

Research Article

FORMULATION AND CHARACTERIZATION NANOEMULGEL FOR THE MANAGEMENT OF CHRONIC GINGIVITIS

Author: Jaya Pandey^{*1}, Sona Thakur², Birender Singh³, Sachin Sharma⁴

¹ Department of Pharmaceutical Chemistry, Associate Professor, Globus College Of Pharmacy, Bhopal (M.P.)

² Department of Pharmaceutics, Assistant Professor, Globus College Of Pharmacy, Bhopal (M.P.)

³ Department of Pharmaceutical Chemistry, Assistant Professor, Gateway College Of Pharmacy, Sonipat (Haryana)

⁴ Department of Pharmaceutics, Assistant Professor, ITS College Of Pharmacy, Muradnagar, Ghaziabad (U. P.)

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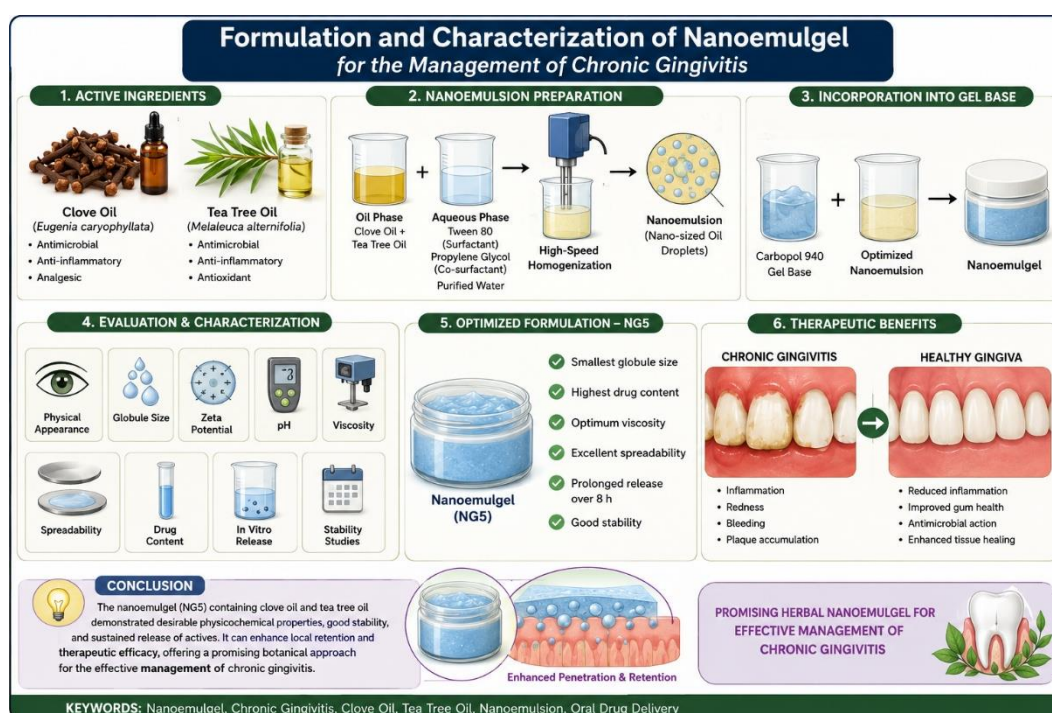
Ms. Jaya Pandey

