INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES
[ISSN: 0975-4725; CODEN(USA): IJPS00]
Journal Homepage: https://www.ijpsjournal.com

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Research Paper

Design And Chacterization of Novel Topical Drug Delivery System

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ARTICLE INFO

Published: 17 May 2025
Keywords:
Vitex negundo, controlled release, microsponges, quasi emulsion solvent diffusion method, gel formulation and in vitro diffusion study.
DOI:
10.5281/zenodo.15450341

ABSTRACT

The present study focuses on the design and characterization of a novel topical drug delivery system incorporating Vitex negundo extract through microsponge technology followed by gel formulation. Vitex negundo, known for its potent anti-inflammatory and antimicrobial properties, and microsponges via the quasi-emulsion solvent diffusion technique, employing ethyl cellulose as the polymer and polyvinyl alcohol as the stabilizer. The prepared microsponges were characterized for particle size, surface morphology, entrapment efficiency, and thermal stability using techniques such as, scanning electron microscopy (SEM), and The optimized microsponges were then incorporated into a carbopol-based gel to develop a stable, non-irritant topical formulation. The gel was evaluated for physicochemical parameters, in-vitro drug release, and release kinetics. Results indicated controlled release of the active constituents, enhanced stability, and improved spreadability. This microsponge-based gel system offers a promising approach for the effective topical delivery of herbal actives, providing a controlled and targeted therapeutic effect with minimal side effects.

INTRODUCTION

Topical drug delivery systems offer significant advantages in localized therapy, including improved patient compliance, targeted action, and reduced systemic side effects. However, conventional formulations often face limitations such as poor skin penetration, rapid drug degradation, and limited drug retention at the site of application. To overcome these challenges, advanced delivery technologies such as microsponge systems have gained considerable attention in recent years. Microsponge drug delivery systems are porous, polymeric microspheres capable of encapsulating a wide range of active pharmaceutical ingredients. They provide controlled release, enhance stability, and improve the bioavailability of topically applied drugs by adhering to the stratum corneum and releasing the drug in a sustained manner.

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Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Vitex negundo, a medicinal plant extensively used in traditional systems of medicine, possesses anti-inflammatory, analgesic, antimicrobial, and antioxidant properties. Despite its potent pharmacological effects, the clinical utility of Vitex negundo extracts in topical formulations is limited due to poor permeability and rapid clearance from the skin surface. The present study aims to develop and characterize a microsponge-based topical drug delivery system for Vitex negundo to enhance its therapeutic efficacy and overcome the limitations of conventional formulations. The microsponge system is prepared using appropriate polymers through a quasi-emulsion solvent diffusion method and evaluated for its physicochemical properties, drug release behavior, and skin permeability.

AIM, OBJECTIVE AND NEED OF STUDY:

The aim of the study is to "Design and chacterization of novel topical drug carrier system".

Objective:

1. To formulate different placebo batches of microsponges by using various polymers.
2. To formulate various drug loaded batch of microsponges by varying the concentration of polymers.
3. To evaluate and optimize the batch of drug loaded microsponges.
4. To formulate and evaluate novel topical drug delivery system by using optimized batch of the microsponge.
5. To increase patient complience.
6. To reduce the dosing frequency.
7. To minimizes side effects.

DRUG PROFILE

1. Vitex negundo:

Botanical Name: Vitex negundo L.
Family: Lamiaceae
Common Names: Five-leaved chaste tree, Nirgundi
Parts Used: Leaves, roots, seeds, bark
Phytoconstituents:
Flavonoids: Vitexin, orientin, luteolin
Terpenoids: Caryophyllene, sabinene, oleanolic acid
Lignans: Negundoside
Phenolic Compounds: Gallic acid, ferulic acid
Alkaloids: Caryophylline, nishindine
Pharmacological Activities: Anti-inflammatory, Analgesic, Antioxidant, Antibacterial and antifungal, Antiasthmatic, Hepatoprotective, Anticancer (invitro studies)
Traditional Uses:
Used in Ayurveda and traditional medicine to treat joint pain, inflammation, respiratory disorders, skin infections, and menstrual disorders.

