INNOSC Theranostics and Pharmacological Sciences 2022 Vol. 5 (No. 1) pp: 1-6

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INNOSC Theranostics and Pharmacological Sciences

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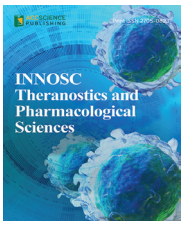


RESEARCH ARTICLE

# Formulation and Pharmacological Evaluation of Herbal Gel Containing *Curcuma longa*

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***Received:*** December 6, 2022; ***Accepted:*** January 13, 2023; ***Published:*** February 3, 2023 ***DOI:*** 10.36922/itps.287



## Abstract:

The aim of the present study is to formulate and evaluate a polyherbal gel that contains *Curcuma longa* extract. The ethanolic extract of *C. longa*'s rhizome was used to create a gel formulation in different concentrations (1, 2, 3, and 4%). Topical anti-inflammatory activity of gel was also assessed. Gel was prepared using Carbopol® 940 (1% w/v), *C. longa* extract, ethanol, propylene glycol 400, methyl paraben, propyl paraben, ethylenediaminetetraacetic acid, tri-ethanolamine, and the necessary amount of distilled water. The prepared formulations were assessed for their physical qualities, pH, spreadability, and ability to irritate skin to detect toxicity or side effects. The findings suggested that gel compositions were good in terms of appearance and uniformity.

**Keywords:** Herbal, Gel, Anti-inflammatory activity, Ethanolic extract of *Curcuma longa*

## 1. Introduction

The Medieval Latin word *liber herbal*, which means "book of herbs," is where the word "herbal" originates. The herb, Sunset-yellow *Curcuma longa*, also known as *C. longa*, is a spice with anti-inflammatory, antibacterial, and antioxidant qualities that is used in wound healing [1]. Its use prevents eczema and psoriasis, and decreases outbreaks that are already present. Herbal medicines are economical in comparison to conventional drugs. Herbal medicines are reported and consumed traditionally by ancient people and can be procured easily from a local market [2]. In the present study, we formulated a gel, which is a stiff jelly-like substance with texture ranging from soft and weak to rigid and durable [3]. Gels are highly diluted crosslinked systems that, in their steady state, do not flow. Gels possess liquid characteristics, but because of a three-dimensional cross-linked complex inside the liquid, they behave like solids [4]. Herbal medicines are still largely consumed by 75 – 80% of the world's population, mainly in developing countries, for primary health and also because of better cultural acceptability, better compatibility with human body and lesser side effects [5].

Turmeric powder consists of 60–70% carbohydrates, 6 – 8% protein, 3 – 7% dietary minerals, 5 – 10% fat, 3 – 7% essential oils, 2 – 7% dietary fiber, and 1 – 6% curcuminoids. Phytochemical components of turmeric consist of diarylheptanoids, for example, curcumin, demethoxycurcumin, and bisdemethoxycurcumin. A number of essential oils are present in turmeric, among which turmerone, atlantone, zingiberene, and germacrone are major constituents [6]. *C. longa* has been reported to possess anti-inflammatory, antioxidant, and anti-aging activities as well as the ability to reduce dandruff and itch.

The formalin-induced rat paw edema model is a useful test for assessing anti-inflammatory drugs, and it has regularly been used to evaluate the drug's anti-edematous effect. Tonic pain has been studied using the rat formalin test that produces a local tissue injury in the paw. These are the first and second stages of the response. The stimulus in the initial stage is a chemical stimulation of the nociceptor, whereas the stimulus in the late phase is inflammation. The use of two fundamentally different stimuli in the same test is an interesting characteristic of this test. The primary cause of formalin-induced pain is peripheral tissue inflammation. During inflammation, dorsal horn neurons become centrally sensitized. Acute inflammation is characterized by the exudation of fluid and plasma proteins as well as the emigration of leukocytes and primarily neutrophils, and lasts for only a few minutes, several hours, or a few days. The present objective of this study is to formulate *C. longa* gel formulation and evaluate the gel for clogging, lumps, and spreadability [7].

## 2. Material and methods

### 2.1. Plant collection

The plant used for the study is *C. longa* (turmeric) family *Zingiberaceae*. Part of the rhizome was collected from the medicinal garden of Sage University, Indore Department of Institute of Pharmaceutical Sciences. This plant was authenticated by the Department of Botany and kept in the herbarium of Holkar College, Indore.

### 2.2. Animals

Wistar rats (180 – 200 g, 8 weeks old) were used in this study. All the rats were divided randomly into six groups, with 6 rats in each group. All the rats were given normal diet and water *add libitum* with maintained humidity control. The animal experiments were approved by the institutional animal ethical committee and all the experiments were conducted as per the guidelines for experiments on animals.

