RESEARCH ARTICLE

Formulation and Evaluation of Babchi Oil loaded Microsponges for the Management of Vitiligo

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ABSTRACT

There are several purported biological effects of babchi oil (BO), including its ability to reduce inflammation, modulate the immune system, fight free radical damage, eliminate fungi and germs, and more. This study aims to develop microsponges containing BO encapsulated in ethyl cellulose (EC) and the natural gum *Sterculia foetida* (SF), hoping to improve their stability, immunomodulatory function, and cutaneous toxicity. Polyvinyl alcohol (PVA) was utilized as a stabilizer, and dichloro methane (DCM) was used as a solvent in a process known as quasi-emulsion solvent evaporation. The produced micro formulations were studied for their *in-vitro* drug release rate, particle size, encapsulation efficiency, and overall manufacturing yield. Stability testing showed that applying the natural gum SFG (*S. foetida* gum) increased the stability of BEO-loaded microsponges, making them suitable for human consumption.

Keywords: Babchi oil, Microsponges, Vitiligo, Antioxidant, Antibacterial.

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INTRODUCTION

The pharmaceutical industry's largest problem in the past year has been regulating the drug delivery rate at a specific human body place. Therefore, many scientists are contemplating the construction of novel controlled drug delivery methods to boost patient safety and effectiveness.[1] Drugs can be administered topically for both local and systemic effects. Problems with ointments' greasiness, stickiness, and other properties make it difficult for patients to apply them as directed. Porous microspheres displaying a regulated release pattern form the basis of the microsponges delivery system (MDS), a delayed-release device. These small sponges have a large permeable surface area but appear to be round granules. Stability is increased, reactions are dampened, and drug release is modified favorably. Porous microspheres displaying a regulated release pattern form the basis of the microsponges delivery system (MDS), a delayed-release device. These small sponges have a large permeable surface area but appear to be round granules. They're more stable, cause fewer reactions, and alter drug release for the better.

MATERIALS AND METHOD

Materials

Babchi oil and *Sterculia foetida* gum were acquired from Wagh and Sons, Nagpur (India). Polyvinyl alcohol was purchased from Thermo Fisher Scientific Indra Pvt. Ltd. Mumbai. Ethylcellulose, dichloromethane, Carbopol940, triethanolamine, triethyl citrate, and methylparaben were purchased from Loba Chemie, Mumbai. Analytical-grade chemicals and solvents were used. In all of the tests, only distilled water was used.

Methods

Preparation of microsponge

- *Quasi-emulsion solvent diffusion method*

In order to create microsponges infused with babchi oil, a quasi-emulsion solvent diffusion approach was used. This method dissolved *S. foetida* gum (SFG) and ethyl cellulose in DCM (20 mL), creating the internal organic phase. DCM is a powerful solvent, dissolving both the oil and the polymer in this

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Table 1: Formulation of microsponges

Batches	*Drug Babchi oil (mg)*	*Sterculia foetida gum (mg)*	*Ethyl Cellulose (mg)*	*Triethylci trate (1%w/v) mL*	*Polyvinyl alcohol (mg)*	*Dichloromet hane (mL)*	*Water (mL)*
F1	100	150	900	2	100	20	50
F2	100	100	900	2	100	20	50
F3	100	50	900	2	100	20	50
F4	100	150	700	2	75	20	50
F5	100	100	700	2	75	20	50
F6	100	50	700	2	75	20	50
F7	100	150	500	2	50	20	50
F8	100	100	500	2	50	20	50
F9	100	50	500	2	50	20	50

case. After placing polyvinyl alcohol in an aqueous solution in a beaker, we added the internal phase drop by drop while stirring the mixture at 2000 rpm (magnetic stirrer) for three hours. Microsponges produced after DCM was eliminated from the reaction mixture. Microsponges were filtered, washed with distilled water, and air-dried at room temperature after formation.

Microsponge preparation was known to be sensitive to a number of different factors. Therefore, by manipulating the ethyl cellulose content, we were able to optimise the performance of microsponges loaded with babchi oil (900, 700, and 500 mg) and SFG (150, 100, 50 mg) and PVA(100, 75 and 50 mg) keeping DCM constant (20 mL) as shown in Table 1.

Nine batches of microsponge, each batch containing 100 mg of babchi oil was prepared by quasi-emulsion solvent diffusion method. PVA was dissolved in sterile water to make the aqueous phase. Babchi oil, ethyl cellulose, and *S. foetida* gum were dissolved in dichloromethane using sonication at 35°C to create the inner phase. Microsponge loaded with babchi oil was formed by the addition of inner phase to an aqueous phase which was kept under a mechanical stirrer for continuous stirring at 2000 rpm for 3 hours.

Experimental Methodology[2]

Purification of gum

In order to create the SFG solution (2.5% w/v), first 25 g of SFG gum was dissolved in 1 L of deionized water in a 50°C water bath for 4 hours, and then the mixture was stirred at room temperature for an additional night. For 15 minutes at 15,180 g, the gum solution (2.5%) was centrifuged. The supernatant was precipitated and drained after adding 100% ethanol (1.2L). A recovery was made, and the residue was stored in 100% isopropanol for one night. To finish making the clean gum, the leftovers were baked at 40°C for a whole night.