EXCIPIENTS PROFILE

Table no:1 Excipients profile

Excipients Profile in Microsponges

Excipient	Type	Role	Attributes
Ethyl Cellulose	Non-ionic cellulose ether (water-insolube)	Polymer for matrix formation	Sustained-release properties
Eudragit RS 100	Ammonio methacrylate copolymer(Typ A)	Polymer for matrix formation	Controlled-release properties
Eudragit RL 100	Ammonio methacrylate copolymer (1:1)	Controlled-release coating	Protection of acid-labile drugs
Carbopol 934	Cross-linked polyacrylic acid polymer	Gel-forming agent	Enhanced drug entrapment
Polyvinyl Alcohol	Water-soluble synthetic polymer	Stabilizer	Improved stability of microsponges

MATERIALS AND METHODS:

1. Analytical chacterization of drug sample:

The drug vitex negundo 100mg dissolved in Phosphate buffer pH 7.4 was taken. From the stock solution 1 ml solution was pipetted out in 100ml calibrated volumetric flask and final volume was made up to 100ml with phosphate buffer 7.4 to obtain stock solution of 10µg/ml concentration, from this solution 1ml, 2ml, 3ml, 4ml, 5 ml was pipetted out in different 100ml volumetric flask respectively and final volume as made up to 100ml with phosphate buffer pH 7.4 to obtain concentration 1µg/ml concentration, and its concentration is determined by UV-spectrophotometer at 264 nm phosphate buffer pH 7.4 as blank by UV spectrophotometric method. A graph is plotted by using concentration at X-axis Vs absorbance at Y-axis.

2. FT-IR SPECTROSCOPY:

The FTIR studies are performed to observe any interaction between drug and polymers in the formulation. FTIR study of optimized microsponges (F1 batch) was carried out. T The FTIR spectra indicate that there is no interaction between ethyl cellulose & drug within microsponges.

The spectrum of optimized microsponges was found to be similar to pure vitex negundo drug. FT-IR spectra of prepared formulation showed there are significant changes in the fingerprint region i.e. 600 to 1500 cm-1. This confirmed the formation of a bond between ethyl cellulose and vitex negundo. There is a significant change in downshift and upshift in the formulation due to cross linking, seen in a condition such as S-O, and C-N stretching. Thus, it can be concluded that no major chemical interaction is taking place between the drug and carrier.

3. Morphological study by using scanning electron microscopy (SEM):

SEM analyses of the formulated vitex negundo microsponges were performed to evaluate the surface morphology of microsponges. SEM images showed the microsponge was porous with a smooth surface morphology and spherical in shape. Due to evaporation of solvent, the microsponge shell found to be smooth porous where outer surface was shiny smooth and inner surface was porous.

4. Prepartion of microsponges:

Two different polymers, Ethyl cellulose and Eudragit RS100 with different ratios were used for formulation. A total of nine formulations were prepared for the further optimization process. Two phases were used, one is organic and the other is the aqueous phase. The organic phase, containing drug and polymer mixture in 30 ml DCM and the aqueous phase containing PVA and in 100 ml distilled water. The aqueous phase was added in a dropwise manner in the organic phase on a magnetic stirrer at 2000 rpm. After two hours of stirring, Microsponges were collected by filtration method and dried in an oven at 40 °C for 24 hours. microsponges are stored in a vacuum desiccator for removal of moisture.

Table no 2: Prepartion of Microsponges

Sr. no	Ingredients (mg/ml)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	Drug	100	100	100	100	100	100	100	100	100
2	Polyvinyl alcohol (% w/v)	500	500	500	500	500	500	500	500	500
3	Ethyl cellulose	100	200	300	-	-	-	200	200	200
4	Eudragit-RS10	-	-	-	100	200	300	200	-	-
5	EudragitRL100	-	-	-	-	-	-	-	200	-
6	EudragitL100	-	-	-	-	-	-	-	-	200
7	Dichloromethane	30	30	30	30	30	30	30	30	30
8	Water	100	100	100	100	100	100	100	100	100

4.1 Determination of Percentage Yield Method:

Vitex negundo loaded microsponges were weighed after drying. Percentage yield was calculated by:

$$\% \text{ Yield} = \frac{\text{Actual weight of product}}{\text{theortical weight drug and excipients}} \times 100$$

4.2 Particle size determination:

The average mean diameter and size distribution of loaded microsponges is found by Litesizer DLS 500 at 25°C. The dried microsponges were dispersed in water to obtain proper light scattering intensity for vitex negundo microsponges.