### 2.3. Preparation of plant extract

The plant materials collected (rhizome) were washed and dried at room temperature and were subjected for size reduction. The prepared powder was used for extract preparation. The powder of plant materials (rhizome) was weighed (25 g) and put into iodine flask containing 100 mL ethanol (70%). After mixing, the solution was kept at room temperature for 7 days before filtration. The filtered solution was again filtered with Whatman filter paper. Solvent was removed from the extract with the help of water bath.

### 2.4. Formulation of herbal gel

To prepare the gel formulation, Carbopol®940 was put in separate container and then dissolved in distilled water with vigorous stirring. All ingredients, such as methyl paraben, propyl paraben, and glycerin, were mixed in increasing order of mass (**Table 1**) and then set aside overnight. Extracts of *C. longa* in different concentrations (1%, 2%, 3%, and 4%) were prepared and then mixed with propylene glycol in separate containers, which was then added with polymer dispersion. Appropriate amount of water was then added into all containers, and the solutions were neutralized to pH = 7.1 with triethanolamine by constant stirring for 10 min. Based on the evaluation parameters such as appearance of the product, pH, and spreadability of the formulation, the gel formulation of control batch was selected [8,9].

### 2.5. Evaluation of gel formulation parameter

#### *2.5.1. External appearance of the gel*

A. Physical evaluation: Visual checks on physical characteristics, such as color, smell and consistency, were performed.
B. Color: A visual inspection was conducted to determine the formulation's color.
C. Consistency: Consistency was evaluated by applying the formulation onto the skin.
D. Odor: The formulation's odor was tested by smelling the odor of the mixture of the gel with water. Table 2 reveals the physical evaluation of the gel formulation.

#### *2.5.2. Percentage yield*

The container which was intended for holding the gel formulation was weighed when it was empty. After filling it with the gel formulation, the container was weighed again. The practical yield was determined by subtracting the weight of the empty container from the weight of the container containing the gel formulation [10].

The following formula was used to determine the percentage yield:

**Table 1.** Herbal gel formulation

| Ingredients | Quantity taken | | | |
|---|---|---|---|---|
| | Formulation 1 (1%) | Formulation 2 (2%) | Formulation 3 (3%) | Formulation 4 (4%) |
| Extract | 0.12 g | 0.24 g | 0.36 g | 0.48 g |
| Carbopol® 934 | 1.0 g | 1.0 g | 1.0 g | 1.0 g |
| Propylene glycol | 10.0 mL | 10.0 mL | 10.0 mL | 10.0 mL |
| Methyl paraben | 0.2 mL | 0.2 mL | 0.2 mL | 0.2 mL |
| Propyl paraben | 0.1 mL | 0.1 mL | 0.1 mL | 0.1 mL |
| Glycerin | 1.0 mL | 1.0 mL | 1.0 mL | 1.0 mL |
| Triethanolamine | q.s | q.s | q.s | q.s |
| Water | q.s. | q.s. | q.s. | q.s. |

q.s: Quantity sufficient

**Table 2.** Physical evaluation of gel formulation

| Formulations | Color | Consistency | Odor |
|---|---|---|---|
| Formulation 1 | Yellowish green | Good | Good characteristic |
| Formulation 2 | Yellowish green | Good | Good characteristic |
| Formulation 3 | Yellowish green | Good | Good characteristic |
| Formulation 4 | Yellowish green | Good | Good characteristic |

Percentage yield = (Actual yield/Theoretical yield)*100

The percentage yield of the gel formulation is presented in **Table 3**.

**Table 3.** Percentage yield of gel formulation

| Formulations | Percentage yield (%) |
|---|---|
| Formulation 1 | 95 |
| Formulation 2 | 97 |
| Formulation 3 | 99 |
| Formulation 4 | 98 |

**Table 4.** pH of gel formulation

| Formulations | pH |
|---|---|
| Formulation 1 | 6.9 |
| Formulation 2 | 7.5 |
| Formulation 3 | 7.1 |
| Formulation 4 | 7.8 |

### *2.5.3. Measurement of pH*

Using a digital pH meter, the pH of the formulation of the herbal gel was assessed. A precise 2.5 g of gel was weighed, dissolved in 25 mL purified water, and kept in storage for 2 h. The pH of the formulation was then measured by fully submerging the glass electrode 3 times in the gel system, and the average values of pH were calculated. The pH of the gel formulation is listed in **Table 4**.

### *2.5.4. Homogeneity*

All generated gels were checked visually for homogeneity after being placed in a container to assess the appearance and the presence of aggregates. They were examined for the presence of aggregates and how they appeared. In **Table 5**, homogeneity of the gel formulation is reported [11].