Characterization of Drug Loaded Microsponges[3,4]

Preformulation studies of Babchi oil[5]

- *Organoleptic characters*

Babchi oil was tested for organoleptic characteristics such as color, odor, taste, and solubility in organic solvents and water. The results are shown in Table 2.

- *Physicochemical parameters*

Babchi oil was tested for physicochemical parameters, including things like density, pH, iodine value, saponification rate, and refractive index. The results are shown in the Table 3.

- *Phytochemical evaluation*

The babchi oil was subjected to phytochemical evaluation by various chemical identification tests and test for reducing sugar, flavonoids, flavonoids, phlobatanins, steroids, glycosides: anthraquinone, terpenoids, tannins, and saponins Table 4.

Preformulation studies of S. foetida gum[6]

- *Organoleptic characters*

S. foetida gum was tested for organoleptic characteristics such as color, odor, taste, and solubility in organic solvent and water. The results are shown in Table 5.

- *Determination of moisture (Loss on Drying)*

Ten grams of SFG powder were placed in an evaporating dish and baked at 105°C for five hours. Then, using desiccators and pressure, it was chilled. The drying, cooling, and weighing process was repeated every hour until there was no more than a 0.25% variation between consecutive readings.

- *Solubility*

All solubility were performed at room temperature in a test tube with vigorous shaking in which a small amount of gum was added in a triethyl citrate, dichloromethane, ethanol, water, methanol and solubility was determined.

- *Density*

Sample of 50 g of SFG powder was added into 100 mL measuring cylinder and the volume occupied was carried out. Bulk density is equal to the sample weight divided by bulk volume.

- *pH measurement*

A pH metre was used to determine the value of the aqueous dispersion of SFG at 1% w/v (Table 6).

- *Swelling index*

A total of 100 mL of water was used to bring the initial volume of SFG powder in the measuring cylinder up to 100 mL. After standing for 24 hours and shaking intermittently for 1-hour, the

volume of the swelled gum in the final was measured (Table 7).
Swelling index = $(w_t - w_0 / w_t) \times 100$
Where,
w_t = final volume occupied by swollen gum
W_0 = intial volume occupied by the gum

Spectrometric Analysis[7]

- *Preparation of standard stock solution*

A volumetric flask containing 10 mL of methanol was used to dissolve 10 mg of babchi oil. The volume was brought up to spec using the same solution after being sonicated for 10 minutes. A standard stock solution (A) of 1000 µg/mL was prepared by adding 1-mL of methanol to a 10 mL volumetric flask. The concentration of stock solution (B) 100 µg/mL. The conc. of stock scanning and determination wavelength of maximum absorption. The wavelength scanning of maximum absorption was performed by using stock solution of pure babchi oil using UV-vis spectrometer with a range of 200 to 400 nm.

- *Standard calibration of babchi oil in methanol*

Serial dilutions of stock solution (100 µg/mL) with methanol was carried out to prepare working standards within a 2 to 12 µg/mL range. Absorption values of above solutions were measured at determined λ_{max} (253 nm) against methanol as blank and the calibration curve was prepared (Table 8).

Standard calibration of babchi oil in combination of methanol and phosphate buffer (pH 6.8) (40:60)

Serial dilutions of stock solution (100 µg/mL) with methanol and phosphate buffer (pH 6.8) (40:60) was carried out to prepare the working standards within the range of 2 to 12 µg/mL.The absorption values of above solutions were measured at the determined λ_{max} (253 nm) against the combination of methanol and phosphate buffer (pH 6.8) (40:60) as blank and the calibration curve was prepared (Table 9).

Drug Excipient Compatibility Study[8]

FT-IR and DSC were used to test the drug-excipient interaction. The drug's compatibility with excipients was determined by analyzing their FTIR spectra. DSC results show the type of the sample (crystalline or amorphous) and drug-excipient interaction has been verified.

Fourier transform infrared spectroscopy

Drug and excipient purity was determined by analysing infrared (IR) spectra. The analysis was performed in the 4000 to 600 cm^{-1} region using a fourier transform infrared (FTIR) spectrophotometer (FTIR, shimadzu 8400S).

Differential scanning calorimetry

Differential scanning calorimetry (DSC) study was performed to evaluate the thermal characteristics of the drug. Nearly 5 mg sample was sealed in an aluminium pan followed by heating at a rate of 10˚C/min over a temperature range of 40 to 200˚C under a nitrogen atmosphere of flow rate 10 mL/min and thermogram (Shimadzu TA60 thermal analyzer), was obtained.

Characterization of Drug Loaded Microsponges[9]

Size analysis of microsponges

The mean diameter of 100 dried microsponges was determined using motic microscopy and size was found (Table 10).

Percentage yield

Raw material weight and final microsponge weight were calculated (Table 11).

$$\% \text{ yield} = \frac{\text{Practical mass of microsponge x 100}}{\text{Theroetical mass (polymer + drug)}}$$

Loading efficiency

The microsponges with BEO put on them were weighed (10 mg) and then triturated with a motor and pestle. After the trituration process, 10 mL of a methanol solution was applied to particles to release the locked-in essential oil. After that, a 0.45 m membrane filter was used to filter the samples before the absorbance was measured at 253 nm using a UV-vis spectrophotometer (Table 12).

