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Formulation and Evaluation of Herbal Cream Used in Treatment of Arthritis



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ABSTRACT

Herbal cream are the preparations used by human beings in the treatment of various diseases. The aim of the present research was to formulate the herbal cream for the treatment of very painful disease i.e arthritis (Arthritis is a disease generally include joint pain, stiffness, swelling and decreased range of motion of the effected joints). The present formulation is composed of Banyan leaf extract {Ficus Benghalensis} from species, Linseed oil and oil of menthol, camphor and Ajwain (carom seed). The herbal cream is formulated by two phase system one is oil phase and another is aqueous phase. Herbal cream is formed by using the infusion technique with this technique the formulation was found to be the best one and it gives accurate result. Cream was tested for its consistency and evaluation, with the result it has been found that Banyan Leaf {Ficus Benghalensis} possess anti-inflammatory, analgesic properties. The cream is evaluated for Colour, Foreign particle, Extrudability etc by which the percent of active constituent Banyan Leaf extract was found to be 98.9, Colour of cream was found to be pale yellowish, the spreadability was found to be easily spreadable on skin surface after application, the extrudability was found to be 92 % and passes all the parameter. A banyan tree is important in the Hindu religion. It is profoundly worshipped and revered in India. In Hindu mythology it is believed that banyan tree fulfils wishes and all material and so it has been given the name 'kalpavriksha'. Makeshift swings can be hung from the branches of a banyan tree and so it is a popular area of play for children.



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1.0 INTRODUCTION

Rheumatoid arthritis (RA) is a chronic disease of unknown cause affecting over 2 million adults in the USA [1]. An inflammatory disease of the synovium, it results in pain, stiffness, swelling, deformity and, eventually, loss of function in the joints. Because there is currently no known cure or means of preventing RA, the American College of Rheumatology recommends the earliest possible diagnosis and treatment with disease modifying anti-rheumatic agents to limit the degree of irreversible joint damage [1]. Despite early detection, current treatment medications are limited in their efficacy and are frequently toxic. Many patients look for complementary and alternative medicine (CAM) options in coping with this debilitating disease. Research has indicated that people suffering from chronic pain, as in RA, and those dissatisfied with current treatment are very likely to seek alternative treatments, and an estimated 60 –90% of persons with arthritis use CAM [2]. Among the most widely used treatments are chiropractic and herbal therapies [2]. This growing interest in alternative medical practices clearly indicates the need for more thorough investigation into the safety and efficacy of CAM. An earlier review [3]. conducted in 2000 was limited in that it excluded trials of herbal preparations against active comparators. Therefore, the purpose of this systematic review was to examine the current clinical evidence for (or against) the use of herbal medicines for RA based on randomized clinical trials (RCTs) of herbal preparations against all control treatments[3].