### *2.5.5. Viscosity*

The Brookfield viscometer was used to measure the viscosity of the created gel at a temperature of 25°C. The dial reading for each speed was recorded as the gels were rotated at 0.3, 0.6, and 1.5 rotations per minute. The gels' viscosity was then determined by multiplying the dial reading by a value listed in the Brookfield viscometer catalogues. **Table 6** presents the gel formulation's viscosity.

### *2.5.6. Spreadability*

Based on the gel's slip and drag properties, spreadability was determined using wooden equipment. On these ground slides, more gel (approximately 2 g) was added to the experiment. Another glass slide oriented with a fixed direction was then given the gel and then sandwiched between these slides. Weight of 1 kg was fixed on the top of

**Table 5.** Homogeneity of gel formulation

| Formulations | Homogeneity |
|---|---|
| Formulation 1 | Good |
| Formulation 2 | Good |
| Formulation 3 | Good |
| Formulation 4 | Good |

**Table 6.** Viscosity of gel formulation

| Formulations | Viscosity (cps) |
|---|---|
| Formulation 1 | 4800 |
| Formulation 2 | 4600 |
| Formulation 3 | 4400 |
| Formulation 4 | 4700 |

the slide for 5 min to eject air and to offer an even film of the gel linking the slides. Surplus of the gel was scrapped off from the boundaries. The apex plate was then subjected to drag of 50 g. A shorter interval indicates better spreadability [12].

Spreadability was calculated using the following formula:

$$S = (M \times L)/T$$

Where S is spreadability; M is weight in the pan; L is length moved by the glass slide; and T is time in seconds taken to separate the slide completely each other.

Spreadability of gel formulations is reported in **Table 7.**

### *2.5.7. Extrudability*

Standard collapsible aluminum tubes with caps were filled with the prepared gel, and the ends were crimped shut to seal. The weight of filled tubes was measured, and the tubes were clamped while being sandwiched between two glass slides. After placing a 500 g weight over the slides, the cover was taken off to allow for extrusion. The amount of extruded gel was gathered, weighed, and then measured. Calculating the percentage of extruded gel allows for determining extrudability. Extrudability is remarkable when it exceeds 90%. When it exceeds 80%, extrudability is of good quality. At 70%, extrudability is reasonable. The extrudability of gel compositions is presented in **Table 8**.

**Table 7.** Spreadability of gel formulation

| Formulations | Spreadability (g.cm/s) |
|---|---|
| Formulation 1 | 5.1 ± 0.5 |
| Formulation 2 | 5.9 ± 0.5 |
| Formulation 3 | 5.4 ± 0.5 |
| Formulation 4 | 5.5 ± 0.5 |

### *2.5.8. Gel strength*

Gel strength was calculated using the weight's time-to-weight conversion in seconds.

### *2.5.9. Formalin preparation (in-vivo study)*

The formalin test was performed in a clear transparent plastic chamber, which is 30 × 30 × 60 cm in size. The formalin was prepared by diluting a commercially available 37% formaldehyde solution in isotonic saline. A 26-gauge needle was used to inject formalin solution into the planter surface of the right hind paw of conscious rats.

The drugs were administered an hour before inducing paw edema with 0.1 mL formalin, which was injected into the sub-plantar part of left hind paws. Measurements of the paw volumes (mL) were made by plethysmometer at 0, 1, 2, 4, 6, 24, and 48 hours after formalin injection. The percentage inhibition of paw inhibition of paw volume was calculated. To evaluate the accuracy of the method, objects with bizarre shapes and different volumes (1 – 6 mL) were dipped into the mercury using a mechanical driver. The values on the digital balance were recorded. Thereafter, according to the mercury gravity, the expected measures were calculated and compared with the observed value. The formula used for this measurement is V = W/p, in which V stands for volume, W for weight, and p for gravity. The procedure was repeated twice.

### *2.5.10. Statistical analysis*

The data are expressed as the mean ± standard error of the mean (SEM). One-way analysis of variance (ANOVA) was used for comparisons between different groups followed by Dunnett's test.

## 3. Results

The prepared formulations were assessed for their physical qualities, pH, spreadability, anti-inflammatory activity, and ability to irritate skin to detect toxicity or side effects.

**Table 8.** Extrudability of gel formulation

| Formulations | Extrudability (%) |
|---|---|
| Formulation 1 | 75.0 |
| Formulation 2 | 72.0 |
| Formulation 3 | 79.0 |
| Formulation 4 | 82.0 |

**Table 9.** Gelling strength of gel formulation

| Formulations | Gelling strength |
|---|---|
| Formulation 1 | 41 ± 0.15 |
| Formulation 2 | 38 ± 0.15 |
| Formulation 3 | 45 ± 0.15 |
| Formulation 4 | 42 ± 0.15 |

