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Formulation and Evaluation of Tephrosa Purpurea Extract-Loaded Nanoemulgel for Topical Delivery in Inflaammatory Skin Disorders

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ABSTRACT

Tephrosia purpurea (L.) Pers. (Fabaceae), commonly associated with the Ayurvedic name Sarapunkha/Sharpunkha, is a medicinal plant distributed across tropical and subtropical regions and reported in traditional medicine for several inflammatory and wound-related conditions. Published investigations identify flavonoids, rotenoids, chalcones, sterols and other secondary metabolites, while pharmacological studies report antioxidant, antimicrobial, anti-inflammatory and wound-healing activities. Evidence is nevertheless heterogeneous: anti-inflammatory effects have been reported in animal models, and topical wound-healing studies provide a more direct rationale for dermal use, but clinical evidence and standardized topical products remain limited. A 2015 study developed a microemulsion gel containing T. purpurea extract and reported acceptable pH, spreadability, viscosity and in-vitro diffusion; this is important formulation precedent but is not equivalent to a validated nanoemulgel. [2,5,6,9]

Nanoemulgels combine a nanoemulsion with a gel matrix and are designed to improve solubilization, skin contact, spreadability and delivery of poorly water-soluble actives. Current topical nanoemulgel literature supports their investigation for inflammatory and dermatological conditions. [13–17] Based on the phytochemical and pharmacological profile of T. purpurea and the existing microemulsion-gel evidence, a T. purpurea nanoemulgel can be proposed as a novel research formulation. The proposed workflow includes botanical authentication, hydroalcoholic extraction, chromatographic standardization, oil/surfactant/co-surfactant screening, nanoemulsion optimization, gel incorporation, physicochemical characterization, skin permeation/retention studies, irritation testing, and efficacy evaluation.

Keywords : Tephrosia purpurea; Fabaceae; Sarapunkha; inflammation; wound healing; flavonoids; topical delivery; nanoemulsion; nanoemulgel; phytoconstituents; skin disorders.

Introduction

Inflammatory skin disorders involve activation of immune and structural skin cells, release of mediators, vascular changes, oxidative stress and disruption of the skin barrier. Depending on the condition, inflammation may present as erythema, edema, itching, pain, scaling or impaired wound repair. Topical delivery is attractive because it can place an active substance near the site of pathology while potentially reducing unnecessary systemic exposure. [14–17]

Medicinal plants are important sources of chemically diverse compounds, but plant extracts also create formulation challenges: variable composition, limited aqueous solubility of some constituents, oxidation, poor reproducibility and uncertain skin deposition. A rational formulation strategy therefore needs both phytochemical standardization and a delivery system suited to the physicochemical properties of the extract. [2,11,13]



Figure 1. Tephrosia purpurea (L.) Pers.

T. purpurea is particularly interesting for this purpose because published literature documents traditional use in wound-related and inflammatory conditions, multiple classes of secondary metabolites, antioxidant activity, antimicrobial activity and experimental wound healing. [2–4,7,8]

The formulation gap is equally important. The literature identified for this review contains a 2015 T. purpurea microemulsion-gel study, whereas the broader nanoemulgel literature provides a modern framework for nanosized topical delivery. Therefore, the central proposal of this review is not that T. purpurea nanoemulgel is already clinically established, but that it is a scientifically testable formulation-development opportunity supported by two separate evidence streams. [9,13– 17]

Aim

To critically review the phytochemical, pharmacological and topical-delivery evidence for T. purpurea and develop a scientifically justified blueprint for a nanoemulgel intended for inflammatory skin disorders.

Objectives

- Summarize taxonomy, morphology and ethnomedicinal relevance.
- Review important phytoconstituents and analytical markers.
- Evaluate anti-inflammatory, wound-healing, antioxidant and antimicrobial evidence.
- Explain the principles and advantages of nanoemulgels for topical delivery.
- Propose a formulation-development and evaluation pathway without presenting untested parameters as established facts.

Botanical Profile and Taxonomy

Kew Plants of the World Online currently accepts Tephrosia purpurea (L.) Pers. as the species name. It belongs to Fabaceae and has a broad native range extending from Africa and the Arabian Peninsula through tropical and subtropical Asia to the South Pacific. Kew describes it as an annual, perennial or subshrub occurring mainly in seasonally dry tropical environments. [1]

Taxonomic rank	**Classification**
Kingdom	Plantae
Order	Fabales
Family	Fabaceae
Genus	Tephrosia

Taxonomic rank	**Classification**
Species	Tephrosia purpurea (L.) Pers.
Accepted status	Accepted name in Kew POWO
Common/vernacular names	Sarapunkha, Sharpunkha, Wild Indigo and regional names