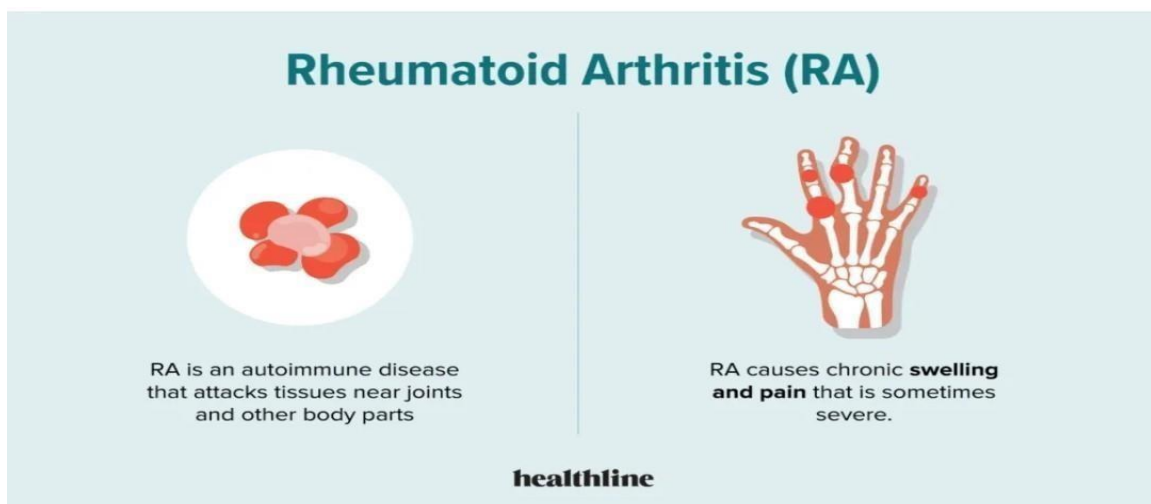


Figure No.1: Figure of Rheumatoid arthritis

Rheumatoid arthritis (RA) is a chronic, symmetrical, inflammatory autoimmune disease that initially affects small joints, progressing to larger joints, and eventually the skin, eyes, heart,

kidneys, and lungs. Often, the bone and cartilage of joints are destroyed, and tendons and ligaments weaken [4]. All this damage to the joints causes deformities and bone erosion, usually very painful for a patient. Common symptoms of RA include morning stiffness of the affected joints for >30 min, fatigue, fever, weight loss, joints that are tender, swollen and warm, and rheumatoid nodules under the skin. The onset of this disease is usually from the age of 35 to 60 years, with remission and exacerbation. It can also afflict young children even before the age of 16 years, referred to as juvenile RA (JRA), which is similar to RA except that rheumatoid factor is not found [5-8]. In the West, the prevalence of RA is believed to be 1 – 2 % [9], and 1% worldwide [10]. Clinically, the diagnosis of RA can be differentiated from osteoarthritis (OA) as the affected areas in RA are the proximal interphalangeal (PIP) and metacarpophalangeal (MP) joints; OA typically affects the distal interphalangeal (DIP) joint. OA is the most common type of arthritis and is caused by wear and tear rather than an autoimmune condition. It has no effects on the lungs, heart, or immune system. In addition, OA typically affects only one side of the body, as opposed to the symmetrical nature of RA. Another differentiating factor is that RA patients suffer from persistent morning stiffness for at least ≥ 1 h. Patients with OA may have morning stiffness, but this typically resolves or decreases within 20–30 min [11,12]. The goals of treatment for RA are to reduce joint inflammation and pain, maximize joint function, and prevent joint destruction and deformity. Treatment regimens consist of combinations of pharmaceuticals, weightbearing exercise, educating patients about the disease, and rest. Treatments are generally customized to a patient's needs and depend on their overall health. This includes factors such as disease progression, the joints involved, age, overall health, occupation, compliance, and education about the disease [13]. This review briefly highlights the classic and current treatment options available to address the discomfort/complications of RA. An exhaustive review was recently published by Smolen et al. [14].



Figure No. 2: Rheumatoid arthritis

BANYAN TREE

Banyan *Ficus Benghlensis* L. (FB) is a large plant and is a member of the family Mulberry (Moraceae). It has been used for thousands of years and has become an essential plant in the medicinal field. Banyan varies in morphology, growth habit, flower color, leaves, stems, and chemical composition. It is available throughout the year in different regions of the world. It grows in evergreen except in some dry areas where it remains leafless for a very short time due to dryness and shortage of water. FB (Banyan tree), *Ficus carica* (Anjir tree) and *Ficus Religiosa* (Pipal tree) are species that are common in the genus *Ficus*, which is classified in the family Moracea [15]. FB has different names depending on the region of the world where it is existing. In English, FB typically is called Banyan, the common name is Bohr. In India, specifically, Hindi native speakers, it is called Bargad. In different places of India, it has different names such as, in Punjab it is known as Bera, in Bengali it is known as Bar, in Malayalam it is called Vatam, in Gujarati it is commonly called Vad, in Kanarese it is famous by the Ala name, in Marathi it is called Vada, in Sanskrit it is called Bahupada, in Tamil it is called Alaiand in Telugu it is called Peddamarri [16]. Probably, the most famous characteristic of banyan is its beautiful flavor. FB has a wide range of varieties and cultivars, varying in flavor and uses. The popular example includes *F. macrophylla*, *F. microcarpa* and *F. pertusa*. The shortleaf fig plant (*Ficus citrifolia*) is native to different region of the world such as southern Florida, South America, south to Paraguay, the Caribbean Islands and Central America. But among these spices, the most common is banyan tree. Banyan has an epiphytic nature. It has large spreading head; it can grow 20 - 30 meters or more. Flowering

