IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 2, October 2025
Impact Factor: 7.67

A Review on Formulation and Evaluation of Anti-Rheumatoid Arthritis jelly

Prasad B. Mhaske[1], Shrikrushana S. Narode[2], Dipali R. Shirsath[3], Kajal K. Warghude[4], Miss. Vidya Anap[5]
Students, Department of Pharmacy[1,2,3,4]
Guide, Department of Pharmacy[5]
Mrs. Saraswati Wani College of Pharmacy, Ganegaon, Maharashtra
Affiliated to Dr Babasaheb Aambedkar Technological University, Lonore, Raigad

Abstract: *Rheumatoid arthritis (RA) is a chronic, systemic autoimmune disorder that leads to progressive joint inflammation, pain, and disability. While systemic pharmacological therapies remain central in RA management, topical semisolid formulations have gained attention as complementary approaches due to their ability to deliver active agents locally, minimizing systemic exposure and adverse effects. Synthetic topical formulations, particularly gels, ointments, and medicated jellies, offer significant promise in enhancing local analgesic and anti-inflammatory efficacy through optimized excipient selection and delivery strategies. Non-steroidal anti-inflammatory drugs (NSAIDs) such as diclofenac sodium, in combination with synthetic excipients including propionic acid homopolymer (Synthalen K), surfactants, and penetration enhancers, have demonstrated improved drug diffusion and bioavailability. Physicochemical characterization methods such as rheological studies, texture profile analysis, in vitro release testing (IVRT), and ex vivo Franz diffusion assays have been widely applied to evaluate formulation performance. Additionally, synthetic systems can be further optimized for stability, controlled release, and patient acceptability. This review highlights advances in synthetic topical drug delivery systems for RA, with a focus on formulation design, evaluation methodologies, and regulatory considerations, aiming to guide the development of effective and patient-friendly therapeutic alternatives.*

Fig. No. 1(Anti-Rheumatoid Arthritis Jelly)

Keywords: Rheumatoid arthritis, Pathophysiology, active agent, formulation, Evaluation

DOI: 10.48175/IJARSCT-29233

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 2, October 2025
Impact Factor: 7.67

I. INTRODUCTION

Rheumatoid arthritis (RA) is a chronic systemic autoimmune disorder characterized by persistent synovial inflammation, cartilage destruction and progressive joint deformities. It affects approximately 0.5–1% of the global population, with a considerable impact on physical function, quality of life and life expectancy.[1],[2] In addition to joint manifestations such as pain, stiffness, swelling and disability, RA is also associated with extra-articular complications including cardiovascular disease, pulmonary disorders, ocular involvement and renal dysfunction, which contribute significantly to morbidity and mortality.[3],[4] Conventional systemic therapies, although effective in suppressing inflammation and slowing disease progression, are frequently associated with adverse effects such as gastrointestinal irritation, hepatotoxicity and cardiovascular complications.[5],[6] These challenges have created a demand for localized, patient-friendly drug delivery systems.

Topical formulations provide the advantage of delivering anti-inflammatory and analgesic agents directly to affected joints, minimizing systemic toxicity while enhancing patient compliance.[7],[8] Among various topical platforms, medicated jellies represent a promising approach due to their semisolid, jelly-like consistency, favorable spreadability, ease of application and improved drug residence time at the site of action.[9] Such formulations can be designed using synthetic polymers and gelling agents to ensure optimum viscosity, bio-adhesion, and controlled drug release. Evaluation parameters including pH, rheological behavior, drug content uniformity, in-vitro release, ex-vivo permeation and stability studies are essential to establish their therapeutic potential.[10] Therefore, the formulation and evaluation of anti-rheumatoid arthritis medicated jellies present an innovative strategy to address the limitations of conventional therapy, offering a safer, more effective, and patient-centric approach in the management of RA.

