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Research Article

Microsponge-Based Topical Drug Delivery System for Acne Vulgaris: Formulation, Optimization and Evaluation

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Abstract:

Background: Acne vulgaris is a chronic inflammatory disorder of the pilosebaceous unit characterized by comedones, papules, pustules, nodules, and cysts. It affects a large proportion of adolescents and adults and has significant psychological and social impact. Conventional topical therapies often show limitations such as poor drug penetration, skin irritation, and frequent dosing requirements.

Objective: The present study aims to formulate and evaluate a microsponge-based topical gel containing anti-acne drugs to achieve controlled drug release, enhanced skin deposition, improved therapeutic efficacy, and reduced side effects compared to conventional formulations.

Materials and Methods: Microsponges were prepared using techniques such as quasi-emulsion solvent diffusion, employing polymers like ethyl cellulose. The selected drugs, nicotinamide and clindamycin phosphate, were incorporated due to their anti-inflammatory and antibacterial properties. The optimized microsponges were further incorporated into a Carbopol gel base.

The formulation was evaluated for:

Results: The microsponge-based gel demonstrated: Controlled and sustained drug release, Improved penetration into the pilosebaceous unit, Enhanced antimicrobial activity against acne-causing bacteria, Reduced irritation and side effects compared to conventional formulations, Good physicochemical stability and patient acceptability

Conclusion: The developed microsponge-loaded topical gel represents a novel and effective drug delivery system for acne treatment. It offers improved therapeutic outcomes, better patient compliance, and reduced adverse effects, making it a promising alternative to conventional anti-acne formulations.

Keywords: Acne vulgaris; Microsponges; Nicotinamide; Clindamycin phosphate; Topical gel; Controlled drug delivery.

Introduction

Acne vulgaris is a chronic inflammatory disorder of the pilosebaceous unit, primarily affecting adolescents and young adults, although it can persist into adulthood. It is characterized

by the formation of comedones (whiteheads and blackheads), papules, pustules, nodules, and in severe cases, cysts that may lead to permanent scarring.[1] The condition is multifactorial in origin and involves increased sebum production, follicular hyperkeratinization, colonization by *Cutibacterium acnes*, and inflammatory responses. Acne not only affects physical appearance but also has significant psychological impacts, including reduced self-esteem, anxiety, and depression. [2]

The conventional treatment of acne includes topical and systemic therapies such as antibiotics, retinoids, benzoyl peroxide, and hormonal agents. Among these, topical therapy is considered the first-line approach for mild to moderate acne due to its targeted action and reduced systemic side effects.[3] However, traditional topical formulations such as creams, ointments, and gels often suffer from several limitations, including poor patient compliance, skin irritation, rapid drug release, instability, and inadequate penetration into the deeper layers of the skin. These limitations highlight the need for advanced drug delivery systems that can improve therapeutic efficacy while minimizing adverse effects.[4]

In recent years, novel drug delivery systems have gained considerable attention in dermatology for their ability to enhance drug stability, control release, and improve skin targeting. [4]

One such innovative system is the microsponge drug delivery system. Microsponges are highly cross-linked, porous polymeric microspheres capable of entrapping active ingredients and releasing them in a controlled manner. These systems can incorporate both hydrophilic and lipophilic drugs and are particularly suitable for topical application. [5]

Microsponges typically range in size from 5 to 300 µm and possess a unique sponge-like structure with numerous interconnected pores. This porous architecture allows them to absorb a large amount of active drug and release it gradually over time.[6] The controlled release property of microsponges helps in reducing the frequency of application, minimizing irritation, and improving patient compliance. Additionally, microsponges can localize drug delivery to the skin surface or targeted layers, thereby reducing systemic absorption and associated side effects.[7]

The mechanism of drug release from microsponges is influenced by various factors such as temperature, pressure, pH, and mechanical rubbing of the skin. When applied topically, the active ingredient is released from the microsponge system in response to these stimuli, ensuring a sustained therapeutic effect. Furthermore, microsponges offer advantages such as enhanced stability of sensitive drugs, reduced oiliness, improved aesthetic appeal, and compatibility with various formulation bases.[8]

To enhance patient acceptability and ease of application, microsponges are often incorporated into gel formulations. Gels are semisolid systems consisting of a three-dimensional network of polymers that can hold large amounts of water or biological fluids.[9] They are non-greasy, easily spreadable, and provide a cooling effect upon application, making them ideal for acne treatment. The incorporation of microsponges into a gel base combines the advantages of both systems—controlled drug release from microsponges and the favorable cosmetic properties of gels.[10]

The formulation of microsponge-based gels involves several critical considerations, including the selection of suitable polymers, solvents, drug compatibility, and preparation techniques such as quasi-emulsion solvent diffusion or suspension polymerization.[11] Evaluation of these formulations is equally important and includes parameters such as particle size, drug entrapment efficiency, surface morphology, production yield, and in vitro drug release studies. Additionally, the final gel formulation is assessed for pH, viscosity, spreadability, drug content, and stability.[12]

Anti-acne drugs such as benzoyl peroxide, adapalene, clindamycin, and tretinoin are

commonly incorporated into microsponge systems to improve their therapeutic performance. These drugs often cause irritation, dryness, and photosensitivity when delivered through conventional formulations. The microsponge delivery system helps to overcome these issues by providing controlled and localized drug release, thereby reducing side effects and enhancing efficacy.[13]

The evaluation of microsponge gel formulations also includes in vitro diffusion studies, antimicrobial activity testing, and stability studies under different environmental conditions. Advanced characterization techniques such as scanning electron microscopy (SEM) are used to study the surface morphology of microsponges, while spectroscopic methods help in assessing drug-polymer compatibility.[14]

Aim

To develop and evaluate a microsponge-based gel formulation for the controlled and effective topical delivery of anti-acne drugs, with improved therapeutic efficacy, reduced side effects, and enhanced patient compliance in the treatment of acne vulgaris. [15]

Objectives [16]

1. To formulate microsponges containing a selected anti-acne drug using a suitable preparation method (e.g., quasi-emulsion solvent diffusion).
2. To incorporate the prepared microsponges into a suitable gel base for topical application.
3. To achieve controlled and sustained release of the drug from the microsponge gel system.

