WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
Coden USA: WJPRAP Impact Factor 8.63
Volume 15, Issue 14, 1220-1239. Research Article ISSN 2277–7105

POLYHERBAL GEL FOR MANAGEMENT OF RHEUMATOID ARTHRITIS

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Article Received on 15 June 2026,
Article Revised on 05 July 2026,
Article Published on 16 July 2026,

https://doi.org/10.5281/zenodo.21369667

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How to cite this Article: Tanisha Raut*[1], Janu Rathod[2], Sejal Potdar[3], Rohan Pawar[4], Ms. Ujwala Khedkar[5]. (2026). Polyherbal Gel For Management of Rheumatoid Arthritis. World Journal of Pharmaceutical Research, 15(14), 1220–1239.

ABSTRACT

Rheumatoid arthritis is a chronic autoimmune inflammatory disorder associated with joint pain, swelling, stiffness, and reduced mobility. There is a need for safer substitutes because long-term usage of traditional anti-inflammatory medications may have negative side effects. The present study was aimed at the formulation and physicochemical evaluation of a novel polyherbal topical gel intended for anti-inflammatory and analgesic application. The formulation was developed using a Carbopol 940 gel base incorporating a polyherbal extract mixture of Caesalpinia bonduc, Vitex negundo and Rubia cordifolia. The prepared gel was evaluated for physical appearance, pH, viscosity, spreadability, homogeneity, skin irritation, and stability. The formulation exhibited acceptable physicochemical properties, skin-friendly pH, good spreadability, and no signs of irritation, indicating its suitability for topical application. The study supports the development of a stable and patient-acceptable polyherbal gel formulation based on documented pharmacological properties of the constituent ingredients.

KEYWORDS: Anti-inflammatory, Gel formulation, *Vitex negundo*, *Caesalpinia bonduc*, *Rubia cordifollia*, Carbopol 940, *Murraya koenigii*.

INTRODUCTION

Rheumatoid arthritis (RA) is a long-term autoimmune inflammatory disease that primarily

targets synovial joints but also affects several extra-articular organs, including the kidneys, heart, lungs, gastrointestinal tract, skin, eyes, and nervous system. The disease involves abnormal immune responses that contribute to persistent inflammation and tissue damage.

Clinically, RA is marked by progressive and irreversible destruction of synovial joints, leading to joint deformities and functional impairment. The pathological process includes degradation of the extracellular matrix, resulting in damage to cartilage, bone, ligaments, and tendons. Although a definitive cure for rheumatoid arthritis has not yet been established, various therapeutic strategies are available to control disease progression and alleviate symptoms. These approaches include pharmacological interventions aimed at reducing immune-mediated inflammation, physical therapy to enhance joint mobility, strength, and functional capacity, and the use of therapeutic injections.

Despite their effectiveness, conventional drug therapies are often associated with high costs and significant adverse effects during long-term use. Current pharmacological management of RA mainly involves nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, and disease-modifying antirheumatic drugs (DMARDs). NSAIDs and corticosteroids provide rapid symptomatic relief, whereas DMARDs generally require extended periods to produce noticeable clinical outcomes. Owing to these limitations, increasing attention has been directed toward the exploration of alternative therapeutic options for the management of rheumatoid arthritis.[1]

Rheumatoid arthritis symptoms, which may occur throughout the body, include

1. Persistent joint pain and tenderness
2. Joint swelling and inflammation
3. Morning stiffness lasting for extended periods
4. Reduced joint mobility and functional limitation
5. Fatigue and generalized weakness
6. Low-grade fever
7. Loss of appetite and unintended weight loss
8. Formation of rheumatoid.[2]

