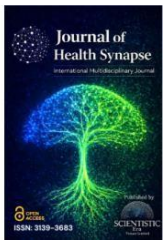
Research Article **ISSN: 3139-3683**

JOURNAL OF HEALTH SYNAPSE (JHS)
Peer Reviewed Refereed Open Access International Multidisciplinary Journal
Publisher: *Scientistic Era Private Limited*
Journal Hompage: *https://healthsynapse.org*



A Review on Polyherbal Topical Gel Formulations for Enhanced Cutaneous Delivery of Anti-Inflammatory Bioactive Compounds

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ARTICLE INFO

KEYWORDS:
Polyherbal gel; Anti-inflammatory activity; Herbal extracts; Carbopol 940; Topical drug delivery; Skin permeation; Franz diffusion cell; Phytoconstituents; Permeation enhancer.

ARTICLE HISTORY
Received Date: 30 September 2026
Revised Date: 15 October 2026
Accepted Date: 30 October 2026
Published Date: 15 November 2026

CITATION
Singh, R. A., A Review on Polyherbal Topical Gel Formulations for Enhanced Cutaneous Delivery of Anti-Inflammatory Bioactive Compounds, *Journal of Health Synapse (JHS), 1(4), 111-119.*
https://doi.org/10.67529/jhs.v1i4.8

A B S T R A C T

Inflammation is a complex, multifactorial immune and vascular response associated with acute tissue injury, microbial infection, and chronic inflammatory disorders. Although non-steroidal anti-inflammatory drugs (NSAIDs) and corticosteroids remain standard pharmacological interventions, their prolonged administration frequently precipitates gastrointestinal ulceration, nephrotoxicity, cardiovascular complications, or dermatological adverse effects such as skin atrophy. Consequently, medicinal plants and polyherbal formulations rich in flavonoids, curcuminoids, phenolic acids, terpenoids, and polysaccharides have attracted considerable pharmaceutical interest due to their complementary anti-inflammatory, antioxidant, and wound-healing properties. Topical drug delivery provides targeted local administration, reduced systemic exposure, avoidance of first-pass gastrointestinal complications, and superior patient compliance. Among topical vehicles, Carbopol 940 hydrogels are widely favored for their non-greasy texture, cooling relief, pseudoplastic spreadability, and controlled release; however, conventional herbal gels often face challenges including limited stratum corneum permeability, phytochemical instability, and batch-to-batch extract variability. This review synthesizes a comprehensive framework for developing, optimizing, and evaluating a standardized polyherbal anti-inflammatory gel, covering herbal selection and extraction, HPLC marker standardization, Carbopol 940 matrix formulation, chemical and plant-derived permeation enhancers, physicochemical and rheological characterization, Franz diffusion kinetics, HaCaT keratinocyte and OECD 439 reconstructed human epidermis biocompatibility, ICH Q1A(R2) stability testing, and in vivo carrageenan-induced paw oedema evaluation.

1. Introduction

Inflammation is a protective physiological response initiated by the innate and adaptive immune systems against noxious stimuli, including microbial pathogens, mechanical trauma, chemical irritants, and necrotic cells [1,16]. Orchestrated by resident mast cells, macrophages, neutrophils, vascular endothelium, and soluble mediators, acute inflammation eliminates tissue injury and initiates structural repair [1]. However, persistent or dysregulated inflammatory signaling drives chronic pathologies such as rheumatoid arthritis, osteoarthritis, psoriasis, atopic dermatitis, and non-healing cutaneous wounds [1,2].

Conventional anti-inflammatory pharmacotherapy relies

primarily on non-steroidal anti-inflammatory drugs (NSAIDs), which inhibit cyclooxygenase (COX-1/COX-2) enzymes to suppress prostaglandin synthesis, and glucocorticoids, which broadly repress pro-inflammatory gene transcription [2,17]. Despite clinical potency, chronic systemic NSAID use frequently induces peptic ulceration, renal impairment, and cardiovascular events [17], whereas prolonged or inappropriate topical corticosteroid application causes epidermal thinning, skin atrophy, striae, telangiectasia, and delayed wound healing [3,18]. Consequently, botanical bioactives—encompassing flavonoids, phenolic acids, curcuminoids, terpenoids, alkaloids, tannins, and polysaccharides—have gained substantial interest as safer, multi-target alternatives [4,19,20].

