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Design, Formulation, and Evaluation of Herbal Microsphere-Based Topical Gel for Treating Bacterial Infections

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A B S T R A C T

The present study focused on the development and evaluation of a controlled-release herbal microsphere-based topical gel for the management of bacterial skin infections. Herbal extracts of Neem (Azadirachta indica) and Aloe vera were incorporated into polymeric microspheres using the solvent evaporation technique. The prepared microspheres were characterized for important formulation parameters and subsequently incorporated into a Carbopol 934-based topical gel. The developed gel formulations were evaluated for physical appearance, homogeneity, pH, viscosity, spreadability, in-vitro drug release, antibacterial activity, and stability. The formulation demonstrated suitable physicochemical characteristics and sustained release behavior, indicating effective retention and controlled delivery of the herbal constituents. Antibacterial evaluation against Staphylococcus aureus, Escherichia coli, and Pseudomonas aeruginosa demonstrated promising antimicrobial activity. Stability studies further indicated that the optimized formulation remained physically and chemically stable during the study period. Overall, the developed herbal microsphere-based topical gel represents a promising localized drug delivery system with potential applications in the treatment of bacterial skin infections while providing the combined benefits of herbal therapy and controlled drug release.

I. Introduction

Bacterial skin infections are among the most frequently occurring dermatological disorders affecting millions of people worldwide. These infections occur when harmful bacteria invade the skin tissues through cuts, abrasions, burns, surgical wounds, insect bites, hair follicles, or damaged skin barriers [1]. The skin normally acts as a protective barrier against microbial invasion [2]; however, when its integrity is compromised, pathogenic bacteria can easily penetrate and multiply within the skin layers, leading to localized or systemic infections. Bacterial skin infections can range from mild superficial conditions to severe life-threatening diseases depending on the type of microorganism involved, immune status of the patient, and extent of infection [3].

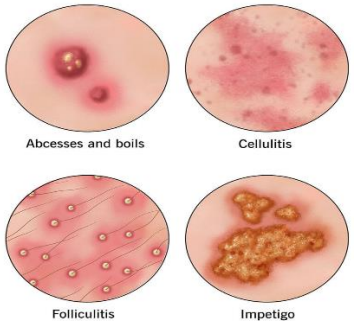

Fig.1. Bacterial Skin Infections.

Global Prevalence and Impact of Bacterial Infections

Bacterial infections represent a major global public health challenge and continue to contribute significantly to morbidity, mortality, and economic burden worldwide [4]. These infections affect individuals of all age groups and are responsible for millions of hospitalizations every year. Bacterial diseases can occur in various parts of the body including the skin, respiratory tract, gastrointestinal tract, urinary tract, bloodstream, and soft tissues. Among these, bacterial skin infections are highly prevalent due to increased exposure to environmental contaminants, injuries, poor hygiene conditions, and compromised immunity. According to global health reports, infectious bacterial diseases remain one of the leading causes of death, particularly in developing and underdeveloped countries where healthcare resources and sanitation facilities are limited [5-6].

The prevalence of bacterial infections has increased considerably over recent decades due to rapid urbanization, population growth, environmental pollution, changing lifestyles, and the emergence of drug-resistant bacterial strains. Common pathogenic bacteria such as *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Streptococcus pyogenes* are widely associated with community-acquired and hospital-acquired infections. These microorganisms possess high adaptability and virulence, enabling them to survive under harsh environmental conditions and develop resistance against multiple antibiotics. Hospital-associated bacterial infections, also known as nosocomial infections, are particularly dangerous because they spread rapidly among immunocompromised patients and increase treatment complications [7-10].

Material and Method

The present research work entitled was carried out to develop a controlled-release herbal topical gel containing herbal extract-loaded microspheres. The study involved extraction of herbal constituents, preparation of microspheres by solvent evaporation technique, incorporation into gel base, and evaluation of physicochemical, microbiological, and stability parameters [5-10].