Loading efficiency was determined using this following equation

$$\frac{C_R \times V_R / M_{mp}}{M_D / M_D + M_P} \times 100$$

Where,
C_R = Drug concentration of the release medium,
V_R = volume of the release medium,
M_{MP} = Mass of microparticle take
M_D=Mass of essential oil encapsulate
M_P= Mass of polymer

Drug Release

Microsponges were used to study the *in-vitro* release of a babchi oil formulation, and the release was measured using a USP type 1 dissolution device. Each jar contained 100 mg of babchi oil-loaded microsponges and 900 mL of dissolution media, i.e., methanolic phosphate buffer (pH 6.8), which was heated to 37.0 ± 0.5ºC and stirred continuously at 100 rpm for 7 hours. Then, a 5 mL sample was taken at regular intervals and replaced with methanolic phosphate buffer (pH 6.8) to keep the volume constant. Absorbance at 253 nm was used in the spectrophotometric analysis of the drug release (Table 13).[8,9]

Scanning electron microscopy

Microsponge formulations were analyzed using scanning electron microscopy (SEM) to ascertain their morphology & surface topography.
Based on evaluation parameters, the three optimized microsponges formulations were evaluated.

RESULT AND DISCUSSIONS

Preformulation Studies of Babchi Oil

Organoleptic characters

From the above result of the organoleptic characterization of babchi oil, it was observed that all the organoleptic

Table 2 : Organoleptic characteristics of babchi oil

Sr.No.	*Organoleptic characters*	*Results*
1	Color	Yellow
2	Odor	Disagreeable
3	Taste	Bitter
4	Solubility in: Organic solventWater	Soluble Insoluble

characteristics like color, odor, taste, solubility were yellow, disagreeable, bitter, soluble in organic solvents and insoluble in water, respectively.

The organoleptic characterization of babchi oil was performed. The results are as follows:

Physicochemical parameters

Specific gravity, acid, saponification, iodine value, and boiling point was found within standard limits/range.

The physicochemical parameters of babchi oil were evaluated. The results are as follows:

Phytochemical evaluation

The flavonoids, steroids, glycosides, terpenoids, tannins, saponins was present in the babchi oil. The vitiligo diseases give the proper effect because of chemical investigations have indicated that flavonoids were the most frequently occuring constituents of the genus *Psoralea*. Stigmasterol indicates the steroids and sesquiterpenoids indicate the terpenoids. These chemicals have the proper effect on vitiligo diseases.[10]

The phytochemical constituent of babchi oil (*Psoralea corylifolia*) were found as given in Table 4.

Charactrization of *S. foetida* Gum (SFG)

Organoleptic characters of SFG

It was observed that all the organoleptic characters like color, odor, taste, were found to pinkish white-off white, odorless, and mucilagenous, respectively.

From the above result of organoleptic characterization of SFG.[11]

Physiological properties of S. foetida gum (SFG)

The loss on drying was found to be 0.1586%w/v. SFG is soluble in water, 5% HCL and sparingly soluble in 5% NAOH and insoluble in ether, chloroform and ethanol. The pH was found to be 4.6 and the melting point was found to be 222ºc and present within their standard range. The density is 0.6097g/mL.[12]

Swelling Index of S. foetida gum (SFG)

The swelling index of SFG was found to be 83.13

Standard Calibration Curve

Determination of λ_{max}

A solution of babchi oil (1000 µg/mL) was cleaned up in methanol and analyzed using a shimadzu (UV-1601) spectrophotometer to get its UV spectrum. Solution was analyzed throughout a 200 to 400 nm wavelength range. Maximum babchi oil absorption was measured at 253 nm[13] (Figure 1).

Table 3 : physicochemical parameters of babchi oil

Sr.No.	*Physicochemical parameters*	*Standard value*	*Obtained value*
1	Specific gravity	0.9502	0.953 ± 0.01
2	Acid value	2.131	2.146 ± 0.01
3	Saponification value	182.35	181.5 ± 0.02
4	Iodine value	89–90	89.81 ± 0.03
5	Boiling point	391.4˚C	392˚C

Table 4 : Phytochemical evaluation of babchi oil

Sr. no.	*Phytochemical constituents*	*Result*
1	Reducing Sugar	-ve
2	Flavonoids	+ve
3	Steroids	+ve
4	Phlobatanins	-ve
5	Flavonosides	+ve
6	Glycosides	+ve
7	Anthraquinone	-ve
8	Terprnoids	+ve
9	Tannins	+ve
10	Saponins	+ve

+ = Present, - = Absent

Standard calibration of babchi oil in methanol

Working standard within the 2 to 12 µg/mL range was prepared by serial dilution of stock solutions (100 µg/mL) with methanol. The standard calibration curve revealed that "beers law was obeyed throughout the concentration range 2–12 µg/mL. The regression equation of absorbance was found to be y=0.0.0352x+0.1089 with a correlation coefficient of 0.9982.[14] (Figure 2).

