



‘Formulation and evaluation of herbal ulcer gel using *Ficus religiosa*, *Zingiberaceae*, *Curcuma longa* and *Apis indica*’

Author: Nanditha V^{V1}, Nagendra R², Anusha M³, Sowjanya.A⁴, Shreevani M⁵ Sindhushree R S⁶,
Janavi M⁷, Hanumanthachar Joshi⁸.

Department of Pharmaceutics, Sarada vilas college of pharmacy krishnamurthy puram mysuru (Karnataka).

Abstract:

Ficus religiosa also known as peepal tree, a large evergreen tree, considered to be sacred in India. It not only emits oxygen but also has many important medicinal benefits. Different parts of the peepal tree such as root bark, stem bark, roots, leaves and fruits are used to manage conditions like high blood sugar levels, constipation, asthma and also peepal is beneficial for managing skin diseases.. It helps in reducing the inflammation related to eczema due to its anti-inflammatory property and antioxidant property, by contracting the mucosal cells or other body tissues due to its astringent property. Ginger and its constituents show antioxidant activity, has anti-inflammatory processes. such as inhibition of COX and inhibition of nuclear factor κB . Ginger also shows antimicrobial activity. Honey is used as antiseptic, used as demulcent and sweetening agent, it is applied to burns and wounds etc. Turmeric has powerful anti-inflammatory effects and is a very strong antioxidant. Turmeric benefits can include reducing inflammation, improving liver function, providing pain relief, and more.

Keywords: herbal preparation, peepal leaves, ginger, turmeric, honey, ulcer.

Introduction:

Herbal preparation is an ancient preparation we can see using of herbs for cosmetic preparation, herbal ingredients occurs naturally and are free from harmful chemicals. Our ancestors were practicing herbs as beautifying products like turmeric, shikakai, sandalwood powder, kesar, amla, multhani mitti, natural oils like coconut, castor, jojoba oil etc. Herbs are gift from the nature, it can't be replaced with chemical product. Herbals products are free from toxins, irritants, and safe and can be trusted blindly to most extent whereas the chemical products can harm the skin, eyes, hair, lips etc. Across the world chemical products are prepared and practiced for fast and speedy recovery of infection and to enhance the beauty. Attractive face colour, eye colour, skin texture and healthy hair are the reason women around the world are falling behind the chemical products but nowadays the chemical products have toxic effects and side effects, that's why herbal products are taking off worldwide by giving good and healthy products that are safe and also fulfil the demands of women, some available herbal products in market for face: face wash, moisturiser, face creams etc., for hair care: herbal shampoo, herbal oil, conditioning shampoo, herbal tablets, herbal tonic, herbal paste are prepared by pharmaceutical company for demand and income purpose. The demand for herbal cosmetic is growing in the world market and is an invaluable gift of nature. Herbal skin cosmetics are formulated using different herbal active ingredients, which are further incorporated in cosmetic base to nourish and cure various skin ailments.

Ficus religiosa (Peepal) has an important place among herbal plants. Almost every part of this tree i.e. leaves, bark, seeds and fruits are used in the preparation of herbal medicines. The Peepal tree is considered the mythical 'Tree of Life' or 'World Tree' in the Indian subcontinent. The Peepal tree, also called *Ficus religiosa*. It is a variation of the fig tree known as the bodhi tree. The word '*Ficus*' in Latin refers to 'fig', the fruit of the tree and the word '*Religiosa*' refers to 'religion', as it is sacred in both Buddhism and Hinduism. Also, for this reason, it is named 'Sacred fig'. It is a huge tree often planted near holy places and temples.

The Honey is also known as madhu, honey is a sugar substance deposited in the honey comb by honey bee *apis mellifera* belonging to family of apidae and the odour of honey is pleasant and taste is sweet, it is soluble in water and insoluble in alcohol and other organic solvents and the honey contain glucose, fructose, small quantities of sucrose, dextrin, formic acid and it also contains proteins, enzymes, vitamins, colouring matter. The honey is used as antiseptic, used as demulcent and sweetening agent, it is applied to burns and wounds etc.