4.3 Determination of Zeta potential:

Zeta potential is a measure of surface charge. The surface charge (electrophoretic mobility) of microsponge can be determined by using Litesizer DLS 500 having measurement cells, polycarbonate cell with gold plated electrodes and using water as medium for sample preparation. It is essential for the characterisation of stability of the microsponges.

4.4 Determination of Entrapment Efficiency:

The entrapment efficiency of microsponges were determined by adding 25ml of methanol and 25 mg microspongs sonicated in a bath sonicator and filtered. 1ml of filtrate is made up to 10 ml with methanol and was assayed spectrophotometrically at 264 nm (UV visible spectrophotometer, model UV-1601 PC, Shimadzu). The amount of entrapped drug was calculated from the equation.

$$\text{Drug content} = \frac{\text{weight of the drug in microsponges}}{\text{weight of microsponges}} \times 100$$

$$\% \text{ DEE} = \frac{\text{actual loading}}{\text{therotical loading}} \times 100$$

4.5 Preparation of *Vitex negundo* microsponge topical gel:

Different amount of gelling agents like Carbopol 934, HPMC K4M was dissolved and soaked over-night insufficient quantity of water to get good dispersion. After 24 hours, to this remaining ingredient i.e. polyethylene glycol as a penetration enhancer, methyl and propylparaben as a preservative was added. In another beaker Vitex negundo equivalent, microsponges were dispersed in water. This was added to the previous beaker containing other excipients. Triethanolamine was added drop by drop to neutralize the pH of the formulation.

Table no:3 Preparation of microsponges gel

Sr. No	Ingredients	Quantity
1	Micro sponges (gm)	0.2
2	Carbopol 934 (gm)	0.5

4	Polyethylene glycol (ml)	10
5	Methyl paraben	0.1
6	Propyl paraben	0.05
7	Triethanolamine (ml)	qs
8	Distilled water(ml)	30ml

6. Valuation of Gel:

6.1 pH measurement:

For pH determination digital pH meter was used. weighed about 1 gm of microsponges based gel and dispersed in 25 ml volume of water.

6.2 Viscosity test:

The viscosity of prepared gel was measured using Brookfield viscometer (Brookfield Engineering, spindle S64) at different RPM viscosity. The measurement was made over a whole range of speed settings from 5-100rpm with 10 seconds between two successive speeds.

6.3 Spreadability test:

The spreadability of the gel formulation was determined by using a sliding plate apparatus and by measuring the diameter of 1 gm of gel between horizontal plates after 1 minute. The standardized weight tied on the upper plate was 125 gm. An excess of gel is placed between two glass slides and a 1000 gm weight is placed on them for 5 minutes, to compress the sample to a uniform thickness. The bottom slide is anchored to the apparatus and weights are placed in the pan. The time in seconds needed to separate the two slides is taken as a measure of spreadability. A shorter time interval indicates better spreadability. Spreadability was determined by using a formula.

S = M*L/ T

S = Spreadbility.
M = weight tied to the upper slide.
L = length of a glass slide
T = Time taken to separate two slides (sec).