**Table 10.** Optimization of batches (Formulation 3)

| Evaluation | Result |
|---|---|
| Color | Yellowish green |
| Odor | Aromatic |
| pH | 7.1 |
| Spreadability | 5.3 ± 0.5 g cm/s |
| Homogeneity | Good |
| Stability | Stable |
| Viscosity (cps) | 4400 |
| Spreadability (g.cm/s) | 5.4 ± 0.5 g cm/s |
| Extrudability (%) | 79.0 |
| Gelling strength | 45 ± 0.15 |

### 3.1. Gel formulation

All of the gel formulations listed in **Table 2** had a smooth feel and did not have lumps, which point to a smooth texture of the system. Using a digital pH meter, the pH of the herbal gel formulation was measured. 2.5 g of the gel was precisely weighed, and then it was dissolved in 25 mL of distilled water and let to sit for 2 h. All generated gels were checked visually for homogeneity after being placed in a container to assess appearance and the presence of aggregates. Spreadability was assessed using an instrument made of a wooden block that was pulled at one end. This approach relied on the gel's slide and drag properties to determine spreadability. A shorter interval indicates better spreadability. In this study, Formulation 3 is better as compared to Formulations 1 and 2 (**Tables 9 and 10**).

### 3.2. Acute study on formalin-induced paw edema model

The formalin-induced acute paw model animals, which were used as negative control, exhibited prominent swellings in hind paw as well as in front paw on the 14$^{th}$ day.The treatment with Formulation 3 significantly reduced the swellings (**Table 11)**. The results demonstrated that the formulation may usually be used without becoming runoff. This ensures that the formulation will have an accurate wet contact time at the application site.

## 4. Discussion

The herbal gel had a translucent color, a yellowish-brown tint, and a smooth spread, and maintained its smoothness followed by a stability test. The pH, which was discovered to be 7.1, was also maintained throughout the investigation. Spreadability was also evaluated and gelling agent is one of the important constituents of the gel formulation. The concentration of the viscosity enhancer or gel former is extremely important because a lower concentration will result in simple solutions or lotions with very low consistency, whereas a higher concentration may lead to the formation of gels with high viscosities, which could lead to problems with handling the gel and non-uniform drug distribution. To select the suitable gelling agent, many gel formers were tested. Carbomer was selected and optimized with different concentrations to use as a gelling agent [13].

The formulation's pH was chosen to ensure that it can be used frequently without running the risk of irritating the skin. Since the gel's pH was discovered to be 7.1 ± 0.5, which is very close to the neutral pH, the formulation can be used frequently without running the risk of irritating the skin. This demonstrated that the formulation's chosen ingredients did not change the pH of the final product. The formalin-induced acute paw model animals, which were used as negative control in this study, exhibited prominent swellings in hind paw as well as in front paw on the 14$^{th}$ day. The treatment with Formulation 3 significantly reduced the swellings **Table 11**. The results demonstrated that the formulation may usually be used without becoming runoff. This ensures that the formulation will have an accurate wet contact time at the application site [14].

**Table 11.** Effect of *Curcuma longa gel on* formalin-induced paw edema model in rats

| Group | % Inhibition of paw edema |
|---|---|
| Negative control | 0.00 ± 0.00 |
| Standard | 40.01 ± 0.08 |
| Formulation 1 | 40.09[a] ± 0.05 |
| Formulation 2 | 45.99[a] ± 0.04 |
| Formulation 3 | 61.47[a] ± 0.03 |
| Formulation 4 | 50.99[a] ± 0.04 |

Data are expressed as mean ± SEM and analyzed using one-way ANOVA followed Dunnett's test. [a]$p < 0.05$ versus negative control

## 5. Conclusion

The majority of herbal remedies used in Indian medicine are made from unprocessed plants, plant parts, or plant extracts. A majority of people in the world receive medical care and drugs in the form traditional medicine. Both traditional healers and medical professionals with Western medical training frequently employ plant-based concoctions to treat burns and wounds in underdeveloped nations. Curcumin topical gel formulation in this study has excellent application value and is a practical choice for managing Inflammation. For further research into its therapeutic capabilities, various animal models will be used.

## Acknowledgments

All the authors want to thanks HOD and HOI, institute of Pharmaceutical Sciences for providing necessary research facility.

## Funding

There is no external funding available to complete this research study.

## Conflict of interest

There is no conflict of interest in regards to the study.

## Author contributions

*Conceptualization:* Souravh Bais
*Formal Analysis:* Puja Kumari
*Investigation:* Puja Kumari
*Writing – original draft:* Souravh Bais
*Writing – review & editing:* Souravh Bais

## Ethics approval and consent to participate

The animal experiments were approved by the institutional animal ethical committee (IAEC/478/IPS/22/01) and all the experiments were conducted as per the guidelines for experiments on animals.

## Consent for publication

Not applicable.

## Availability of data

Data can be obtained from corresponding authors on reasonable request.

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