Ginger (*Zingiber officinale* Rosc.) belongs to the family Zingiberaceae. It originated in South-East Asia and then used in many countries as a spice and condiment to add flavour to food. Besides this, the rhizome of ginger has also been used in traditional herbal preparation. The health-promoting perspectives of ginger are well known. It can treat a wide range of diseases via immuno-nutrition and anti-inflammatory responses. As a result of anti-inflammatory effect of ginger, it can reduce muscle pain after intense physical activity. Likewise, the anticancer potential of ginger is well documented and its functional ingredients like gingerols, shogaol, and paradols are the valuable ingredients which can prevent various cancers, angiogenesis and metastasis, induction of apoptosis, and inhibition of cell-cycle progression. Besides these, it improves cardiovascular disorders, diabetes mellitus, and gastrointestinal health.

Turmeric botanical name is *Curcuma longa* it has actually been used medicinally for over and grows in Asia and Central America. Curcumin is the main active ingredient in turmeric. It has powerful anti-inflammatory effects and is a very strong antioxidant. Turmeric benefits can include reducing inflammation, improving liver function, providing pain relief and more.

Need of the work

- Increase the use of Herbal ingredients has it contains natural nutrients to get better results which ensures customer satisfaction, and to reduce the side effects which is causes from the chemicals.
- To make the herbal ulcer gel available to everyone with less price.
- It exerts analgesic activity.
- It shows anti-inflammatory action so it is used to decrease the inflammation in mouth.
- To avoid enzymatic activity and drug interaction with food and drinks.
- To show anti-microbial action.
- It shows antiseptic activity that effectively reduces inflammation and pain.
- They can substitute for oral administration of medication when the route is unsuitable.
- for easy application.
- Gels are not deactivated by liver enzymes because the liver is bypassed.
- It avoids systemic and portal circulation following gastrointestinal absorption.

F. religiosa has been reported to have antidiabetic property , anti-inflammatory , potential antioxidant , have an analgesic (pain-killing) property, an antimicrobial (kills microbes). It helps in wound healing and act as an anti-ulcer agent.

Ginger and its constituents show antioxidant activity. Ginger and its constituents also have a vital role as anti-inflammatory processes such as inhibition of COX and inhibition of nuclear factor κ B. Ginger also acts as antitumor and also shows antimicrobial activity.

Honey is used as antiseptic, as demulcent and sweetening agent, it is applied to burns and wounds etc.

Turmeric has powerful anti-inflammatory effects and is a very strong antioxidant. Turmeric benefits can include reducing inflammation, improving liver function, providing pain relief, and more.

Aim of the study:

The present research work is aimed to formulate and evaluate herbal ulcer gel using *Ficus religiosa*, *Zingiberaceae*, *Curcumin longa*, *Apis indica*.

Objectives:

- To perform pre-formulation studies of herbs and excipients.
- To perform formulation of herbal ulcer gel.
- To perform evaluation of gel.
 - A) Measurement of PH.
 - B) Homogeneity.
 - C) Viscosity.
 - D) Spreadability.
 - E) Drug content.
 - F) *In-vitro* drug release studies.
 - G) Stability studies

Materials & Methods:

Peepal leaves:

F. religiosa has been reported to have medicinal properties like anti-bacterial, anti-diabetic, anti-amnesic, anti-ulcer and anti-oxidant properties in the presence of chemical compounds. The leaves have been reported to have bioactive compounds (campsterol, stigmasterol, iso-fucosterol, tannins, arginine, serine, aspartic acid, glycine, threonine, alanine, proline, tryptophan, tyrosine, methionine, valine, iso-leucine).

- It have an anti-inflammatory potential.
- It act as an antioxidant.

- It have an analgesic (pain-killing) property.
- It act as an anticonvulsant (reduces or prevents the severity of fits).
- It have an antimicrobial property (kills microbes).
- It helps in wound healing.
- It has an anti-amnesic (prevents loss of memory).
- It act as an anti-ulcer agent.
- It might have an anti-asthmatic action.
- It might help as a kidney-protective agent.