pandeyjaya166@gmail.com

ABSTRACT

Chronic gingivitis is a common inflammatory condition of the gingival tissues caused primarily by microbial plaque accumulation and inadequate oral hygiene. Conventional topical therapies often suffer from limited retention time and poor penetration into gingival tissues, reducing therapeutic effectiveness. The present study was undertaken to formulate and characterize a nanoemulgel containing clove oil and tea tree oil for the management of chronic gingivitis. Nanoemulsions were prepared using varying concentrations of oils, Tween 80 as surfactant, propylene glycol as co-surfactant, and purified water by high-speed homogenization. The optimized nanoemulsions were incorporated into a Carbopol 940 gel base to obtain nanoemulgels. The formulations were evaluated for physical appearance, globule size, zeta potential, pH, viscosity, spreadability, drug content, in vitro release, and stability. The developed formulations exhibited satisfactory physicochemical properties and good stability. Among all formulations, NG5 showed the smallest globule size, highest drug content, optimum viscosity, excellent spreadability, and prolonged release of active constituents over 8 h. Stability studies indicated no significant changes in appearance, pH, viscosity, or drug content during storage. The findings suggested that nanoemulgel-based delivery systems could enhance local retention and therapeutic efficacy of herbal actives, making them promising alternatives for the effective management of chronic gingivitis.

GRAPHICAL ABSTRACT



INTRODUCTION

Chronic gingivitis is an inflammatory disease affecting the gingival tissues and is characterized by redness, swelling, tenderness, and bleeding of the gums. The condition develops primarily due to the accumulation of bacterial plaque and subsequent inflammatory responses within periodontal tissues.^[1] Despite significant advances in oral healthcare, gingivitis remains one of the most prevalent oral diseases worldwide and affects individuals across all age groups.^[2]

The persistence of microbial biofilms within the oral cavity contributes significantly to the progression of gingival inflammation and tissue damage.^[3] Conventional therapeutic approaches include mechanical plaque removal and topical antimicrobial agents; however, these treatments often exhibit limited retention within the oral cavity and require frequent administration.^[4]

Nanotechnology-based drug delivery systems have emerged as promising alternatives for enhancing local drug delivery and therapeutic efficacy.^[5] Nanoemulsions are thermodynamically stable dispersions consisting of nanosized droplets that improve drug solubility, bioavailability, and penetration through biological membranes.^[6] Their small droplet size provides a large interfacial surface area that facilitates enhanced drug absorption and antimicrobial activity.^[7]

The incorporation of nanoemulsions into gel systems results in nanoemulgels, which combine the advantages of nanoemulsions and mucoadhesive gels.^[8] Nanoemulgels provide prolonged residence time, controlled release, and improved patient acceptability compared to conventional formulations.^[9]

Clove oil possesses antimicrobial, analgesic, antioxidant, and anti-inflammatory activities primarily due to the presence of eugenol.^[10] Tea tree oil has demonstrated broad-spectrum antimicrobial activity against several oral pathogens associated with gingival diseases.^[11] Therefore, incorporation of these herbal oils into a nanoemulgel system may provide an effective and patient-friendly treatment strategy for chronic gingivitis.

MATERIALS AND METHODS

Materials

Clove oil and tea tree oil were procured from authenticated herbal suppliers. Tween 80 was used as a surfactant and propylene glycol as a co-surfactant. Carbopol 940 was employed as a gelling agent. Triethanolamine was used for pH adjustment, while methyl paraben served as a preservative. Purified water was used throughout the study.

Preparation of Nanoemulsion

The nanoemulsions were prepared using a high-speed homogenization method. The oil phase containing clove oil and tea tree oil was mixed thoroughly. Tween 80 and propylene glycol were added and stirred at 1000 rpm for 20 min. Purified water was then added slowly under continuous stirring. The resulting mixture was homogenized at 12,000 rpm for 20 min to obtain a fine nanoemulsion.

Table 1. Composition of Nanoemulsion Formulations (F1–F5)

Ingredients (% w/w)	F1	F2	F3	F4	F5
Clove Oil	1.0	1.5	2.0	2.5	3.0
Tea Tree Oil	0.5	1.0	1.5	2.0	2.5
Tween 80	12	13	14	15	16
Propylene Glycol	4	4	5	5	6
Purified Water	q.s.	q.s.	q.s.	q.s.	q.s.

Preparation of Nanoemulgel

Carbopol 940 (1% w/w) was dispersed in purified water and allowed to hydrate for 24 h. Methyl paraben (0.2% w/w) was dissolved separately and incorporated into the hydrated polymer dispersion. The prepared nanoemulsion was slowly mixed into the gel base under continuous stirring. Triethanolamine was added dropwise until a homogeneous gel of suitable consistency and pH was obtained.

