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Research Paper

Formulation and Evaluation of Nanoemulgel loaded with Ethanolic Extract of Polianthes tuberosa for Topical Anti-Inflammatory and Antioxidant Activity

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ABSTRACT

The aim of the current study was to develop and test a topical anti-inflammatory gel formulation of ethanol extract of Polianthes tuberosa with improved therapeutic activity. The flowers of Polianthes tuberosa were collected, dried, powdered and ethanol extraction was obtained by adopting cold maceration method. The phytochemical monitoring of the extract showed the presence of alkaloids, flavonoids, presence of protein, tannins, and phenolic compound, Glycosides, Terpenoids and Saponins indicating the possible applications of the extract in pharmaceutical or pharmacological activities. Formulated gel products (F1- F3) with Carbopol 940 as gelling agent as topical dosage were evaluated on some physicochemical properties which include appearance, homogeneity, pH, viscosity, spreading time and drug content. The drug content uniformity, spread ability and optimum viscosity and drug pH values of the formulations were satisfactory among all the formulations F2 was having maximum drug content uniformity and it was very much appropriate in respect of other parameters. Antioxidant activity of the optimized formulation was determined by DPPH radical scavenging assay where considerable free radical scavenging activity of the formulation of increasing concentrations was observed. Further in-vitro anti inflammatory activity was also performed using protein denaturation assay which showed good anti-inflammatory effect on the sample. Moreover, in-vitro drug release study was also carried out on Franz diffusion cell indicating controlled and sustained drug release of the active constituents

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for a long period. The results of the stability studies showed that the optimized formulation is stable upon the different storage conditions in term of physical / chemical property. It can be concluded from the result of the present investigation that, the herbal gel formulation created in the present investigation appears to be expected in its promising antioxidant and anti-inflammatory activity which can be a substitute of synthetic topical anti-inflammatory formulation.

INTRODUCTION

Inflammation is a natural process of the body which occurs when there is a threatening invasion such as bacteria or other harmful microbes, damaged cells or irritants, it's characteristics include redness, swelling, pain, heat or loss of function. Acute (shortterm) inflammation is a protective process and chronic (longterm) is related to arthritis, dermatitis, and auto-immune diseases. Although systemic therapies (e.g., oral anti-inflammatory drugs) are often used, they are known to have some unwanted side effects such as gastrointestinal irritation, four, cardiovascular issues and poor patient compliance. The drug delivery systems are therefore very attractive because of the localized action, systemic exposure is reduced, first pass effect is avoided and higher therapeutic effects are obtained. Gels are particularly preferred among a variety of topical formulations because they have desirable characteristics which include non-greasy, ease of application, good spreadability, and controlled drug release. [1,2]

Anti-inflammatory medications such as non-steroidal anti-inflammatory drugs (NSAIDs) like diclofenac and ibuprofen also help to reduce inflammation, by inhibiting enzymes called cyclooxygenases in the body which suppress the production of prostaglandins. Long term use of these agents, however, might result in side effects such as ulcers, allergic reactions, skin irritations and poor penetration of the skin using topical products. This has motivated people in search for

alternative herbs which maybe safer and effective. Mutually derived medications that are used in herbal remedy are a great source of bioactive compounds such as flavonoids, alkaloids, tannins, phenolics and essential oils which exhibit strong anti-inflammatory and antioxidant potencies. In addition, herb based formulation may have the synergistic therapeutic effects with minimal side effects and biocompatible with the human body. Moreover, the advancement in technology of modern pharmaceutical preparations has led to the development of novel drug delivery approaches to aid stability and bioavailability of herbal compounds, which includes gels, nanoemulgels and transdermal patches. [3,4]

Tuberoze or Polianthes tuberosa (L.) Spreng. – Perennial shrub with fragrant flowers, and a popular ornamental plant. Not only its ornamental and perfumery properties, but the plant has also been a source of scientific interest for its possible use as a medicinal plant. Phytochemical analysis has revealed that the extract of this plant contains flavonoids, phenolic compounds, glycosides and essential oils, particularly the ethanolic extract, with antioxidant, anti-inflammatory, antimicrobial and analgesic properties. Various bioactive compounds in it can help abolish inflammatory pathways, and act as a free radical scavenger; that property can be utilized to make it as a natural anti-inflammatory. However, the use of Polianthes tuberosa in any formulation (particularly for topical use) is still relatively unknown and another study for making “effective herbal topical product” is needed. [5,6]