2. Rheumatoid Arthritis: Pathophysiology & Rationale for Topical Therapy:

Rheumatoid arthritis (RA) is characterized by aberrant immune activation leading to synovial hyperplasia, pannus formation and progressive joint destruction. The pathogenesis is driven by pro-inflammatory cytokines such as tumor necrosis factor-α (TNF-α), interleukin-1β (IL-1β) and interleukin-6 (IL-6), which perpetuate synovial inflammation and cartilage degradation.[11],[12] These mediators stimulate the release of matrix metalloproteinase and promote prostaglandin synthesis, further aggravating tissue damage and pain. Infiltration of activated T cells, B cells, macrophages and neutrophils into the synovium contributes to chronic inflammation, autoantibody production (e.g., rheumatoid factor and anti-cyclic interlineated peptide), and systemic manifestations.[13]

While systemic therapy with disease-modifying antirheumatic drugs (DMARDs) and biologics remains the cornerstone of treatment, long-term use of oral nonsteroidal anti-inflammatory drugs (NSAIDs) and corticosteroids is associated with gastrointestinal, renal, hepatic and cardiovascular adverse effects.[5],[6],[14] Topical therapy offers an attractive alternative by delivering the active agent directly to inflamed joints, thereby achieving localized inhibition of prostaglandin synthesis and cytokine activity at the site of articulation.[7],[8],[15] This localized approach minimizes systemic drug exposure, reduces safety liabilities, and may improve patient adherence, particularly in chronic management. Moreover, natural anti-inflammatory compounds (e.g., curcumin, boswellic acid, capsaicin) and synthetic NSAIDs have shown promise in topical formulations for reducing pain and joint stiffness without systemic toxicity.[16],[17] Thus, the rationale for topical delivery in RA lies in its ability to target the pathological site directly, reduce systemic adverse events and enhance therapeutic outcomes, making it a valuable strategy in the formulation of medicated jellies and other innovative topical systems.

3. Active agents suitable for anti-RA topical jellies:

Common active ingredients and rationale:

Topical NSAIDs (e.g., diclofenac, ketoprofen, ibuprofen, naproxen): well-documented local analgesic and anti-inflammatory effects; efficacy supported in osteoarthritis and joint pain studies.[15],[18]

Local corticosteroids (short-term use) — potent anti-inflammatory but systemic absorption and skin atrophy risk require careful control.[14]

Disease-modifying agents are typically systemic and not suitable for topical jellies, but research explores Nano-carriers to enhance local delivery of DMARDs.[19]

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 2, October 2025
Impact Factor: 7.67

Natural anti-inflammatories (e.g., curcumin, boswellic acids, capsaicin, menthol combinations) as adjuncts — promising preclinical data.[16],[17]
Combination approaches (NSAID + permeation enhancer or natural anti-inflammatory) to improve efficacy.[20]

4. Polymers and excipients for jelly formulation:

Polymers used to form jelly matrices include natural polysaccharides (pectin, carrageenan, agar, gelatin), cellulose derivatives (HPMC, CMC), and synthetic carbomers (Carbopol® 934/940).[21] Choice depends on desired texture, rheology, drug compatibility and release profile. Common excipients: humectants (glycerin, propylene glycol), preservatives (parabens, phenoxyethanol), permeation enhancers (ethanol, DMSO, propylene glycol, oleic acid), neutralizers (triethanolamine for carbomers) and antioxidants.[22]
Typical choice examples and their properties:
Carbopol 934/940: high viscosity at low concentration, shear-thinning behavior, common for topical gels.
HPMC: thermoreversible thickening, good clarity and spreadability.
Carrageenan: natural ionic polysaccharide, firm gel networks with salts.
Pectin: forms jellies by cooling/congealing with sugar/acid—used in oral jellies but adaptable.
Agar/gelatin: used for jelly-like textures; gelatin less thermally stable.