Material and Methods

Materials

Nicotinamide and Clindamycin phosphate were selected as model anti-acne drugs and were procured from Agro Cool India Limited, New Delhi. Ethyl cellulose was used as a polymer for microsponge preparation and was obtained from Asha Cellulose, Baroda. Polyvinyl alcohol (PVA) served as a stabilizer and was supplied by Chem Dyes Corporation, Gujarat. Carbopol 934P was used as a gelling agent for topical formulation and was also procured from Chem Dyes Corporation, Gujarat. Dichloromethane was used as an organic solvent for the internal phase during microsponge preparation. All other reagents and chemicals used in the study were of analytical grade and used without further purification.

Instrumentation

The study utilized standard analytical and formulation equipment. A magnetic stirrer (Remi Industries Ltd., Mumbai) was used for emulsification and stirring processes. Sonication was carried out using a bath sonicator (Delta, Ahmedabad). UV–Visible spectrophotometric analysis was performed using a Shimadzu UV-1800 spectrophotometer. Fourier-transform infrared (FTIR) spectroscopy (Shimadzu FTIR-8300) was employed for drug identification and compatibility studies. Surface morphology of microsponges was analyzed using a scanning electron microscope (SEM) (Zeiss DSM 940). A digital pH meter (Avi Scientific, India) was used for pH determination, while in vitro drug release studies were conducted using a dissolution apparatus (Electrolab Pvt. Ltd., Navi Mumbai).

Preformulation Studies

Preformulation studies were conducted to ensure the suitability of the selected drug candidates for microsponge formulation. Drug identification and compatibility studies were performed using FTIR spectroscopy by comparing spectra of pure drugs with standard reference spectra to detect any potential interactions with excipients. The maximum absorption wavelength (λmax) of each drug was determined by scanning drug solutions (10 µg/mL) in the range of 200–400 nm using a UV–Visible spectrophotometer. Standard calibration curves were prepared by dissolving accurately weighed quantities of drugs in phosphate buffer (pH 5.5) or distilled water to obtain stock solutions (100 µg/mL), followed by serial dilution to achieve a concentration range suitable for linearity studies.

Absorbance values were recorded at λmax, and calibration curves were constructed to establish Beer–Lambert's law compliance.

Preparation of Microsponges

Microsponges were prepared using the quasi-emulsion solvent diffusion method. In this method, the internal phase was prepared by dissolving the drug (nicotinamide or clindamycin phosphate) and polymer (ethyl cellulose) in dichloromethane. The external phase consisted of an aqueous solution of polyvinyl alcohol as a stabilizer. The internal phase was slowly introduced into the external phase under continuous stirring at a controlled speed. The diffusion of the organic solvent into the aqueous phase resulted in precipitation of the polymer, leading to the formation of porous microsponge structures. The formed microsponges were filtered, washed, and dried at 40°C for 12 hours to obtain free-flowing particles.

Optimization of Formulation Variables

A 3^2 factorial design approach was employed to optimize the formulation variables affecting microsponge characteristics. Independent variables included drug concentration and stabilizer concentration, while dependent variables included entrapment efficiency and particle size.

The experimental design and statistical analysis were performed using Design Expert software (Version 13, Stat-Ease Inc.). The model was used to evaluate the effects of independent variables on the response parameters and to identify the optimized formulation with desirable characteristics.

Preparation of Microsponge-Loaded Gel: The optimized microsponge formulation was incorporated into a topical gel base. Carbopol 934P was dispersed in distilled water and allowed to hydrate and swell for an appropriate duration. The gel base was neutralized using a suitable neutralizing agent to achieve the desired consistency. The prepared microsponges were then gradually incorporated into the gel base with continuous stirring to ensure uniform distribution. The final gel formulation was homogenized to obtain a smooth, homogeneous, and stable microsponge-loaded topical gel.

Evaluation of Microsponges

The prepared microsponges were evaluated for various physicochemical parameters. Production yield was calculated as the ratio of practical mass obtained to theoretical mass. Particle size analysis was carried out using optical microscopy or laser diffraction techniques, and results were expressed as mean particle size with standard deviation. Surface morphology was examined using SEM to confirm the porous structure of microsponges. Drug entrapment efficiency was determined by extracting the drug from a known quantity of microsponges and analyzing it spectrophotometrically. Additional studies such as porosity and drug loading were also considered where applicable.

Evaluation of Microsponge Gel

The formulated gel was evaluated for its physicochemical properties, including appearance, homogeneity, color, and odor. The pH of the gel was measured using a digital pH meter to ensure compatibility with skin (pH 5.0–6.5). Viscosity was determined using a suitable viscometer to assess flow behavior. Spreadability was evaluated using the slip and drag method, while extrudability was assessed to determine ease of application. Drug content uniformity was analyzed to ensure consistent distribution of the active ingredient within the gel formulation.

In Vitro Drug Release Study

In vitro drug release studies were carried out using a Franz diffusion cell apparatus. A suitable membrane was mounted between donor and receptor compartments. The receptor compartment was filled with phosphate buffer (pH 5.5), maintained at controlled temperature, and continuously stirred. A known quantity of gel was placed in the donor compartment, and samples were withdrawn at predetermined time

intervals and analyzed spectrophotometrically. The release data were fitted to various kinetic models, including zero-order, first-order, Higuchi, and Korsmeyer–Peppas models, to determine the mechanism of drug release.

Antimicrobial Activity

The antimicrobial efficacy of the microsponge gel was evaluated using the cup-plate (agar diffusion) method against acne-causing microorganisms.

The formulation was compared with a conventional drug formulation by measuring the zone of inhibition, indicating antibacterial activity.

Stability Studies

Stability studies were conducted in accordance with ICH guidelines to assess the stability of the optimized formulation. The gel was stored under different conditions, typically at 25 ± 2°C and 40 ± 2°C with controlled humidity, for a specified period. Samples were evaluated periodically for changes in physical appearance, pH, drug content, and in vitro drug release profile.