Materials

Table 1. Materials Used in the Study

S.No.	Material	Category	Purpose
1	Neem Extract (Azadirachta indica)	Herbal Drug	Antibacterial activity
2	Aloe vera Extract	Herbal Drug	Wound healing and soothing agent
3	Eudragit RS100	Polymer	Microsphere formation
4	Ethyl Cellulose	Polymer	Sustained release carrier
5	Polyvinyl Alcohol (PVA)	Stabilizer	Emulsifying agent
6	Carbopol 934	Gelling Agent	Gel preparation
7	Triethanolamine	Neutralizer	pH adjustment
8	Ethanol	Solvent	Extraction and formulation
9	Distilled Water	Vehicle	Formulation medium
10	Methyl Paraben	Preservative	Prevent microbial growth

Equipment Used

Table 2. Instruments and Equipment

S.No.	Instrument
1	Magnetic Stirrer
2	UV-Visible Spectrophotometer

3	Digital pH Meter
4	Brookfield Viscometer
5	Hot Air Oven
6	FTIR Spectrophotometer
7	Scanning Electron Microscope (SEM)
8	Franz Diffusion Cell
9	Analytical Balance
10	Stability Chamber

Methodology

1. Collection and Authentication of Plant Material

Fresh leaves of Neem (Azadirachta indica) and Aloe vera were collected from local herbal gardens. The plant materials were authenticated by a qualified botanist and assigned voucher specimen numbers for future reference.

2. Preparation of Herbal Extract

Procedure

1. Fresh leaves were washed thoroughly.
2. Shade dried for 10–15 days.
3. Pulverized into coarse powder.
4. Powder subjected to Soxhlet extraction using ethanol.
5. Extract concentrated under reduced pressure.
6. Dried extract stored in desiccator until use.

Table 3. Extraction Yield

Batch	Weight of Powder (g)	Weight of Extract (g)	Percentage Yield (%)
E1	100	18.2	18.2
E2	100	19.5	19.5
E3	100	20.1	20.1

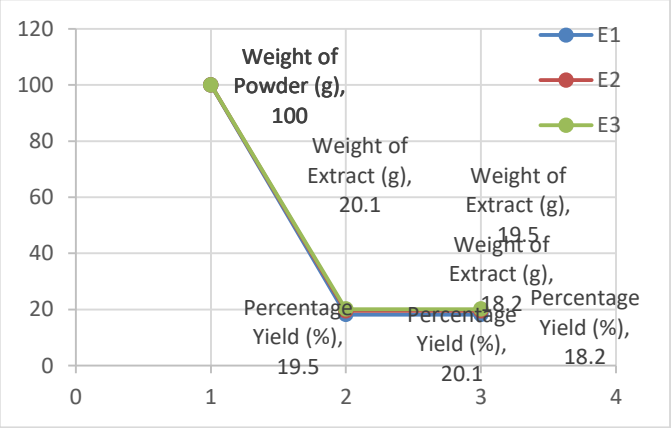

Fig.2. Extraction Yield

3. Preparation of Herbal Microspheres

Solvent Evaporation Method

Procedure

1. Polymer dissolved in ethanol.
2. Herbal extract dispersed into polymer solution.
3. Mixture added dropwise into aqueous PVA solution.
4. Stirring continued for 3–4 hours.
5. Solvent evaporated completely.
6. Microspheres filtered and washed.
7. Dried at room temperature.

