



Formulation and Evaluation of aqueous Anti-inflammatory gel of “*Emblica Officinalis*”

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ABSTRACT

Background: The plants of genus *Emblica Officinalis* has been used in traditional medicine for many diseases from history. *Emblica Officinalis*. Is also a medicinally important plant and it has been proved by modern scientific research. **Objective:** This study is aimed to formulate and characterize a topical gel from *Emblica Officinalis* leaf methanol extract and evaluate. **Materials and Methods:** The methanol extract was prepared by successive solvent extraction using soxhlet apparatus. Topical gel was designed to prepare by Dispersion method using Carbopol 940 as polymer. The various gel characteristics was studied by standard procedures like Homogeneity, grittiness, Extrudability, drug content, spread ability and in-vitro diffusion study. **Results:** The herbal gel was found homogeneous with good Extrudability, no grittiness, pH 6.79 and drug content 93.167%. The anti-inflammatory activity of herbal gel was found comparable with standard *Emblica Officinalis* gel and has shown 82.71% edema inhibition after 4 h of treatment. **Conclusion:** *Emblica Officinalis* gel was found suitable as a standard topical gel formulation and it can be used safely for treatment of edema.

Key words: Carbopol 940, *Emblica Officinalis*, In-vitro diffusion, Topical gel.

INTRODUCTION –

An anti-inflammatory (or anti-inflammatory) substance or substance that reduces inflammation or inflammation. Anti-inflammatory drugs make up about half of analgesics, which relieve pain by reducing inflammation rather than opioids, affecting the central nervous system to prevent pain that reflects the brain. Drug delivery through the traditional route is a simple and effective form of local treatment. Topical gel is a local drug delivery system anywhere in the body through the skin, rectangular, eye and vaginal tract. The skin is a broad and easily accessible organ in chemical treatment and the gel formulation is stable and provides better absorption and availability of the drug compared to other fruit formulas. It has a variety of healing functions as traditional and some of them have been shown by modern research. In our previous research, we conducted phytochemical studies and evaluated the anti-inflammatory activities of *Emblica Officinalis* leaf ethanol. It has been found to be rich in phenolics, flavonoids, alkaloids, Glycosides and steroids with a good antioxidant effect compared to other leaf extracts It has also shown significant anti-inflammatory activity. Prior to functional testing, the maximum safe dose for leaf removal was also determined as 2000 mg / Kg by oral toxicity study. The leaf extract was therefore selected for the gel composition. The purpose of this study was to develop a particle gel for *Emblica Officinalis* leaf methanol extract, to learn about various gel parameters and to test. *Phyllanthus emblica*, also known as emblic, Indian shrub, Malacca tree, or amla from Sanskrit lakes is a

deciduous tree of the family Phyllanthaceae. It has an edible fruit, named after the same name. the tree is small to medium in size, reaching 1-8 m (3 ft 3 in - 26 ft 3 in) in height. The leaflets are not glabrous or pubescent finely, 10-20 cm (3.9-7.9 in) long, usually simple, low leaves and arranged near branches, green, like opposing leaves. The flowers are green. The fruit is almost round, light green, smooth and hard looking, with six vertical lines or furrows. Ripe in autumn, the berries are harvested by hand after ascending to the upper branches that bear fruit. The taste of Indian cuisine is sour, bitter and confusing, and quite complex. These fruits are said to contain high levels of ascorbic acid (vitamin C), and have a bitter taste that can result from large amounts of ellagitannins, such as emblicanin A (37%), emblicanin B (33%), punigluconin (12%) , And pedunculagin Amla contains punicafolin and phyllanemblinin A, phyllanemblin and other polyphenols, such as flavonoids, kaempferol, ellagic acid, and gallic acid.