MATERIALS AND METHODS

1. Plant Collection, Authentication, and Processing

Polianthes tuberosa flowers were collected right from the field during the flowering period from Kolhapur, Maharashtra, India. The plants of the study was identified and purity of plant specimen



was maintained with the help of an expert Dr. Yogesh Suresh Kolekar, Department of Pharmaceutical Quality Assurance, New College of Pharmacy, Kolhapur from normal taxonomical characters according to the guidelines of World Health Organization (WHO). [7]

The gathered flowers were washed well with tap water and then double distilled water to eliminate soil particle, other foreign contaminant and dust. Cleaned material was then shade dry at room temperature till it attained a constant weight to preserve thermolabile phytoconstituents.

The flowers were powdered using a mechanical grinder, after drying. The powdered materials was stored in clean, dry, airtight glass container and stored under proper condition to be used in extraction and formulation studies.

2. Plant Material Extraction

Preliminary phytochemical screening was conducted by extracting powdered dried compound by different solvents nhexane, Ethyl Acetate and methanol. Solution cold maceration method was used for extraction. [8]

To maximize the extraction of phytoconstituents in this method each plant substance powder (1g) was individually used with 1000ml of respective solvents and kept for 72 hours at room temperature with occasional shaking.

After maceration all the mixtures was first filtered with muslin cloth and then with Whatmann No.1 filter paper to obtain clear filtrates without coarser plant residue. Evaporation of the solvents from the filtrates was accomplished on a steam bath at about 50°C.

The concentrated extracts were subsequently stored under refrigerating temperature 4°C in covered container to be analyzed for its phytochemical constituents and formulation.

3. Phytochemical Screening (Qualitative Analysis)

The hydroalcoholic (ethanolic) extract of Polianthes tuberosa flowers was dizzyed and preliminary phytochemical screening was made to study different bioactive chemical constituents (alkaloids, flavonoids, tannins, phenolics, saponins, glycosides and terpenoids) through standard qualitative chemical tests.

The extract was made by dissolving a small amount of the dried extract in ethanol or distilled water whichever was appropriate to the constituents' solubility. The solution prepared was then subjected to various phytochemical tests of color reaction, precipitate formation and foam production. These tests provide a preliminary information whether a phytoconstituent is present or absent which is responsible for biological activity in bulk quantity.

Tests for Phytoconstituents:

1. Test for Alkaloids (Mayer's Test)

A small quantity of extract was added a few drops of Mayer's reagent.

Observation: A cream or light yellow precipitate may be due to the presence of alkaloids.

2. Test for Flavonoids (Shinoda Test)

The extract was treated with a small amount of magnesium turnings and concentrated hydrochloric acid.

Observation: Development of a pink, red, or orange color indicates the presence of flavonoids.

3. Test for Tannins (Ferric Chloride Test)

A few drops of 5% ferric chloride solution were added to the extract.

Observation: Formation of a blue-black or greenish-black coloration indicates the presence of tannins.

4. Test for Phenolic Compounds

The extract was treated with ferric chloride solution.



Observation: A deep blue or black coloration confirms the presence of phenolic compounds.

5. Test for Saponins (Foam Test)

The extract was diluted with distilled water and shaken vigorously.

Observation: Persistent foam formation for several minutes indicates the presence of saponins.

6. Test for Glycosides (Keller–Killiani Test)

The extract was treated with glacial acetic acid, ferric chloride, and concentrated sulfuric acid.

Observation: Formation of a brown ring at the

interface indicates the presence of cardiac glycosides.

7. Test for Terpenoids (Salkowski Test)

The extract was mixed with chloroform and concentrated sulfuric acid was added carefully.

Observation: A reddish-brown coloration at the interface indicates the presence of terpenoids.

8. Test for Proteins (Biuret Test)

The extract was treated with sodium hydroxide and copper sulfate solution.

Observation: Formation of a violet color indicates the presence of proteins.