occurs from May to August. The banyan tree has leaves, which are very large, glossy green, leathery and elliptical in shape. Young leaves seem to be an attractive reddish tinge. FB fruit color at ripening time change from orange to red. It is also used as ornamental plant in different regions of the world [17].

The essential oil, which extracted from FB has different compounds such as sesquiterpene and monoterpene, as well as α -cadinol, γ -cadinene, α -muurolene and germacrene- D-4-ol. FB also has tannins, sterols, phenols, β flavonoids and saponins in large amounts. Some compounds such as aromatic acids, triterpenoids, mucilage, carbohydrates, gums and volatile oils are totally absent in the leaf extract of this plant [18].

History/Origin

FB is native to a wide area of Asia from India through Myanmar (Burma), Thailand, Malaysia, Southern China and Southeast Asia. The name; *F. benghalensis* was originated in India. In the Gujarati language, "banya" means "grocer or merchant", which is not "tree". The Portuguese used this word to show the Hindu's merchants, and it entered into English as early as 1599 with the same meaning and became popular. In 1634, English writers started to call the banyan tree as a tree. Under the shade of this tree, Hindu merchants sat and offered their business. Villages meetings also held under the shade of this tree. Eventually, "banyan" became the name of the tree itself [19]. In Australia Banyans also commonly endemic, also it can be found in different areas such as raintree and rainforest in Queensland's far north [20]. Some people are being scared from Banyan tree and called it the vat Vriksh, others believed that the God Shiva was always descend quietly and stood under the tree on his feet.

Chemical composition

FB has a green pale, fine and odorless powder which is slightly acrid and sweetish in taste. The microscopic powder shows the presence of trichrome and fibers. Many qualitative chemical analysis tests on FB were done, the ethanolic extracts indicates the presence of sterols, flavonoids, phenols, tannins, and saponins in large amounts [21]. Extracts of the stem bark showed that various chemical components are present such as methyl ethers of leucodelphinidin rhamnoside, leucopelargonidin rhaamnoside, lecocyanidin, galactosylcellobioside, pentatriacontan-5-one, tetratriacont-20-en-2one, heptatriacont-6-en-10-one, beta-sitosterol glucoside and isoinositol. However, the main chemical compounds that were found in the essential oils of the banyan are, sesquiterpene α -cadinol (25.1%),

germacrene-D-4-ol (14.9%), γ -cadinene (11.8%) and α -muurolene (9.6%) [18].

Flavonols and Flavonoids:

Leaves of *F. benghalensis* contain Flavonols that are responsible for its antioxidant effects. These flavonols include quercetin-3-galactoside and rutin (Vikas and Vijay, 2010). Stem bark of *F. benghalensis* also contains bengalenosides that is, glycosides or flavonoids, 5, 7 Dimethyl ether of Leucoperalgonidin-3-0- α -L-rhamnoside and 5, 3 dimethyl ether of leucocyanidin 3-O- β -D- galactosyl cellobioside, and 5, 7, 3 trimethoxy leucodelphinidin 3 - O- α -L- Rhamnoside [32]. All these flavonoids consist of various sugars attached with OH groups of Leucoperalgonidin, Leucodelphinidin and Leucocyanidin.