Ginger :

Ginger contains ~1–4% of volatile oils, which are the medically active constituents of ginger. The phenols detected in solvent extracts of ginger were mainly gingerol and zingerone.

Ginger has:

- Anti-oxidant activity.
- Anti-inflammatory activity.
- Anti-tumour activity.
- Anti-microbial activity.
- Anti-diabetic activity.
- Neuroprotective effect.
- Effect on osteoarthritis.
- Gastroprotective effect.
- Carminative .

Honey :

Honey has a content of 80–85% carbohydrates, 15–17% water, 0.3% proteins, 0.2% ashes and minor quantities of amino-acids, phenols, pigments and vitamins.

- Hypolipidemic cardiovascular disease.
- Antioxidant.
- Anti-inflammatory.
- Wound care.
- Anti-tumour.
- Gastrointestinal diseases.
- Anti-microbial.
- Oral health.
- Athletic performance.

Turmeric:

- Natural antiseptic.
- Natural analgesic.
- Speeds up wound healing.
- Improves digestion.
- Blood purifier.
- Strengthens ligaments.
- Helps alleviate coughing.
- Improves asthma.
- Anti-arthritis.
- Slows progression of MS (multiple sclerosis).
- Helps prevent gas/bloating.
- Lower's cholesterol.
- Heals stomach ulcers.
- Improves skin conditions (psoriasis, eczema).
- Reduces side effects of chemotherapy.

Carbopol:

- Is used as a thickener.
- It is also used to stabilize, suspend, and control the release of pharmaceutical product.

Methyl paraben:

To prevent the growth of mould and other harmful bacteria.

Propyl paraben:

Has antifungal and antibacterial properties.

Propylene glycol:

Is commonly used as drug solubilizer.

Triethanolamine:

Is used as a neutralizer and the pH of the gels.

Glycerine:

Is a natural humectant. It is used as a carrier.

Methods of collection of data

- **Methodology:**

Extraction:

1. Peepal leaves , rhizomes of ginger and turmeric powder was taken.
2. After drying it is grounded to a coarse powder and passed through the sieve no. 40.
3. 100g of dried peepal leaves powder 100g of ginger powder and 100g of turmeric powder were macerated in 500ml of ethanol, methanol and in water in separate conical flask for 24hrs at room temperature with occasional shaking.
4. After 24hrs mixtures were filtered out and filtrates were collected in separate beakers.
5. In order to obtain extract the solvent were removed from the filtrate under reducing pressure by using a rotary vacuum evaporator at 45-50 °C.

Melting and mixing:

Mix Carbopol-940 in distilled water add methyl paraben, propyl paraben, propylene glycol and honey.

Labelling and packing:

The gel is transferred to suitable container with proper labelling.

Formulation:

Ingredients	Quantity taken
Peepal leaf extract	0.6ml
Ginger extract	0.3ml
Honey	0.3ml
Turmeric	0.3ml
Methyl paraben	0.06g
Propyl paraben	0.03g
Propylene glycol	1.5ml
Triethanolamine	0.36ml
Glycerine	0.45ml
Distilled water	Upto 30 ml
Carbopol940	3g

Method:

- A sufficient quantity of Carbopol 934 was soaked in distilled water overnight.
- Mix the carbopol with distilled water by using stirrer.
- In a separate beaker no.2 methyl paraben and propyl paraben. Propylene glycol was also added.
- The contents in beaker 2 was added to carbopol solution with. continuous stirring.
- Then Add honey then add extract of peepal leaves and ginger.
- The volume was made to 30ml with purified water.
- The pH was maintained by addition of triethanolamine to obtain gel of required consistency.
- It is transferred to suitable container.

Evaluation tests:**• PHYSICAL TEST:**

Physical parameters such as colour, odour and consistency were checked visually.

1. Colour: The colour of the formulations was checked by visual inspection.
2. Consistency: The consistency of formulations was checked by applying on skin.
3. Odour: The odour of the formulations was checked by mixing the gel in water and observing the smell.