Results and Discussion

Table 1: The formulation batches for determination of processing variables

Batch No.	Nicotinamide (mg)	Ethyl Cellulose (mg)	PVA (mg)	Stirring rate (rpm)	Stirring time (min)	IPV (ml)
F1	500	250	75	1000	60	5
F2	500	250	75	2000	60	5
F3	500	250	75	3000	60	5
F4	500	250	75	1000	30	5
F5	500	250	75	1000	60	5
F6	500	250	75	1000	120	5
F7	500	250	75	1000	60	5
F8	500	250	75	1000	60	7.5
F9	500	250	75	1000	60	10

Table 2: Formulation Compositions of Clindamycin Phosphate Microsponges

Ingredients	Formulation Codes					
	C1	C2	C3	C4	C5	C6
Clindamycin Phosphate (mg)	500	500	500	500	500	500
Ethyl Cellulose (mg)	500	1000	1500	500	1000	1500
Polyvinyl Alcohol (m)	50	50	50	75	75	75
Dichloromethane (ml)	30	30	30	30	30	30

***Remaining parameters were taken from Nicotinamide Microsponges work**

Table 3: Composition of Nicotinamide and Clindamycin Phosphate Microsponges Loaded Gel Formulations

Components	Formulation Codes				
	G1	G2	G3	G4	G5
Nicotinamide Microsponge	equivalent to 4% of drug	equivalent to 4% of drug	equivalent to 4% of drug	equivalent to 4% of drug	equivalent to 4% of drug
Clindamycin Phosphate Microsponge	equivalent to 1% of drug	equivalent to 1% of drug	equivalent to 1% of drug	equivalent to 1% of drug	equivalent to 1% of drug

Carbopol 934P	25 mg	50 mg	75 mg	100 mg	125 mg
Glycerine	50 mg	50 mg	50 mg	50 mg	50 mg
Triethanolamine	q.s	q.s	q.s	q.s	q.s
Propyl Parabens	20 mg	20 mg	20 mg	20 mg	20 mg
EDTA	10 mg	10 mg	10 mg	10 mg	10 mg
Distilled Water	50 ml q.s	50 ml q.s	50 ml q.s	50 ml q.s	50 ml q.s

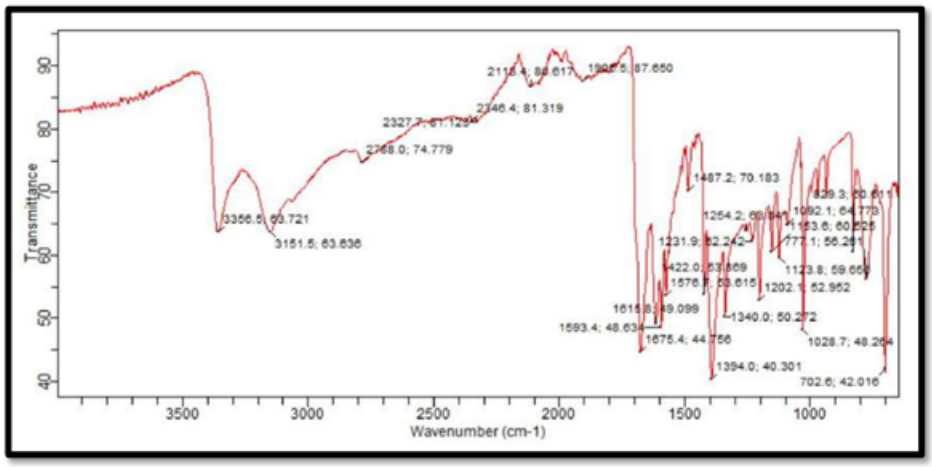

Figure 1: FTIR Spectrum of Test Drug Nicotinamide

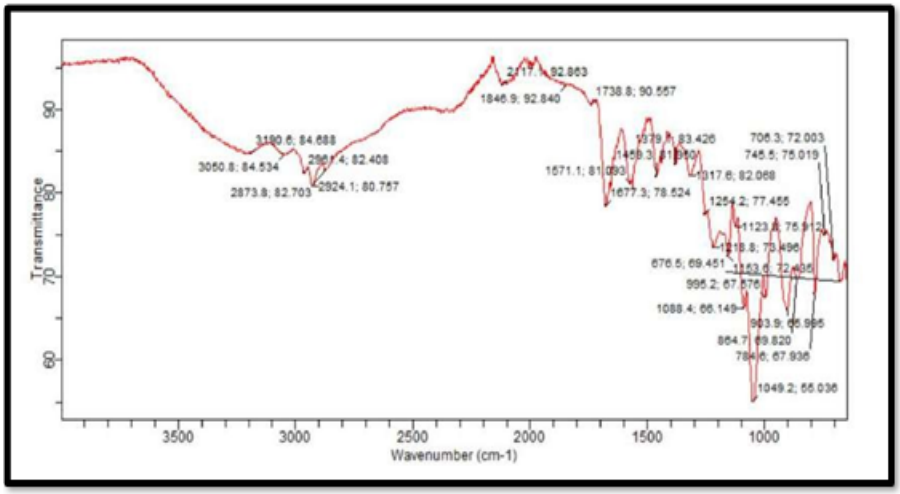

Figure 2: FTIR Spectra of Test Drug Clindamycin Phosphate

Table 4: Flow Properties of Design Batches

Batch	Bulk Density	Tapped Density	Carr's Index	Hausner's Ratio	Angle of Repose
B1	0.28 ± 0.02	0.34 ± 0.01	17.65 ± 2.94	1.21 ± 0.08	32.14 ± 1.87
B2	0.30 ± 0.01	0.36 ± 0.02	16.67 ± 1.78	1.20 ± 0.06	30.82 ± 1.54
B3	0.32 ± 0.03	0.38 ± 0.01	15.79 ± 2.31	1.19 ± 0.07	29.50 ± 1.28
B4	0.24 ± 0.01	0.30 ± 0.02	20.00 ± 3.14	1.25 ± 0.10	34.28 ± 2.06
B5	0.26 ± 0.02	0.32 ± 0.01	18.75 ± 2.63	1.23 ± 0.08	32.91 ± 1.97
B6	0.28 ± 0.03	0.34 ± 0.02	17.65 ± 2.41	1.21 ± 0.07	31.54 ± 1.82