Standard calibration curve of babchi oil in combination of methanol and phosphate buffer(pH 6.8) (40:60)

Working standard within the range of 2 to 12 µg/mL was prepared by serial dilution of stock solutions (100 µg/mL) with a combination of methanol and phosphate buffer (pH 6.8) 40:60. Standard calibration curve revealed that beer's law was obeyed throughout concentration range 2 to 12 µg/mL. The regression equation of absorbance was found to bey = 0.0492x+0.0386 with a correlation coefficient of 0.994 (Figure 3).[15]

Excipients- Drug Compatibility Study

FTIR

Infrared absorption spectroscopy (IR) of babchi oil, *S. foetida* gum, ethyl cellulose and PVA and physical mixture were recorded using an FTIR Spectrometer (FTIR. Shimadzu 8400S, japan). Babchi oil and the other excipient did not interact, as evidenced by their separate infrared (IR) spectra and by those of the medication and the polymer in combination. The IR spectra of the isolated medication made this very obvious, displaying all frequencies characteristic of functional groupings. The FTIR spectra of BEO, PVA, EC, SGF, and BEO-loaded microsponges showed distinctive peaks.

Table 5 : Estimation of organoleptic characteristics of SFG

S.NO.	*Characteristics*	*Results*
1.	Color	Pinkish white – off white
2.	Odor	Odorless
3.	Taste	Mucilagenous

Table 6: Estimation of physiological properties of SFG

1.	Loss on drying	0.1586%w/v
2.	Solubility	Soluble in – Water, 5% HCL, sparingly soluble in 5%NAOH, conc. H_2SO_4 Insoluble in – Ether, chloroform, ethyl acetate, ethanol.
3.	pH	4.65
4.	Melting point	222°C
5.	Density	0.6097 g/mL

Table 7 : Swelling index of *S. foetida* gum

Sr. No.	*Observation*		*Result*
	Intial volume occupied by the swollen gum (mL)	*Final volume occupied by Swollen gum (mL)*	*Swelling index (%)*
1	14	83	83.13

The spectrum of BEO showed distinguishing peaks at 3479 cm^{-1}(-OH), 2921.89 cm^{-1} (Methyl streching), 1742.50 cm^{-1}, (carbonyl streching), 1458.55 cm^{-1} (Aromatic).

The spectrum of *S. foetida* gum (SFG) 1731 and 1254 cm^{-1} (Acetyl group), 1376 cm^{-1} (Carboxy and hydroxy group), 1110 cm^{-1} (Ether group stretching), 2978 cm^{-1} (Methyl stretching).

The spectrum of ethyl cellulose 3438 cm^{-1} (Alcohol streching), 1376 cm^{-1} (carboxy and hydroxy group), 1110 cm^{-1} (Ether group streching), 2978 cm^{-1} (methyl streching) etc.

The spectrum of (Polyvinyl alcohol) PVA 1412 cm^{-1} (Hydroxy group), 1144 cm^{-1} (methyl group), 1653 cm^{-1} (C=C streching), 1421 cm^{-1} (CH_2 group).

The spectrum of the physical mixture of gel 2977 cm^{-1} (-CH2 group), 724 cm^{-1} (Ether group), 2976 cm^{-1} (Methyl group), 1465 cm^{-1}(Alcohol group).

There is no evidence of a chemical reaction between BEO and EC in the FTIR spectrum, either in the form of new peaks or the disappearance of previously observed ones. As may be seen from their spectra, BEO is compatible with several polymers and excipients (such as PVA, EC, and SFG) (Figures 4 to 7). Therefore, the FTIR data demonstrates that BEO is contained and stable within the fabricated porous microstructures.[15]

DSC

Thermal analysis of chemicals was scanned at a rate of 10°C/minute on a Shimadzu TA Instrument 010–0436 Q Series in a dynamic nitrogen atmosphere. The DSC thermograms were recorded (Figures 8 to 10).

When molecules become trapped in the pores of microsponges, differential scanning calorimetry can be used to determine the type of microsponges present. The transition temperatures at which guest molecules boil, melt, or sublimate

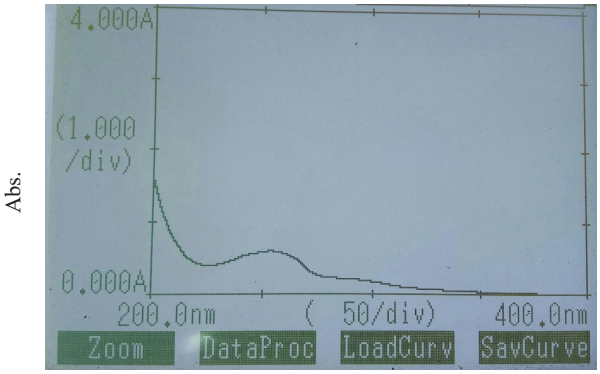

Figure 1: λ_{max} spectrum for babchi oil in methanol

Table 8: Standard calibration of babchi oil in methanol

Sr.no.	*Concentration (µg/mL)*	*Absorbance*
1	2	0.180
2	4	0.246
3	6	0.320
4	8	0.400
5	10	0.454
6	12	0.533

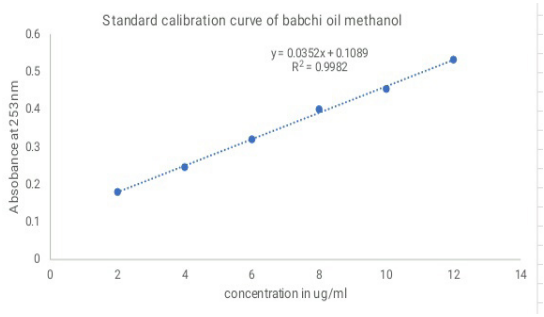

Figure 2: Calibration curve of babchi oil in methanol

are typically altered or lost throughout this process. The thermograms also show that the microsponges manufactured from BEO retain their original thermal properties. Ethyl cellulose and *S. foetida* gum did not exhibit characteristics of melting endothermic due to melting with decomposition. The findings matched those found in the published literature.[16]

Characterization of Drug Loaded Microsponges[17]

Size analysis of microsponges

Microsponges in babchi oil have an average particle size between 20.04 ± 1.19 microns and a maximum of 42 microns. As polymer concentration increased, so did the average particle size.