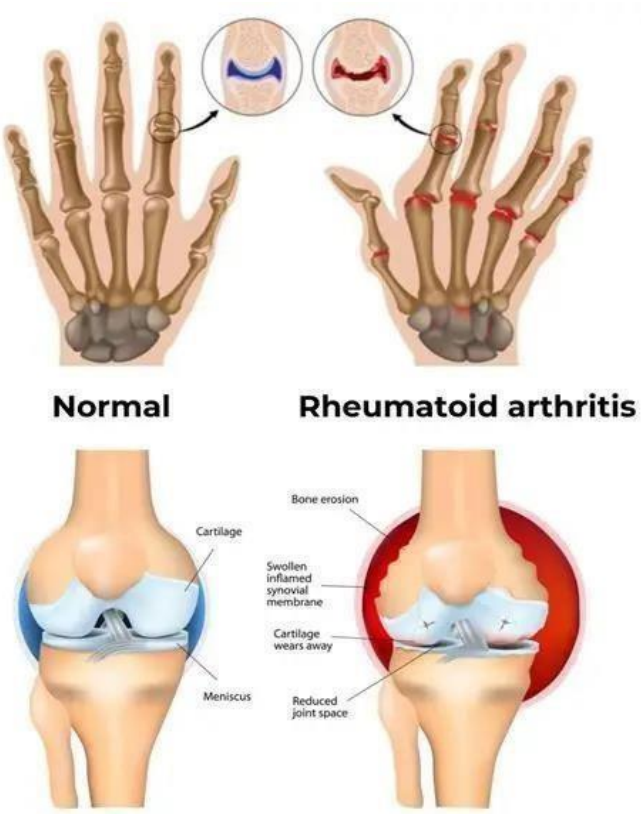

Fig. no. 1: Rheumatoid arthritis.[3]

The present research focuses on the development of a polyherbal gel formulation containing polyherbal extract using appropriate pharmaceutical excipients such as Carbopol 940 as a gelling agent, emulsifier, preservatives, and penetration enhancers. The formulated gel is intended for topical application to provide effective anti-inflammatory and anti-rheumatic activity with enhanced stability, skin compatibility, and patient compliance. This study aims to establish a safe and effective herbal alternative for the management of inflammatory and rheumatic disorders.

POLYHERBAL GEL

Polyherbal formulation (PHF) refers to a preparation in which two or more herbs are combined for medicinal or therapeutic use. This concept originates from Ayurvedic and other traditional systems of medicine, where different herbs are mixed in specific ratios to treat diseases effectively. The idea of polyherbalism was described in the ancient Ayurvedic text Sarangdhar Samhita. In the traditional Indian medicinal system, formulations made from multiple plant extracts are generally preferred over single-herb preparations because the combination can provide better therapeutic effects.[3]

A polyherbal gel is a topical semisolid preparation formulated by incorporating extracts of multiple medicinal plants into a suitable gel base. The principle of polyherbalism is based on the synergistic interaction of different herbal constituents, which enhances therapeutic efficacy and provides a broader spectrum of pharmacological activity compared to single-herb formulations. Each plant extract contributes distinct bioactive compounds that collectively improve the overall effectiveness and safety of the formulation.[4]

Topical gels are widely preferred as drug delivery systems due to their non-greasy nature, ease of application, good spreadability, and rapid penetration into the skin. The use of gelling agents such as Carbopol 940 provides desirable consistency, clarity, and stability to the formulation, while penetration enhancers facilitate improved transdermal absorption of the herbal active constituents. Additionally, gel formulations offer controlled drug release and localized therapeutic action, thereby minimizing systemic exposure and associated adverse effects.

In the management of inflammatory and rheumatic disorders, polyherbal gels are particularly advantageous as they deliver active phytoconstituents directly to the affected area, resulting in effective relief from pain, swelling, and stiffness. Herbal constituents such as flavonoids, alkaloids, tannins, glycosides, and essential oils present in medicinal plants exhibit anti-inflammatory, analgesic, antioxidant, and antimicrobial properties, which contribute to the therapeutic potential of polyherbal gels. In some formulations, the base itself provides therapeutic benefits, such as protecting the skin, giving a soothing effect, or acting as an emollient to moisturize and soften the skin. The skin is the largest organ of the body. Its thickness is not the same in all areas of the body; some regions have thinner skin while others are thicker. Generally, the average thickness of human skin is around 1 to 2mm.[2]

Fig. no. 2: Structure of skin.[5]

REVIEW OF LITERATURE

Table no. 1: Literature Review.