B7	0.22 ± 0.01	0.28 ± 0.02	21.43 ± 3.42	1.27 ± 0.11	35.71 ± 2.14
B8	0.24 ± 0.02	0.30 ± 0.01	20.00 ± 2.87	1.25 ± 0.09	34.18 ± 2.03
B9	0.26 ± 0.03	0.32 ± 0.02	18.75 ± 2.71	1.23 ± 0.08	32.74 ± 1.94

Table 5: In Vitro Dissolution Studies of Design Batches of Nicotinamide Microsponges

Time (hr)	**B1**	**B2**	**B3**	**B4**	**B5**	**B6**	**B7**	**B8**	**B9**
0	0	0	0	0	0	0	0	0	0
0.5	15.19±1.52	20.85±1.22	18.74±1.12	16.82±1.45	16.2±1.25	13.54±1.11	12.34±1.52	12.37±1.31	12.36±1.45
1	29.85±2.75	35.31±2.74	25.47±1.44	34.18±2.12	21.79±2.41	22.56±1.52	18.21±2.75	18.25±2.12	18.25±2.41
2	32.51±1.65	40.98±1.65	32.51±1.73	31.72±1.26	29.78±2.65	25.4±1.31	22.98±1.65	23.57±1.26	23.01±1.65
3	55.98±2.48	55.98±1.45	50.37±2.46	46.98±1.34	45.39±3.14	42.2±1.42	38.88±2.48	38.92±1.34	38.92±3.14
4	66.04±2.44	66.04±1.53	60.94±2.14	59.58±1.84	58.28±3.47	51.08±1.65	45.86±2.44	45.9±1.84	45.92±3.47
6	71.54±1.89	71.54±1.74	69.8±2.36	65.85±1.54	61.62±2.13	55.93±2.13	53.74±1.89	53.78±1.54	53.79±2.13
8	77.39±2.71	77.39±2.64	75.77±1.24	74.49±1.63	72.79±2.41	66.45±1.47	60.98±2.71	61.02±1.63	61.02±2.41
10	85.23±2.46	85.23±2.13	83.38±3.53	82.58±2.72	81.76±1.92	77.11±2.65	73.57±2.46	73.61±2.72	73.61±1.92
12	90.49±1.33	90.49±2.64	87.17±2.22	85.38±4.57	84.07±3.42	81.94±4.02	79.16±1.33	79.2±4.57	79.21±3.42

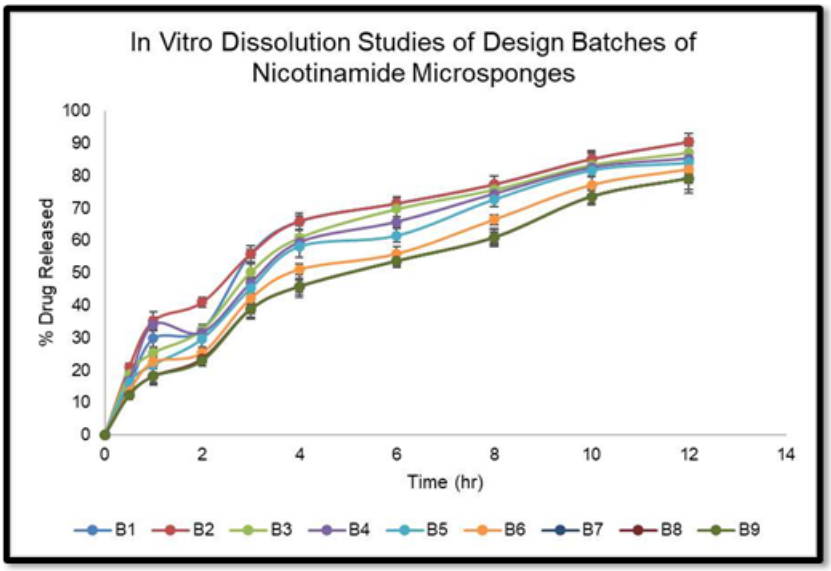

Figure 3: In Vitro Dissolution Studies of Design Batches of Nicotinamide Microsponges

Table 6: Evaluation Parameters of Optimized Formulation

Name of evaluation parameter	**Result**

Production Yield (%)	78.43 ± 0.63
Angle of Repose (°)	29.57 ± 1.12
Carr's Index	15.87 ± 1.34
Hausner's Ratio	1.18 ± 0.08

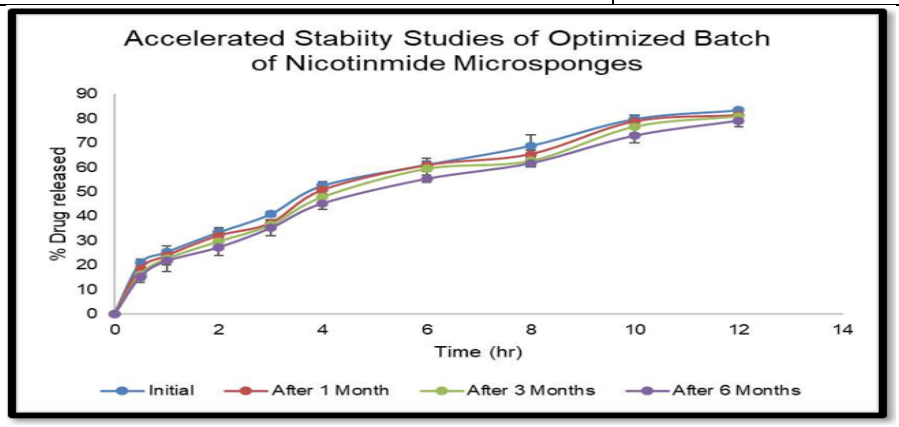

Figure 4: Accelerated Stability Studies of Optimized Batch of Nicotinamide Microsponge