Microscopic analysis of microsponges

The drug-loaded microsponges were examined under a microscope, and their spherical shape was confirmed (Figure 11).

Percentage yield

Between 61.53 and 86.95% of the time, micropsonges were performed. Drug: The output yield was shown to

Table 9: Standard calibration of babchi oil in combination of methanol and phosphate buffer (pH 6.8)(40:60)

Sr. No.	*Concentration (µg/mL)*	*Absorbance*
1	2	0.237
2	4	0.288
3	6	0.327
4	8	0.394
5	10	0.456
6	12	0.486

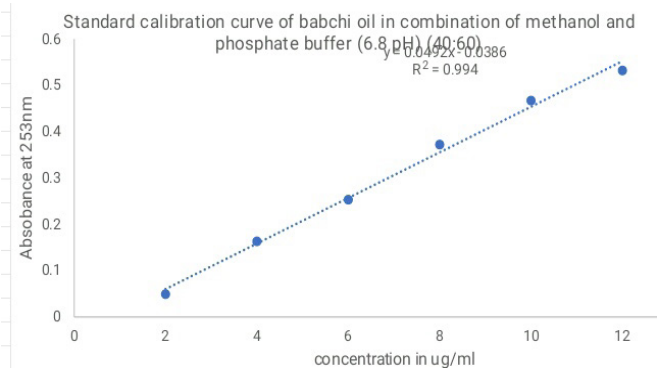

Figure 3: Calibration curve of babchi oil in methanol and phosphate buffer

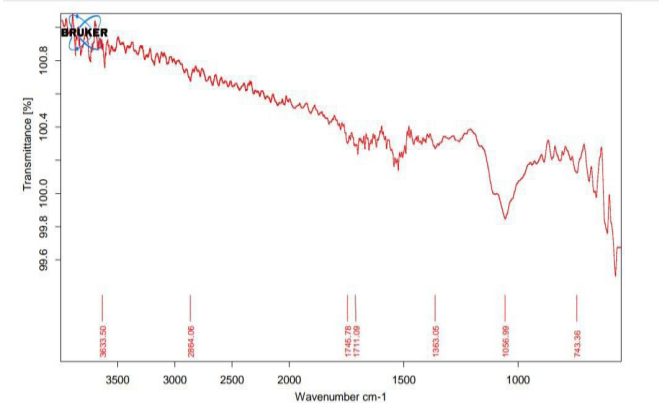

Figure 4: IR Spectums of babchi oil

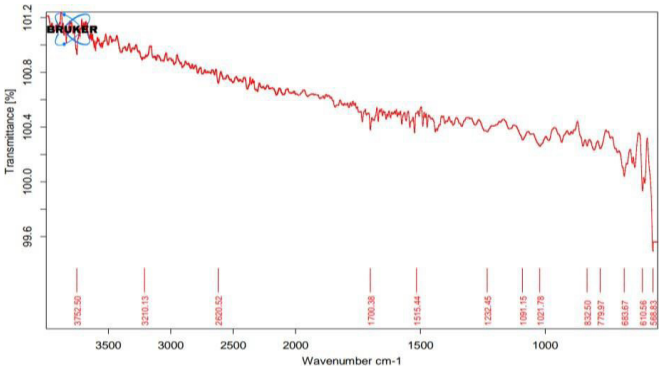

Figure 5: Infrared spectrum of polyvinyl alcohol

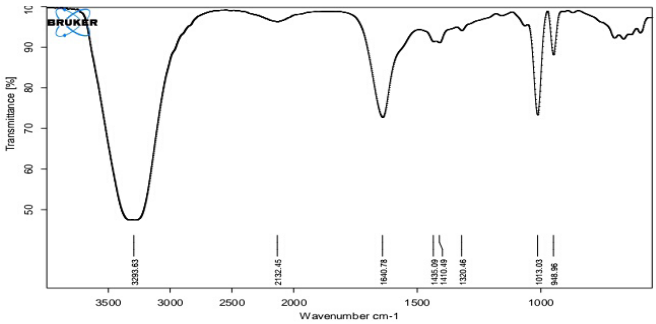

Figure 6: Infrared spectrum of S. foetida Gum

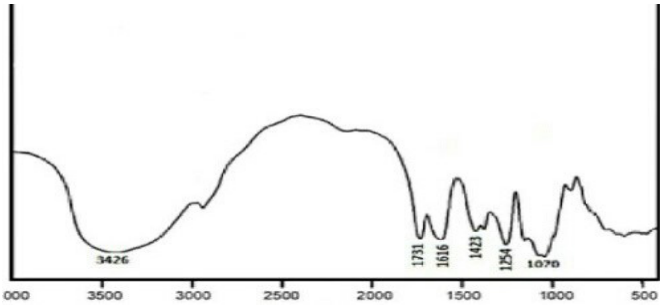

Figure 7: Infrared spectrum of physical mixture of babchi oil, SFG, EC and PVA

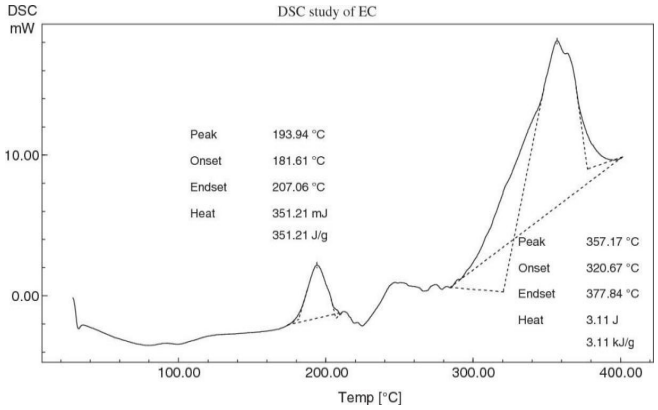

Figure 8: Differential scanning calorimetry thermo-gram of Ethyl cellulose(EC)