Macroscopic features

The species is described as erect to procumbent, annual or short-lived perennial, reaching roughly 80–150 cm in some floristic descriptions. Leaves are imparipinnate with multiple leaflets; flowers are reddish-purple or pink and occur in lax pseudoracemes or upper leaf axils. These characters support field recognition but authenticated herbarium material should be used for pharmaceutical research. [1]

Pharmacognostic importance

Root standardization work has described diagnostic tissues including xylem vessels, fibres and xylem parenchyma, together with transverse-section, powder-microscopy, fluorescence and physicochemical data. Such authentication steps are important because botanical misidentification can directly affect extract composition and formulation reproducibility. [10]

Ethnomedicinal Uses

Traditional uses reported in the literature include applications for wounds, inflammatory complaints, rheumatism, asthma, digestive disorders and several other conditions. The 2020 comprehensive review describes the plant as an established component of Ayurvedic knowledge and highlights its historical use in wound-related applications. [2]

Reported use/context	Plant part or preparation reported	Relevance to this review
Wound healing	Whole plant/aerialpart preparations	Directly supports dermal research rationale
Inflammatory conditions	Different extracts/parts	Supports antiinflammatory screening
Skin eruptions/boils	Traditionalexternal/internal uses reported	Suggests topical exploration
Pain/inflammation	Pod/extract reports	Potential supportive activity
Rheumatism	Traditional medicinal use	Indicates antiinflammatory interest

Traditional use should be treated as a hypothesis-generating source rather than proof of clinical efficacy. For a modern topical product, the relevant questions are: which plant part is selected, which extraction method is reproducible, which chemical markers define the extract, what dose reaches the skin, and whether the final formulation is safe and effective in appropriate models.

Ethnomedicinal-to-formulation logic

Traditional claim → botanical authentication → standardized extract → mechanistic screening → topical delivery optimization → safety testing → controlled efficacy studies. This sequence avoids the common error of moving directly from traditional use to a therapeutic claim.

Phytochemistry

Chemical investigations of T. purpurea have identified several classes of secondary metabolites, including flavonoids, rotenoids, chalcones, isoflavones, flavanones, flavanols and sterols. Reviews list compounds such as semiglabrin, pongamol/pongamole, lanceolatins, rutin, lupeol, βsitosterol, tephrosin, tephrosone and tephropurpurin among reported constituents. [3,4,20]

Chemical class	Representative reported constituents	Potential relevance
Flavonoids	Rutin, quercetin-related compounds, tephrorins	Antioxidant and possible antiinflammatory contribution
Rotenoids	Tephrosin and related rotenoids	Characteristic chemistry; requires safety attention
Chalcones	Tephropurpurin and related compounds	Bioactivity and chemical diversity
Sterols	β-Sitosterol	Reported anti- inflammatory/ other biological relevance
Triterpenes	Lupeol	Reported anti-inflammatory relevance
Phenolics	Phenolic acids and related compounds reported in subspecies studies	Antioxidant potential

Seasonal variation is a major quality-control consideration. A 2016 study found that total phenolic and flavonoid contents and antioxidant activity varied with season and extraction solvent; the 95% ethanolic sample collected in August showed the highest values among the conditions studied. This does not mean August is universally optimal for every formulation, but it demonstrates why harvest season and extraction conditions should be standardized. [8]

Implication for formulation

A complex extract should not be treated as a single chemical entity. The formulation program should define a reproducible extract specification using chromatographic fingerprints and, where possible, one or more quantitative marker compounds.

Key Bioactive Constituents

The anti-inflammatory rationale is commonly associated in reviews with flavonoid and triterpenoid constituents, particularly quercetin, rutin, β-sitosterol and lupeol. However, attribution of the complete plant activity to any one compound is premature because extracts contain multiple constituents and possible synergistic interactions. [2,3]

Constituent/group	Reported occurrence	Proposed relevance to skin research	Caution
Quercetin	Reported in T. purpurea extracts	Antioxidant; commonly studied anti-inflammatory flavonoid	Amount depends on plant part and extraction
Rutin	Reported and used as an analytical marker	Antioxidant; qualitycontrol candidate	Marker ≠ proof of clinical efficacy
β-Sitosterol	Reported constituent	Potential antiinflammatory contribution	Need extract-specific quantitation
Lupeol	Reported constituent	Potential antiinflammatory contribution	Need direct topical evidence
Tephrosin/rotenoids	Characteristic Tephrosia chemistry	Useful for chemical profiling	Toxicological assessment is essential
Flavonoid-rich fraction	Demonstrated in wound-healing work	Potential multicomponent activity	Synergy must be experimentally demonstrated

Quality-control marker concept

HPTLC-chemometric work evaluated several compounds for quality control and identified rutin as a primary marker, followed by β-sitosterol and lupeol in the reported multivariate analysis. This supports a practical strategy in which rutin is used as one marker while the full fingerprint is retained to capture broader extract identity. [11]

Important distinction

A marker compound is used to control identity/consistency; it should not automatically be described as the active principle. This distinction is especially important in herbal formulation papers.