Table.1 Phytochemical Screening

Sr. No.	Phytoconstituent	Test Performed	Observation	Result
1	Alkaloids	Mayer's Test	Cream ppt formed	+
2	Flavonoids	Shinoda Test	Pink/red color	+
3	Tannins	Ferric Chloride Test	Blue-black color	+
4	Phenolics	Ferric Chloride Test	No Deep blue/black color	-
5	Saponins	Foam Test	foam formation	+
6	Glycosides	Keller–Killiani Test	Brown ring at interface	+
7	Terpenoids	Salkowski Test	Reddish-brown coloration	+
8	Proteins	Biuret Test	Violet coloration	+

FORMULATION OF TOPICAL GEL

For preparing the Topical Gel, the Ethanolic extract of *Polianthes tuberosa* was mixed with gelling agent Carbopol 940. Carbopol was selected as the most suitable polymer based on the following properties: Good viscosity building properties, transparency and compatibility with most actives. Dispersion was neutralized with Triethanolamine, to make the stable gel matrix. [10]

The desired quantity of Carbopol 940 was first moisturized in distilled water for 24 hours before hydration is completed. *Polianthes tuberosa* ethanolic extract was individually dissolved in little quantity of ethanol, propylene glycol to improve its solubility. Methyl paraben was used as this preservative, dissolved in some warm water. The extract solution, Propylene Glycol and preservative solution were then gradually added

into the hydrated polymer with constant stirring to get a homogeneity in the mixture. Lastly, triethanolamine was added drop-wise to set the pH level and to form the dispersion in to a clear gel. The final product was made up to volume with distilled water and the solution well mixed to obtain a uniform gel consistency. [11]

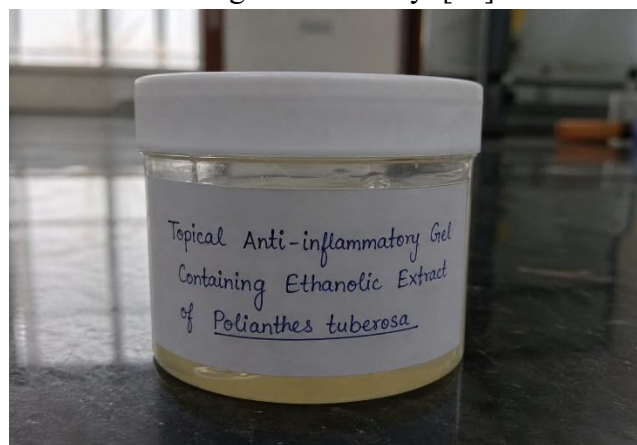


Figure 1. Gel Formulation

Table 2. Composition of Gel Formulations (F1, F2, F3)

Ingredients	F1 (% w/w)	F2 (% w/w)	F3 (% w/w)	Function
<i>Polianthes tuberosa</i> Extract	1	2	3	Active ingredient
Carbopol 940	0.5	1.0	1.5	Gelling agent
Propylene Glycol	10	10	10	Penetration enhancer
Methyl Paraben	0.2	0.2	0.2	Preservative
Triethanolamine	q.s.	q.s.	q.s.	pH adjuster/neutralizer
Distilled Water	q.s. to 100	q.s. to 100	q.s. to 100	Vehicle

EVALUATION OF GEL FORMULATION

The prepared gel formulations were evaluated for various physical and physicochemical parameters to ensure their suitability for topical application. [11]

1. Physical Evaluation

Color and Appearance

The prepared gels were visually inspected for color, transparency, and overall appearance against a white and black background.

Odor

The odor of the gel was evaluated manually by smelling the formulation to ensure acceptability.

Consistency

The consistency was determined by visual inspection and touch to assess smoothness, uniformity, and absence of grittiness.

2. Physicochemical Evaluation

pH Measurement

The pH of the gel was determined using a calibrated digital pH meter. About 1 g of gel was dispersed in 100 mL of distilled water and allowed to stand for 2 hours. The electrode was then immersed in the solution, and the pH was recorded.

Viscosity

Viscosity of the gel was measured using a Brookfield viscometer using appropriate spindle (e.g., spindle no. 64) at a fixed speed (e.g., 10 rpm) at room temperature.

