substance and impaired tissues surrounding traumatic wound unless early wound management is implemented using antibiotic treatment. In an infected condition, a wound fails to heal, causing trauma, costly treatment and wound management becomes more critical. Ideal wound management is dependent on personal assessment, physician's knowledgeon wound healing process and wound diagnosis. In case of patients presented with wounds, where the risk of spreading of infection and other complications are high, immediate first line treatment with antibiotics should be provided. **[1-5]** the use of wound dressings is important as it maintains a good healing environment.Conventional wound dressings primarily isolate the wound and show antibacterial effect, but, they often cause wound drying, destruction of healthy growth factors, and easily adhere to nascent tissues **[6]** When traditional dressings are removed they can cause secondary wounds to the wound leading to worsening of the condition **[7]** First line treatments for wound healing majorly include ointment, creams, gels anddressings. These contain a very high concentration of active ingredients which may rapidly penetrate into the skin and enter the systemic circulation **[1]** Marketed formulations are not able of absorbing skin secretions and reducing oiliness and have increased frequency of application **[7-8]** The formulations available for wound healing have a need to be applied at least 3 to4 times a day and mainly focus on providing an effective treatment against bacterialinfection but do not focus on skin rejuvenation which can further lead to scar formation **[9]**

Microsponges are polymeric delivery systems composed of porous microspheres. The sizes of microsponge range from 5µm to 300µmin diameter, which is lesser than most of the microorganisms and have an average poresize of 0.25µm. Because of this reason, microsponges are also called as self-sterilizingas a result of which it does not need any excipients for stability. As the pore size is verysmall it restricts the infiltration of microorganisms into the microsponge. Like a true sponge, microsponge consists of huge inter-connecting voids inside a non-collapsible structure.This results in large reservoir within the microsponge that can be loaded with the activeingredient to up to its own weight. These systems are microscopic, the drug is loaded into polymer-based microspheres that can be then easily suspended into various formulations like cream, gel, powder or liquid. Microsponges allow sustained release of the medicament and are mostly used for topical application also, they are widely studied for oral administration. Microsponges are capable of delivering the drug to the affected site at a very low dosewith reduced side effects and increased stability. Microsponges show non-mutagenicity, non-irritancy and non-allergenic properties. It uses low dose of drug to show the desired effect as compared to conventional dosage forms. The microsponge delivery system fulfils all of these requirements and has resulted in very well tolerated and efficacious novel delivery systems. **[8, 10-11]** Microsponge systems do not cause toxicity and are non-allergic. It can show controlled release for upto 8 to10 hours. It can overcome the problems related to patient compliance such as greasiness andstickiness. It can control and absorb exudates, and keep the wound moist without affecting the other tissues another advantage is the drug stays on the epidermis maximizing the concentrationof active ingredient on the affected site Delayed release of the drug from the microsponges reduces the application frequency and scar formation. **[12]** It shows better thermal, physical and chemical stability and is easy to formulate. Itprovides improved bioavailability and allows incorporation of immiscible drugs **[13]** these are designed to carry the active ingredient efficiently at minimum dose withincreased efficacy **[7]** it can provide a bacterial barrier, create a good environment suitable for tissue growth. It can show better permeability for gas and water vapor **[14]** Sizes of microsponges range between 5 and 300µm which restricts its penetration into the skin and to the systemic circulation. Due to this advantage the bacteria is unable to penetrate into the microsponges **[15]** Kumar et al (2015) prepared microsponges of

metronidazole by w/o/w emulsion solvent evaporation method for the treatment of superficial surgical wound infection. These microsponges were then incorporated into gel base for topical delivery of the drug. The prepared microsponge gel showed effective activity against the bacteria and prevented the infection. It showed enhanced benefits like improved compliance, good aesthetic appeal and decreased frequency ofapplication **[16]** Pandit A et al (2016) formulated nebivolol loaded microsponge gel for the treatment of diabetic wounds. The microsponges showed slow release of drug on the wound surface from the porous structure and gel was helpful in management of wound byproviding moist environment **[12]**

Framycetin sulphate is the sulphated form of neomycin B, belonging to the class ofaminoglycoside antibiotics having a broad-spectrum antimicrobial activity **[17]** it belongs to BCS class III having high solubility and low permeability. Due to its low permeability it acts as the best candidate for topical administration. It is active against gram positive cocci and gram-negative rods and highly effective against aerobic bacteria **[18]** Framycetin sulphate is active against *Staphylococcus spp*, *Escherichia coli*, *Klebsiella spp*, *Salmonella*, *Shigella*, *Mycobacterium tuberculosis*, *Leptospira spp* and *Pseudomonas aeruginosa*. This makes it an effective drug for the treatment of various wound conditions this drug shows no contact sensitivity or irritation there is a need to formulate a microsponge loaded gel which can reducethe frequency of application, decrease the side effects and can deliver skin healingand rejuvenation beyond the activity of framycetin sulphate in a way that the therapeutic effect of the main API is enhanced **[7]**