Table 1: SCIENTIFIC CLASSIFICATION OF EMBLICA OFFICINALIS MATERIAL AND METHODS

Name	Embllica Officinalis
Synoname	<i>Cicca emblica, Diasperus emblica, Emblica arborea, Emblica officinalis</i>
Family	Phyllanthaceae
Genus	<i>Phyllanthus</i>
Species	<i>P. emblica</i>

PREPARATION OF ETHANOLIC EXTRACT OF EMBLICA OFFICINALIS.

5 gm of the air dried drug coarsely powdered drug (Leaf), with 100 ml of ethanol the specified strength in a closed flask for twenty-four hours shaking frequently during six hours and followed to stand for eighteen hours. Filtered rapidly, taking precautions against loss of solvents, evaporate 25 ml of the filtrate to dryness in a tared flat bottomed shallow dish, and dried at 1000c to constant weight and weighed.

METHOD OF PREPARATION FOR GEL

To prepare the main gel, a dispersion method was used because the polymers in Carbopol could be easily dispersed in water

by stirring at room temperature. All ingredients were accurately weighed in Table 1. Then the Carbopol 940 was dispersed in 50 ml of distilled water with continuous stirring. Methyl Paraben and Propyl Paraben are dissolved separately in 5 ml of distilled water at room temperature. The solution cooled and then added Propylene Glycol 400. After the infusion was added the Carbopol 940 solution was added and the volume was formed up to 100 ml of distilled water. Finally, a sufficient amount of Triethanolamine (TEA) was added to the component for further promotion of the required strength of the gel. Then the weight and pH of the gel formation are determined.

Table 2: FORMULATION TABLE

Sr. No	Drug/ Chemical Name	Quality
1.	Leaf extract of Emblica Officinalis	5 gm. (5%)
2.	Carbopol 940	1 gm (1%)
3.	Methyl Paraben	0.2ml (0.5%)
4.	Propyl Paraben	0.1ml(0.2%)
5.	Propylene Glycol 400	5 ml (5%)
6.	Triethanolamine (TEA)	q.s. (1.2 ml)
7.	Water	Up to 100 ml

VISCOSITY

Viscosity of gel was measured by using Brookfield viscometer with spindle.

EXTRUDABILITY

The gel structure was filled with standard aluminum composite tubes and sealed with wrap until the end. Tuber bells were made. Tubes are placed between two glass slides and fastened. 500 gm was placed over the slides and the cap was removed. The amount of gel removed was collected and measured. Percentage of gel extracted is calculated (> 90% extrudability: excellent, > 80% extrudability: good, > 70% extrudability: fair). distribution is measured on the basis of signs of slippery and slippery gels. Excess gel (approximately 2 g) in the study was applied to the soil slide. The jelly was then wrapped between the slide and another glass slide with the size of a ground slide suspended and delivered with a hook. 1 kg weight was placed on top of two slides for 5 minutes to exhale and provide the same gel film between the slides. The gel skip was removed from the edges. The top plate was then pulled with 80 g with the help of a string attached to the hook and the time (seconds) required for the top slide to cover a distance of 7.5 cm was observed. The shorter duration shown for better distribution ability was calculated using the following

FORMULA:

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

Where,

S = Spread ability

M = Weight in the pan (tied to the upper slide)

L = Length moved by the glass slide

T = Time (in sec.) taken to separate the upper slide from the ground slide

SPREAD ABILITY

The distribution power is determined by the equipment containing the wooden block, which is provided by a pulley on one side. In this way the distribution of energy was measured on the basis of the smoothness and gravity of the gel structures. Excess gel (approximately 2 g) in the study was applied to the soil slide. The jelly was then wrapped between the slide and another glass slide with the size of a ground slide set and delivered with a hook. 1 kg weight was placed on top of two slides for 5 minutes to extract and give the same gel film between the slides. The gel escape was removed from the edges. The top plate was then drawn with 80 g with the help of a string attached to the hook and the time (seconds) required for the top slide to cover a distance of 7.5 cm. The shorter time has shown better distribution ability. Distribution power is calculated using the following formula:

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

Where,

S = Spread ability

M = Weight in the pan (tied to the upper slide)

L = Length moved by the glass slide

T = Time (in sec.) taken to separate the upper slide from the ground slide.