Spreadability

Spreadability was determined using the slip and drag method.

Procedure:

- A known quantity of gel was placed between two glass slides
- A weight (e.g., 500 g) was placed on the upper slide
- Time taken for the upper slide to move a specified distance was noted

Formula:

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

Where:

- S = Spreadability (g·cm/sec)
- M = Weight tied to upper slide (g)
- L = Length of glass slide (cm)
- T = Time taken (sec)

Homogeneity

The gel formulations were tested for homogeneity by visual inspection after setting in the container. The formulations were checked for the presence of lumps, aggregates, or phase separation.

Drug Content Uniformity

Procedure:

- Accurately weighed quantity of gel (e.g., 1 g) was dissolved in suitable solvent (ethanol/phosphate buffer)
- The solution was filtered
- Absorbance was measured using UV-Visible spectrophotometer at λ_{max} of extract

Calculation:



Drug Content (%)

$$= \frac{\text{Actual drug content}}{\text{Theoretical drug content}} \times 10$$

Table 3. Combined Evaluation of Gel Formulations (F1–F3)

Parameter	F1	F2	F3
Color	Pale yellow	Light yellow	Yellowish
Appearance	Transparent	Transparent	Slightly opaque
Odor	Characteristic	Pleasant characteristic	Characteristic
Consistency	Smooth	Smooth and uniform	Highly viscous
Homogeneity	Good	Excellent	Good
pH	6.2 ± 0.03	6.8 ± 0.02	7.1 ± 0.04
Viscosity (cP)	4210 ± 15	4985 ± 18	5890 ± 20
Spreadability (g·cm/sec)	18.2 ± 0.4	24.6 ± 0.5	16.5 ± 0.3
Drug Content (%)	92.4 ± 0.8	98.7 ± 0.5	95.2 ± 0.7
Extrudability	Good	Excellent	Moderate
Washability	Good	Good	Moderate
Skin Irritation	No irritation	No irritation	Slight redness observed
Stability	Stable	Highly stable	Stable

Among all formulations, F2 showed optimum physicochemical characteristics with satisfactory pH, viscosity, spreadability, homogeneity, and highest drug content. The formulation also exhibited good stability and absence of skin irritation, indicating its suitability for topical anti-inflammatory application.

IN-VITRO ANTIOXIDANT ACTIVITY

1. DPPH Radical Scavenging Assay

The in-vitro antioxidant activity of the ethanolic extract of *Polianthes tuberosa* and the developed gel formulations was evaluated using the DPPH (2,2-diphenyl-1-picrylhydrazyl) radical scavenging assay. [12]

Principle

DPPH is a stable free radical that exhibits a deep violet color with a characteristic absorption at 517 nm. In the presence of an antioxidant, DPPH accepts hydrogen or electrons, resulting in a color change from violet to yellow. The degree of discoloration indicates the scavenging potential of the sample. [13]

Procedure

A 0.1 mM solution of DPPH was prepared in methanol. Different concentrations of the test samples (20, 40, 60, 80, and 100 µg/mL) were prepared. To 1 mL of each sample solution, 3 mL of DPPH solution was added and mixed thoroughly. The reaction mixtures were incubated in the dark at room temperature for 30 minutes.

After incubation, the absorbance was measured at 517 nm using a UV–Visible spectrophotometer against a blank. Methanol with DPPH served as the control, while ascorbic acid was used as a standard antioxidant for comparison. All experiments were carried out in triplicate (n = 3), and results were expressed as mean ± standard deviation. [14]

Calculation

$$\% \text{ Inhibition} = \frac{A_{\text{control}} - A_{\text{sample}}}{A_{\text{control}}} \times 100$$

Where:

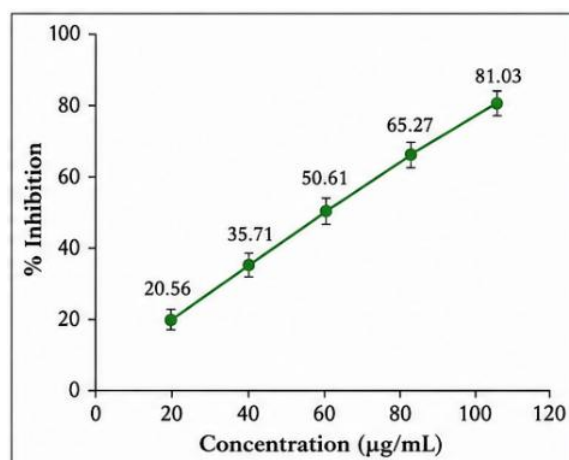
- A_{control} = Absorbance of control
- A_{sample} = Absorbance of sample

The IC₅₀ value (concentration required to inhibit 50% of DPPH radicals) was determined from the graph plotted between % inhibition and concentration. [15]



Table 4. DPPH Radical Scavenging Activity

Concentration (µg/mL)	Control Absorbance	Sample Absorbance	% Inhibition (Mean ± SD)
20	0.812	0.645	20.56 ± 0.42
40	0.812	0.522	35.71 ± 0.38
60	0.812	0.401	50.61 ± 0.45
80	0.812	0.282	65.27 ± 0.51
100	0.812	0.154	81.03 ± 0.63

**Figure 2. DPPH Antioxidant Activity Graph**

IN-VITRO ANTI-INFLAMMATORY ACTIVITY

1. Protein Denaturation Assay

Principle

Some known factors of inflammation are denaturation of proteins. Substance which can inhibit the denaturation of protein means that they may be anti-inflammatory. The agents that can inhibit the denaturation process are probably high in anti-inflammatory activity and, conversely, protein denatured can stimulate inflammation. [16]

Procedure

A milliliter of test sample (extract or gel formulation) was added to a 1 mL of A 1% BSA (reaction mixture). Phosphate buffer was used to adjust the pH of the mixture to 6.8.

This mixture was kept for 15 minutes at 37°C then denatured for 5 minutes at 70°C. The absorbance was then measured at 660 nm at various

temperature using UV–Visible spectrophotometer. Diclofenac sodium was also applied as a standard treatment, medications regularly used for the public. Each experiment was repeated 3 times and the data presented as mean ± SD. [17,18]

Calculation

$$\% \text{ Inhibition} = \frac{A_{\text{control}} - A_{\text{sample}}}{A_{\text{control}}} \times 100$$

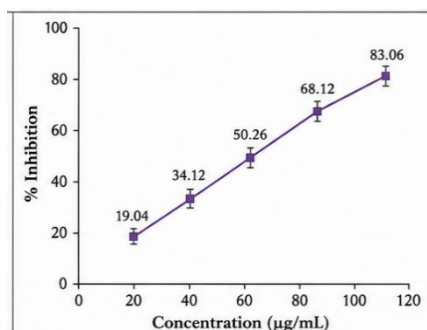
Where:

- A_{control} = Absorbance of control
- A_{sample} = Absorbance of sample

A higher percentage inhibition of protein denaturation indicates greater anti-inflammatory activity of the test sample. [19]

Table 5. Anti-inflammatory Activity by Protein Denaturation

Concentration ($\mu\text{g/mL}$)	Control Absorbance	Sample Absorbance	% Inhibition (Mean $\pm$ SD)
20	0.756	0.612	19.04 $\pm$ 0.31
40	0.756	0.498	34.12 $\pm$ 0.44
60	0.756	0.376	50.26 $\pm$ 0.47
80	0.756	0.241	68.12 $\pm$ 0.52
100	0.756	0.128	83.06 $\pm$ 0.65

**Figure 3. Anti-inflammatory Activity Graph**

IN-VITRO DRUG RELEASE STUDY

In-vitro drug release study of the formulated *Polianthes tuberosa* gel was performed by Franz diffusion cell where the release profile of the active constituents is tested from the formulated gel. [20]

1. Apparatus and Materials

The study examined the vertical Franz diffusion cell (consisting of donor and receptor compartment). The diffusion area was approximately 2-3 cm² and the receptor compartment volume was approximately 20mL - 25mL. The two compartments were separated from each other by a dialysis membrane (or appropriate synthetic membrane).