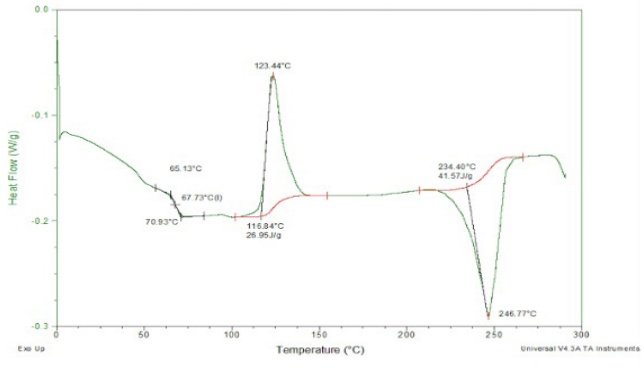

Figure 9: DSC thermo-gram of S. foetida gum(SFG)

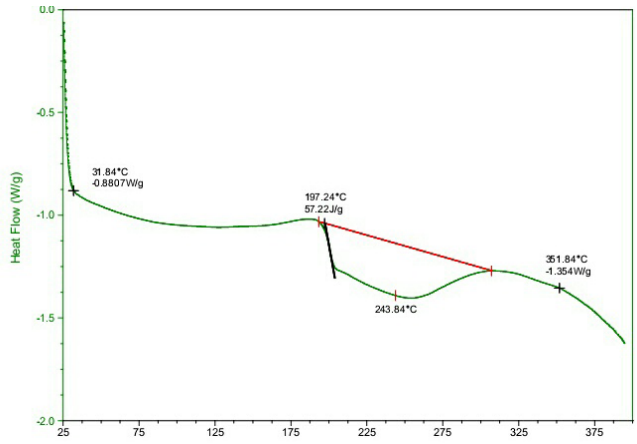

Figure 10: DSC thermo-gram of babchi oil

Figure 11: Motic microscopic image of microsponge

Table 10: Average particle size

Code of formulation	*Average particle size (µm)*
F1	42.35 ± 1.02
F2	36.56 ± 1.04
F3	32.20 ± 1.03
F4	30.45 ± 1.01
F5	29.49 ± 1.54
F6	25.49 ± 1.25
F7	28.75 ± 1.31
F8	27.89 ± 1.23
F9	20.04 ± 1.19

Table 11: Percentage yield of microsponges formulation

Sr. No.	*Formulations*	*Percentage yield(%)*
1	F1	86.95 ± 0.3
2	F2	85.45 ± 0.02
3	F3	84.76 ± 0.07
4	F4	78.94 ± 0.15
5	F5	73.33 ± 0.33
6	F6	62.35 ± 0.61
7	F7	64.00 ± 0.24
8	F8	62.85 ± 0.36
9	F9	61.53 ± 0.33

*All the reading taken in triplicate(mean ± SD, n=3)

Table 12: Loading efficiency of batches of microsponges

Sr. No.	*Formulations*	*Loading efficiency (%)*
1	F1	73.59 ± 1.54
2	F2	72.72 ± 0.01
3	F3	80.87 ± 1.96
4	F4	65.68 ± 0.47
5	F5	65.72 ± 0.71
6	F6	75.80 ± 1.54
7	F7	74.29 ± 0.68
8	F8	50.08 ± 0.16
9	F9	40.90 ± 1.00

*All the reading taken in triplicate (mean ± SD, n=3)