6.4 In vitro diffusion studies:

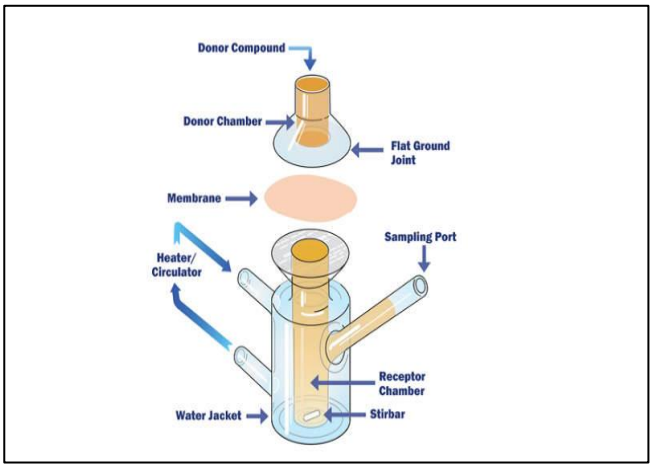

Fig 1: Franz Diffusion cell

In-vitro diffusion study of microsponge formulation was performed through the cellulose membrane by using Franz diffusion cell. The receptor compartment was filled with 7.4 pH phosphate buffer and kept at 32 ± 0.5 °C with continuous stirring with help of a magnetic stirrer. 1gm of the gel was placed over the cellulose membrane. An interval of 30min, 60min, and upto 5 hours ,1 ml sample was withdrawn and suitably diluted. The withdrawn sample was replaced with the same amount of 7.4 pH phosphate buffer to maintain the sink condition. Diluted samples were analyzed for Vitex Negundo content with help of UV at 264 nm.

RESULT

1. Preparation of standard calibration curve of Vitex negundo in buffer7.4:

Table No. 4: conc vs absorbance of Vitex negundo in phosphate buffer 7.4

Sr. no	Concentration (µg/ml)	Absorbance ƛmax=264nm
1	0	0
2	10	0.083
3	20	0.175
4	30	0.260
5	40	0.335
6	50	0.415

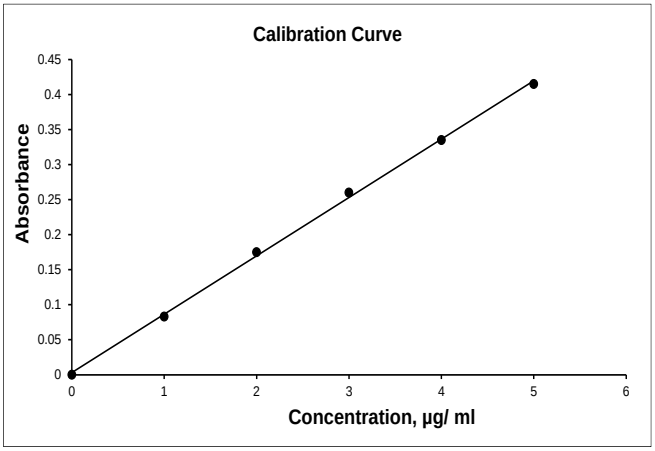

Figure 2: Standard calibration curves of vitex negundo

The FTIR studies are performed to observe any interaction between drug and polymers in the formulation. FTIR study of optimized microsponges (F1 batch) was carried out. The FTIR spectra of optimized microsponges were shown in Figure 3. The FTIR spectra indicate that there is no interaction between ethyl cellulose & drug within microsponges.

The spectrum of optimized microsponges was found to be similar to pure vitex negundo drug. FT-IR spectra of prepared formulation showed there are significant changes in the fingerprint region i.e. 600 to 1500 cm-1. This confirmed the formation of a bond between ethyl cellulose and vitex negundo . There is a significant change in downshift and upshift in the formulation due to cross linking, seen in a condition such as S-O, and C-N stretching. Thus, it can be concluded that no major chemical interaction is taking place between the drug and carrier.