MATERIALS AND METHODS

Materials:
Framycetin Sulphate was purchased and obtained from Encube Ethicals Mumbai Maharashtra India as a gift sample. Eudragit RS-100, Xanthan gum and polyvinyl alcohol was purchased from Research Lab Fine Chem Industries Mumbai. Acetone and Dichloromethane was purchased from Chemdyes Corporation Ahmedabad. Tween 80 and Span 80 were purchased from Research Lab Fine Chem Industries Mumbai. Carbopol 934 was purchased from Chemdyes Corporation Ahmedabad. Triethanolamine was purchased from Research Lab Fine Chem Industries Mumbai.
Methodology [19-21]

Pre-formulation Studies Physical Appearance:
Identifying physical state and colour of framycetin sulphate visually in whitebackground

Melting Point [22]
Melting point of framycetin sulphate will be determined manually with the help of Veego melting point apparatus. In this method, small amount of drug will be crushed and powdered as to avoid any crystals of drug. This powder will then be filled into thecapillary tube that will be placed in the stand. Once the apparatus is switched on the oil will start heating and the capillary tube will be observed. Once the drug melts the melting will be recorded.

Determination of λ max of framycetin Sulphate
Weigh accurately 1g of framycetin sulphate and dissolve it in 1000ml of distilled water. Withdraw 25ml from the above solution into a volumetric flask and make up the volumeto 50ml using distilled water. Again, withdraw 1ml from the above solution and make up the volume upto 10ml with distilled water and derivatization was done to produce a colored solution. Place the resulting solution in cuvette and calculate the absorbance using UV-spectroscopy in the range of 200 to 800nm.

Standard calibration curve of Framycetin Sulphate

Prepare a stock solution by dissolving accurately weighed 1g of framycetin sulphate in 100ml of distilled water. Withdraw 25ml from the stock solution and dilute upto 50ml in volumetric flask with water. Further dilute the above solution in such a way so as to obtain various dilutions with different concentrations ranging from 50 to 250µg/ml. Using UV-spectroscopy measure the absorbance of the resulting dilutions with differentconcentrations in the range of 200 to 800nm. Plot the graph of abs vs conc and calculatethe slope and correlation co-efficient 'R^2'.

Identification and Chemical Compatibility study of drug and excipients

Identification study of framycetin sulphate will be carried out using 8400S Shimadzu FT-IR spectrophotometer. The test sample of framycetin sulphate will be prepared using potassium bromide pellet method. Once the pellet is prepared, run the FT-IR inthe range of 4000 to 500 cm^{-1}. Compatibility study of framycetin sulphate andexcipients will be carried out by mixing then and keeping overnight, then prepare thepotassium bromide pellet of the above mixture and run in FT-IR

Determination of physical property of drug

The drug and prepared drug loaded microsponges were analysed by differential scanning colorimeter to identify physical compatibility between drug and polymers.

Method for preparation of Microsponge loaded gel Preparation of primary emulsion

In the first phase, a primary emulsion is prepared. Accurately weighed quantity of drugis dissolved in an aqueous solvent. A required amount of xanthan gum was dispersed in the above solution. The polymers will be dissolved in an organic solvent. The aqueous phase will then be dispersed into organic phase with the help of surfactant to form a solution: this will form the primary emulsion (W/O).

Preparation of secondary emulsion: m The primary emulsion was added into an aqueous phase containing PVA as polymer and tween 80 as surfactant to form secondary emulsion (W/O/W) under continuous stirring.

Formation of Microsponge

The stirring was continued at specific rpm for the next 1.5 hours. After 1.5 hrs, the emulsion was taken and filtered using vacuum pump. The filtered microsponges were then air dried and weighed.

Preparation of Microsponge loaded Gel

The prepared microsponges will then be incorporated into gel which will be prepared by dissolving appropriate amount of gelling agent in water.

Evaluation studies for Microsponge Surface Morphology

The surface morphology of prepared microsponges will be examined with the help of a scanning electron microscope.

Particle size Analysis

The particle size were measured using an optical microscope

Drug entrapment efficacy

Precisely weigh accurate quantity of microsponges containing drug and dissolve it in 5ml methanol in magnetic stirrer for 20 min. Once clear solution is formed, add 20ml of freshly prepared solution of phosphate buffer solution and heat the solution at 45- 50˚C. After the methanol is completely evaporated, cool down the solution to room temperature. Filter the samples and further analyse it at specific nm using ultraviolet- visible (UV) spectrophotometer.