Table 4. Formulation of Herbal Microspheres

Ingredients (mg)	F1	F2	F3	F4	F5
Herbal Extract	100	100	100	100	100
Ethyl Cellulose	100	150	200	250	300
PVA (%)	0.5	0.5	0.5	0.5	0.5
Ethanol (mL)	20	20	20	20	20

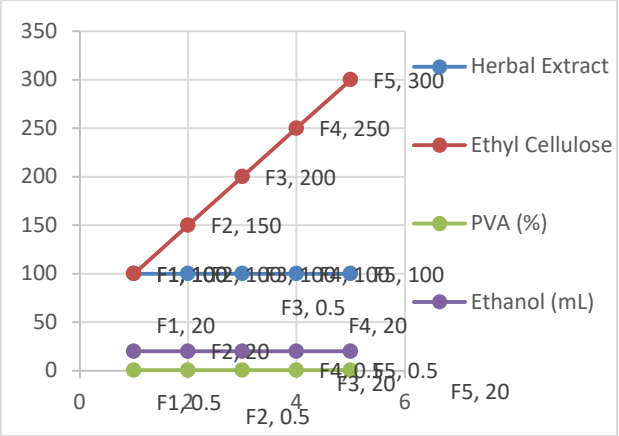

Fig.3. Formulation of Herbal Microspheres

4. Characterization of Microspheres

Particle Size Analysis

Microsphere size measured using optical microscopy.

Formula

$$\text{Average Particle Size} = \frac{nd}{n}$$

Table 5. Particle Size Distribution

Formulation	Particle Size (µm)
F1	112.5
F2	125.8
F3	138.4
F4	151.7
F5	168.3

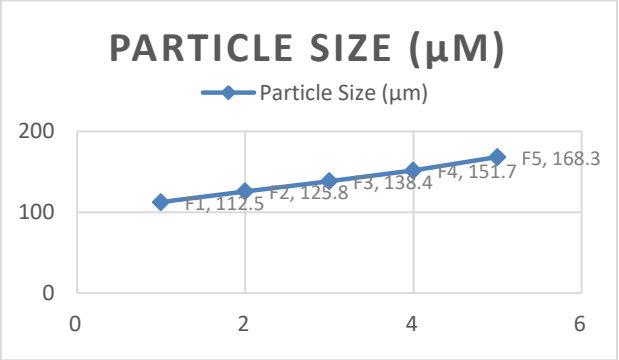

Fig.4. Particle Size (µm).

Percentage Yield

Formula

$$\% \, Yield = \frac{Practical\ Yield}{Theoretical\ Yield} \times 100$$

Table 6. Percentage Yield

Formulation	Yield (%)
F1	78.2
F2	82.4
F3	85.7
F4	88.5
F5	90.1

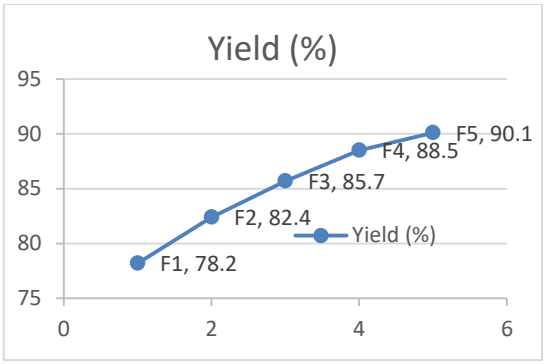

Table 7. Entrapment Efficiency

Formulation	Entrapment Efficiency (%)
F1	70.5
F2	75.2
F3	81.4
F4	86.8
F5	89.5

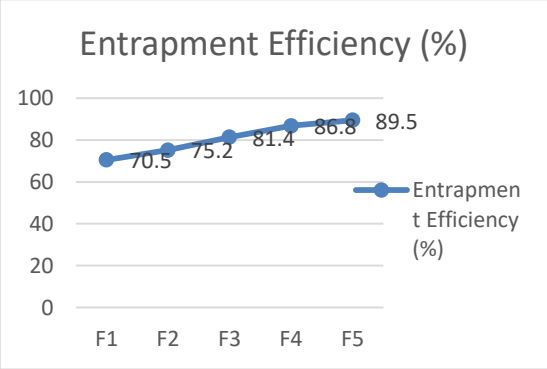

Fig.5. Entrapment Efficiency.