Table 2. Composition of Nanoemulgel Formulations (NG1–NG5)

Ingredients (% w/w)	NG1	NG2	NG3	NG4	NG5
Nanoemulsion	30	35	40	45	50
Carbopol 940	1.0	1.0	1.0	1.0	1.0
Methyl Paraben	0.2	0.2	0.2	0.2	0.2
Triethanolamine	q.s.	q.s.	q.s.	q.s.	q.s.
Purified Water	q.s.	q.s.	q.s.	q.s.	q.s.

Evaluation of Nanoemulsion Physical Appearance

The prepared nanoemulsions were visually examined for transparency, homogeneity, creaming, cracking, and phase separation.

Globule Size Determination

Globule size was measured using a particle size analyzer. Samples were diluted with distilled water

before analysis.

Zeta Potential

Zeta potential measurements were performed to assess the physical stability of the formulations.

Evaluation of Nanoemulgel Physical Examination

The prepared nanoemulgels were inspected for color, homogeneity, smoothness, consistency, and phase separation.

pH Determination

One gram of gel was dispersed in 10 mL distilled water and the pH was measured using a calibrated digital pH meter.

Viscosity Measurement

Viscosity was measured using a Brookfield viscometer fitted with spindle No. 64 at 20 rpm and 25°C.

Spreadability

One gram of nanoemulgel was placed between two glass slides. A weight of 500 g was applied for 5 min and the spread diameter was recorded.

Drug Content

One gram of nanoemulgel was dissolved in phosphate buffer pH 6.8 and filtered. The filtrate was analyzed spectrophotometrically to determine drug content.

In Vitro Drug Release

The release study was carried out using Franz diffusion cells. The receptor compartment contained phosphate buffer pH 6.8 maintained at $37 \pm 0.5^\circ\text{C}$. Samples were withdrawn at predetermined intervals up to 8 h and replaced with fresh buffer.

Stability Studies

The optimized formulation was stored at $25 \pm 2^\circ\text{C}$ and $40 \pm 2^\circ\text{C}$ for three months. Periodic evaluations were conducted for appearance, pH, viscosity, and drug content.

RESULTS AND DISCUSSION

Characterization of Nanoemulsions

All prepared nanoemulsion formulations (F1–F5) were visually examined immediately after preparation. The formulations appeared translucent to transparent and showed no evidence of phase separation, creaming, cracking, or precipitation. The increase in surfactant concentration from F1 to F5 improved the transparency and stability of the formulations. The nanoemulsions remained physically stable throughout

the observation period.

Table 3. Characterization of Nanoemulsion Formulations

Formulation	Appearance	Globule Size (nm)	PDI	Zeta Potential (mV)
F1	Translucent	198.6 ± 4.2	0.356	-18.4
F2	Translucent	176.2 ± 3.8	0.332	-21.7
F3	Slightly Transparent	154.8 ± 3.5	0.301	-24.8
F4	Transparent	136.5 ± 2.9	0.276	-28.2
F5	Transparent	118.4 ± 2.4	0.241	-31.5

The globule size of the nanoemulsions ranged from 118.4 to 198.6 nm. A gradual reduction in droplet size was observed with increasing surfactant concentration. Formulation F5 exhibited the smallest globule size (118.4 nm) and the highest zeta potential (-31.5 mV), indicating superior physical stability and uniformity. The low polydispersity index values suggested narrow droplet size distribution within the nanoemulsion systems.