Polyherbal formulations combine two or more standardized plant extracts to achieve complementary antioxidant, anti-inflammatory, antimicrobial, and tissue-regenerative activities [7,30]. Delivering polyherbal bioactives via the topical route bypasses hepatic first-pass metabolism, minimizes systemic toxicity, and enables direct localization at inflamed tissues [5]. Among semisolid vehicles, Carbopol 940 hydrogels provide an optically clear, non-greasy, cooling three-dimensional polymer network with favorable spreadability [32]. Nevertheless, the dense lipid architecture of the stratum corneum limits passive diffusion of hydrophilic and bulky phytoconstituents [5,33]. Integrating standardized polyherbal extracts into an optimized Carbopol 940 matrix paired with a safe chemical or plant-derived permeation enhancer represents a rational strategy for enhanced topical anti-inflammatory therapy [6,34,35].

2. Background and Formulation Rationale

2.1. Inflammatory Mediators and Phytochemical Mechanisms

Vascular and cellular inflammation is mediated by prostaglandins (PGE2), leukotrienes (LTB4), histamine, nitric oxide (NO), reactive oxygen species (ROS), and pro-inflammatory cytokines including tumor necrosis factor-alpha (TNF-α), interleukin-1β (IL-1β), and IL-6 [1,16]. As categorized in Table 1, distinct classes of plant secondary metabolites modulate specific biochemical checkpoints along these inflammatory pathways [4,19–31].

Table 1. Major Anti-Inflammatory Phytochemical Classes, Representative Bioactives, and Biological Mechanisms

Phytochemical Class	Representative Compounds	Potential Anti-Inflammatory & Protective Activity
Flavonoids	Quercetin, luteolin, apigenin, kaempferol	Inhibition of COX-2, 5-LOX, iNOS, and pro-inflammatory cytokine release [4]
Phenolic Acids	Gallic acid, caffeic acid, rosmarinic acid	Scavenging of ROS/RNS and attenuation of oxidative vascular permeability [19]
Terpenoids	Boswellic acids, ursolic acid, lupeol	Suppression of 5-lipoxygenase, leukocyte elastase, and inflammatory signaling [29,31]
Curcuminoids	Curcumin, demethoxycurcumin	Downregulation of NF-κB nuclear translocation, TNF-α, IL-1β, and PGE2 [21,22]
Glycosides & Polysaccharides	Acemannan, iridoid and flavonoid glycosides	Modulation of macrophage activation, skin hydration, and fibroblast repair [23,24]

2.2. Polyherbal Combinations and Topical Gel Challenges

A rationally designed topical polyherbal gel combines complementary botanicals—such as Curcuma longa (curcuminoids for NF-κB/COX-2 inhibition) [21,22], Ocimum sanctum (eugenol, rosmarinic acid, and ursolic acid for antioxidant and dual COX/LOX inhibition) [25,26], Aloe vera (acemannan polysaccharides for hydration and fibroblast wound repair) [23,24], and Celosia argentea (flavonoids and phenolics for free-radical scavenging) [28]. As illustrated in Figure 1, these constituents act concurrently across epidermal and dermal compartments to attenuate eicosanoid and cytokine cascades while accelerating tissue recovery. Importantly, true pharmacological synergy must be experimentally validated against individual extract controls rather than assumed from multi-plant inclusion [7,30].

Figure 1. Multi-Target Anti-Inflammatory and Tissue-Protective Mechanism of Standardized Polyherbal Carbopol 940 Gel