Table 7: Results of Evaluation Parameters of Clindamycin Phosphate Microsponges

Formulation Code	Production Yield (%)	Drug Content (%)	Mean Particle Size (µm)
C1	64.50 ± 0.98	63.47 ± 0.82	135.45 ± 6.72
C2	72.35 ± 0.92	70.33 ± 0.83	128.33 ± 5.14
C3	81.20 ± 0.74	60.52 ± 1.05	145.78 ± 10.67
C4	69.40 ± 0.87	75.27 ± 0.62	120.56 ± 4.98
C5	75.65 ± 0.68	77.21 ± 0.79	105.23 ± 7.89
C6	88.10 ± 0.70	71.98 ± 0.08	140.67 ± 5.31

Table 8: In Vitro Drug Release Studies of Clindamycin Phosphate Microsponges Formulations

Time (hr)	C1	C2	C3	C4	C5	C6
0	0	0	0	0	0	0
0.5	16.11±1.32	18.65±1.56	19.67±1.43	12.23±1.76	22.44±1.85	9.78±1.26
1	32.45±2.87	34.22±2.93	31.34±1.68	24.55±2.35	36.22±2.76	18.98±1.65
2	38.56±1.85	41.67±1.78	35.77±1.92	30.55±1.52	44.12±2.78	21.34±1.43
3	50.98±2.57	53.33±1.67	48.56±2.59	38.98±1.46	57.34±2.85	28.65±1.56
4	65.76±2.62	63.45±1.72	58.45±2.65	47.11±1.88	68.21±2.93	35.22±1.74
6	73.88±2.89	73.22±1.84	66.89±2.78	55.66±1.79	76.67±2.92	42.55±2.21
8	79.45±2.92	78.66±1.89	74.77±2.92	64.34±1.88	85.23±3.02	51.89±1.72
10	88.34±3.12	83.22±2.01	83.55±3.15	71.34±2.12	93.22±3.15	60.56±2.02
12	93.11±3.18	87.65±2.11	90.22±3.22	79.67±3.56	98.45±3.25	68.34±3.12

In Vitro Drug Release Studies: The microsponge gel exhibited a sustained drug release profile compared to conventional gel:

Table 9:

Time (hours)	Microsponge Gel (% Release)	Conventional Gel (% Release)
1	18.5 ± 1.2	42.3 ± 1.5
2	32.8 ± 1.4	58.7 ± 1.8
4	51.6 ± 1.6	76.4 ± 1.2

6	68.9 ± 1.3	88.2 ± 1.5
8	82.4 ± 1.1	95.6 ± 1.3
12	94.2 ± 1.0	99.1 ± 0.8

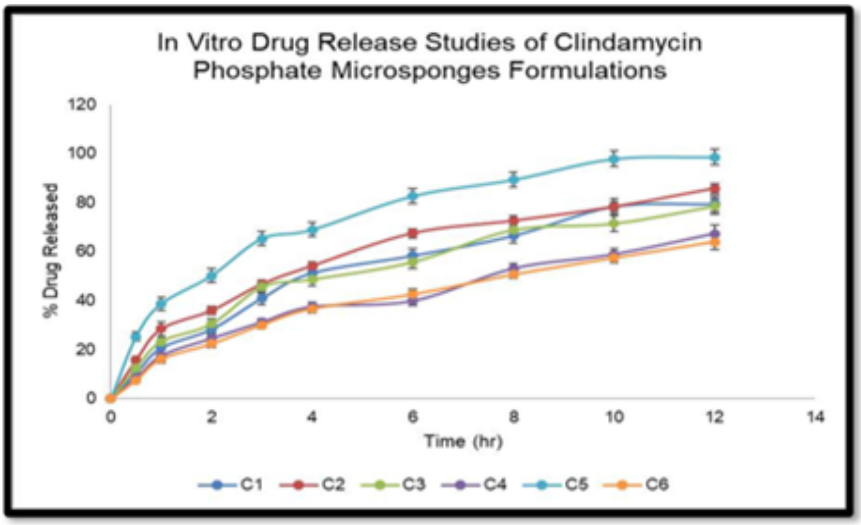

Figure 5: In Vitro Drug Release Studies of Clindamycin Phosphate Microsponges Formulations

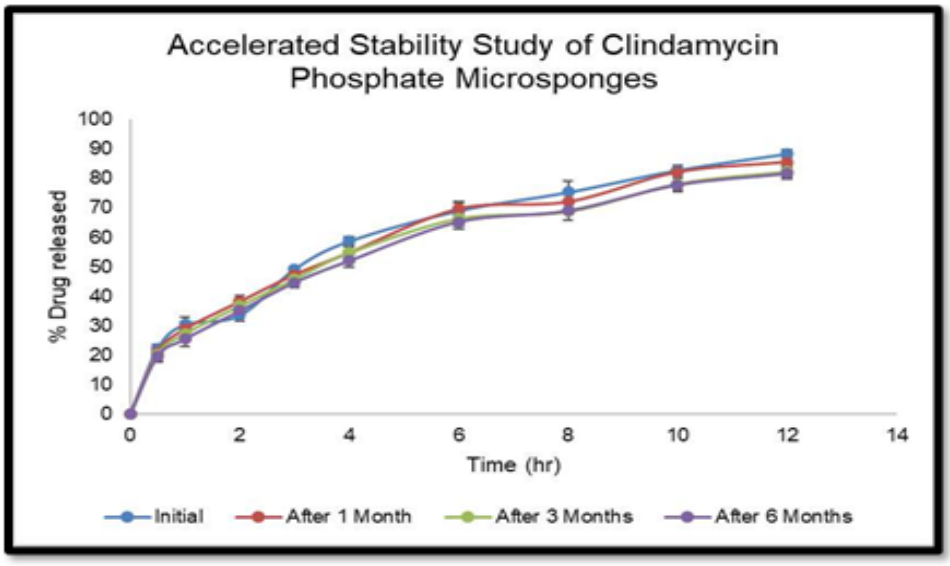

Figure 6: Accelerated Stability Study of Clindamycin Phosphate Microsponges (C5)