2. Drug – Excipient Interaction Study:

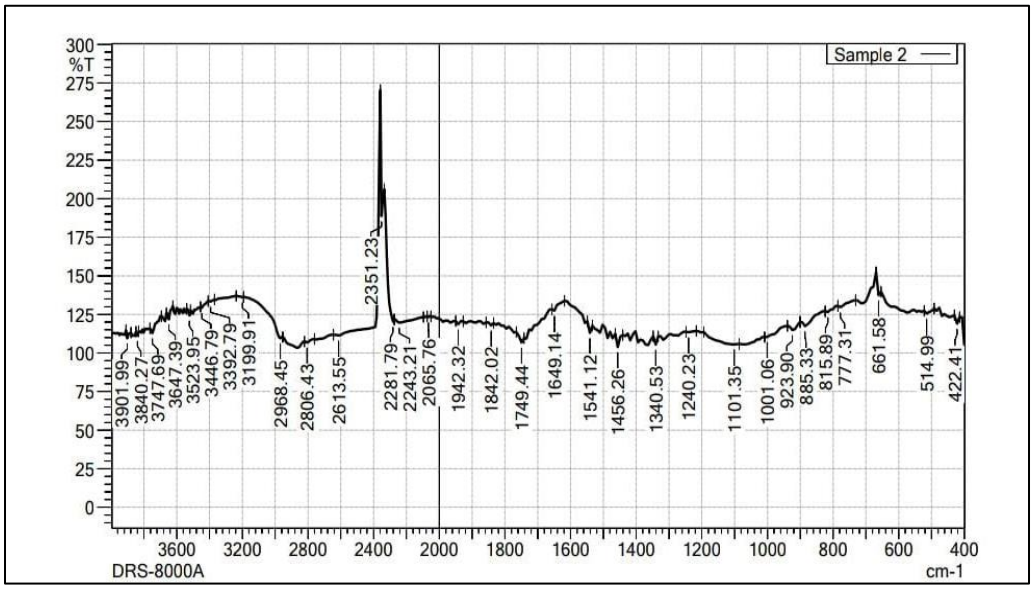

Fig 3: FTIR of Vitex negundo

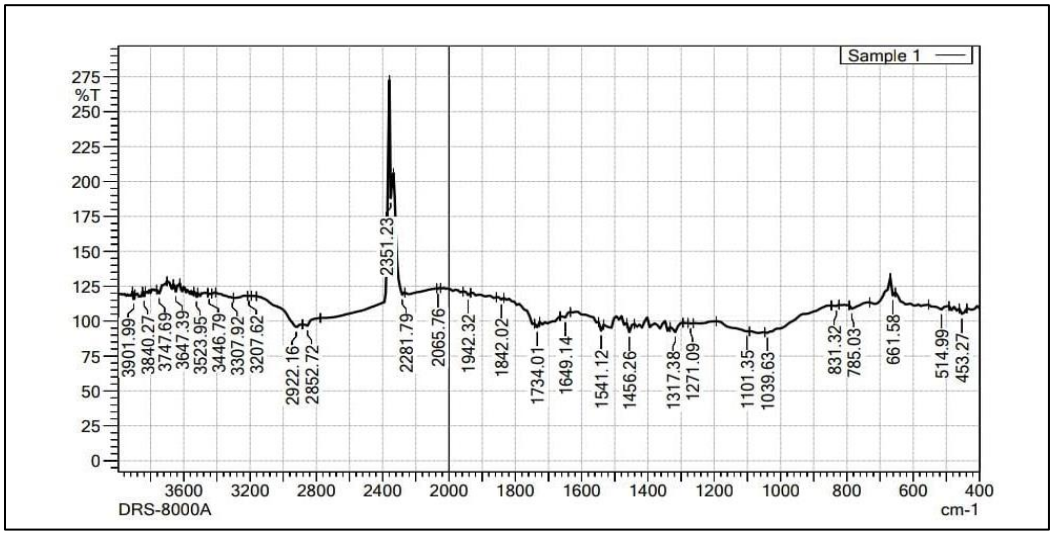

Fig4: Mixture of drug and polymer (optimized batch)

3. Evaluation of microsponges:

3.1 Determination of Percentage Yield:

Table no 5: determination of %yield of microsponges

Sr.no.	Batches	Percentage yield (%)
1	F1	70%
2	F2	45%
3	F3	60%
4	F4	Negligible
5	F5	Negligible
6	F6	46%
7	F7	35%
8	F8	54%
9	F9	65%