Evaluation of Microsponge loaded gel Visual Inspection
Physical appearance such as appearance and texture of gel containing microsponges will be checked by visual observation.

pH measurement
Gel formulation pH will be recorded using pH meter. 5 g gel will disperse in 45 mldistilled water at 27°C and solution pH will be measured.

Spreadability studies
Spreadability studies were performed with help of two Petri plates. One plate was kept on the flat surface. Weighed quantity (0.5gms) of gel was placed above the first petri plate followed by the second petri plate. A constant weight of 500gms was kept on that assembly for 5min and the increase in diameter was noted. The Spreadability of the developed formulation 4.5 cm.

Viscosity studies
Viscosity of drug loaded Microsponge gel was determined with the help of Brookfield viscometer having a T bar spindle.

***In vitro* release studies**
The *in vitro* release of gel formulations will be studied using Franz diffusion cell. Membrane used will be dialysis membrane. The sample will be placed in the donor compartment while the receiver compartment will have fresh medium and the membrane will be placed between these two compartments. Aliquots of 0.5ml will be taken from the receiver compartment at regular intervals and fresh medium will be added to maintain the sink conditions. Samples will be filtered through Whatman filterpaper and analyzed using UV spectrophotometer.

***In vitro* antibacterial activity [23]**
In vitro antibacterial activity of framycetin sulphate loaded microsponge gel will be carried out by Disc-plate method

RESULTS & DISCUSSION

OrganolepticProperties

Table 1: Organoleptic Properties of Framycetin Sulphate

Sr. No	OrganolepticProperties	Results
1	Physical Nature	Amorphous Powder (Hygroscopic)
2	Color	White to off-white
3	Odour	Odorless

Melting Point

Table 2: Melting Point of Framycetin Sulphate

Sr. No	Specification	Observed Value (±SD)
1	220˚C - 222˚C	220.12˚C (±1.13)

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UV Analysis

Determination of λ max of Framycetin Sulphate

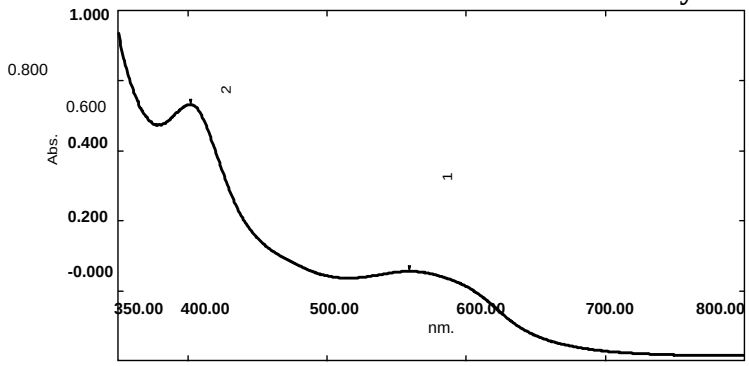

Figure 1: λ max of Framycetin Sulphate

The chemical structure of framycetin sulphate shows no conjugation and as result it shows no UV absorbing chromophore, so derivatization method was used for the determination of λ max. The spectroscopic analysis showed absorbance at a wavelengthof 404nm.

Calibration curve of Framycetin Sulphate:

The solutions of Framycetin Sulphate were prepared of various concentrations ranging from 50µg/ml to 250µg/ml.

Table 3: Calibration Curve Of Framycetin Sulphate

Concentration(µg/ml)	A1	A2	A3	Absorbancen=3; mean(±SD)
50	0.133	0.162	0.184	0.160 (±0.021)
100	0.253	0.24	0.276	0.256 (±0.015)
150	0.382	0.378	0.367	0.376 (±0.006)
200	0.493	0.524	0.497	0.505 (±0.014)
250	0.533	0.732	0.634	0.633 (±0.081)