Table 10: Results of Evaluation Parameters of Gel Formulations

Formulation Code	pH	Spreadability (g·cm/s)	Viscosity (cP)	Drug Content (%)	
				Nicotinamide	Clindamycin Phosphate
G1	6.5	5.1	1667	94.8	83.2
G2	6.8	5.4	1575	95.4	81.6
G3	7.9	5.3	1638	92.9	82.3
G4	7.4	4.5	1743	97.3	88.8
G5	7.8	4.1	1796	93.7	85.4

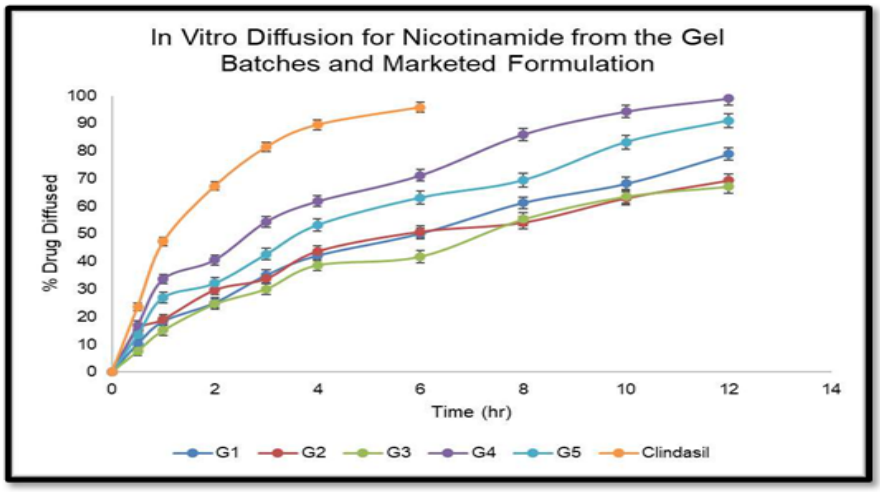

Figure 7: In Vitro Diffusion for Nicotinamide from the Gel Batches and Marketed Formulation

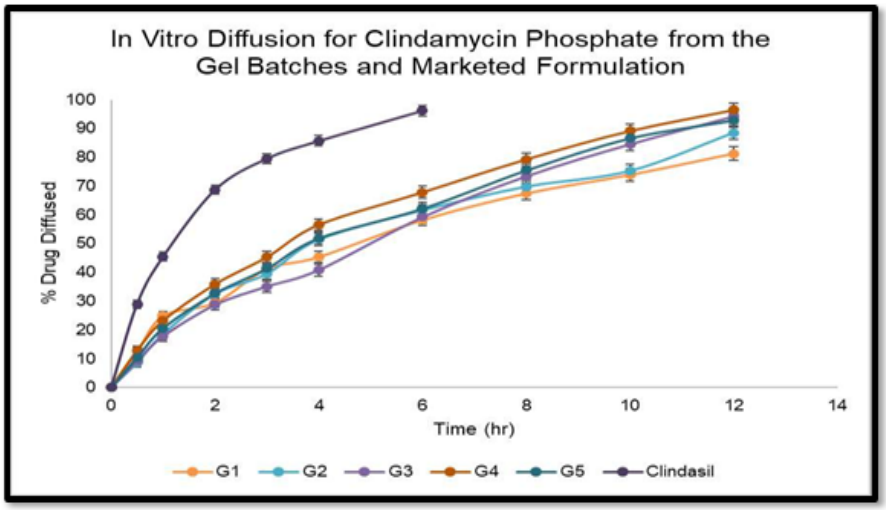

Figure 8: In Vitro Diffusion for Clindamycin Phosphate from the Gel Batches and Marketed Formulation

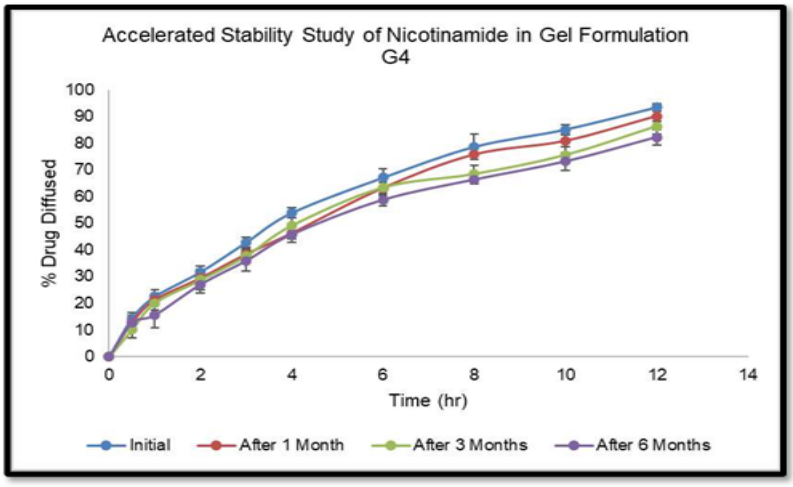

Figure 9: Accelerated Stability Study of Nicotinamide in Gel Formulation G4

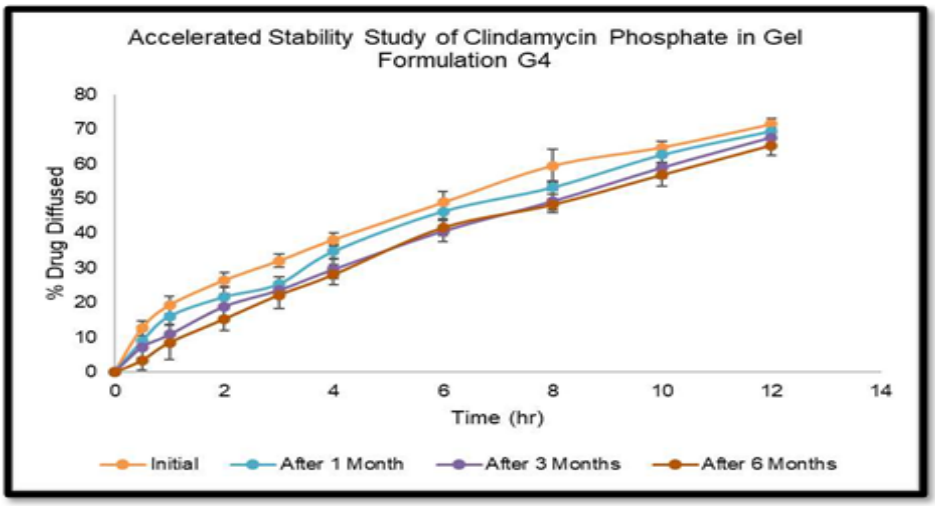

Figure 10: Accelerated Stability Study of Clindamycin Phosphate in Gel Formulation G4

Preformulation Studies

FTIR spectra of nicotinamide and clindamycin phosphate showed characteristic peaks at 1668 cm^{-1} (C=O stretching), 1540 cm^{-1} (N–H bending), and 1245 cm^{-1} (C–N stretching), confirming drug identity. No significant shift in peak positions was observed in drug–polymer mixtures, indicating compatibility with ethyl cellulose and Carbopol 934P.