5. Preparation of Microsphere-Based Gel

Procedure

1. Carbopol 934 dispersed in distilled water.
2. Allowed to hydrate overnight.
3. Microspheres added slowly under stirring.
4. Preservative incorporated.
5. pH adjusted with Triethanolamine.
6. Gel packed in airtight containers.

Table 8. Gel Formulation Composition

Ingredients	G1	G2	G3
Microspheres (%)	1	2	3
Carbopol 934 (%)	1	1	1
Methyl Paraben (%)	0.1	0.1	0.1
TEA q.s.	q.s.	q.s.	q.s.
Water	Up to 100 g	Up to 100 g	Up to 100 g

6. Evaluation of Microsphere-Based Gel

Appearance

Color, homogeneity and consistency visually examined.

Table 9. Physical Appearance

Formulation	Color	Homogeneity	Consistency
G1	Light Green	Good	Smooth
G2	Light Green	Excellent	Smooth
G3	Green	Excellent	Smooth

pH Determination

Table 10 pH Measurement

Formulation	pH
G1	6.2
G2	6.5
G3	6.8

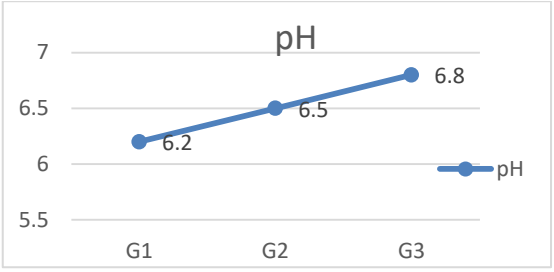

Fig.6. pH Measurement

Viscosity

Measured using Brookfield Viscometer.

Table 11 Viscosity

Formulation	Viscosity (cps)
G1	24500
G2	27100
G3	29500

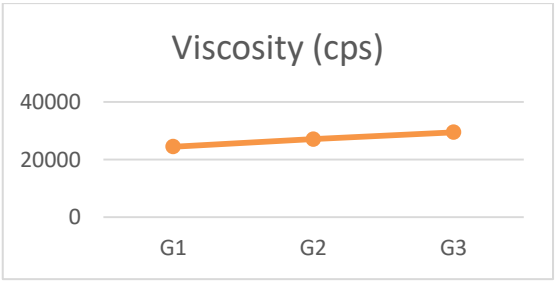

Fig.7. Viscosity.

Spreadability

Formula

$$S = \frac{M \times L}{T}$$

Where:

- S = Spreadability
- M = Weight tied to upper slide
- L = Length moved by slide
- T = Time taken

Table 12 Spreadability

Formulation	Spreadability (g.cm/sec)
G1	12.8
G2	14.5
G3	16.2

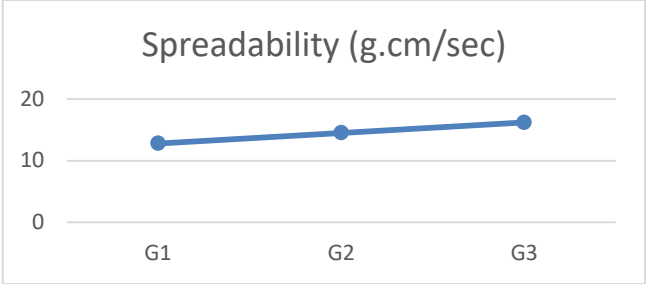

Fig.8. Spreadability.

7. In-Vitro Drug Release Study

Drug release performed using Franz diffusion cell.