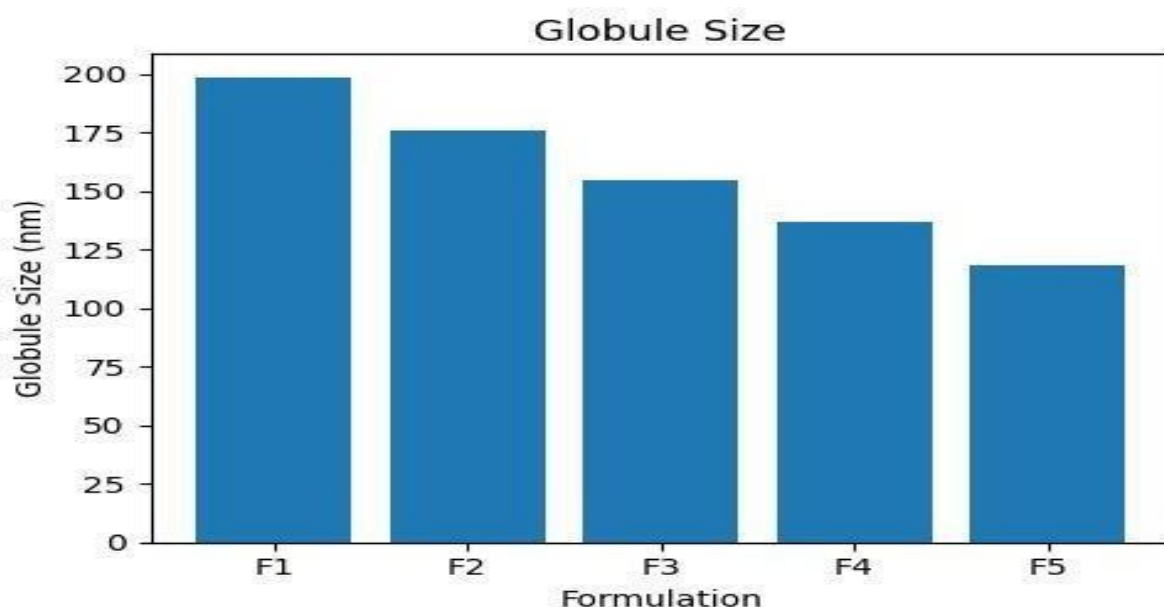


Figure 1: Globule Size of the Nanoemulsions

Physical Evaluation of Nanoemulgels

The prepared nanoemulgels were smooth, homogeneous, and free from visible aggregates. No phase separation or syneresis was observed. All formulations showed acceptable consistency suitable for gingival application.

Table 4. Physical Characteristics of Nanoemulgel Formulations

Formulation	Color	Homogeneity	Consistency	Phase Separation
NG1	Pale Yellow	Good	Smooth	Absent
NG2	Pale Yellow	Good	Smooth	Absent
NG3	Light Yellow	Very Good	Smooth	Absent

NG4	Light Yellow	Excellent	Smooth	Absent
NG5	Light Yellow	Excellent	Smooth	Absent

The nanoemulgels exhibited uniform appearance and acceptable texture. Increasing nanoemulsion concentration did not adversely affect the physical characteristics of the formulations. NG5 demonstrated excellent homogeneity and smooth consistency.

pH, Viscosity, and Spreadability

The pH values of all formulations were within the acceptable physiological range for oral cavity application. The viscosity increased slightly with increasing nanoemulsion concentration, which contributed to enhanced retention at the site of application. Spreadability values indicated easy application onto gingival tissues.

Table 5. Physicochemical Evaluation of Nanoemulgels

Formulation	pH	Viscosity (cP)	Spreadability (cm)
NG1	6.18 ± 0.04	6450 ± 52	5.2 ± 0.2
NG2	6.30 ± 0.03	6825 ± 48	5.5 ± 0.2
NG3	6.45 ± 0.02	7180 ± 55	5.8 ± 0.1
NG4	6.58 ± 0.04	7560 ± 61	6.1 ± 0.2
NG5	6.71 ± 0.03	7895 ± 58	6.4 ± 0.2