Figure No.3: Figure of BANYANTREE

Phytochemistry

Studies revealed that leaves of FB plant contain quercetin-3-galactoside, rutin, friedelin, taraxosterol, lupeol, β -amylin, psoralen, bergapten, β -sisterol, and quercetin-3-galactoside. The latex contains the caoytchoue, resin, albumin, cerin, sugar, and malic acid [21]. The bark of FB have 5, 7 dimethyl ether of leucopelargonidin-3-0- α -L rhamnoside and 5, 3 dimethyl ether of leucocynidin 3-0- α -D galactosyl cellobioside, beta sitosterol-alpha-Dglucose, as well as meso- inositol. Earlier, glucoside, heptatriacontene10-one, tetratriacontene-2-one, 6-heptatriacontene- 10-one, β sitosterol-alpha- Dglucose, andmeso-inositol, leucodelphinidi

derivative, bengalenoside, agluconide, leucopelargonin derivative, leucocynidin derivative, and glycoside of leucopelargonidin.[22]. FB is unusual rich source of oil containing fatty acids which can be used for industrial utilization. Usually, GC-MS analysis is used to find out the chemical profile of seed oil [23-25], which was showed to contain vernolic acid (8.2%), malvalic acid (3.7%) and sterculic acid (1.6%) along with the other normal fatty acids like linoleic acid (15.4%) lauric acid (1.5%), myristic acid (1.3%), oleic acid (20.3%), palmitic acid (35.2%), stearic acid (4.2%), and linolenic acid (8.7%) in addition to vernolic, malvalic, sterculic and some other normal fatty acids.

Table No. 1: Scientific classification

Scientific classification	
Kingdom:	Plantae
Division:	Magnoliophyta
Class:	Magnoliopsida
Order:	Urticales
Family:	Moraceae
Genus:	<i>Ficus</i>
Subgenus:	<i>(Urostigma)</i>

General uses

Many of the therapeutic properties of FB have been attributed to the diverse compounds of polyphenols. Bioactive peroxides are used as anticancer, antiviral [23-24], antidiabetic, and against malaria, as well as cardioprotective, hepato-protective, and neuroprotective effects.

According to Ayurvedic system of medicines, bark, fruits, and aerial roots of FB are used for the curing diabetes. Leucopelargonin are flavonoids which are used as worthy hypoglycemic agents and as antioxidants. The bark of FB antipyretic, antiseptic, and vermicide activity,

decoction of the bark is used to cure different skin disorders and ulcers. It is used as a plaster in the inflammatory swellings. It is effective in the curing of asthma, piles, dysentery, gonorrhoea, hemoptysis and also in urinary disorders [26]. The decoction of leaf, buds, and aerial roots of Nyagrodha were mixed with honey and used for the treatment of vomiting and thirst. The leaves are used for ulcers, leprosy, burning sensations, allergic situations of skin and abscesses. The buds are used in diarrhea and dysentery. The latex is used in neuralgia, otorrhagia, lumbago, bruises rheumatism, nasties, ulitis, odontopathy, hemorrhoids, gonorrhoea, and inflammations. For some skin disorders, it is widely used in cracks of the sole[27].

Biological activities

In traditional system of medicine, different parts of FB plant, such as, stem bark, root bark, leaves, vegetative buds, fruits and latex are used to treat dysentery, nervous disorders, diarrhea, diabetes, leucorrhoea, menorrhagia, and acerbic [28-29]. In Ayurvedic system of medicine, FB is used in wound healing [30].

Anti-inflammatory

Anti-inflammatory effects of ethanolic and petroleum ether extracts of the bark of banyan were measured in different animals. The animals were given orally doses of 300 and 600 mg/kg/day of body weight to the dietary fiber content of foods namely, khejri (*Prosopis cineraria*), peepal banti (*Ficus religiosa*), banyan (*Ficus bengalensis*), gullar (*Ficus glomerata*) and tents (*Capparis decidua*) mottled from 38.5% to 55.7%. Fibre from all these plant foods, fed at the 10% dietary levels to rats. Results showed that banyan extract were of high potential anti-inflammatory activity [31].