STABILITY STUDY

Stability research was performed as guidelines for ICH. The synthetic gel was filled with translucent tubes and stored at various temperatures and humidity conditions, viz. $25 \pm 2^\circ\text{C} / 60 \pm 5\% \text{RH}$, $30 \pm 2^\circ\text{C} / 65 \pm 5\% \text{RH}$, $40 \pm 2^\circ\text{C} / 75 \pm 5\% \text{RH}$ for 3 months and studied appearance, pH and distribution ability.

PRIMARY DERMAL IRRITATION INDEX (PDII)

Skin irritation is the production of recurrent damage to the skin following the use of a test device for up to 4 hours. The dermal irritation index (PDII) is a method of classifying the composition of the head into different categories based on the harmful toxic reactions observed in a single application of the skin structure. Depending on the PDII standard, the composition can be classified as irritating or non-irritating.

MEASUREMENT OF PH

The pH of formulation was determined by using digital pH meter. 1 g of gel was dissolved in 100 ml of distilled water and stored for 2 h. The pH measurement of formulation was done in triplicate and standard deviation was calculated. The pH of gel must be ideally near to normal pH of the skin to avoid any irritation.

IN-VITRO DIFFUSION STUDY

In-vitro diffusion analysis of the prepared gel was performed on the Keshary- Chein diffusion cell apparatus. In the Keshary-Chein dispensing cell, 500 mg of the gel was distributed evenly in a

cellophane membrane previously immersed in a phosphate buffer pH 5.5 for 24 h and was switched between the donor site and the receptor. 6 ml of phosphate buffer was used as a reception. The temperature was maintained at $37 \pm 0.5^\circ\text{C}$. The whole assembly was centered on a magnetic stirrer and the solution in the reception room was constantly stirred using magnetic beads at 450 rpm. The 1 ml sample was withdrawn at rest and was replaced with 1 ml of fresh buffer. The concentration of the drug in the receptor fluid was determined by the spectrophotometric counter against the negative at 275.5 nm. The aggregate value of the extracted drug expressed in% is planned for construction.

APPLICATION OF THE HERBAL GEL

Half a gram of vegetable gel, as a test material, was placed on an area of about 6 cm² of skin and covered with a lump of gauze. The episode was freely held in contact with the skin in a suitable form of dressing for four hours and then removed. At the end of the exposure time, i.e. 4 hours, the residual test material is removed without altering the existing response or integrity of the epidermis. The look was recorded an hour after the episode was removed. Control animals were prepared in the same way as 0.5 gram base gel, meaning that the gel was made using all the ingredients except a combination of herbs, was applied to the control animals and detection was performed similarly to experimental animals. Both control and experimental animals were monitored daily for any appearance of skin irritation or toxic reactions such as edema or erythema. From a skin point of view, a value between 0 and 4 was recorded where 0 could not indicate erythema formation and eschar formation and 1, 2, 3 and 4 represented very small, well-defined, moderate erythema formation and strong eschar formation, respectively. It also received points from 0–4, with 0 representing edema and 4 representing severe edema.

Table 3: EXTRUDABILITY OF THE HERBAL GEL AT THE TIME OF PREPARATION (MEAN ± SEM)

Extrudability	Mean of three tubes (Initial month)
Net wt of formulation in tube (g)	13.34±0.011
Wt. of gel extruded (g)	12.32±0.014
Extrudability amount percentage	95.73±0.005

Table 4: VISCOSITY OF THE EMBLICA OFFICINALIS GEL AT THE TIME OF PREPARATION.