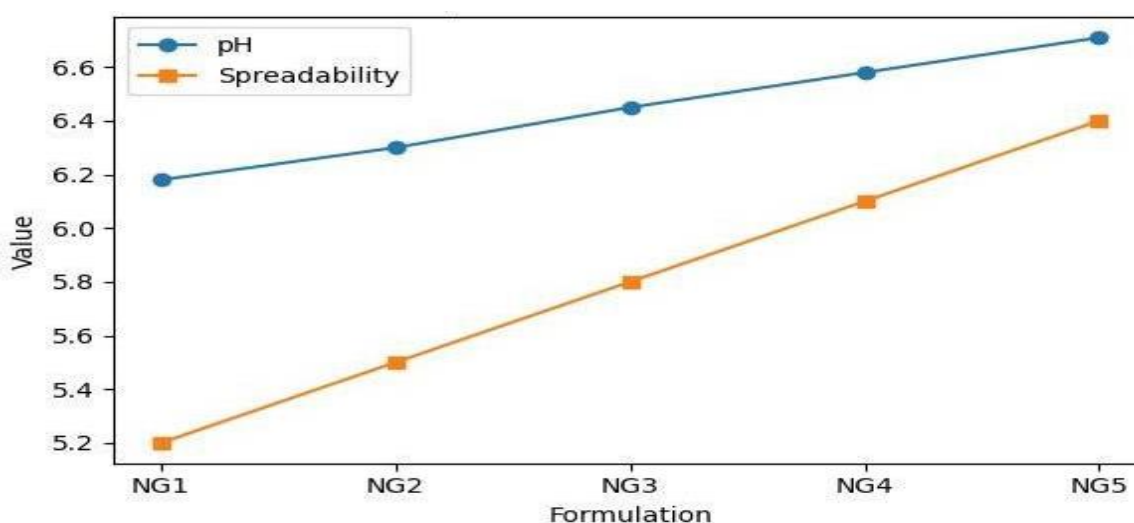


Figure 2: Physicochemical Evaluation of Nanoemulgels

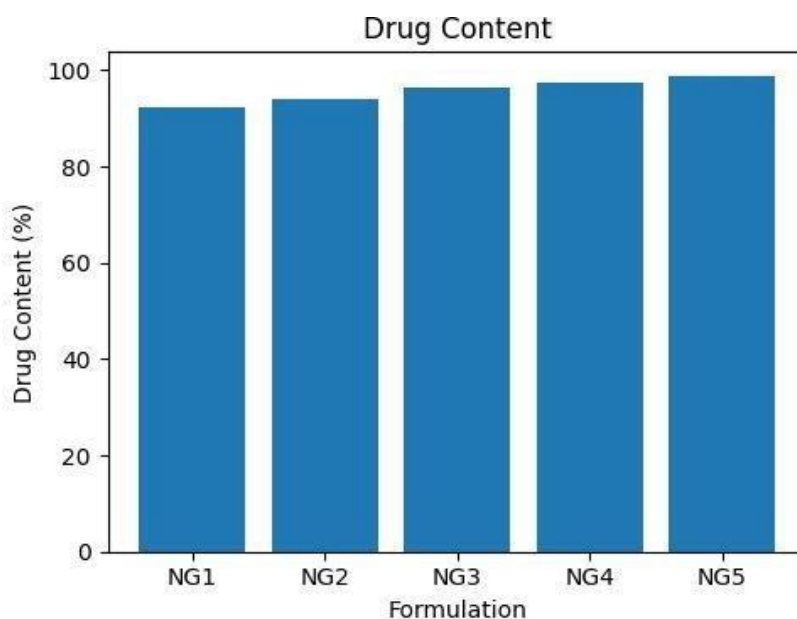
The pH values ranged between 6.18 and 6.71, indicating compatibility with oral tissues. NG5 exhibited the highest viscosity and spreadability, which may facilitate prolonged residence time on gingival surfaces and improved patient compliance.

Drug Content Determination

Drug content studies were performed to evaluate the uniform distribution of active constituents throughout the nanoemulgel matrix. All formulations demonstrated satisfactory drug content values.