Title of article	Author name	Content
1] Formulation and Evaluation of Polyherbal Gel for Anti-Inflammatory Activity	Patel R.P., Patel G., Baria A.	The study involved formulation of a polyherbal gel and evaluation for pH, viscosity, spreadability, and in-vitro anti-inflammatory activity, showing good stability and efficacy.
2] Botanical and pharmacognostic evaluation of Caesalpinia bonduc seed, a prevalent Indian traditional drug having vivid therapeutic prospects	Shan Sasidharan, Srinivasakumar KP, Amiya Bhaumik, Sreemoy Kanti Das and Hareendran Nair J	The review highlights Caesalpinia bondac strong anti-inflammatory and antioxidant properties useful in managing rheumatoid arthritis.
3] Vitex negundo inhibits inflammatory cytokines	Pronobesh Chattopadhyay et al.	This research shows that *Vitex negundo* inhibits COX-2 mediated inflammation, confirming its effectiveness in anti-inflammatory therapy
4] Topical Drug Delivery System: A Review	Jain N.K., Mishra V	This review discussed advantages of topical gels such as localized action, reduced systemic side effects, and suitability for chronic
5] Withania somnifera: A Review of Pharmacological Properties	Mishra L.C., Singh B.B., Dagenais S.	The review described immunomodulatory and anti-arthritic properties of Ashwagandha useful in autoimmune disorders.
6] Formulation and Evaluation of Polyherbal Pain Relief Gel for its Effect on Rheumatoid Arthritis	Bratati Bandyopadhyay, Arif Munsi	Material, method and evaluation parameter can clearly explain so its help for our study.
7] Formulation and Evaluation of Polyherbal Gel	Priya Arun Walke1, Dhananjay Chandrakant Abhang1	This study outlines formulation and evaluation methods of polyherbal gel, which were adopted as a reference for performing evaluation tests in the present study.
8] Pharmacological Review of *Rubia cordifolia*	K. K. Johar, S. Singh, A. Kumar	The review highlights anti-inflammatory, antioxidant, and wound healing properties of *Rubia cordifolia*, supporting its use in topical formulations.

AIM AND OBJECTIVES

AIM: Formulation and Evaluation of Polyherbal Gel for Rheumatoid Arthritis Management.

Objectives of the Study

1 To develop a stable, safe, and effective polyherbal topical gel suitable for rheumatoid arthritis.

2 To evaluate the gel for essential physicochemical properties like pH, viscosity, spreadability, and homogeneity.

3 To perform stability studies under various storage conditions to assess the shelf- life,

physical integrity, and retention of therapeutic activity of the formulated gel over time.

4 To optimize the concentration of herbal extracts and gelling agent (Carbopol 940) for best performance.

DRUG PROFILE

Vitex Negundo

Table no. 2: Taxonomical classification of *Vitex negundo.*

Category	Botanical Descreption
Kingdom	Plantae – Plants
Subkingdom	Tracheobionta – Vascular plants
Super Division	Spermatophyta – Seed plants
Division	Magnoliophyta – Flowering plants
Class	Magnoliopsida – Dicotyledons
Sub Class	Asteridae Order – Lamiales
Family	Verbenaceae – Verbena family
Genus	Vitex
Species	Vitex negundo Linn. – (Chastetree)

DESCRIPTION

Vitex negundo is a woody, aromatic deciduous shrub that may also grow as a small tree. It is commonly known as monk's pepper or five-leaved chaste tree. One of its distinctive features is the presence of five palmately arranged pointed leaflets resembling the shape of a palm. The leaflets are lanceolate, pointed at both ends, glabrous on the upper surface, hairy beneath, and measure about 4–10 cm in length. The terminal leaflet possesses a longer petiole, while the lateral leaflets have shorter petioles. The flowers are bluish-purple in colour and occur in axillary or terminal panicles that may reach up to 30 cm in length. The fruits are small, spherical, and contain four seeds which become black, globose, and spongy upon ripening

Fig. no. 3: Vitex negundo.[14]

Chemical constituents

1. Negundin A

2. Casticin
3. Isoorientin
4. Sabinene
5. Terpinen-4-Ol
6. Caryophyllene[15]

Pharmacological activity

1. Anti-Nociceptive and Anti-Inflammatory Activity
2. Anti-Tumour Activity
3. Insecticidal Activity
4. Anti-Androgenic Activity
5. Antimicrobial Effect
6. Anti-Osteoporotic Activity
7. Anti-Hyperglycaemic Activity.

Caesalpinia bonduc

Taxonomic classification

The taxonomical classification of C. bonduc is given below:

Table no. 3: Taxonomical classification of C. bonduc.