Table 13 Cumulative Drug Release

Time (hr)	G1 (%)	G2 (%)	G3 (%)
1	18.2	15.8	12.6
2	30.4	28.5	24.1
4	48.6	45.2	40.8
6	65.5	60.3	56.2
8	79.8	75.6	71.5
12	91.2	88.4	84.8

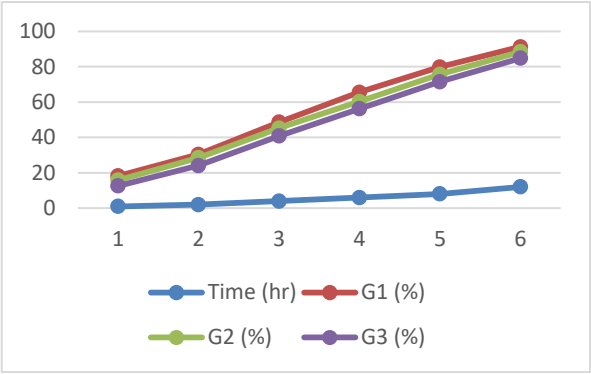

Fig.9. Cumulative Drug Release.

8. Antibacterial Activity Study

Test Organisms

- Staphylococcus aureus
- Escherichia coli
- Pseudomonas aeruginosa

Agar well diffusion method was employed.

Table 14 Zone of Inhibition

Formulation	S. aureus (mm)	E. coli (mm)	P. aeruginosa (mm)
Standard	25.3	24.8	22.5
G1	18.4	17.2	16.8
G2	21.7	20.9	19.4
G3	24.5	23.2	21.6

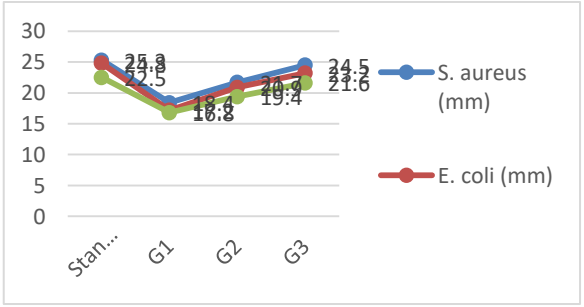

Fig.10. Zone of Inhibition.

9. Stability Studies

According to ICH Guidelines.

Storage Conditions:

- 25 ± 2°C / 60 ± 5% RH
- 40 ± 2°C / 75 ± 5% RH

Table 15 Stability Study Results

Month	pH	Viscosity (cps)	Drug Content (%)
Initial	6.5	27100	99.2
1 Month	6.5	26980	98.8
2 Month	6.4	26850	98.4
3 Month	6.4	26720	97.9

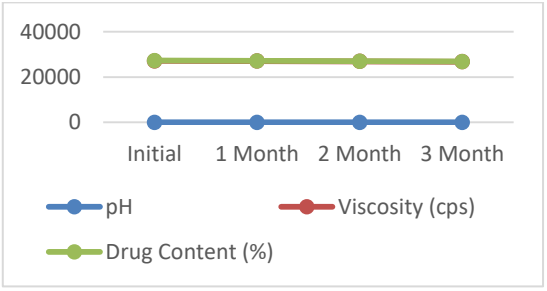

Fig.4.11 Stability Study Results.

10. Statistical Analysis

All experiments were conducted in triplicate (n=3). Data were expressed as Mean ± SD. Statistical analysis was performed using one-way ANOVA followed by Tukey's post hoc test. A value of $p < 0.05$ was considered statistically significant.

Results and Analysis

The present study was undertaken to develop and evaluate a herbal microsphere-based topical gel containing antibacterial herbal extracts for the treatment of bacterial skin infections. Various formulations of herbal microspheres (F1–F5) were prepared using different polymer concentrations and incorporated into topical gel formulations (G1–G3). The prepared formulations were evaluated for particle size, percentage yield, entrapment efficiency, morphology, physicochemical characteristics, drug release behavior, antibacterial activity, and stability.

The obtained results demonstrated that the prepared herbal microspheres successfully encapsulated the herbal extract and provided controlled drug release with enhanced antibacterial activity.