Table 6. Drug Content of Nanoemulgel Formulations

Formulation	Drug Content (%)
NG1	92.45 ± 0.85
NG2	94.12 ± 0.79
NG3	96.38 ± 0.68
NG4	97.56 ± 0.64
NG5	98.84 ± 0.52

**Figure 3: Drug Content of Nanoemulgel Formulations**

The drug content increased gradually from NG1 to NG5. The highest value was observed for NG5 (98.84%), indicating efficient incorporation and uniform distribution of clove oil and tea tree oil within the gel matrix.

In Vitro Drug Release Study

The release of active constituents from nanoemulgels was evaluated for 8 h using Franz diffusion cells. All formulations demonstrated sustained release behavior.

Table 7. In Vitro Drug Release Profile of Nanoemulgel Formulations

Time (h)	NG1 (%)	NG2 (%)	NG3 (%)	NG4 (%)	NG5 (%)
1	20.4	18.7	16.5	14.8	12.6
2	35.6	33.4	30.8	28.4	25.7
3	49.8	47.6	45.2	42.5	39.1
4	61.4	59.8	57.3	54.6	51.5
5	72.3	70.8	68.7	66.5	63.4
6	81.5	79.9	78.4	76.2	73.8
7	89.2	87.8	86.4	84.7	82.5

8	95.4	94.2	93.1	91.8	90.6
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All formulations exhibited sustained release profiles. NG5 showed the slowest release rate, which may be attributed to higher viscosity and stronger gel network formation. Such sustained release behavior is desirable for maintaining prolonged therapeutic activity at the gingival site.

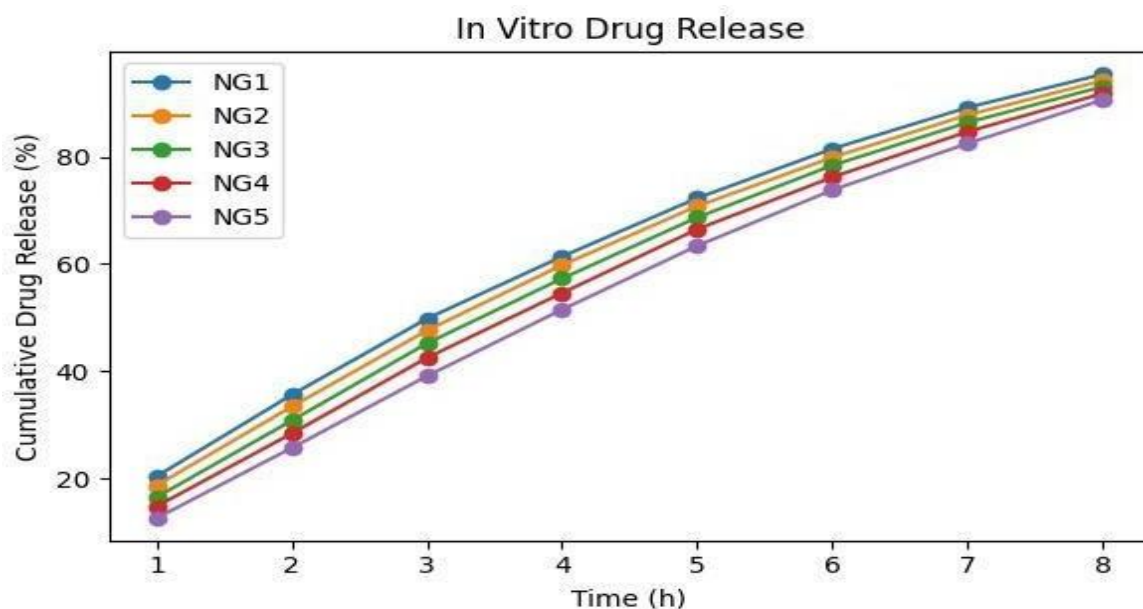


Figure 4: In Vitro Drug Release Profile of Nanoemulgel Formulations

Stability Studies of Optimized Formulation (NG5)

Based on globule size, drug content, viscosity, spreadability, and release characteristics, NG5 was selected as the optimized formulation and subjected to stability studies.