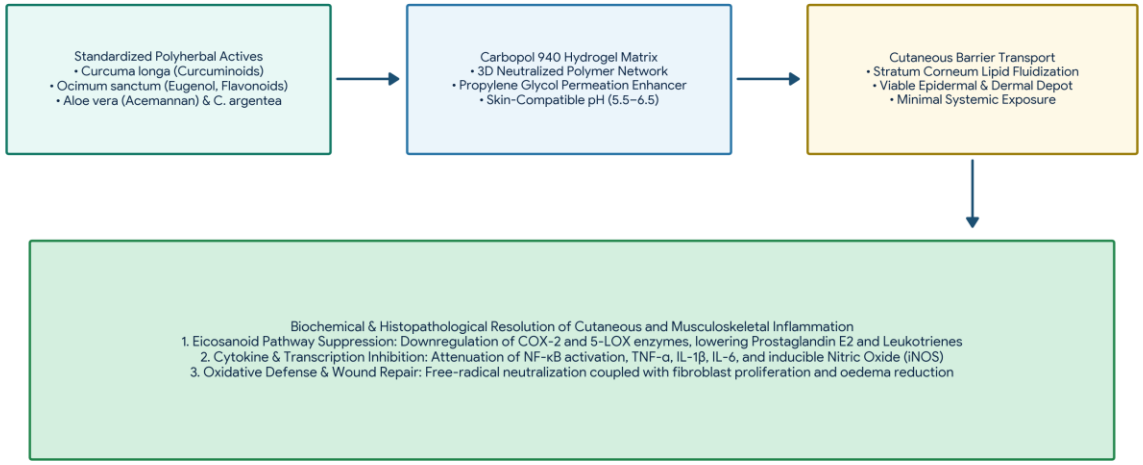


Figure 1. *Multi-target anti-inflammatory and tissue-protective mechanism of a standardized polyherbal Carbopol 940 topical gel.*

Despite their therapeutic appeal, conventional herbal gels face critical pharmaceutical hurdles: poor stratum corneum permeability of polar or high-molecular-weight actives, oxidative/photolytic instability, geographical and seasonal extract variability, drug–polymer incompatibility, viscosity-induced diffusion retardation, and microbial susceptibility in aqueous bases [5,7,44].

3. Materials and Methods: Polyherbal Gel Development Framework

3.1. Botanical Authentication, Extraction, and Marker Standardization

Medicinal plant selection relies on ethnomedicinal relevance, phytochemical profile, topical safety, and analytical marker availability [19,44]. Raw botanical materials must be authenticated by a qualified taxonomist with preserved voucher specimens, followed by pharmacognostic moisture, ash, extractive value, heavy-metal, pesticide, and microbial screening [44]. Extraction is tailored to target polarity using maceration, Soxhlet extraction, ultrasonic-assisted extraction (UAE), or hydroalcoholic (ethanol–water) extraction, concentrated under reduced pressure at controlled temperatures [44,55].

Following qualitative screening for flavonoids, phenolics, tannins, alkaloids, saponins, terpenoids, and glycosides, total phenolic content is quantified via the Folin–Ciocalteu assay (mg gallic acid equivalents/g) and total flavonoid content via aluminum chloride colorimetry (mg quercetin equivalents/g) [48–50]. Validated high-performance liquid chromatography (HPLC) quantifies specific marker compounds (e.g., curcumin, rosmarinic acid) to eliminate batch-to-batch inconsistency [46, 76-80].

3.2. Carbopol 940 Gel Matrix Preparation and DoE Optimization

Carbopol 940, a high-molecular-weight cross-linked polyacrylic acid polymer, forms a clear, shear-thinning hydrogel upon aqueous hydration and neutralization with triethanolamine [32,37, 69-75]. Table 2 details the baseline formulation architecture, wherein Carbopol 940 is slowly dispersed in 60–70% purified water, hydrated for 30–60 minutes, blended with standardized polyherbal extracts, propylene glycol (humectant and permeation enhancer), glycerin, and dissolved paraben preservatives, and neutralized dropwise with triethanolamine to physiological skin pH (5.5–6.5) before final weight adjustment and deaeration.