Category	Botanical Descreption
Kingdom	Plantae – Plants
Subkingdom	Tracheobionta
Super Division	Spermatophyta
Division	Magnoliophyta
Class	Magnoliopsida
Sub Class	Rosidae
Family	Fabaceae / Leguminosae
Genus	Caesalpinia
Species	Caesalpinia bonduc (L.) Roxb

Fig. no. 6: Caesalpinia bonduc.[16]

Botanical characters

Caesalpinia bonduc is a vine-like shrub that grows up to about 6 m in length and climbs over surrounding vegetation. The stems are covered with curved spines, while the branches possess hooked and straight hard yellow prickles. The plant bears grey coloured seeds, commonly known as nicker nuts, measuring about 2 cm in length. These seeds are buoyant and can be dispersed through ocean currents. The leaves are compound and approximately 36–60 cm long.[17]

Chemical constituent

The seeds of Caesalpinia bonduc contain various bioactive constituents including sitosterol, caesalpins, bonducin, caesane, flavonoids, and caesalpinianone. The seeds are rich in starch and fixed oil, and also contain sugar along with bitter principles such as natin and phytosterinin. The fatty oil mainly consists of glycerides of palmitic and stearic acids along with sitosterol. In addition, the seeds contain saponins such as bonducin which contribute to their medicinal properties.[18]

Pharmacological activity

1. Antiinflammatory activity
2. Antioxidant activity
3. Antimicrobial activity
4. Anthelmintic activity
5. Hypoglycaemic activity

Rubia cordifolia

Table no. 4: Taxonomical classification of *Rubia cordifolia.*

Category	Botanical Description
Kingdom	Plantae
Class	Dicotyledonae
Subclass	Sympetalae
Order	Rubiales
Family	Rubiaceae
Genus	Rubia
Species	cordifolia

Description of plant

Rubia cordifolia is a perennial prickly climber that can grow up to 12 m in length. The stem is slender and climbing in nature. Leaves are ovate to lanceolate, highly variable, 2–10 cm long

and 2–5 cm broad, arranged in whorls of 4–6. The flowers are small, fragrant, and whitish to greenish-yellow in colour. The fruits are minute, smooth, one to two seeded, and become dark purplish to black on maturation. Flowering and fruiting generally occur during August to October. The roots are long, cylindrical, perennial, and rusty brown in colour

Fig. no. 9: Rubia cordifolia.[19]

Chemical constituent

Anthraquinones and their glycosides, naphthoquinones, terpenes, hexapeptides, carboxylic ac ids, iridoids, and saccharides are among the groups of bioactive substances that have been fou nd in various portions of Manjistha. The root, in particular, is rich in compounds such as purpurin, munjistin (a coloring agent), xanthine (yellow pigment), xanthopurpurin, pseudopurpurin, and alizarin (orange-red pigment). It also contains other constituents like mollugin, garancin, rubimallin, rubicoumaric acid, rubifolic acid, β-sitosterol, naphthohydroquinone, di-β-D-glucoside, and daucosterol.[20]

Pharmacological activity

1. Anti-acne property
2. Anti-inflammatory activity
3. Anti-convulsant properties
4. Anti-diabetic activity
5. Anti-microbial activity
6. Wound healing activity
7. Anti-oxidant activity
8. Anti-platelet activating effect
9. Anti-stress and nootropic activity
10. Anti-ulcer activity

Murraya koenigii

Taxonomical classification

Table no. 5: Taxonomical classification of *murraya koenigii.*

Category	Botanical Descreption
Kingdom	Plantae
Subkingdom	Tracheobionta
Super Division	Spermatophyta
Division	Magnoliophyta
Class	Magnoliopsida
Sub Class	Rosidae
Family	Rutaceae
Genus	Murraya J. Koenig
Species	Murraya koenigii

Morphological description

Murraya koenigii is a small aromatic shrub or tree that generally grows up to 2–2.5 meters in height with a dark green to brown coloured stem. The leaves are elongated with prominent reticulate venation. The plant produces white, funnel-shaped fragrant flowers and bears round fruits measuring about 1.4–1.6 cm in length. It is widely distributed across India and commonly cultivated in regions such as Sikkim, Assam, and the Western Ghats. The plant usually grows in moist forests at altitudes of 500–1600 meters. In addition to India, it is also found in Sri Lanka, Nepal, Bhutan, Laos, Thailand, Vietnam, Hainan, Guangdong, and Yunnan. Due to migration and cultivation, curry leaves have also spread to countries such as Malaysia, South Africa, and Réunion Island.[21]

Fig. no. 12: Murraya koenigii.[22]

Pharmacological activity

1. Antibacterial activity
2. Antibacterial activity
3. Anti-ulcer activity

4. Anti-diarrheal activity
5. Neuroprotective activity.[23]

PHARMACOGNOSTIC EVALUATION

Test for alkaloids

Table no. 6: Test for alkaloids.