3.2 Scanning Electron Microscopy:

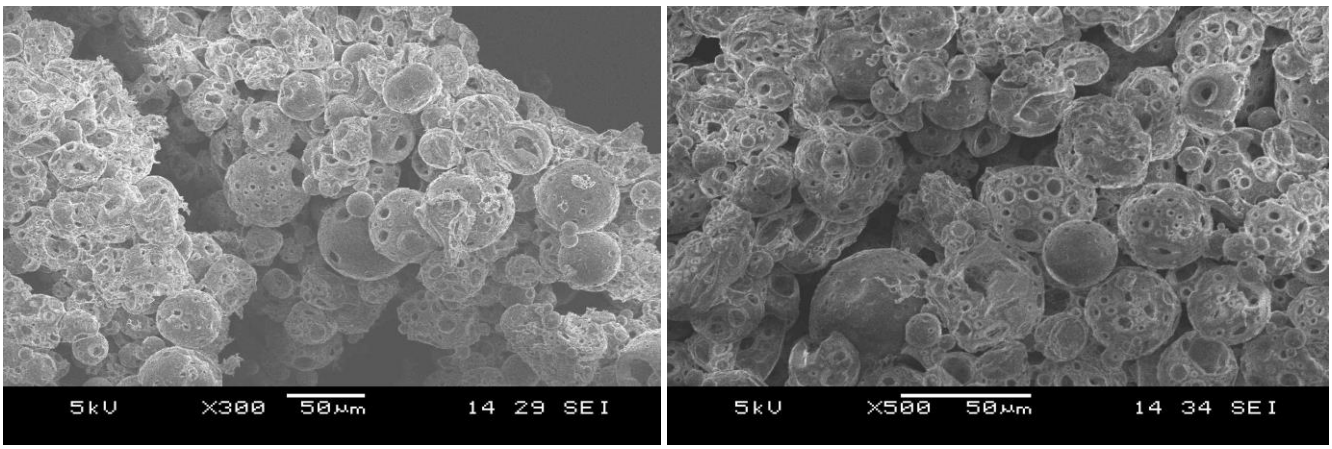

Fig 5: Close view of SEM

3.3 Particle size determination:

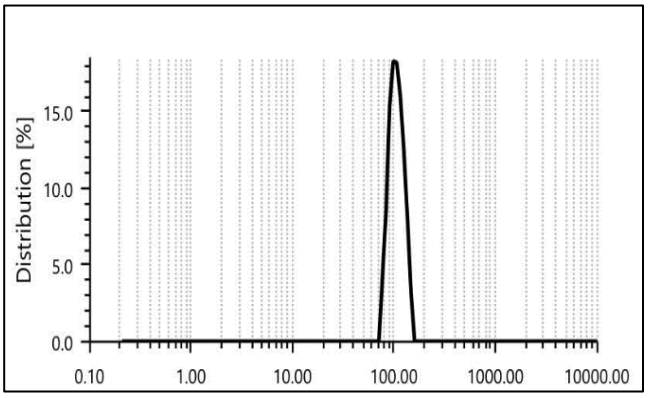

Fig.6 Graph of particle size distribution microsonges

Particle size analysis showed that the average particle size of vitex negundo microsponges formulated using ethyl cellulose was found to be 205.33µm with PDI value 0.886 and with intercept 0.9585 The particle size distribution of ethyl cellulose - microsponges

3.4 Determination of Zeta potential:

For Vitex negundo microsponges using ethyl cellulose zeta potential was found to be -2.8 mV with peak area of 100% intensity. These values indicate that the formulated viex negundo microsponges (F1) are stable.

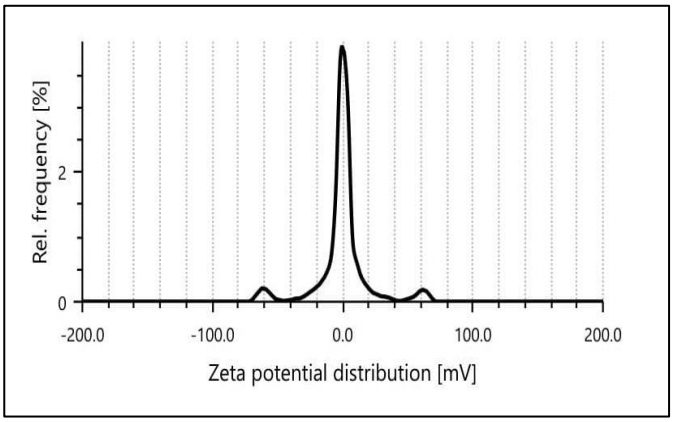

Fig.7 Graph zeta potential of microsponges

3.5 Determination of Entrapment Efficiency:

Table No. 6: Entrapment efficiency of microsponges

Sr no	Formulation code	Entrapment Efficiency (%)
1	F1	57.53%
2	F2	27%
3	F3	45%
4	F4	Negligible
5	F5	Negligible
6	F6	19.80%
7	F7	31.40%
8	F8	24.8%
9	F9	21.5%

5. Evalutation of microsponges gel:

5.1. pH measurement:

pH was determined using digital pH meter, the pH range of F1 batch in between range **5-7.**

Table No 7: pH of gel

Formulation	pH
F1	5.97

5.2. Determination of viscosity:

Optimum viscosity of the formulation plays an important role in the development of successful gel drug delivery system because viscosity is the deciding factor for ease of application of formulation for topical use, in determining the residence time of formulation on skin . (Brookfield viscometer, spindle S46) at different RPM viscosity. The measurement was made over a

whole range of speed settings from 5-100 rpm with 10 seconds between two successive speeds.