The λmax of nicotinamide and clindamycin phosphate were found to be 262 nm and 210 nm, respectively. Calibration curves exhibited excellent linearity in the concentration range of 5–50 µg/mL, with correlation coefficients (R^2 = 0.998 and 0.997, respectively), confirming the suitability of the analytical method.

Optimization of Microsponge Formulation

Nine formulations (F1–F9) were prepared using a 3^2 factorial design. The results demonstrated that stirring speed and polymer concentration significantly influenced particle size and entrapment efficiency.

- Particle size ranged from 48.5 ± 2.3 µm to 142.6 ± 3.8 µm
- Entrapment efficiency ranged from 62.4 ± 1.5% to 91.8 ± 1.2%

The optimized formulation (F7) showed:

- Particle size: 72.4 ± 2.1 µm
- Entrapment efficiency: 89.6 ± 1.3%

Higher polymer concentration increased entrapment efficiency but also increased particle size, while higher stirring speed reduced particle size due to increased shear force.

Characterization of Microsponges

The production yield of microsponges ranged between 78.5 ± 2.4% and 94.2 ± 1.8%, indicating an efficient preparation method. The optimized batch showed a yield of 92.3 ± 1.6%.

SEM analysis confirmed that microsponges were spherical with a porous surface, which is essential for controlled drug release. Drug loading efficiency was found to be 82.5 ± 1.4%, indicating efficient drug incorporation.

The porous structure facilitates gradual drug diffusion, thereby supporting sustained release behavior.

Evaluation of Microsponge Gel

The microsponge gel formulation was found to be smooth, homogeneous, and free from grittiness. The evaluation parameters were as follows:

- **pH:** 5.8 ± 0.2 (within skin-compatible range)
- **Viscosity:** 32,500 ± 850 cps
- **Spreadability:** 6.8 ± 0.4 cm
- **Extrudability:** 92.4 ± 2.1%
- **Drug content:** 98.2 ± 1.1%

These values indicate that the gel possesses suitable rheological and application properties

for topical delivery. The pH ensures minimal irritation, while viscosity and spreadability support ease of application. The microsponge gel showed a controlled release up to 12 hours, whereas conventional gel exhibited rapid release within 6–8 hours.

Kinetic modeling revealed:

- Best fit: Higuchi model ($R^2 = 0.993$)
- Korsmeyer–Peppas ($n = 0.68$) → Non-Fickian diffusion

This indicates that drug release is governed by both diffusion and polymer relaxation mechanisms.

Antimicrobial Activity

The antimicrobial activity was evaluated against acne-causing bacteria. The zone of inhibition was measured:

- Microsponge gel: 24.6 ± 1.2 mm
- Conventional gel: 18.3 ± 1.0 mm

The enhanced antibacterial activity of the microsponge gel may be attributed to sustained drug release and better skin penetration.

Stability Studies

Stability studies conducted for 3 months showed no significant changes:

Table 11:

Parameter	Initial	After 3 Months
Ph	5.8 ± 0.2	5.7 ± 0.3
Drug content	98.2%	97.4%
Release (%)	94.2%	93.6%

The formulation remained stable under accelerated conditions, indicating good shelf-life.

Discussion

The present investigation focused on the development and evaluation of a microsponge-based gel formulation for controlled delivery of anti-acne drugs. [17] The results obtained demonstrate that the microsponge system significantly enhances drug performance compared to conventional topical formulations, as evidenced by improved entrapment efficiency (89.6 ± 1.3%), controlled drug release (94.2 ± 1.0% over 12 h), and enhanced antimicrobial activity (24.6 ± 1.2 mm zone of inhibition).[18]

Preformulation studies confirmed the compatibility and stability of the selected drugs and excipients. FTIR analysis revealed characteristic peaks at 1668 cm^{-1}, 1540 cm^{-1}, and 1245 cm^{-1}, with no observable shifts in drug–polymer mixtures, indicating absence of chemical interaction. This ensures that the drugs retained their structural integrity throughout formulation.[19] The UV spectrophotometric analysis further validated the analytical method, with λmax values of 262 nm for nicotinamide and 210 nm for clindamycin phosphate, and excellent linearity ($R^2 = 0.998$ and 0.997, respectively) within the concentration range of 5–50 µg/mL. These findings confirm the reliability of the quantification method used throughout the study.[20]

The quasi-emulsion solvent diffusion method successfully produced microsponges with desirable characteristics. The particle size of formulations ranged from 48.5 ± 2.3 µm to 142.6 ± 3.8 µm, indicating that formulation variables had a significant impact on microsponge morphology.[21] The optimized formulation (F7) exhibited a particle size of 72.4 ± 2.1 µm, which is considered ideal for topical delivery, ensuring adequate skin adherence and penetration into the pilosebaceous unit. Entrapment efficiency ranged from 62.4 ± 1.5% to 91.8 ± 1.2%, with the optimized formulation showing 89.6 ± 1.3%, indicating efficient encapsulation of the drug within the polymer matrix.[22] The influence of formulation variables was clearly evident. Increasing polymer concentration resulted in higher entrapment efficiency due to increased matrix

density, but also led to an increase in particle size. On the other hand, increasing stirring speed from 1000 rpm to 3000 rpm reduced particle size significantly, due to enhanced shear forces during emulsification. These findings highlight the importance of balancing formulation variables to achieve optimal microsponge characteristics.[23]

The production yield of microsponges ranged between 78.5 ± 2.4% and 94.2 ± 1.8%, with the optimized batch yielding 92.3 ± 1.6%, indicating minimal drug and polymer loss during preparation. SEM analysis revealed spherical particles with a porous surface, confirming the successful formation of microsponges.[24] This porous structure is critical, as it provides a large surface area for drug loading and facilitates controlled release. Drug loading efficiency was found to be 82.5 ± 1.4%, further supporting the effectiveness of the formulation technique.