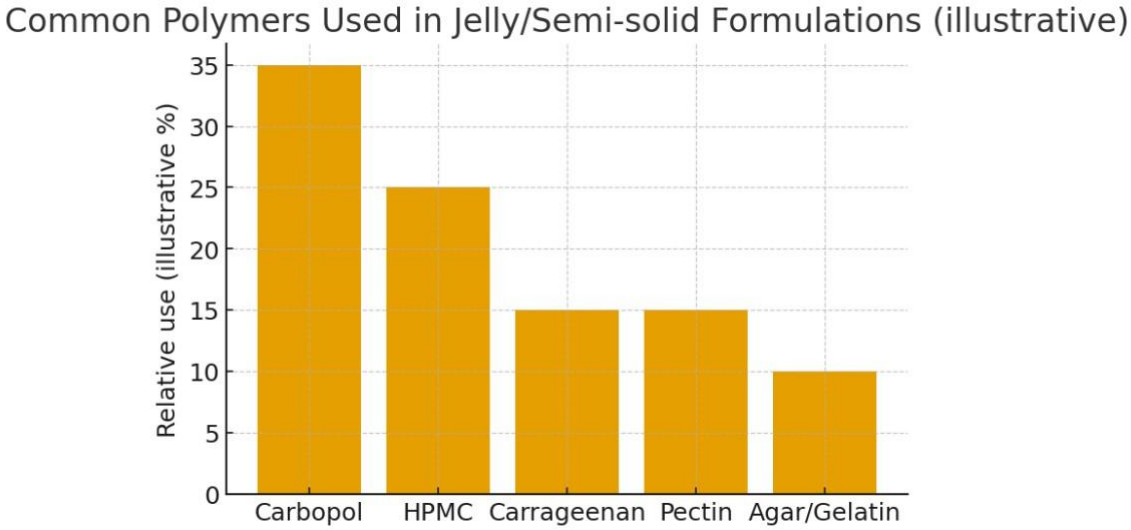

Fig. No. 2(Common Polymers Used in jelly)

5. Methods of preparation:

Common preparation methods for medicated jellies:[15],[23]
1. Heating and congealing method (suitable for pectin/agar-based jellies): dissolve polymer and active in aqueous/hydro alcoholic phase, heat, then cool to set.
2. Cold dispersion method (Carbopol): disperse polymer in water, allow hydration, add humectant and API (dissolved), adjust pH to thicken.
3. Emulsion-gel method for hydrophobic actives: prepare oil phase with drug and emulsify into aqueous polymer solution to create organo-jellies.
4. Use of co-solvents and solubilizers (ethanol, propylene glycol, surfactants) to dissolve poorly soluble actives.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 2, October 2025
Impact Factor: 7.67

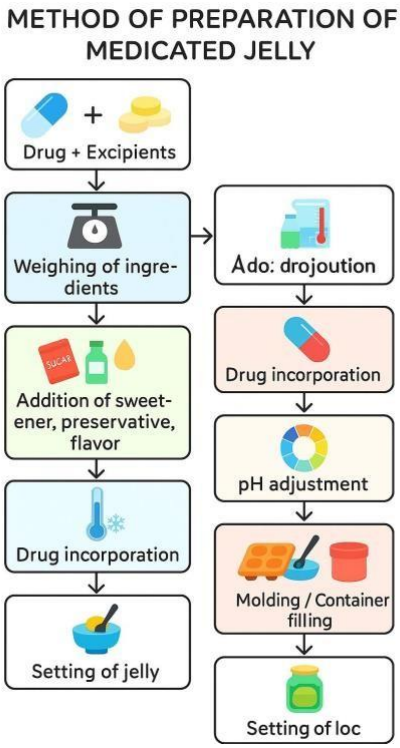

Fig. No. 3 (Method of Preparation of Medicated Jelly)

6. Characterization and evaluation:

Essential physicochemical and performance tests:[23]

Appearance, homogeneity and clarity.

pH measurement (skin-compatible range ~5–7).

Viscosity and rheological profiling (rotational rheometer — shear rate sweep, thixotropy).

Spreadability and extrudability tests (texture analyzer or bespoke spreadability apparatus).

Drug content and content uniformity (HPLC/UV assay).

In-vitro release testing (IVRT) — Franz diffusion cell or vertical diffusion cell using synthetic membranes.[20]

Ex-vivo skin permeation (Franz cell, human/porcine skin) to evaluate local delivery and flux.[24]

Microbial limit tests and preservative efficacy (challenge tests).

Stability studies (accelerated and long-term per ICH guidelines).[25]

Compatibility studies (FTIR, DSC) and microstructure

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 2, October 2025
Impact Factor: 7.67