The medium used was phosphate buffer (pH 6.8) which is used to simulate the physiological conditions of the skin. The drug was distributed uniformly by stirring constantly in the medium and kept in thermostatically controlled water bath incubator at $37 \pm 0.5^\circ\text{C}$. [21]

2. Preparation of Membrane

The dialysis membrane was soaked in phosphate buffer (pH 6.8) for not less than 12 hours before

use to ensure that it is soaked sufficiently inside and out of the preservatives that are present in the membrane. Now, it was carefully hydrated and placed between the donor and the receptor compartment in the Franz diffusion cell.

3. Procedure

A known amount of weight of the gel formulation (known dose of drug/extract) was evenly applied to the donor side of the membrane. The receptor compartment was filled with newly-prepared phosphate buffer (pH 6.8) and an external voltage was applied to polarize. The receptor compartment was refilled with fresh phosphate buffer (pH 6.8) and avoid bubbles under the membrane.

The entire set up was maintained at the specified temperature ($37 \pm 0.5^\circ\text{C}$) and the velocity of stirring of the receptor medium was kept at a constant (e.g., 50-100) RPM. Sink was maintained by removing at certain time intervals (0, 15, 30, 60, 120, 180, 240, 300, 360-minutes) a constant aliquot (1mL) of receptor media and replacing it by the same volume of buffer media. [22]

The withdrawn samples were diluted suitably, if necessary and were analysed with a UV-Visible spectrophotometer at the predetermined λ_{max} of the extract. Triplicate experiments ($n = 3$) were



performed and the data are shown as the mean $\pm$ SEM. [23]

4. Calculation of Drug Release

The cumulative amount of drug released was calculated based on the absorbance values obtained from the calibration curve.

Cumulative % Drug Release

$$= \frac{\text{Amount of drug released at time } t}{\text{Total drug content}} \times 100$$

The cumulative percentage drug release was plotted against time to evaluate the release profile and release kinetics of the gel formulation [24]

Table 6. In-vitro Drug Release Profile

Time (min)	Absorbance	Drug Released (mg)	Cumulative Drug Release (%)
0	0.000	0.00	0
15	0.112	1.12	12.4
30	0.185	1.85	24.8
60	0.276	2.76	38.6
120	0.391	3.91	54.2
180	0.512	5.12	68.5
240	0.628	6.28	79.6
300	0.704	7.04	88.2
360	0.781	7.81	96.4

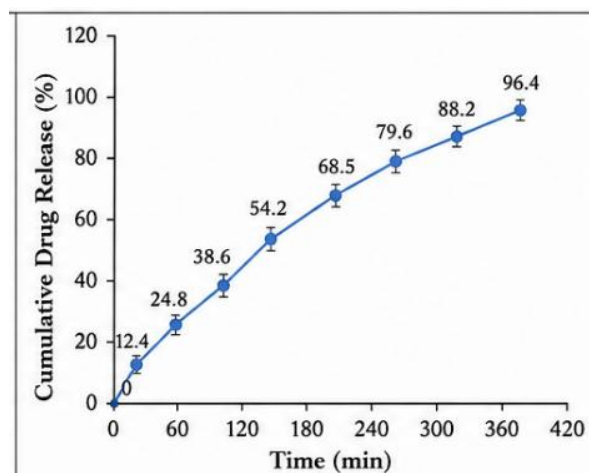


Figure 4. Cumulative percentage drug release profile of optimized formulation (F2).

STABILITY STUDY

The stability study of the formulated *Polianthes tuberosa* gel was carried out to evaluate the effect of storage conditions on its physicochemical properties and performance over time. The study was conducted in accordance with ICH guidelines (Q1A(R2)) for stability testing. [25]

The prepared gel formulations (F1, F2, and F3) were filled in airtight containers and stored under the following conditions:

- Room temperature: $25 \pm 2^\circ\text{C}$ / $60 \pm 5\%$ RH

- Accelerated condition: $40 \pm 2^\circ\text{C}$ / $75 \pm 5\%$ RH

The study was carried out for a period of three months, and samples were analyzed at 0, 1, 2, and 3 months. [26]

The formulations were evaluated for:

- Physical appearance (color, odor, consistency)
- pH
- Viscosity
- Spreadability
- Drug content