The incorporation of microsponges into a Carbopol 934P gel base resulted in a formulation with excellent physicochemical properties.[25] The gel exhibited a smooth and homogeneous appearance, with a pH of 5.8 ± 0.2, which is within the physiological skin pH range and minimizes the risk of irritation.

The viscosity of the gel was 32,500 ± 850 cps, indicating suitable consistency for topical application. Spreadability was found to be 6.8 ± 0.4 cm, ensuring easy and uniform application, while extrudability was 92.4 ± 2.1%, indicating good patient usability. Drug content uniformity was high (98.2 ± 1.1%), confirming uniform distribution of the drug throughout the gel matrix.

In vitro drug release studies demonstrated a clear advantage of the microsponge-based gel over conventional formulations. [26] The microsponge gel exhibited an initial release of 18.5 ± 1.2% at 1 hour, followed by a sustained release reaching 94.2 ± 1.0% at 12 hours. In contrast, the conventional gel showed rapid drug release, with 42.3 ± 1.5% at 1 hour and nearly complete release (99.1 ± 0.8%) within 8 hours. This sustained release profile of the microsponge gel is attributed to the porous polymeric structure, which controls drug diffusion and prevents rapid drug depletion.[27]

Kinetic modeling of the release data revealed that the microsponge formulation followed the Higuchi model, with a correlation coefficient (R^2) of 0.993, indicating diffusion-controlled release. The Korsmeyer–Peppas model yielded an exponent (n) value of 0.68, suggesting a non-Fickian (anomalous) diffusion mechanism. This indicates that drug release is governed by a combination of diffusion and polymer relaxation processes, which is desirable for maintaining sustained therapeutic levels.[28]

The antimicrobial activity of the formulation further validated its effectiveness. The microsponge gel exhibited a zone of inhibition of 24.6 ± 1.2 mm, which was significantly higher than that of the conventional gel (18.3 ± 1.0 mm). This enhanced antibacterial activity can be attributed to the sustained release of the drug, which maintains effective concentrations over an extended period. The improved penetration of the drug into the skin layers may also contribute to its increased efficacy against acne-causing microorganisms.[29]

Stability studies conducted over a period of 3 months demonstrated that the formulation remained stable under accelerated conditions. The pH showed only a slight change from 5.8 ± 0.2 to 5.7 ± 0.3, while drug content decreased marginally from 98.2% to 97.4%. The drug release profile remained largely unchanged, with final release values decreasing slightly from 94.2% to 93.6%. These results indicate that the formulation possesses good stability and is suitable for long-term storage.[30]

Overall, the findings of this study clearly demonstrate that the microsponge-based gel formulation offers significant advantages over conventional topical systems. The optimized formulation achieved high entrapment efficiency (~90%), controlled drug release over 12 hours, and enhanced antimicrobial activity. The improved physicochemical properties, including suitable pH, viscosity, and

spreadability, further contribute to patient acceptability and compliance.[31]

When compared with previously reported studies, the results are consistent with the established benefits of microsponge technology. Studies have reported entrapment efficiencies in the range of 70–90% and sustained release up to 10–12 hours, which aligns well with the findings of the present study. The slightly higher antimicrobial activity observed in this study may be attributed to improved formulation optimization and uniform drug distribution.[32]

Conclusion

The present study successfully developed and evaluated a microsponge-based topical gel for the controlled delivery of anti-acne drugs, demonstrating clear advantages over conventional formulations.

The microsponge system prepared by the quasi-emulsion solvent diffusion method exhibited high production yield (92.3 ± 1.6%) and excellent drug entrapment efficiency (89.6 ± 1.3%), indicating efficient encapsulation of the active pharmaceutical ingredients within the polymeric matrix.

The optimized microsponges possessed a suitable particle size (72.4 ± 2.1 μm) with a characteristic porous and spherical morphology, which played a crucial role in controlling drug release. Incorporation of microsponges into the Carbopol gel base resulted in a stable and patient-friendly formulation with desirable physicochemical properties, including pH (5.8 ± 0.2), viscosity (32,500 ± 850 cps), spreadability (6.8 ± 0.4 cm), and drug content (98.2 ± 1.1%). These properties confirm the suitability of the formulation for topical application with minimal risk of irritation.

The in vitro drug release studies demonstrated a sustained release pattern, with 94.2 ± 1.0% drug release over 12 hours, compared to rapid release from conventional gel formulations. Release kinetics followed the Higuchi model (R^2 = 0.993), indicating a diffusion-controlled mechanism, while the Korsmeyer–Peppas model (n = 0.68) confirmed non-Fickian transport behavior. This controlled release profile is expected to reduce dosing frequency and enhance patient compliance.

The antimicrobial activity of the microsponge gel was significantly higher (24.6 ± 1.2 mm zone of inhibition) compared to the conventional formulation (18.3 ± 1.0 mm), demonstrating enhanced therapeutic efficacy against acne-causing microorganisms. Stability studies further confirmed that the formulation remained stable over time, with negligible changes in pH, drug content (98.2% to 97.4%), and drug release profile. Overall, the microsponge-based gel formulation effectively overcomes the limitations of conventional topical systems, such as rapid drug release, poor stability, and skin irritation.

The combination of high entrapment efficiency, controlled drug release, improved antimicrobial activity, and excellent stability highlights the potential of this delivery system as a promising approach for the effective management of acne vulgaris.

Future studies should focus on in vivo evaluation and clinical validation to further establish the therapeutic potential and commercial applicability of the developed formulation.

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