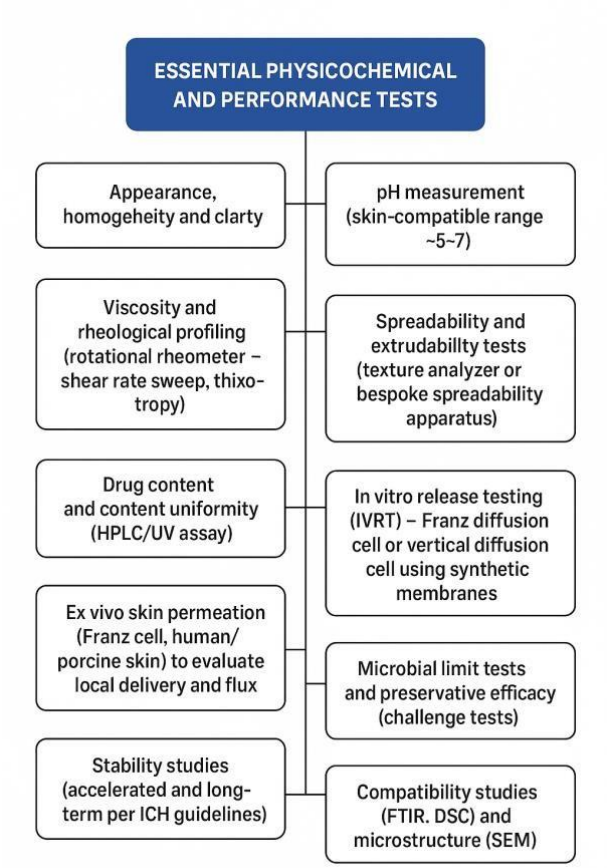

Fig. No.4 (Essential Physicochemical and Performance Tests)

7. In-vitro and ex-vivo testing: IVRT and permeation:

In-vitro release tests (IVRT) are essential for semisolid topical products and guidance is provided by regulatory agencies.[20] IVRT uses synthetic membranes to compare release rates; method development includes membrane selection, receptor media, temperature (32°C for skin), and validation. Ex-vivo permeation with porcine or human cadaver skin quantifies drug flux and predicts local tissue exposure.[24]

8. In-vivo efficacy models (CFA, CIA, others):

Preclinical efficacy for anti-arthritic jellies can be demonstrated in established animal models such as Complete Freund's Adjuvant (CFA)-induced arthritis in rats and Collagen-Induced Arthritis (CIA) in mice.[23],[24] Typical readouts: paw swelling (volume), clinical scoring, histopathology, regulatory and inflammatory cytokine measurements (TNF-α, IL-1β).

9. Stability, & safety considerations:

Stability testing should follow ICH Q1A(R2) guidelines (accelerated and long-term).[25] Topical safety includes skin irritation/sensitization testing, systemic exposure assessment, and preservative efficacy.[22] For IVRT and bioequivalence, follow FDA/EMA guidance where applicable for topical semisolids.[20]

10. Challenges, gaps and future directions:

Challenges include achieving sufficient local penetration for targets deep within joints, balancing permeation enhancer safety, quantifying local tissue concentrations, and establishing bioequivalence for complex semisolid products. Future

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 2, October 2025
Impact Factor: 7.67

directions include Nano-carriers in jellies, mucoadhesive or thermoresponsive jellies, patient-centered sensory optimization, and robust in vitro–in vivo correlation.[19],[25]

11. Example experimental plan for a final year project:

An example 6-month experimental plan:[15],[23]

1. Literature review and selection of API (e.g., diclofenac, ketoprofen, naproxen) and polymer matrix (Carbopol vs HPMC vs carrageenan).
2. Preformulation: solubility, excipient compatibility (FTIR/DSC).
3. Formulation development: 3–4 prototype jelly formulations using different polymers and permeation enhancers.
4. Physicochemical characterization (viscosity, pH, spreadability, drug content).
5. IVRT and ex-vivo porcine skin permeation for best prototypes.
6. Short-term stability (1–3 months accelerated) and microbial challenge tests.
7. Optional small animal efficacy in CFA model (ethics permitting), histology and cytokine assays.
8. Data analysis, graphical abstract and paper writing.

II. CONCLUSIONS

Medicated jellies represent a pragmatic and patient-friendly topical platform for local management of joint pain and inflammation. With careful selection of active, polymer matrix and methodical evaluation (IVRT, ex-vivo permeation, rheology and stability), a robust project can be executed within an undergraduate final year timeline and yield publishable results.