Sr. No	Test	Observation	Inference of vitex negundo (sample 1)	Inference of *Murraya koenigii* (sample 2)
1	**Dragendorff's test:** 2 ml of aqueous extract was taken, a few drops of Dragendorff's reagent added in it. Presence of reddish brown/ orange precipitate obtain.	A yellow ppt observe in sample1, and orange ppt observ in sample 2.	Alkaloid's present	Alkaloid's present
2	**Mayer's test:** To a few ml of extract 1 or 2 ml of Mayer's reagent is added. Cream, Pale yellow colour obtain.	A Pale-Yellow Colour Observe in both samples.	Alkaloid's present	Alkaloid's present

Fig. No. 15: Dragendroff test for vitex negundo.

Fig. No. 16: Dragendroff test for murraya koenigii.

Fig. No. 17: Mayers test for vitex negundo.

Fig No. 18: Mayers test for murraya koenigii.

- ***Test for flavonoids***

Table no. 7: Test for flavonoids.

Sr. No	Test	Observation	Inference of Rubia Cordifolia	Inference of Vitex Negundo	Inference of Caesepinia Bondac
1	**Lead acetate test:** Add few drops of lead acetate to the filtrate. Obtain yellow ppt.	Yellow ppt observe	Flavonoids absent	Flavonoid's present	Flavonoid's present
3	**Alkaline reagent test:** Sodium hydroxide gave a	Observ yellow colour that became colourless	Flavonoid's present	-	Flavonoid's present

	yellow colour that became colourless with acid, indicating flavonoids.				

Fig. No. 19: lead acetate test for *vitex negundo.*

Fig. No. 20: Lead acetate test for *Caesalpinia.*

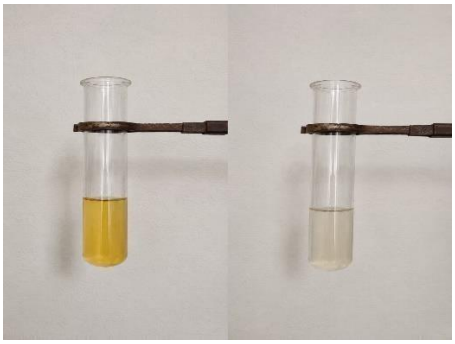

Fig. No. 21: Alkaline test for *Rubia cordifolia.*

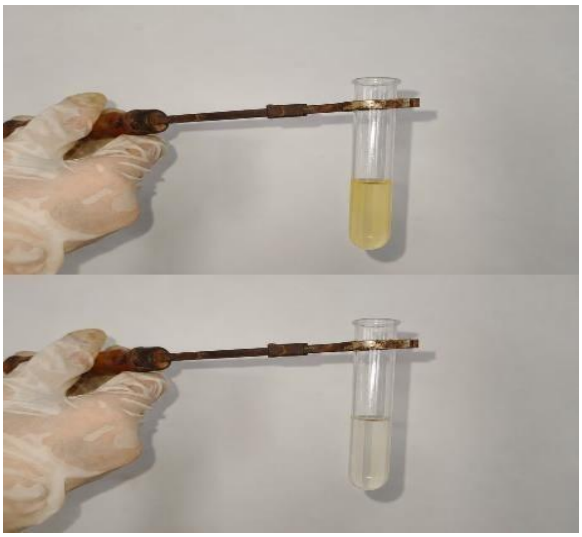

Fig. No. 21: Alkaline test for *C.bondac.*

- ***Test for phenolic compounds***

Table no. 8: Test for phenolics.

Sr. No	Test	Observation	Inference of Rubia Cordifolia	Murraya Koenigii
1	**Ferric chloride test:** 2ml extract and add few drops of FeCl3 solution.	Blue, Green Colour observe	Phenolics present	Phenolics present

Fig No. 24: Test for *Rubia cordifolia.* **Fig. No. 25: Test for murraya koenigii.**

- ***Test for tannins***

Table no. 9: Test for tannins.