Skin Inflammation and Therapeutic Rationale

Skin inflammation is a coordinated response involving keratinocytes, immune cells, endothelial cells and extracellular mediators. The clinical appearance of inflammation reflects interactions among cytokines, lipid mediators, reactive oxygen species, vascular permeability and tissue remodeling. The exact pathways differ among eczema, psoriasis, contact dermatitis, acneassociated inflammation and wounds.



Figure 2. Tephrosia purpurea (L.) Pers.

For a botanical extract, an anti-inflammatory hypothesis can be investigated through multiple endpoints: inhibition of inflammatory edema in animal models, suppression of mediator production in cell-based assays, antioxidant capacity, reduction of histological inflammatory changes, and improvement in wound closure. A strong review should distinguish each endpoint rather than combine them into a single generalized claim.

Why topical delivery?

A topical formulation can be designed to increase residence at the skin surface, improve contact with damaged or inflamed tissue, and reduce the need for oral administration. Nanoemulgels are particularly relevant when the extract contains poorly water-soluble constituents and when a nongreasy, spreadable semisolid is desired. [13–17]

Anti-inflammatory Evidence

Shenoy and colleagues evaluated orally administered ethanolic T. purpurea extract in acute and subacute rat inflammation models. In carrageenan-induced acute paw edema, the extract did not produce a significant decrease compared with controls, whereas in the cotton-pellet granuloma model a significant reduction in granuloma weight was reported. This is important because it shows that anti-inflammatory evidence is model-dependent rather than uniformly positive. [6]

A separate report evaluating aerial and root extracts described dose-related inhibition of carrageenan-induced paw edema and cotton-pellet granuloma, supporting further investigation but using systemic administration rather than a topical nanoemulgel. [23]

Study	Model	Preparation/route	Main observation	Interpretation
Shenoy et al., 2010	Carrageenan paw edema	Ethanolic extract, oral	No significant acute effect reported	Acute antiinflammatory effect not established in that model
Shenoy et al., 2010	Cotton-pellet granuloma	Ethanolic extract, oral	Significant reduction in granuloma weight	Supports activity in subacute inflammation
Praveena et al.	Carrageenan paw edema	Root extract, systemic	Significant reduction reported	Supports further pharmacological study
Reviews	Multiple historical/preclinical studies	Different plant parts/extracts	Antiinflammatory activity repeatedly reported	Evidence is heterogeneous

Critical appraisal

The strongest formulation rationale comes from combining anti-inflammatory evidence with direct topical/wound evidence, rather than assuming that oral animal findings automatically translate to skin treatment. A proposed nanoemulgel should therefore be evaluated directly in dermal models.

Wound-Healing Evidence

Wound healing is particularly relevant because inflammation is one phase of the repair process. Lodhi et al. studied an ethanolic aerial-part extract formulated as a simple ointment in incision, excision and dead-space wound models in rats. The study reported improved wound contraction and tensile strength and histological changes involving fibroblasts, collagen fibres and bloodvessel formation. [5]

Another study evaluated an ethyl-acetate fraction of T. purpurea aerial parts in dead-space and burn wound models. A 5% w/w ointment of the fraction increased hydroxyproline and protein measures and showed favorable histological findings. The authors suggested that the fraction could benefit from synergistic interactions among flavonoids and other constituents. [7]

Evidence area	Observed outcome reported	Why it matters for nanoemulgel
Wound contraction	Improved in animal models	Suggests dermal biological activity
Tensile strength	Improved in wound model	Indicates functional repair
Hydroxyproline/collagen	Increased with active fractions	Supports collagen remodeling hypothesis
Histology	Fibroblast, collagen and vascular changes reported	Provides tissue-level evidence
Topical administration	Ointment used in studies	Direct precedent for dermal delivery

Interpretation

The wound-healing literature is a stronger direct bridge to topical formulation than systemic antiinflammatory studies. Nevertheless, the existing evidence is preclinical and should not be interpreted as proof of effectiveness in human inflammatory skin disorders.