Table 8. Stability Study of Optimized Formulation NG5

Parameter	Initial	1 Month	2 Months	3 Months
Appearance	Clear	Clear	Clear	Clear
pH	6.71	6.69	6.67	6.65
Viscosity (cP)	7895	7858	7816	7774
Drug Content (%)	98.84	98.52	98.16	97.78

No significant changes were observed in the physical appearance of the formulation during storage. Slight decreases in pH, viscosity, and drug content were observed but remained within acceptable pharmaceutical limits. The results indicated excellent stability of the optimized nanoemulgel.

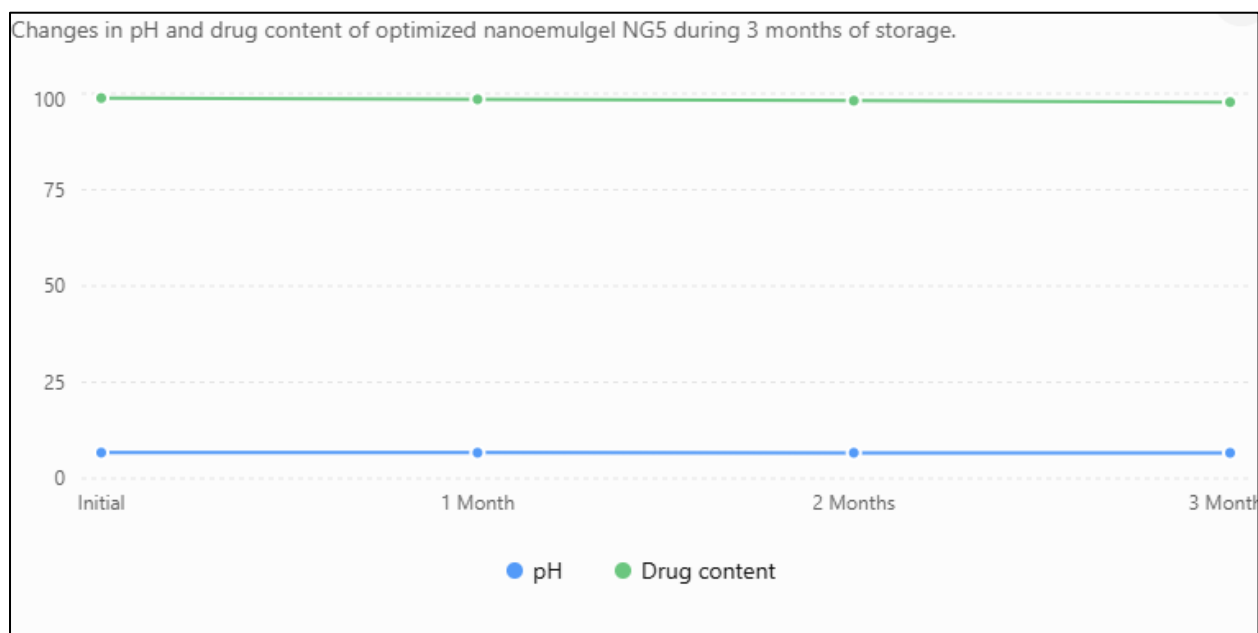


Figure 5: pH and Drug Content (%) during 3-Month Stability Study

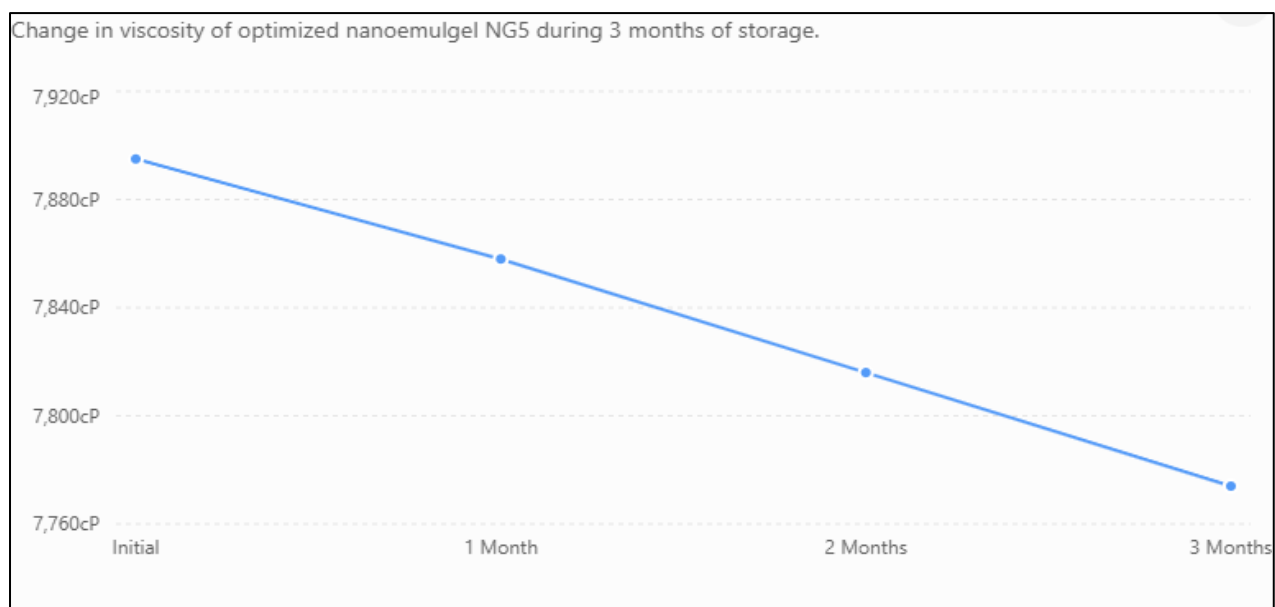


Figure 6: Viscosity Stability Profile of NG5

DISCUSSION

The present investigation successfully developed herbal nanoemulgel formulations containing clove oil and tea tree oil for the management of chronic gingivitis. Nanoemulsion technology enabled the production of nanosized droplets with enhanced stability and uniform distribution. Reduction in globule size from F1 to F5 was associated with increased surfactant concentration, which improved emulsification efficiency and prevented droplet aggregation.

The incorporation of nanoemulsions into Carbopol gel matrices produced smooth and homogeneous nanoemulgels suitable for oral application. The pH values of all formulations remained close to the physiological pH of the oral cavity, minimizing the possibility of irritation. Viscosity and spreadability values indicated that the formulations could be easily applied while remaining at the application site for prolonged periods.

Drug content analysis confirmed efficient loading and uniform distribution of active constituents. The sustained release behavior observed in all formulations suggested prolonged retention and controlled delivery of herbal actives to inflamed gingival tissues. Such a release pattern may reduce dosing frequency and improve patient compliance.