REFERENCES

[1]. Smolen JS, Aletaha D, McInnes IB. Rheumatoid arthritis. Lancet. 2016;388(10055):2023-38.
[2]. Cross M, Smith E, Hoy D, et al. The global burden of rheumatoid arthritis. Ann Rheum Dis. 2014;73(7):1316-22.
[3]. McInnes IB, Schett G. Pathogenetic insights from the treatment of rheumatoid arthritis. Lancet. 2017;389(10086):2328-37.
[4]. Smolen JS, Landewé RB, Bijlsma JW, et al. EULAR recommendations for the management of rheumatoid arthritis with DMARDs: 2022 update. Ann Rheum Dis. 2023;82(1):3-18.
[5]. Singh JA, Saag KG, Bridges SL Jr, et al. 2016 ACR guideline for the treatment of rheumatoid arthritis. Arthritis Care Res (Hoboken). 2016;68(1):1-25.
[6]. Bjarnason I, Scarpignato C, Holmgren E, et al. Mechanisms of damage to the gastrointestinal tract from NSAIDs. Gastroenterology. 2018;154(3):500-14.
[7]. Benson HAE, Watkinson AC. Topical and Transdermal Drug Delivery: Principles and Practice. 2nd ed. Wiley; 2019.
[8]. Prausnitz MR, Langer R. Transdermal drug delivery. Nat Biotechnol. 2008;26(11):1261-8.
[9]. Prakash P, Maiti S, Bhattacharya P. Formulation and evaluation of topical gels and jellies for anti-inflammatory therapy: a review. Int J Pharm Sci Res. 2022;13(9):3400-10.
[10]. Hossain MN, Rahman MA. Evaluation of topical gels and jellies: physicochemical characterization and in-vitro performance. J Appl Pharm Sci. 2020;10(7):27-37.
[11]. Firestein GS, McInnes IB. Immunopathogenesis of rheumatoid arthritis. Immunity. 2017;46(2):183-96.
[12]. Scott DL, Wolfe F, Huizinga TW. Rheumatoid arthritis. Lancet. 2010;376(9746):1094-108.
[13]. McInnes IB, Schett G. Cytokines in the pathogenesis of rheumatoid arthritis. Nat Rev Immunol. 2007;7(6):429-42.
[14]. Bijlsma JWJ, Berenbaum F, Lafeber FPJG. Glucocorticoids in the treatment of rheumatoid arthritis. Arthritis Res Ther. 2019;21(1):105.
[15]. Aithal KC, Udupa N. Formulation and evaluation of topical diclofenac sodium gels using various polymers. Indian J Pharm Sci. 2015;77(4):423-31.

IJARSCT
International Journal of Advanced Research in Science, Communication and Technology
International Open-Access, Double-Blind, Peer-Reviewed, Refereed, Multidisciplinary Online Journal
ISSN: 2581-9429
Volume 5, Issue 2, October 2025
Impact Factor: 7.67

[16]. Sharma A, Saini S, Sinha S, et al. Curcumin-based topical formulations for inflammatory disorders. Pharmaceutics. 2021;13(8):1134.
[17]. Kaur L, Gulati M, Narang R. Boswellic acid formulations for topical anti-inflammatory therapy. Curr Drug Deliv. 2020;17(9):794-804.
[18]. Moore RA, Derry S, Wiffen PJ. Topical NSAIDs for chronic musculoskeletal pain in adults. Cochrane Database Syst Rev. 2015;(9):CD007400.
[19]. Kumar L, Verma R. Nano-based topical formulations for management of arthritis. Drug Dev Ind Pharm. 2021;47(10):1571-83.
[20]. U.S. Food and Drug Administration. In Vitro Release Test (IVRT) for Topical Products – Draft Guidance. Silver Spring (MD); 2022.
[21]. Rowe RC, Sheskey PJ, Quinn ME, eds. Handbook of Pharmaceutical Excipients. 9th ed. Pharmaceutical Press; 2020.
[22]. OECD. Guidelines for the Testing of Chemicals: Skin Irritation/Corrosion Test. OECD Publishing; 2021.
[23]. Thakur S, Sharma N, Singh R, et al. Natural polymers in topical gel formulations: a review. J Drug Deliv Sci Technol. 2021;61:102250.
[24]. OECD. Guidelines for Testing of Chemicals: Skin Absorption: In Vitro Method (Test No. 428). OECD Publishing; 2019.
[25]. ICH. Q1A(R2): Stability Testing of New Drug Substances and Products. International Council for Harmonisation; 2003