Table 2. Standard Excipient Composition and Functional Roles in a Carbopol 940 Polyherbal Topical Gel

Ingredient	Pharmaceutical Function	Formulation Rationale
Standardized Polyherbal Extract	Active pharmaceutical ingredient	Delivers standardized anti-inflammatory, antioxidant, and wound-healing markers
Carbopol 940	Primary gelling polymer	Forms a non-greasy 3D hydrogel matrix with desirable yield stress and clarity
Propylene Glycol	Humectant, cosolvent & permeation	Improves phenolic solubility and

	enhancer	enhances stratum corneum lipid partitioning
Glycerin	Moisturizer and humectant	Prevents surface desiccation and maintains stratum corneum hydration
Triethanolamine (TEA)	Neutralizing agent	Ionizes polyacrylic acid chains to trigger gelation and adjust skin-compatible pH
Methyl Paraben & Propyl Paraben	Antimicrobial preservative system	Prevents bacterial and fungal growth in the water-rich herbal gel matrix
Purified Water (q.s.)	Continuous aqueous vehicle	Provides cooling hydration and medium for polymer swelling

To balance viscosity against cutaneous drug flux, independent formulation variables—Carbopol 940 level, extract blend ratio, permeation enhancer concentration, neutralizer quantity, and total extract loading—are systematically optimized using factorial or response surface Design of Experiments (DoE) matrices summarized in Table 3 [14,32, 63-68]. Figure 2 illustrates the end-to-end development, optimization, and preclinical evaluation workflow.

Table 3. Design of Experiments (DoE) Independent Variables and Critical Response Parameters for Polyherbal Gel Optimization

Formulation Factor	Independent Variable	Measured Response Parameter (CQA)
Polymer Concentration	Carbopol 940 (% w/w)	Brookfield viscosity, spreadability, extrudability, and release rate
Extract Combination Ratio	Relative proportion of individual plant extracts	Synergistic anti-inflammatory activity and marker uniformity
Permeation Enhancer Level	Propylene glycol or herbal terpene (% w/w)	Steady-state Franz diffusion flux (Jss) and dermal retention
Neutralizer Quantity	Triethanolamine volume / concentration	Surface pH (5.5–6.5), optical clarity, and gel consistency
Active Extract Loading	Total standardized polyherbal extract (% w/w)	HPLC marker assay, physical stability, and cytocompatibility

Figure 2. Systematic Pharmaceutical Development, Optimization, and Evaluation Pipeline for Polyherbal Topical Gel

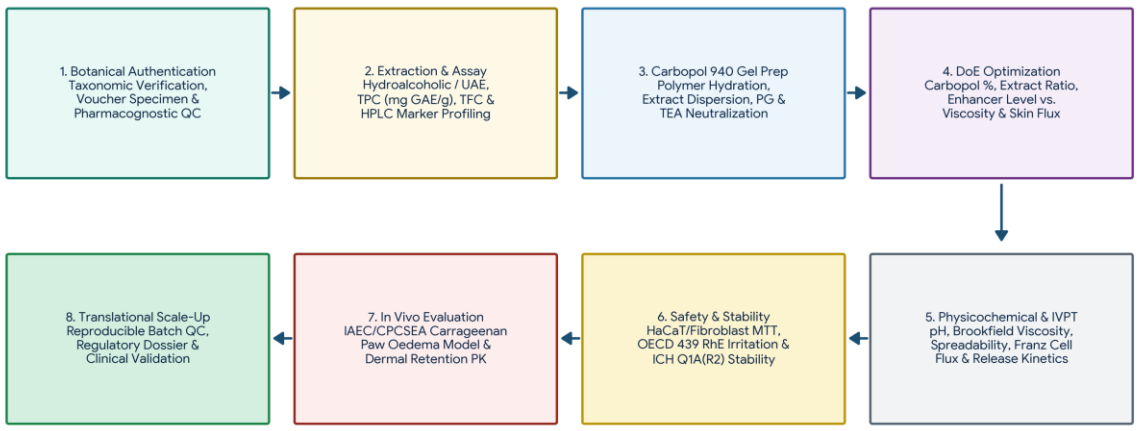


Figure 2. *Systematic pharmaceutical development, Design of Experiments (DoE) optimization, and preclinical evaluation pipeline for polyherbal topical gels.*

3.3. Physicochemical and Rheological Characterization

Formulated gels are evaluated for: (1) organoleptic appearance, color, odor, and absence of phase separation; (2) digital pH (1 g gel dispersed in purified water); (3) Brookfield rotational viscosity (cP); (4) parallel-plate spreadability calculated as $S = (M \times L) / T$ (where M is applied weight, L is plate glide distance, and T is time) [36]; (5) collapsible-tube extrudability; (6) glass-slide homogeneity; and (7) validated HPLC marker assay (% Drug Content = [Actual / Theoretical] × 100) [37].