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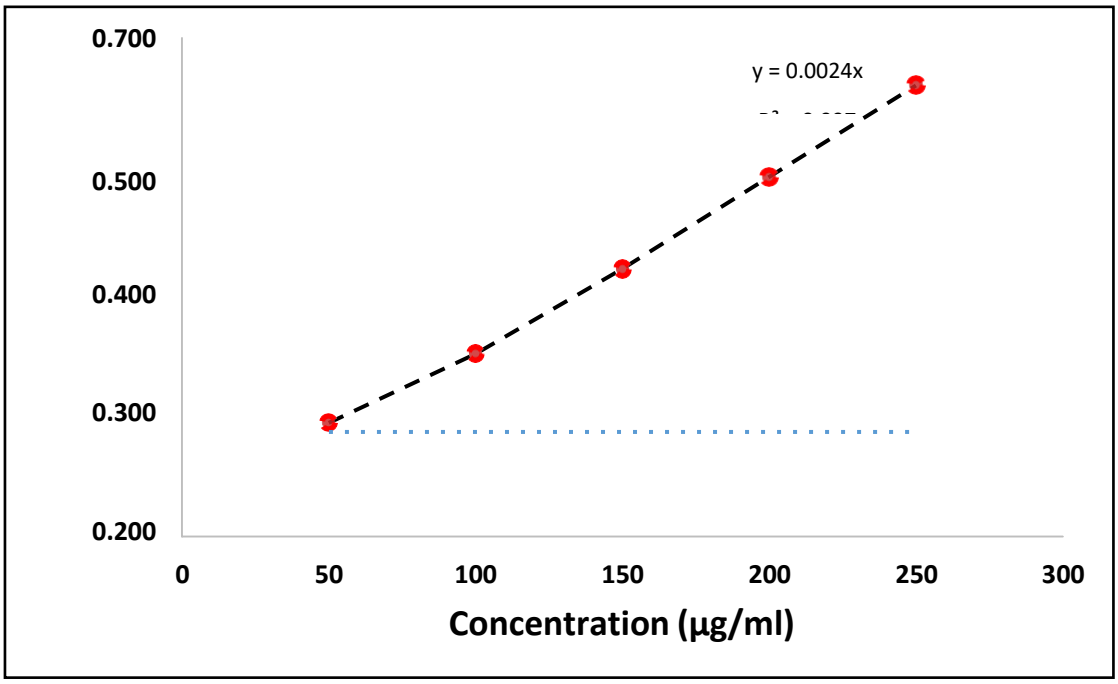

Figure 2: Calibration plot of Framycetin Sulphate

FT-IR Analysis:

FT-IR analysis of Framycetin Sulphate

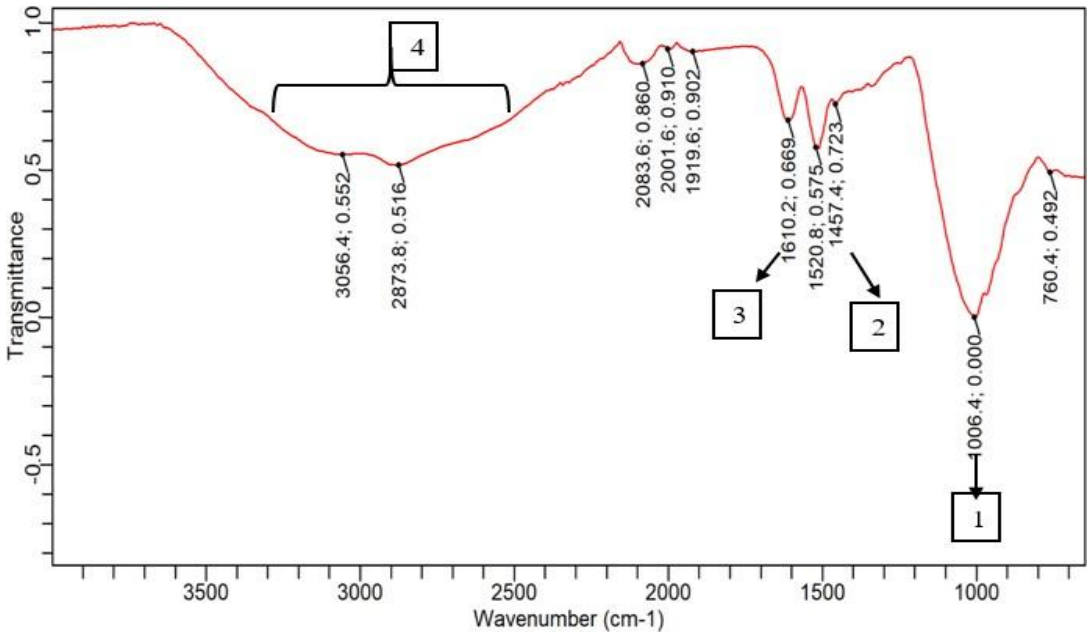

Figure 3: FT-IR spectra of Framycetin Sulphate

Table 4: FT-IR peaks of Framycetin Sulphate

Sr. No.	Functional groups	Wavenumber (cm^{-1})

		Reported	Observed
1	C-O-C stretch	1250-1050	1006.4
2	S=O stretch	1415-1380	1457.4
3	NH2 stretch	1650-1550	1610.2
4	OH stretch	3300-2500	3300-2500

FT-IR spectra of Framycetin Sulphate is shown in the fig 3 and the study was carriedout in Cary630 FT-IR spectrophotometer. The FT-IR analysis showed peaks of functional groups present in the pure Framycetin Sulphate. The characteristics peaks of the functional groups are shown in table 4