• PERCENTAGE YIELD:

Weigh the empty container in which the gel formulation was stored then again weigh the container with gel formulation. To obtain the practical yield subtract the weight of empty container with the container containing gel formulation.

Then the percentage yield was calculated by the formula given below:

Percentage yield = (practical yield / theoretical yield) × 100.

• MEASUREMENT OF PH:

The pH of gel formulations were determined by using digital pH meter. Take 1 gram of gel. Then the measurement of pH of formulations was done by dipping the glass electrode completely into the gel system three times and the average values are reported.

• HOMOGENEITY:

All prepared gel formulations were tested for homogeneity by visual inspection after the gels have been set into the container. They were tested for their presence and appearance of any aggregates.

• VISCOSITY:

The measurement of viscosity of the formulated gel was determined by Brookfield Viscometer with spindle no.1 at 25°C. The gels were rotated at speed 0.3, 0.6 and 1.5 rotations per minute and at each speed, the corresponding dial reading was noted. Then viscosity of the prepared gels were obtained by multiplication of the dial reading with factor given in the Viscometer catalogues.

• SPREADABILITY:

Spreadability is expressed in terms of time in seconds taken by two slides to slip off from gel that is placed in between the slides under the direction of certain load. If the time taken for separation of two slides is less then better the spreadability.

Spreadability is calculated by using the formula;

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

Where,

M = Weight tied to upper slide.

L = Length of glass slides.

T = Time taken to separate the slides.

Spreadability of gel formulations were reported.

• CLARITY TEST:

The clarity of all the three batches was determined by visual inspection.

• GEL STRENGTH:

Gel strength was determined by the time in seconds required by the weight to penetrate in the gel. A 3.5g weight was placed on the surface of 5g formulated gel. Gel strength was determined by reporting the time in seconds required by the weight to penetrate 0.5cm in the gel. The gel strength was then reported.

• ANTIFUNGAL ACTIVITY:

The antifungal activity of all optimized formulation and blank formulation were carried out by Cup-plate method in comparison with marketed antifungal formulation (Daktarin oral gel). The antifungal activity test was performed by using Candida albicans. Prepared nutrient brought and poured in to sterile petriplates and kept aside for drying and cooling. After that Candida albicans culture were spread by micron wire loop. A sterile cork-borer 6mm diameter was used to drill holes 4mm deep. Then place 0.5g of gel from each formulations into this holes. Plates were then incubated at 27°C for 48hrs. Then the zone of inhibition (diameter in mm) was measured.

• **STABILITY STUDY:**

Stability studies were performed to observe the effect of environmental conditions or storage conditions on formulation. The optimized formulation was kept in accelerated stability condition at 25°C temperature 60 ± 5% relative humidity, 30°C temperature 65 ± 5% relative humidity and 40°C temperature 75 ± 5% for a period of 3 months as per ICH guidelines. The placed sample was withdrawn at 1, 2 and 3 months interval and evaluation was carried out for physical appearance, pH, viscosity, spreadability, extrudability and gelling strength.

• **ACID VALUE:**

Weigh & Take 10g of formulated gel dissolved in accurately weighed in 50ml mixture of equal volume of alcohol and solvent ether. Then attached to the flask with the condenser and reflux it with the slow heating until the sample gets dissolve and then add 1ml of phenolphthalein then titrate it with 0.1N NaOH until it gets faint pink colour after shaking it 20 seconds.

$$\text{Acid value} = n \times 5.61 / w$$

Where;

w = Weight of the substances. n = The number of ml in NaOH required.

• **SAPONIFICATION VALUE:**

Weigh and take 2g of the prepared gel and then add 25ml of 0.5N alcoholic KOH and reflux it for 30 minutes. Add 0.1ml of phenolphthalein as an indicator and titrate it with the 0.5N HCl.

$$\text{Saponification value} = [b-a] \times 28.05 / w$$

where;

a = Volume of titrate.

b = Volume of titrant

w = Weight of substances in gram.

Acknowledgement

Principal and teaching staff, Sarada vilas college of Pharmacy, Mysuru for providing and encouragement. Rajiv Gandhi University for providing financial assistance.