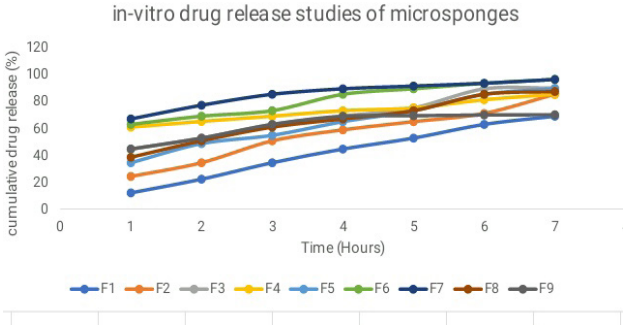

Figure 12: *In-vitro* drug release studies of microsponges

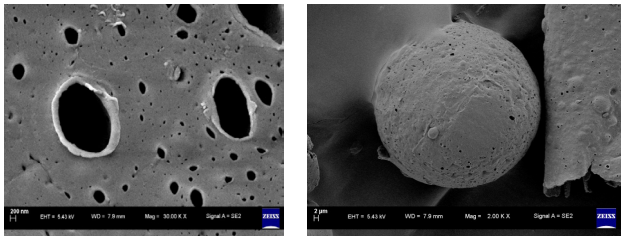

Figure 13: Scanning Electron Microscopy (SEM) Analysis of Microsponge formulations to analyze morphology

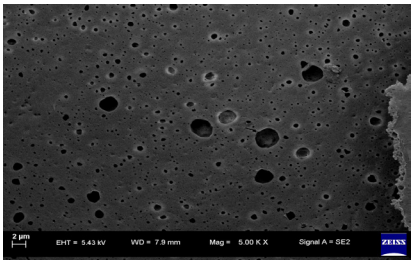

Figure 14 : Scanning Electron Microscopy (SEM) Analysis of Microsponge formulations to analyze Surface topography

be significantly influenced by the polymer, EC, and PVA concentrations. For the drug:polymer ratio 1:1.5:9:1 (F1), the yield was extremely high at 86.95%, while for the drug:polymer ratio 1:0.5:5:0.5 (F9), it was just 61.53%. A higher drug polymer ratio (i.e., a higher concentration of EC and SFG) was shown to result in a higher output yield. Since dichloromethane diffused slower through concentrated solutions to the water phase when

Table 13 : %Cumulative Drug Release of microsponge containing babchi oil

Formulations	*Time (hours)*						
	1	*2*	*3*	*4*	*5*	*6*	*7*
F1	11.96 ± 0.1	22.16 ± 0.01	34.41 ± 0.2	44.61 ± 0.7	52.77 ± 0.03	62.98 ± 0.3	69.10 ± 0.21
F2	24.20 ± 0.04	34.41 ± 0.09	50.73 ± 0.03	58.90 ± 0.2	65.02 ± 0.07	71.14 ± 0.06	85.43 ± 0.05
F3	44.61 ± 0.03	52.77 ± 0.06	62.98 ± 0.08	69.10 ± 0.03	75.22 ± 0.4	89.51 ± 0.1	89.52 ± 0.01
F4	60.94 ± 0.02	65.02 ± 0.03	69.10 ± 0.01	73.18 ± 0.07	75.22 ± 0.01	81.35 ± 0.02	85.43 ± 0.05
F5	34.41 ± 0.02	48.69 ± 0.04	54.82 ± 0.03	65.02 ± 0.06	73.18 ± 0.06	85.43 ± 0.05	89.51 ± 0.02
F6	62.98 ± 0.05	69.10 ± 0.0	73.18 ± 0.07	85.43 ± 0.04	89.51 ± 0.03	93.59 ± 0.04	96.50 ± 0.06
F7	67.06 ± 0.01	77.26 ± 0.06	85.43 ± 0.03	89.51 ± 0.08	91.55 ± 0.08	93.59 ± 0.07	96.50 ± 0.04
F8	60.94 ± 0.07	69.10 ± 0.02	79.31 ± 0.04	85.43 ± 0.05	95.63 ± 0.02	95.65 ± 0.08	95.69 ± 0.07
F9	87.47 ± 0.01	89.51 ± 0.09	91.55 ± 0.02	96.50 ± 0.02	99.71 ± 0.01	99.65 ± 0.03	99.72 ± 0.09

the drug-to-polymer ratio was raised, the manufacturing yield increased. As a result, the enhanced yield had additional time for droplet formation.

Loading efficiency

Loading efficiency formulations were estimated by UV spectrophotometric method. The loading efficiency of the drug depend on the successful molecular association of the drug with the polymers loading efficiency of the microsponges were found in the range of 40.90 ± 1.00 to 73.59 ± 1.54 of different batches (Table 12). The values of loading efficiency were found maximum for the formulation F3, F6 and F7 having the drug to polymer ratio of 1:9.Adrop in loading efficiency was observed on further increasing drug/polymer ratio. The probable reason for this decrease in the loading efficiency could be that the optimum concentration of polymer is not available to coat or entrap the drug molecule.[18]

Drug release

The medication release slowed down when more polymer was added to each formulation (Figures 12 to 14). One possible explanation for this is that the longer it takes for the polymer to fully inflate, the longer it takes for the medicine to be released from the polymer matrix. The discharge followed a biphasic pattern, with a burst impact noticeable at the outset. Possible causes include drug contamination of microsponge pores or inadequate drug trapping. Cumulative present release foe F1 to F9 at the end of 8 h in different ranges shows in Table 13.[18]

CONCLUSION

Drug delivery systems (DDS) that can precisely control the release rate or target drugs to specific body sites have a massive impact on the health care system. The efficiency of drug therapy can be described by providing a therapeutic amount of drug to the proper site of action to accomplish the desired concentration of drug in blood or tissue for the desired therapeutic response, which is therapeutically effective and non-toxic for a prolonged period of time.