- In-vitro drug release

Any changes in physicochemical characteristics and drug release behavior during the storage period were carefully recorded and compared with

the initial values to determine the stability of the formulations. Formulations showing minimal variation in the evaluated parameters were considered stable. [27]

Table 7. Stability Study of Formulation

Time	pH	Viscosity (cP)	Drug Content (%)	Appearance
Initial	6.8 $\pm$ 0.02	4985 $\pm$ 18	98.7 $\pm$ 0.5	Smooth
1 Month	6.8 $\pm$ 0.03	4972 $\pm$ 16	98.1 $\pm$ 0.4	No change
2 Months	6.7 $\pm$ 0.02	4958 $\pm$ 15	97.6 $\pm$ 0.6	No change
3 Months	6.7 $\pm$ 0.03	4935 $\pm$ 17	97.2 $\pm$ 0.5	Stable

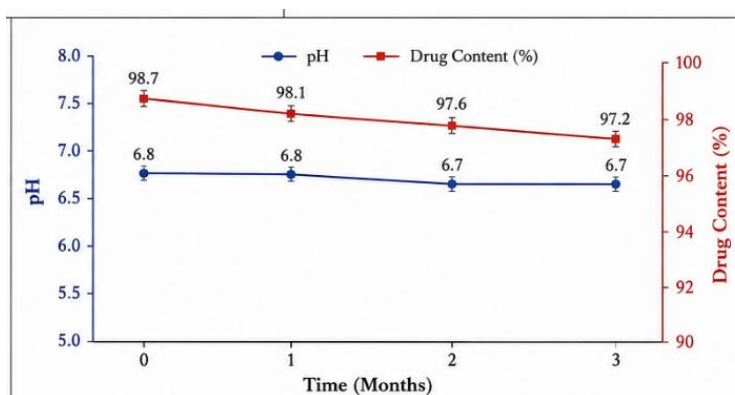


Figure 5. Stability profile of optimized formulation (F2) during storage period.

The stability study results indicated that the optimized gel formulation (F2) remained stable under both room temperature and accelerated storage conditions over a period of three months. No significant changes were observed in physical appearance, and the formulation retained its smooth consistency without any phase separation. A slight decrease in pH, viscosity, and drug content was observed under accelerated conditions; however, these changes were within acceptable limits. The drug content remained within the range of 95–105%, indicating minimal degradation of active constituents.

The in-vitro drug release profile (not shown here) also remained consistent throughout the study period, confirming the stability of the formulation. Statistical analysis revealed no significant difference ($p > 0.05$) in the evaluated parameters over time.

The results demonstrated that the developed *Polianthes tuberosa* gel formulation (F2) is stable under both normal and accelerated storage conditions, maintaining its physicochemical properties and drug content within acceptable limits. Hence, the formulation can be considered suitable for topical application with good stability.

STATISTICAL ANALYSIS

All experimental data were expressed as mean $\pm$ standard deviation (SD) and performed in triplicate ($n = 3$). Statistical analysis was carried out using one-way Analysis of Variance (ANOVA) followed by appropriate post hoc testing to evaluate the significance of differences among the formulations (F1, F2, and F3). [28] A p -value < 0.05 was considered statistically significant.

The analysis was used to compare parameters such as drug release, antioxidant activity, anti-

inflammatory activity, viscosity, spreadability, and drug content. The optimized formulation (F2) showed statistically significant improvement ($p < 0.05$) in performance parameters compared to other formulations, indicating better formulation characteristics and therapeutic potential. [29]

Table 8. Statistical Analysis of Formulations

Parameter	F1	F2	F3	p-value
Drug Content (%)	92.4 ± 0.8	98.7 ± 0.5	95.2 ± 0.7	<0.05
Spreadability	18.2 ± 0.4	24.6 ± 0.5	16.5 ± 0.3	<0.05
Viscosity (cP)	4210 ± 15	4985 ± 18	5890 ± 20	<0.05
Drug Release (%)	82.3 ± 0.9	96.4 ± 0.6	88.7 ± 0.8	<0.05

RESULT AND DISSCUSSION

1. Evaluation of Gel Formulations

It was noticed from figure 3 that the physically prepared gel formulations (F1, F2 & F3) appeared as white and it is seen that the gel was homogeneous. The physical appearance and homogeneity of the prepared gel formulation (F1, F2 & F3) was shown in Fig. 3 which indicated that the gel was white in color and found to be homogeneous. The texture, appearance and homogeneity of all the formulations were smooth with no phase separation. The pH values were obtained within acceptable range of the skin pH which makes it safe for topical application without irritation.