Ayurvedic practitioners in India are using the milky juice (latex) of stem bark of *F. benghalensis* for the treatment of rheumatism and other inflammatory diseases [33]. A study was designed to demonstrate the anti-inflammatory activity of the methanolic extract of FB (MEFB) and possible mechanisms of its anti-inflammatory activity. MEFB inhibited the carrageenan induced edema. It is likely that it elicits its anti-inflammatory response by inhibiting the synthesis and release of prostaglandins, proteases and lysosomal enzymes like non-steroidal anti-inflammatory drugs [34]. Anti-inflammatory activity of MEFB is due to its multiple effects on mediators of inflammation, lysosomal enzymes, oxidative stress and vascular permeability. Myeloperoxidase (MPO) is enzyme present in neutrophils, monocytes

and macrophages at lesser concentration. The level of MPO activity is directly proportional to neutrophils concentration in inflamed tissue. MEFB decreases MPO activity in edematous tissues. MEFB has an inhibitory effect on malondialdehyde (MDA) which is an index of lipid peroxidation and shows that anti-oxidant activity of MEFB contributes to a great extent to its anti-inflammatory activity [35].

2.0 MATERIALS AND EQUIPMENTS

Drug and materials used in dissertation work is listed in Table 2.1.

Table 2 .1: List of drug and materials used in dissertation work

Sr. No.	Material	Supplier
1	Banyan Leaf Extract	Local Banyan Tree
2	Linseed Oil	Loba Chem
3	Liquid Paraffin	Loba Chem
4	Bees Wax	Loba Chem
5	Ceto-strearyl alcohol	Loba Chem
6	Menthol, Camphor	Loba Chem

2.2 List of Equipments

Sr. No.	Equipments	Manufacturer
1	Digital weighing balance	Shimadzu, Japan
2	Heating Mentle	Bio Technique, India
3	Soxhlet apparatus	Bio Technique, India
4	Therostat Waterbath	Bio Technique, India

2.3 Experimental work

2.3.1. Drug and excipients profile:

- **Rutin:**

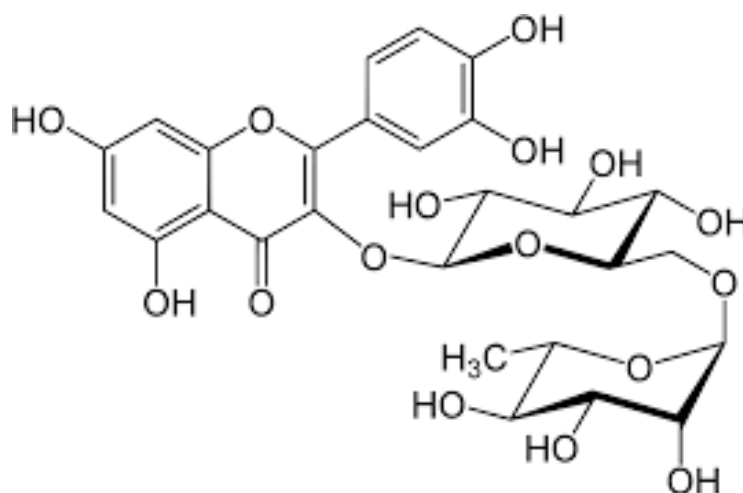
Rutin is a citrus flavonoid glycoside, which is a low molecular weight polyphenolic

compound. Rutin has various pharmacological activities such as anti-inflammatory. **Rutin**, also called **rutoside**, **quercetin-3-O-rutinoside** and **sophorin**.

1. **Chemical Formula:** $C_{27}H_{30}O_{16}$

2. **Appearance:** Solid

3. **IUPAC name:** 3',4',5,7-Tetrahydroxy-3-[α -L-rhamnopyranosyl-(1 \rightarrow 6)- β -D-glucopyranosyloxy]flavone



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- **Bees Wax:**

Beeswax is a product made from the honeycomb of the honeybee and other bees. The mixing of pollen oils into honeycomb wax turns the white wax into a yellow or brown color. Bees wax is used for high cholesterol, pain, fungal skin infections, and other conditions.