Sr. No	Test	Observation	Inference of vitex negundo	Inference of Rubia cordifolia
1	**Ferric chloride test:** 2ml extract and add few drops of FeCl3 solution.	Blue, Green Colour observe	Tannin's present	Tannin's present

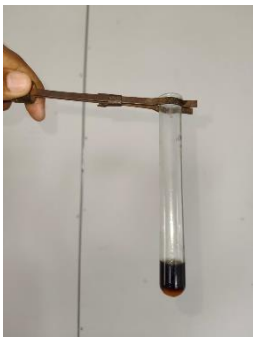

Fig No.26: Ferric chloride test for *vitex negundo.* **Fig. No. 27: Ferric chloride test for Rubia cordifolia.**

- ***Test for anthraquinone glycosides***

Table no. 10: Test for Anthraquinone Glycosides.

Sr. No	Test	Observation	Inference of *Rubia cordifolia*
1	**Borntrager's test:** Extract was boiled with dilute H_2SO_4, cooled and filtered. Filtrate was extracted with benzene and treated with ammonia → pink to red colour in ammoniacal layer indicates presence of anthraquinone glycosides**.**	Observe Pink colour in ammoniacal layer	anthraquinone glycosides present

Fig. No. 28: Anthraquinone glycoside test for *Rubia cordifolia.*

- ***Test for saponin***

Table no. 11: Test for saponin.[24]

Test	Observation	Inference of *Rubia cordifolia*	Inference of *C. bonduc*
Foam test: A small amount of powdered drug or extract is taken in a test tube, mixed with 5–10 mL distilled water and shaken vigorously for 1–2 minutes. The mixture is then allowed to stand for a few minutes	formation of stable persistent froth or foam in both sample	Saponin is present	Saponin, is present

Fig no. 29: Test for saponin of Rubia cordifolia.

Fig no. 30: Test for saponin of C. bonduc.

Experimental section

Material

Table no. 12: Master Formula.

Sr.	Ingredient	QTY. (50g) F1	QTY. (25g) F2	QTY. (25g) F3 (stable)	Role
1	*Vitex negundo*	1gm	0.5g	0.5g	API
	Rubia cordifolia	1gm	0.5g	0.5g	API
	Caesalpinia bondac	1gm	0.5g	0.5g	API
	Murraya koenigii	1gm	0.5g	0.5g	API
2	Carbopol 934	0.5gm	0.25g	0.3g	Thickening agent and foam

					gel base
3	Propylene glycol	3.5 ml	1.75ml	1.5ml	Humectant and penetration enhancer
4	Glycerin	2.5ml	1.25ml	1.5ml	Moisturizing agent
5	Methyl paraben	0.15gm	0.075g	0.075g	Preservative
6	PEG-400	1.5ml	0.75ml	0.75ml	Solvent and Plasticizer
7	Menthol	0.15gm	0.075g	0.075g	Counter irritant and analgesic
8	Triethanolamine	Q.S (~0-5g)	Q.S(~0-2.5g)	Q.S(~0-2.5g)	Neutralizing and PH adjusting agent
9	Distilled water	Q.S	Q.S	Q.S	Vehicle

METHOD OF PREPARATION OF POLYHERBAL GEL

Step 1: preparation of herbal extract

Ethanolic extracts of *Vitex negundo, Rubia cordifolia, Caesalpinia bonduc, murraya koenigii* were prepared using the maceration method. In this process, 10 g of dried plant material was coarsely powdered and soaked in ethanol to facilitate extraction. The obtained extracts were then incorporated into a polyherbal gel formulation, with Carbopol 940 used as the gelling agent.[25]

Fig. no. 31: Extraction of crude drug by maceration.

Step 2: Carbopol Gel Base

Disperse Carbopol 940 (0.3 g) in distilled water Stir using magnetic stirrer (~30 min)

Allow to hydrate and remove air bubbles.

Step 3: Prepare Extract Phase

Mix all herbal extracts

Add propylene glycol + PEG-400 + glycerine stir properly to get uniform solution.

Step 4: Preservative Solution

Dissolve methylparaben + propylparaben in small amount of warm water or propylene glycol.

Step 5: Menthol Solution

Dissolve menthol in PEG-400 or propylene glycol.

Step 6: Mixing

Take extract phase and add into the Carbopol gel with continuous stirring Add preservative solution, Add menthol solution.

Step 7: Neutralization

Add triethanolamine dropwise

Stir gently → gel becomes thick and clear Adjust pH (~6–7)

Step 8: Final Volume

Add distilled water Q.S to 25 g Mix properly to get uniform gel.