In drug delivery, topical drug administration is a localized drug delivery system wherever in the body. Drugs are administered topically for their action at the site of application or for systemic effect.

Vitiligo is a non-contagious, genetic disease of the immune system that affects the skin. Vitiligo can be limited to a few lesions or can include moderate to large areas of skin. There are various effective topical treatments for vitiligo. Topical treatments are medications applied to skin, are usually the first line to defense in treating vitiligo. Researchers believe vitiligo occurs when faulty signals in the immune system attack skin cells to stop melanin pigment synthesis.

The Babchi oil is a non-edible semi-drying fixed oil obtained from seeds of *Psoralea corylifolium Linn* belonging to the family Leguminosae. It has effective anti-vitiligo activity. Hence babchi oil was selected for the formulation and microsponges dosage form was selected for the formulation. In the present research work we have attempted to formulate and evaluate a microsponge-based gel containing babchi oil for managing vitiligo. Microsponges loaded with babchi oil were prepared by using the quasi-emulsion solvent diffusion method using external phase(PVA) and internal phase (Ethyl cellulose) and *S. foetida* gum (SFG) and total nine batches were formulated by varying the concentration of PVA, SFG and EC throughout the batch(F1-F9). Microsponge formulations were subjected for evaluations which include particle size analysis, percentage yield, drug release and loading efficiency and drug-polymer compatibility study, and scanning electron microscopy of the optimized batch of microsponges. The outcomes of various evaluations parameter depicted that out of all prepared microsponge formulations, formulations F4, F6 and F7 showed the maximum drug content, loading efficiency, percentage yieid and particle size, motic microscopy of microsponge revealed that formed microsponges were spherical as each single entity and has porous nature.

In this study, researchers discovered that microsponges made from Babchi oil could be an effective alternative to traditional topical medication formulation.

Thus, the microsponge drug delivery system is a promising new area that will require extensive study in the years to come.

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REFERENCES

1. Banker GBS, Rodes CT, Modern Pharmacist, Marcel Dekker, NewYork, 1979, 40 (2): 263-311.
2. Draize JH. Methods for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes. J. Pharmacol. Exp. Ther.. 1944;82:377-90.
3. Guyot M, Fawaz F. Nifedipine loaded-polymeric microspheres: preparation and physical characteristics. International journal of pharmaceutics. 1998 Nov 26;175(1):61-74.
4. Mandava SS, Thavva V. Novel approach: microsponge drug delivery system. International Journal of Pharmaceutical Sciences and Research. 2012 Apr 1;3(4):967.
5. Tile MK, Pawar AY. Microsponges: a novel strategy for drug delivery. International Journal of Pure and Applied Bioscience. 2015;3(1):224-35.
6. Kawashima Y, Niwa T, Takeuchi H, Hino T, Ito Y. Control of prolonged drug release and compression properties of ibuprofen microsponges with acrylic polymer, Eudragit RS, by changing their intraparticle porosity. Chemical and pharmaceutical bulletin. 1992 Jan 25;40(1):196-201.
7. Khopade AJ, Jain S, Jain NK. The microsponge. Eastern pharmacist. 1996;39(459):49-53.
8. Patil N, Tadavi SA, Pawar SP. A research on formulation and evaluation of microsponge loaded in topical gel of ritonavir. World J Pharm Pharm Sci. 2018;7:855-96.
9. Peppas NA. Analysis of Fickian and non-Fickian drug release from polymers. Pharmaceutica Acta Helvetiae. 1985 Jan 1;60(4):110-1.
10. Gangadharappa HV, Vishal Gupta N, Chandra Prasad M S, Shivakumar HG. Current trends in microsponge drug delivery system. Current drug delivery. 2013 Aug 1;10(4):453-65.
11. Srivastava R, Pathak K. Microsponges: a futuristic approach for oral drug delivery. Expert opinion on drug delivery. 2012 Jul 1;9(7):863-78.
12. Nareswari TL, Vrince FO, Syafitri E. Formulation and Evaluation of Citronella Oil (Cymbopogon nardus (L.) Rendle) Cream for Acne Treatment. International Journal of Drug Delivery Technology. 2023;13(1):418-422.
13. Moin A, Deb TK, Osmani RA, Bhosale RR, Hani U. Fabrication, characterization, and evaluation of microsponge delivery system for facilitated fungal therapy. Journal of basic and clinical pharmacy. 2016 Mar;7(2):39.
14. Kokate C, Purohit A, Gokhale S. Pharmacognosy, 38th edithion, Nirali Prakashan, Pune,2007; 295-296.
15. Pandey A, Khatri P, Patel R, Jakhetia V, Sharma S. Pharmacognostic and phytochemical evaluation of Pongamia pinnata Linn. family Fabaceae. International Journal of Pharmaceutical Research and Development. 2002;3:11-9.
16. Majumdar D. Unexploited botanical nitrification inhibitors prepared from karanja plant.Nature Product Radiance 2008; 7(1):58-67.
17. Singh S, Sahu D. A review on novel drug delivery system: Microsponges. Int. J. Drug Deliv. Technol. 2017;7(4):298-303.
18. Chowdary KP, Rao YS. Mucoadhesive microspheres for controlled drug delivery. Biological and pharmaceutical Bulletin. 2004;27(11):1717-24.