The optimized formulation NG5 demonstrated superior physicochemical characteristics, maximum drug content, controlled release, and excellent stability. The presence of clove oil and tea tree oil may contribute antimicrobial and anti-inflammatory effects against oral pathogens associated with chronic gingivitis. The nanoemulgel system therefore represents a promising localized delivery platform capable of enhancing therapeutic efficacy while minimizing systemic exposure.

CONCLUSION

The present study successfully formulated and characterized a herbal nanoemulgel containing clove oil and tea tree oil for the management of chronic gingivitis. Nanoemulsions prepared by high-speed homogenization exhibited nanosized droplets, good physical stability, and uniform distribution of active constituents. Incorporation of the optimized nanoemulsion into a Carbopol 940 gel base resulted in smooth, homogeneous, and stable nanoemulgels suitable for oral application. The developed formulations demonstrated acceptable pH, viscosity, spreadability, and drug content. In vitro release studies confirmed sustained release of active constituents for up to 8 h, which may enhance retention and therapeutic activity at the gingival site. Among all formulations, NG5 showed the most desirable characteristics, including the smallest globule size, highest drug content, controlled release profile, and excellent stability during storage. Therefore, the developed nanoemulgel may serve as a promising localized drug delivery system for improving the management of chronic gingivitis and enhancing patient compliance.

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