Step 9: Packing

Transfer into suitable container (preferably airtight plastic/laminated tube)

❖ **EVALUATION TEST OF POLYHERBAL GEL**

1. Physical Evaluation

All formulated gels were filled into containers and evaluated for homogeneity through visual inspection. The formulations were examined for their appearance and checked for the presence of any aggregates or inconsistencies.

2. *Colour, Odour, Appearance, and Feel*

The formulated gels were visually examined for their colour, appearance, and the presence of any clogs or particulate matter. To evaluate the feel of the gels, the formulations were applied to the skin.

Fig. no. 32: Prepared gel.

3. *Viscosity Test*

The viscosity of individual and polyherbal gels was measured by Brookfield viscometer at 6.0 rpm using spindle no 3 Viscosity of gel was done by using Brooke field viscometer at temperature of 25 °C at 6.0 RPM.

Fig. no. 33: Viscosity of gel.

4. *Determination of pH (Normal range 5-7)*

The pH was determined by using pH strip. The strip was deep into the gel and the obtained colour was compared with the chart provided with strip.

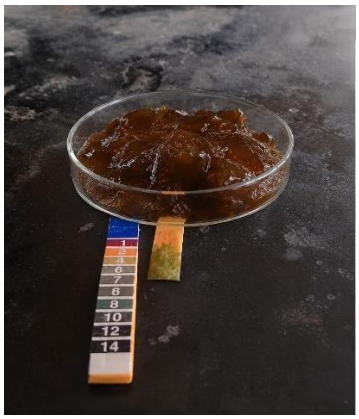

Fig. no. 34: PH test.

5. Swelling

For determination of swelling index, a known quantity of gel was taken in a graduated cylinder and a specified amount of distilled water was added. The mixture was allowed to stand for 24 hours at room temperature to permit complete swelling of the gel. After the

specified time, the increase in volume of the gel was noted and the swelling index was evaluated based on the extent of swelling observed.

6. *Washability test*

Formulations were applied on the skin and then ease and extent of washing with water were checked manually.[25]

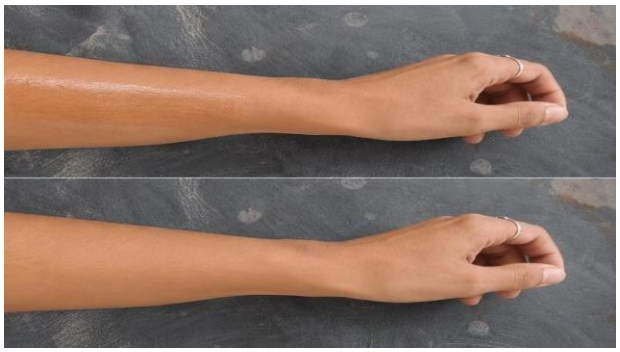

Fig. no. 35: Washability Test.

❖ RESULT

Table no. 13: Evaluation result.

Sr no.	Evaluation parameter	Result
1	Colour	Brownish
2	Odour	Characteristic aromatic
3	Appearance	Smooth semi-solid gel
4	Homogeneity	Homogeneous with no lumps/gritty particles
5	Determination of pH	6.5
6	Viscosity Measurement	21620 cps
7	Washability	Easily washable with water

Viscosity of gel

RPM	Spindle No.	Viscosity (cps)
6.0 rpm	3	21,620 cps

CONCLUSION

In the present study, three different formulations (F1, F2, and F3) of a polyherbal anti-rheumatoid gel were successfully prepared using extracts of Vitex negundo, Rubia cordifolia, Caesalpinia bonduc, and Murraya koenigii along with suitable excipients. The formulations were evaluated for various physicochemical parameters such as colour, odour, appearance, homogeneity, pH, washability, viscosity and swelling behaviour.

Among all the prepared formulations, formulation F3 showed comparatively better

characteristics with good consistency, smooth semi-solid appearance, satisfactory homogeneity, acceptable pH, viscosity, good washability. The modifications made in the composition of F3 resulted in improved gel properties and better overall performance compared to F1 and F2.

Therefore, the optimized F3 formulation can be considered as a promising polyherbal anti-rheumatoid gel for topical application and may provide beneficial effects in the management of rheumatoid arthritis and inflammatory conditions.

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