As medicine, beeswax is used for **lowering cholesterol and for relieving pain**. It is also used for swelling (inflammation).

- **Liquid Paraffin:**

LIQUID PARAFFIN is a lubricant that works by lubricating.

2.4 Experimental Work

In the present research, herbal cream was formulated by using infusion method. In this method yellow bees wax was mixed in liquid paraffin, cetostreayl alcohol, linseed oil and menthol, camphor and then heated on heating mental at 80 degree temperature after that

active ingredient Banyan extract weighed on weighing balance and dissolve in water and then boil the mixture for 15 min at 100 degree temperature after that we have removed the beaker from heating mental and let the mixture to be cool till room temperature and then the infusion was filtered through Whatman filter paper and extract out the active constituent and then the infusion solution again heated upto 70 degree temperature and mixed both aqueous and nonaqueous mixture at same temp. mixture was stirred by stirrer, when the temperature decreases the cream ready to formed . The effect of different formulation trials were prepared in table.

Table no. 2: Formulation Of herbal Cream

Formulation	Banyan Extract (gm)	Linseed oil(ml)	Liq. Paraffin (ml)	Bees Wax (gm)	Cetosteryl alcohol(ml)	Menthol, Camphor (gm)
Test1	2	1	4	2	2	--
Test2	8	8	9	4	4	6



Fig no.4: Soxhlet Apparatus Extraction Method



Fig no. 5: Infusion Method

3.0 RESULTS AND DISCUSSION

The infusion method was used for the smoothness of cream no solid particle in trap tetin it.

After observation it was found that cream did not leave greasy substance on skin surface after application. In the above formulations trials Test 2 trial is our best one and our cream passes all the parameters like its colour, visual appearance, Foreign particle, odour, Extrudability and spreadability which were prepared in table 3.1.

Evaluation of Herbal cream:

The Herbal cream was then evaluated for the following physical parameters.

Properties of the cream were studied by Colour, Visual appearance, Foreign particles, Odour, Extrudability and Spreadability.

- Foreign particles** -- Small amount of herbal cream was taken and spread on a glass slide and was observed against diffused light to check for presence of foreign particles and the cream was found to be free from foreign particles.
- Colour** -- Colour of cream was observed visually. Cream having Colour in our final Test trail.
- Extrudability** -- Extrudability test is useful empirical test to measure the force which required to extrude the material from a tube and the extrudability of herbal cream was found to be good.
- Spreadability** -- The spreadability was found to be easily spreadable on skin surface after application.
- Odour**—The Herbal cream was found to be in pleasant odour.
- Visual appearance** -- The Herbal cream was found to be smooth and consistent cream did not leave greasy substance on skin surface after application.

Table no. 3.1: Evaluation Of Herbal Cream Formulation

Parameters	Test1	Test2
Colour		
Visual appearance	Constancy is slightly Hard	Smooth and Consistent cream
Foreign particles	Free from foreign particles	Free from foreign particles
Odour	Pleasant odour	Pleasant odour
Extrudability	Good	Good
Spreadability	Slight hard spreadable	Easily spreadable

4.0 CONCLUSION

Ficus Benghalensis species plant parts have attracted much attention for their various pharmacological potentials contributed by the phytochemicals present in plant matrix. The species contain range of flavonoids, phenolics, terpenes and terpenoids, fatty acids sterols, organic acids, proteins and some long-chained hydrocarbon compound. Besides that, the presence of flavonoids and terpenoids is potential responsible for their pharmacological activity.

This study involves anti-inflammatory activity which provides use of species in traditional medicines.

In this research, the banyan tree leaves extract cream formulation was found to be stable (test 2) after performing suitable physicochemical evaluation studies.

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Fig no. 3.1: Formulated Herbal Cream