F2 had optimum viscosity and high spreadability with maximum amount of drug content among all the formulations. F2's spreadability can possibly be linked to the well-balanced concentration of Carbopol 940 that gave the product the needed consistency but not too much stiffness. Based on overall the evaluation parameters, F2 was selected for further studies as an optimized formulation.

2. In-vitro Antioxidant Activity

Optimized formulation was optimized as an antioxidant through DPPH radical scavenging assay. The antioxidant activity of the formulation was concentration-dependent and percentage inhibition was found to be increasing gradually while increasing the concentration from 20 µg/mL to 100 µg/mL.

The potential was observed in good free radical scavenging activity which might be due to flavonoids and phenolic compounds present in ethanolic extract of *Polianthes tuberosa*. These phytoconstituents can function as antioxidants by donating an electron or a hydrogen atom from the competency of free radicals and thereby they can reduce the oxidative stress and produce an anti-inflammatory effect.

3. In-vitro Anti-inflammatory Activity

The protein denaturation assay was employed to analyze Anti-inflammatory activity of Optimized formulation gel. The formulation exhibited good protein denaturation inhibitory activity and this had indicated the good anti-inflammatory potential of the formulation.

The activity observed could be attributed to the presence of these phytoconstituents in the plant extract such as flavonoids, tannins and phenolic compounds. These compounds have been found to have anti-inflammatory effects and to help protect proteins from denaturation. From developed Herbal Gel, we can foresee a potential in use of the developed gel for alternative synthetic topical anti-inflammatory formulations.

4. In-vitro Drug Release Study

From the in-vitro drug release study the results revealed showed that the optimized formulation (F2) exhibited sustained and controlled drug release up to 360 min. The cumulative drug release showed a gradual rise with respect to time



indicating a good diffusion of the extract through the gel matrix.

The viscosity building and controlled release properties of Carbopol 940 might be responsible for the sustained release behavior. This result indicates an approximate cumulative release of 96% of the drug after the end of the formulation, indicating that the drug released will be more available at the site of application, which will provide a better therapeutic effect.

5. Stability Study

The optimized gel formulation was found to be stable under the storage conditions during the stability study. The differences in physical appearance, homogeneity and consistency of the formulation were not significant. The pH, viscosity and drug content are slightly affected in storing, however, within acceptable pharmaceutical limit. These results suggest a good physical and chemical stability of the formulation, for use as a topical drug for a longer time period.

CONCLUSION

In the present study, formulation and evaluation of gel portioning the ethanolic extract of *Polianthes tuberosa* was successfully done for topical application as anti-inflammatory one. Various physicochemical evaluations, in-vitro antioxidant and anti-inflammatory studies of formulated gels were conducted. The F2 exhibited the most desirable attributes in terms of pH, viscosity, spreadability and uniformity etc. of the drug content of the various formulations.

The in-vitro evaluation of the drug release has shown that the release pattern of the drug was controlled and sustained and the spherical F2 formulation showed the maximum release of the drug when compared with the other formulations. The antioxidant activity, using DPPH assay, revealed very good free radical scavenging activity and anti-inflammatory activity revealed the good

protein denaturation inhibitory activity. The drug release pattern showed that the formulation was exhibiting diffusion controlled drug release with good permeation of the drug.

Finally, the results demonstrate that gel formulation developed showed antioxidant and anti-inflammatory properties and can be utilized as topical therapeutic agent. The researchers say that their study will help identify the potentiality of herbal formulations for its use in a safer alternative remedy to manage inflammatory diseases as compared to synthetic drugs.

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ETHICAL APPROVAL

In this study only in-vitro experimental procedures were performed, there were no human test subjects and no live test animals. Therefore, the institutional/international guidelines did not require the ethical approval.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest regarding the publication of this research work.

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