FT-IR analysis of Eudragit RS100

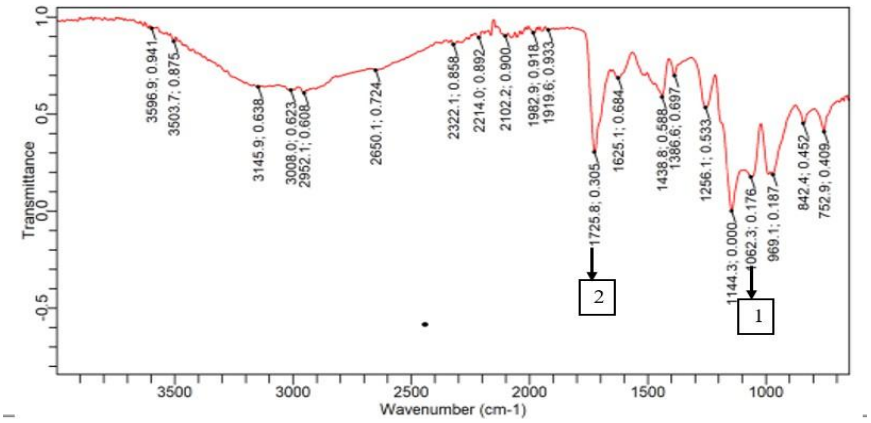

Figure 4: FT-IR spectra of Eudragit RS100

Table 5: FT-IR peaks of Eudragit RS100

Sr. No	Functional groups	Wavenumber (cm^{-1})	
		Reported	Observed
1	C-O-C stretch	1250-1050	1144.3
2	C=O stretch	1745-1715	1725.8

T-IR spectra of Eudragit RS100 is shown in the fig 4 and the study was carried outin Cary630 FT-IR spectrophotometer The FT-IR analysis showed peaks of functional groups present in the polymer, EudragitRS100. The characteristics peaks of the functional groups are shown in table 5

FT-IR spectra of polyvinyl alcohol:

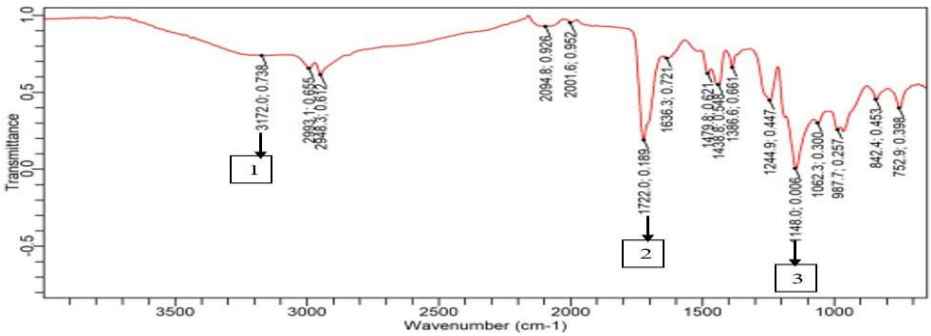

Figure 5: FT-IR spectra of Eudragit RS100

Table 6: FT-IR peaks of Eudragit RS100

Sr. No	Functional groups	Wavenumber (cm^{-1})	
		Reported	Observed
1	OH stretch	3550-3200	3172.0
2	C=O stretch	1750-1735	1722.0
3	C-O-C stretch	1150-1085	1148.0

FT-IR spectra of Polyvinyl Alcohol is shown in the fig 5 and the study was carriedout in Cary630 FT-IR spectrophotometer. The FT-IR analysis showed peaks of functional groups present in the polymer, Polyvinyl Alcohol. The characteristics peaks of the functional groups are shown intable 6.

FT-IR spectra of Drug loaded Microsponge gel:

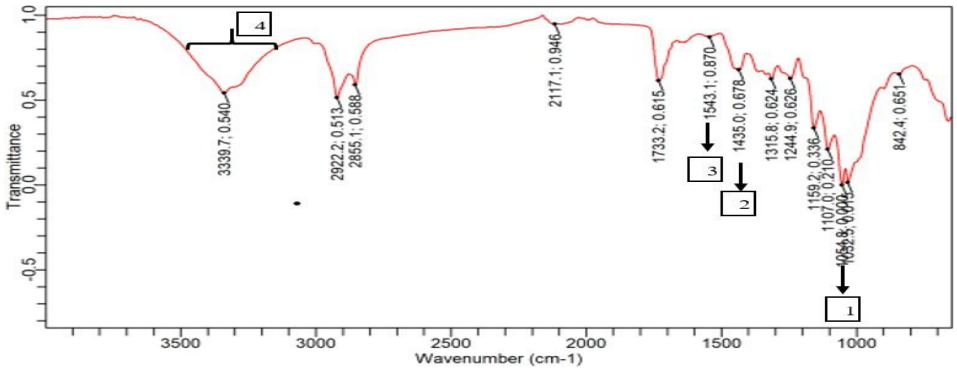

Figure 6: FT-IR spectra of Eudragit RS100:

Table 7: FT-IR peaks of Eudragit RS100

Sr. No	Functional groups	Wavenumber (cm^{-1})	
		Reported	Observed
1	C-O-C stretch	1250-1050	1054.8
2	S=O stretch	1420-1370	1435.0
3	NH_2 stretch	1650-1550	1543.1
4	OH stretch	3300-2500	3500-3100

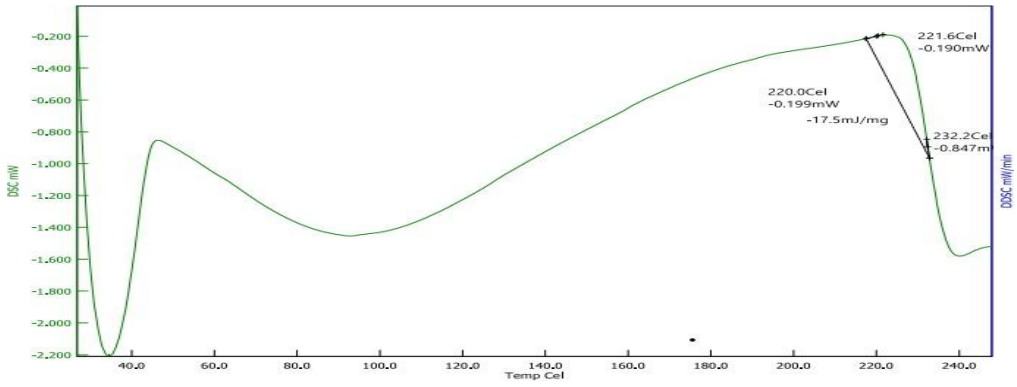

Figure 7: DSC Thermogram of Framycetin Sulphate

The DSC Thermogram of framycetin sulphate is shown in the figure 16. As framycetin sulphate is hygroscopic in nature, there is presence of a broad peak at around 95˚C which shows loss of moisture. DSC Thermogram showed an exothermic peak of framycetin sulphate at a temperature of 220 ˚C.

Preparation of various batches:

The batches were prepared by changing the drug: polymer ratio and stirring speed. The quantity of DCM was kept constant throughout the batches.

Table 8: Different batches of drug loaded Microsponge

Sr. No	Batches	Drug: Polymer	DCM	Stirring Speed
1	F1	1:2	30	3000
2	F2	1:4	30	3000
3	F3	1:6	30	3000
4	F4	1:2	30	5500
5	F5	1:4	30	5500
6	F6	1:6	30	5500
7	F7	1:2	30	8000
8	F8	1:4	30	8000
9	F9	1:6	30	8000

Table 9: Effect of drug: polymer ratio and stirring speed on particle size, % yield and drug entrapment efficacy.

Sr. No	Batches	Particle size (µm)	% yield	% Drug entrapment efficiency
1	F1	163.34 (±4.65)	93.63	80.17 (±1.04)
2	F2	273.31 (±6.32)	86.09	81.26 (±1.98)
3	F3	187.43 (±5.54)	53	79.5 (±2.84)
4	F4	262.05 (±7.32)	65.27	51.09 (±4.10)
5	F5	233.09 (±4.93)	61.08	56.29 (±3.68)
6	F6	194.76 (±7.04)	85.43	33.33 (±2.13)
7	F7	192.67 (±9.87)	65.45	30.07 (±2.59)
8	F8	177.38 (±4.11)	93.67	92.15 (±2.25)
9	F9	223.76 (±6.78)	61.69	44.6 (±1.97)

From the above table it can be seen that F8 batch showed maximum percent yield along with increased drug entrapment efficacy. Also the particle size of this batch was seen to be optimum. Therefore, F8 was selected as the optimized batch and was considered for further evaluation processes.