Table No. 8: Viscosity of gel

Formulation	Viscosity in cp
F1	12200

5.3 Spreadability of gel:

Spreadability is an important characteristic of topical formulation and it's responsible for correct dosage transfer to the target site. Spreadability is an important factor to consider in the formulation of gel. The viscosity and spreadability are inversely proportional to each other. The spreadability of prepared microsponges gel formulation was in the range between 5.5 ± 6.5gm.cm/sec.

Table No.9: Spreadability of gel

Formulation	Spreadability(gm.cm/sec)
F1	5.564 ± 5.685 gm.cm/sec.

5.4 In vitro diffusion studies:

In vitro diffusion drug released of by vitex negundo using cellophane membrane was carried out. From the results it was concluded that the initial release rate was very rapid due to incomplete gel formation, but the release became slow after complete gel formation and remained so. The release profiles exhibited an inflection point, which indicated gel formation on the diffusion membrane in donor compartment of diffusion cell. During gel formation, formulation got converted into the gel phase and thus drug release became slow. In vitro release study indicated that the release of drug varied according to concentration of polymers., gel were prepared using Carbopol 934, Polyethylene glycol, Triethanolamine, Distilled water. Then formulation F1 was considered as optimized formulation as it showed the best in-vitro diffusion rate i.e. 76.23 %.

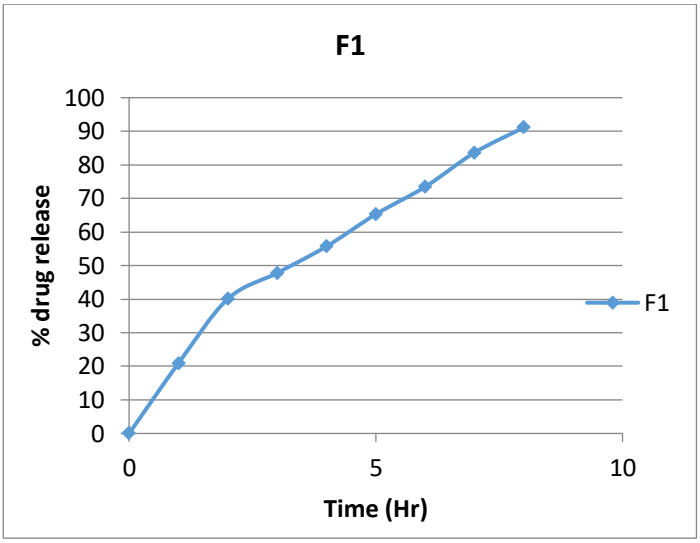

Fig No.8: In vitro diffusion profile of drug formulation (F1)

Table No. 10: In vitro release profile of drug formulation

Time (hr)	F1
0	0
1	20.90
2	40.06
3	47.80
4	55.69
5	65.28
6	73.43
7	83.62
8	91.13
9	93.77

SUMMARY AND CONCLUSION

The study developed a Vitex negundo-based microsponges gel using the quasi-emulsion solvent diffusion method for controlled topical drug delivery. The optimized formulation (F1) showed 57.53% drug entrapment efficiency, uniform particle size, moderate zeta potential (-2.8 mV), and good spreadability. SEM confirmed spherical, porous microsponges. The gel exhibited sustained drug release up to 5 hours (76.42%),

significant antimicrobial activity, and anti-inflammatory effects due to Vitex negundo's flavonoid content.

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HOW TO CITE: Anjali Bhansali, Dr. A. Chandewar, Dr. Madhuri Channawar, Ashwini warnkar, Anisha kohale, Design And Chacterization of Novel Topical Drug Delivery System, Int. J. of Pharm. Sci., 2025, Vol 3, Issue 5, 2915-2925. https://doi.org/10.5281/zenodo.15450341