4.1 Evaluation of Herbal Microspheres

1. Particle Size Analysis

Particle size plays a significant role in determining drug release and skin penetration characteristics. The particle size increased with increasing polymer concentration due to higher viscosity of the dispersed phase.

Table 16 Particle Size of Microspheres

Formulation	Polymer Concentration (mg)	Particle Size (µm)
F1	100	112.5 ± 2.1
F2	150	125.8 ± 2.4
F3	200	138.4 ± 3.2
F4	250	151.7 ± 2.8
F5	300	168.3 ± 3.4

Interpretation

The particle size of the prepared herbal microspheres increased with increasing polymer concentration. Formulation F1 showed the smallest particle size (112.5 ± 2.1 µm), while F5 exhibited the largest particle size (168.3 ± 3.4 µm). This increase may be attributed to the higher viscosity of the polymer solution, which produced larger emulsion droplets during microsphere formation. The results indicate a direct relationship between polymer concentration and particle size. Among all formulations, F3 (138.4 ± 3.2 µm) showed an optimum particle size suitable for topical drug delivery, with good uniformity and controlled release characteristics.

2. Percentage Yield

Percentage yield indicates the efficiency of the preparation method.

Table 17 Percentage Yield of Microspheres

Formulation	Practical Yield (mg)	Percentage Yield (%)
F1	156	78.2 ± 1.2
F2	165	82.4 ± 1.4
F3	171	85.7 ± 1.1
F4	177	88.5 ± 1.3
F5	180	90.1 ± 1.5

Interpretation

The percentage yield of the prepared herbal microspheres increased from 78.2 ± 1.2% for F1 to 90.1 ± 1.5% for F5 as the polymer concentration increased. The higher polymer content reduced material loss during the preparation process and improved microsphere formation efficiency. Formulation F5 exhibited the highest percentage yield, indicating better recovery of the formulated product. The results demonstrate that polymer concentration significantly influences microsphere yield, and all formulations showed satisfactory production efficiency with good reproducibility.

3. Entrapment Efficiency

Entrapment efficiency determines the amount of herbal extract encapsulated within microspheres.

Table 18 Entrapment Efficiency

Formulation	Drug Content (%)	Entrapment Efficiency (%)
F1	70.5 ± 1.2	70.5 ± 1.2
F2	75.2 ± 1.4	75.2 ± 1.4
F3	81.4 ± 1.3	81.4 ± 1.3
F4	86.8 ± 1.5	86.8 ± 1.5
F5	89.5 ± 1.6	89.5 ± 1.6

Interpretation

The entrapment efficiency of the herbal microspheres increased with increasing polymer concentration, ranging from 70.5 ± 1.2% in F1 to 89.5 ± 1.6% in F5. The higher polymer content provided a larger matrix for encapsulation, thereby reducing drug leakage during microsphere preparation and enhancing drug retention. Formulation F5 showed the highest entrapment efficiency, indicating superior encapsulation of the herbal extract. These results suggest that polymer concentration plays a crucial role in improving drug loading and encapsulation efficiency in microsphere formulations.

Conclusion

The present research work was successfully carried out with the objective of developing a controlled-release herbal topical formulation capable of enhancing antibacterial efficacy while minimizing the limitations associated with conventional topical therapies. The study focused on the encapsulation of herbal extract into polymeric microspheres followed by incorporation into a topical gel base to improve drug stability, controlled release, and therapeutic effectiveness.

Herbal microspheres were successfully prepared using the solvent evaporation technique with different polymer concentrations. The prepared microspheres exhibited satisfactory physicochemical characteristics, including acceptable particle size, high production yield, and efficient drug entrapment. The particle size of the microspheres increased with increasing polymer concentration, indicating the influence of polymer content on microsphere formation. Entrapment efficiency was found to increase significantly with increasing polymer concentration, demonstrating the ability of the polymer matrix to effectively encapsulate the herbal extract and prevent drug loss during formulation.

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