Evaluation of Microsponge:

Surface Morphology:

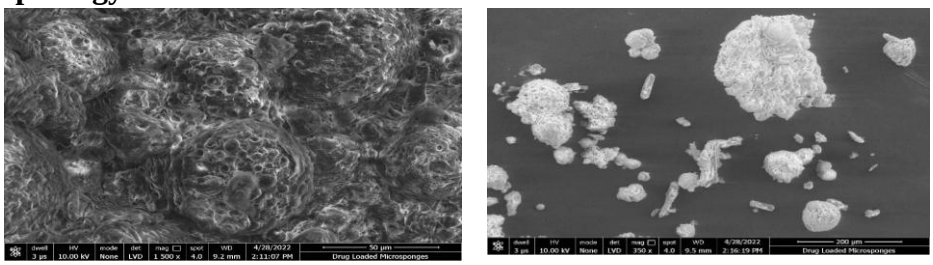

Figure 18: Electron micrographs of drug loaded Microsponge

The shape and morphology of the optimized drug loaded microsponges were investigation by Scanning Electron Microsponge. Electron micrographs showed that the microsponges were spherical and porous. Surface morphology revealed the porousnature of microsponges and no drug crystals on the surface

Particle Size Analysis: From the particle size analysis, it can be concluded that, F1 batch showed minimum particle size of 163.34µm as compared to other batches, whereas, the optimized batch showed slightly higher particle size of 177.38µm

Drug Entrapment Efficiency:

Table 10: Drug Entrapment Efficiency

		% Drug Entrapped				
Sr. No.	Batch No.	T1	T2	T3	Mean	SD
1	F1	80.51	78.76	81.23	80.17	1.04
2	F2	83.72	81.2	78.87	81.26	1.98
3	F3	82.34	75.63	80.54	79.50	2.84
4	F4	56.67	46.91	49.7	51.09	4.10
5	F5	57.13	51.43	60.32	56.29	3.68
6	F6	35.12	34.54	30.33	33.33	2.13
7	F7	33.74	27.76	28.9	30.13	2.59
8	F8	95.18	89.8	91.48	92.15	2.25
9	F9	45.66	41.84	46.3	44.60	1.97

Evaluation of Microsponge loaded Gel:

Visual Inspection|:

Table 11: Visual Inspection

Sr. No	Parameters	Analysis
1	Appearance	Clear and transparent
2	Texture	Smooth

pH Measurement: The pH was measured using digital pH meter. The pH of the optimized microspongeloaded gel was found to be 7.2, which complies with the pH of the infected wound

Spreadability: The Spreadability was found to be 44 g.cm/sec which indicated easy application of gelto the skin surface

Viscosity Studies:

Table 12: Viscosity Studies

Time (min)	spindle	RPM	Viscosity (cps)
5	T bar spindle	4	38470

The viscosity studies were done in Brookfield viscometer using a T bar spindle which was rotated at a speed of 4 rpm. The results showed that the optimized microsponge loaded gel had good viscosity properties.

In vitro release studies:

Table 13: In vitro Drug Release Studies

Sr. No	Time (hrs.)	% CDR (±SD)
1	0	0.00 (±0.00)
2	0.5	0.00 (±0.00)
3	1	1.45 (±0.00)
4	2	3.05 (±1.14)
5	4	5.46 (±1.14)
6	6	8.67 (±1.97)
7	8	14.10 (±4.03)
8	24	21.52 (±4.09)

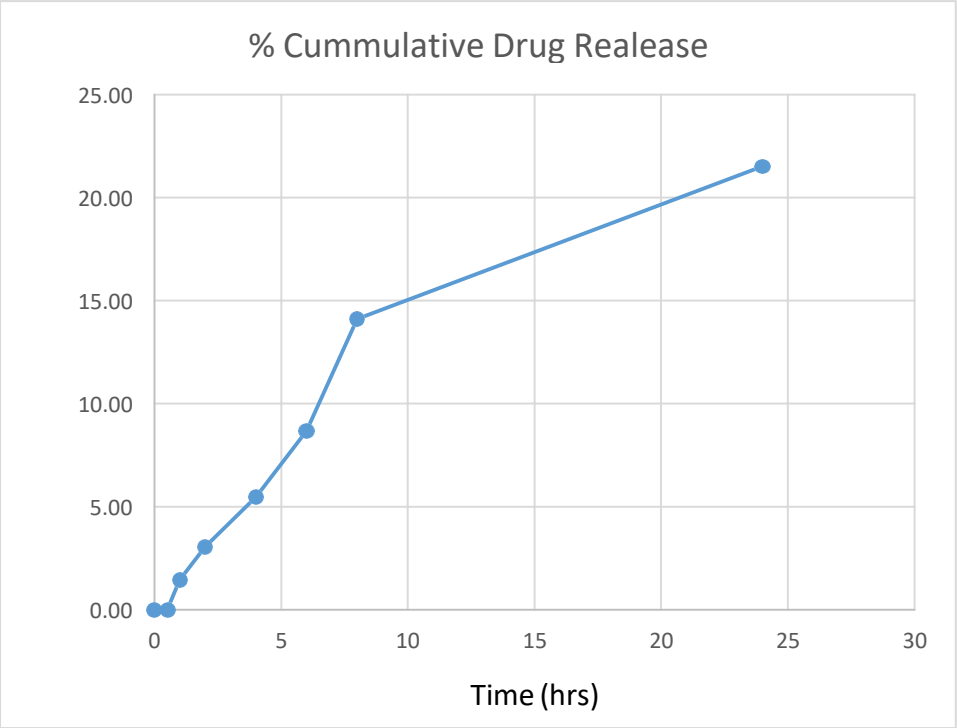

Figure 19: Graph of Time (hrs) vs % cumulative drug release

1 gram of optimized gel was placed in the donor compartment above the dialysis membrane and aliquots were taken at specific time interval. The studies showed that there was very less amount of drug release in 8 hours. Also, release was slightly higherafter 8 hours.