RPM	Viscosity
50	22910
75	18790
100	15260
150	13089

Table 5: IN-VITRO DIFFUSION STUDY EMBLICA OFFICINALIS GEL

Sr. no	Time in hr.	Cumulative % Drug release
1.	0	0
2.	1	23.28
3.	2	28.43
4.	3	31.25
5.	4	36.40
6.	5	38.60
7.	6	43.00

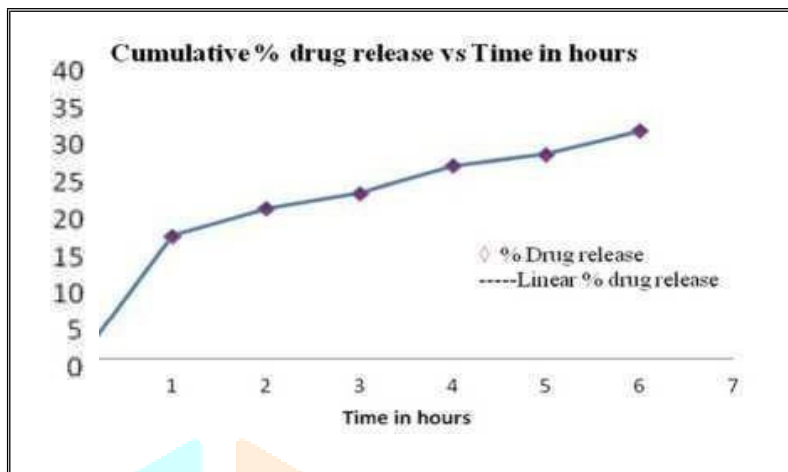


Table 6: EVALUATION PARAMETERS FOR EMBLICA OFFICINALIS LEAF METHANOL EXTRACT TOPICAL GEL

Sr.no	Evaluation parameter	Observation
1.	Gel appearance	Light Green
2.	Homogeneity	Good
3.	Grittiness	Absent
4.	Extrudability	Good (70.63%)
5.	Viscosity	22910±716 cps
6.	pH	6.79±0.02
7.	Spread ability	3.8±0.36 cm
8.	Drug content	93.167%
9.	Skin irritation	None observed (Score= 0)
10.	Cumulative drug release	43%

CONCLUSION-

Anti-inflammatory pain pills are used to relieve muscle pain, sprains and stiffness. They can also help reduce painful arthritis. Topical anti-inflammatory paininkers are sometimes

substituted for oral anti-inflammatory drugs because they have fewer side effects. Anti-inflammatory painkillers are a group of drugs used to relieve muscle pain, rash, cramps and arthritis. They can be taken orally (pills, pills or drinks), injected, or injected into the skin. When applied to

the skin they are called topical anti-inflammatory painkillers. They are sometimes referred to as 'non-steroidal anti-inflammatory drugs' (NSAIDs), or simply 'topical anti-inflammatory' drugs. When oral anti-inflammatories work by blocking (inhibiting) the effect of chemicals (enzymes) they are called cyclo-oxygenase (COX) enzymes. COX enzymes that help make other chemicals called prostaglandin. Some prostaglandins are involved in producing pain and inflammation in areas of injury or trauma. Reduced prostaglandin production reduces pain and inflammation. Great job of fighting inflammation in the same way but, instead of having an impact on the whole body, it only works in the area where you used it. When they are used they are taken (into) your skin. Then they go deeper into areas of the body where there is inflammation (for example, your muscles). They relieve pain and reduce inflammation that affects the joints and muscles when applied to the skin in the affected area. Using a head conditioner means that the total amount of anti-inflammatory in your body is very low. This also means that you are less likely to have side effects. Apply on the affected area and rub the skin gently. Wash your hands often after applying the cream, gel or spray on the skin. This is to ensure that you avoid applying the ointment to sensitive areas of the body such as the eyes. Do not apply to broken skin, or near eyes, nose, mouth, genitals or bottom (buttocks). Do not use plasters or bandages (clothing) on top of these medications. These drugs are usually applied to the skin 2-4 times a day. However, for specific advice on your medication, see the pamphlet that fits inside the package.

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