4. In Vitro Permeation, Biocompatibility, and Stability Assessment

4.1. Franz Diffusion Permeation and Release Kinetics

In vitro release and ex vivo skin permeation are evaluated using vertical Franz diffusion cells maintained at 32 ± 1°C under continuous receptor stirring and sink conditions, sampling at predetermined intervals with fresh medium replacement [8,9,13]. Steady-state flux is computed as $J = dQ / (A \cdot dt)$, where dQ/dt is permeation rate and A is effective diffusion area, alongside cumulative release, permeability coefficient, and dermal retention [8,9]. Drug release profiles are fitted to four mathematical kinetic models summarized in Table 4 [40,41].

Table 4. Mathematical Models for Evaluating Drug Release Kinetics and Transport Mechanisms from Polyherbal Gels

Kinetic Model	Mathematical Expression	Mechanistic Interpretation
Zero-Order Model	$Qt = Q0 + k0t$	Describes constant-rate, concentration-independent drug release
First-Order Model	$\log Qt = \log Q0 - k1t / 2.303$	Describes release rate proportional to remaining drug concentration
Higuchi Model	$Qt = kH \cdot \sqrt{t}$	Characterizes Fickian square-root-of-time diffusion from a polymeric matrix [40]
Korsmeyer–Peppas Model	$Mt / M\infty = k \cdot tn$	Elucidates Fickian ($n \leq 0.5$), anomalous ($0.5 < n < 1$), or erosion transport [41]

4.2. Cytotoxicity, Biocompatibility, and ICH Q1A(R2) Stability

Preliminary cytocompatibility is evaluated via the MTT tetrazolium assay (% Cell Viability = [Absorbance_treated / Absorbance_control] × 100) [10,42]. Methodologically, skin-relevant human keratinocytes (HaCaT cells) and dermal fibroblasts—rather than non-cutaneous colorectal lines such as HCT-116—should be used alongside OECD Test Guideline 439 reconstructed human epidermis (RhE) models to assess topical irritation [12,43]. Storage stability is conducted per ICH Q1A(R2) protocols monitoring appearance, pH, viscosity, homogeneity, HPLC marker content, in vitro release, and microbial quality in sealed containers [11, 57-62].

5. In Vivo Pharmacodynamic, Safety, and Statistical Considerations

Following Institutional Animal Ethics Committee (IAEC) approval and CPCSEA compliance, in vivo anti-inflammatory efficacy is evaluated in the carrageenan-induced rat paw oedema model (or topical croton-oil/TPA ear oedema model) across normal control, inflammatory control, standard topical NSAID/corticosteroid, individual herbal extracts, unenhanced polyherbal gel, and enhancer-loaded polyherbal gel groups [7,38,39]. Percentage oedema inhibition is measured plethysmometrically as $[(Vc - Vt) / Vc] \times 100$, paired with skin-layer retention pharmacokinetics and OECD 439 dermal tolerability screening [12,38]. Experimental triplicates (mean ± SD) are analyzed using one-way ANOVA with Tukey's post-hoc test or Student's t-test ($p < 0.05$) and nonlinear kinetic regression.

6. Limitations, Future Perspectives, and Conclusion

Key limitations requiring systematic control include botanical raw-material variability, poor solubility of lipophilic terpenoids/curcuminoids, potential enhancer-induced skin irritation, analytical complexity of multi-herb matrices, and imperfect extrapolation from synthetic membranes to clinical efficacy [5,7]. Future research should integrate LC-MS metabolomic profiling, DoE optimization of multi-herb ratios, nanoemulsion- and phytosome-loaded hybrid gels (nanogels), reconstructed human skin models, and controlled clinical trials [35,45,51–53].

In conclusion, a standardized polyherbal gel formulated in a neutralized Carbopol 940 hydrogel matrix with a validated permeation enhancer provides a promising, non-greasy, patient-acceptable platform for localized anti-inflammatory delivery, provided that extract standardization, Franz diffusion dermal retention, OECD 439 biocompatibility, and experimentally verified synergistic efficacy are rigorously established.

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