In vitro antibacterial study:

Table 14: In vitro antibacterial study

Microorganisms	Antibiotic	Zone of Inhibition [ZOI] (mm)				Mean (±SD)	Interpretation
		T1	T2	T3	T4		
Bacillus subtilis	Marketed formulation (Sanofi Aventis)	17	17	18	19	17.5 (±1.12)	Susceptible
Bacillus pumilis	Marketed formulation (Sanofi-Aventis)	17	19	17	18	17.8 (±0.83)	Susceptible
Bacillus subtilis	Optimized gel (Batch F8)	16	21	17	17	17.8 (±1.92)	Susceptible
Bacillus pumilis	Optimized gel (Batch F8)	19	18	20	15	18 (±1.87)	Susceptible

In vitro Antibacterial studies were performed by using Disc plate method. For this study two bacterial species were used, Bacillus subtilis and Bacillus pumilis. The study results when compared to the results of marketed formulation showed a zone of inhibition of more than 17mm which indicates that the bacterial species are susceptible to the antibiotic.

(a) Bacillus subtilis

(b) Bacillus pumilis

(c) Bacillus subtilis

(d) Bacillus pumilis

Figure 20: In vitro antibacterial activity shown by Marketed formulation on (a) Bacillus subtilis (b) Bacillus pumilis and optimized gel on (a) Bacillus subtilis (b) Bacillus pumilis

Stability Studies:

Table 15: Stability data of optimized Batch

Sr.No.	Evaluation Parameters	Optimized batch (Batch F8) at 30 days	
		Day 0	Day 30
1	Physical appearance	Clear, transparent and smooth	The gel was observed to be clear, transparent and smooth
2	Viscosity	38470 cps	38400 cps

3	**pH**	**7.2**	**7.2**
4	**Spreadability**	**44 g.cm/sec**	**44 g.cm/sec**

CONCLUSION

Framycetin sulphate microsponges were prepared by w/o/w emulsion solvent diffusion method. Here, Eudragit RS100 polymer was dissolved in dichloromethane to form the organic phase. Drug was dispersed in xanthan gum solution which was then poured into the organic phase and was emulsified with the help of surfactant to form primary emulsion. This emulsion was then poured into the external phase containing PVA solution and surfactant to form w/o/w emulsion.The study successfully concluded the preparation, characterization and optimization of framycetin sulphate microsponge loaded topical gel for the treatment of wound healing. The F8 batch of microsponges were seen to have decreased particle size as compared to the other 8 batches of microsponges prepared. The microsponges had a rough surface morphology and showed presence of pores on the surface. The optimum size of microsponges were found to be around 177.38µm in the F8 batch. The percentage yieldof optimized F8 batch was found to be 93.67%, which was highest when compared against the remaining batches. Also, it was found out that when the concentration of Eudragit RS100 and stirring speed was increased the particle size decreased and the amount of drug entrapped was more, that is, 92.15%. The formulated optimized Microsponge loaded gel was clear and transparent having a smooth texture with good aesthetic appeal. The pH of the gel was 7.2 which is appropriate for application on the injured skin surface. The viscosity of the gel was optimum for topical application having a viscosity of 38470 cps. The gel was studied for spreadability properties which indicated that the gel can easily spread on the skin surface. The in vitro release studies showed that the there was no release in the beginning 0.5 hours. After 1 hour 1.45% drug was released from the formulation into the donor compartment. A steady drug release was seen for the next 3 hours with a concentration of 6.26%. The concentration remained the same after 2 hours and againincreased with a concentration of 15.90%. This indicates that the drug release was very negligible after 24 hours, which is desired as the drug will remain on the skin surface without much penetration into the skin. The antibacterial studies revealed the antibacterial effect of Framycetin Sulphate Microsponge loaded topical gel. The optimized gel was compared to the marketed formulation of Soframycin cream (Sanofi Aventis). The antibacterial effect of optimized gel was closely similar to the marketed formulation. The developed Microsponge loaded gel was seen to be effective against combating the bacteria and thus preventing the infection. The study delivers future insights for developing controlled release Microsponge based gels for healing skin related disorders.

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