Antioxidant and Antimicrobial Relevance

Oxidative stress can amplify inflammatory responses and interfere with tissue repair. Studies of T. purpurea leaves and seasonal extracts report measurable polyphenol/flavonoid content and freeradical-scavenging activity. In one study, ethanolic extracts showed higher phenolic/flavonoid content than aqueous extracts, and antioxidant activity correlated with phenolic content. [8,21]

The 2015 topical microemulsion-gel study also screened T. purpurea extract and optimized formulation against Staphylococcus aureus, Candida albicans and Pseudomonas aeruginosa, reporting antimicrobial activity and acceptable topical formulation properties. [9]

Property	**Evidence source**	**Potential formulation relevance**
Antioxidant activity	Seasonal study [8]; leaf study	Supports evaluation of oxidative-stress-related endpoints
Antimicrobial activity	2015 microemulsion-gel study	Potential support for secondary infection research
Flavonoid content	HPLC/colorimetric studies	Useful for standardization
HPTLC fingerprint	2015 topical study and qualitycontrol studies	Supports batch-to-batch identity

Antimicrobial activity should not be used to claim treatment of infection unless the final formulation is tested against relevant organisms and compared with appropriate controls. Similarly, antioxidant assays are supportive biochemical evidence, not direct clinical proof of antiinflammatory efficacy.

Consolidated Evidence Table

Research focus	**Plant material**	**Model/approach**	**Key finding**	**Directness to proposed topical nanoemulgel**
Wound healing	Aerial-part ethanolic extract	Incision, excision, deadspace rat models	Wound contractio n, tensile strength and histology improved	High: topical ointment precedent
Anti-inflammatory	Ethanolic extract	Carrageenan + cottonpellet granuloma	Subacute effect reported; acute effect not significant	Moderate: systemic route
Cutaneous wound healing	Ethylacetate fraction	Dead-space and burn wounds	5% ointment improved woundrelated endpoints	High: topical
Phytochemistry/antioxi dant	Whole plant extracts	Seasonal HPLC/TPC/TFC/DPPH	Strong seasonal and solvent effects	Indirect but important
Topical formulation	Hydroalcoholic wholeplant extract	Microemulsion gel; diffusion/antimicrobial/irrit ation	F3 gave 62.65% release at 6 h	Very high: formulation precedent
Quality control	Whole plant/marker s	HPTLC-chemometrics	Rutin identified as primary marker in study	High for standardizati on
Nanoemulgel	Multiple	Topical delivery reviews	Improved solubilizati	High for platform, not
technology	drugs/ actives		on, skin contact and delivery are reported advantages	plant-specific
Toxicology	T. purpurea extract	Rodent acute/subacute studies	No major toxicity at tested oral doses up to 2000 mg/kg in acute study	Supportive, not topical safety proof

Evidence hierarchy for the proposed project

- Direct topical T. purpurea studies: strongest translational starting point.
- Systemic anti-inflammatory studies: mechanistic support but not direct topical proof.
- Phytochemical/antioxidant studies: support extract selection and standardization.
- Nanoemulgel reviews: support delivery-system design, not T. purpurea efficacy.
- A new formulation must generate its own physicochemical, safety and efficacy data.

Rationale for Topical Delivery

The skin is both the target organ and a major barrier. A conventional plant gel may provide good acceptability but may not adequately solubilize hydrophobic constituents or maintain a fine dispersion. A nanoemulsion can provide a large interfacial area and can incorporate an oil phase, while conversion to a gel can improve viscosity, residence time and handling. [13–17]

Conventional herbal gel	**Microemulsion gel**	**Proposed nanoemulgel**
Simple polymeric vehicle	Microemulsion + gel	Nanoemulsion + gel
May have limited solubilization	Improved solubilization	Potentially enhanced solubilization/skin interaction
Good viscosity	Good topical handling	Good topical handling + nanoscale droplets
No nanoscale carrier	Small emulsion droplets	Nano-sized droplets
Plant extract stability depends on base	Improved formulation environment possible	Optimization needed for physical/chemical stability

The proposed system should be designed as an oil-in-water nanoemulsion incorporated into a suitable hydrogel. The choice of oil, surfactant and co-surfactant must be justified by solubility, skin compatibility, droplet size, physical stability and irritation considerations. [13,14,16,17]

Novelty statement

Based on the literature located for this review, T. purpurea has been investigated in a microemulsion-gel system [9], but the plant-specific evidence does not establish a clinically validated nanoemulgel. Therefore, the novelty should be stated as 'development and evaluation of a T. purpurea extract-loaded nanoemulgel' and experimentally demonstrated rather than assumed.

Skin Barrier and Penetration: the stratum corneum is the principal barrier to many topically applied substances. Topical delivery can proceed through intercellular, transcellular and appendageal pathways. Nanoemulsion droplets and formulation excipients may alter partitioning, hydration and interfacial contact, but the exact contribution depends on composition and drug properties. [14–17]

Desired behavior

- Rapid but controlled release from the formulation.
- Adequate partitioning into the outer skin layers.
- High local skin retention with limited unnecessary systemic exposure.
- Non-irritating, non-greasy and spreadable dosage form.
- Chemical stability of plant markers during storage.
- Reproducible droplet size and physical stability.

A critical point is that smaller droplets do not automatically guarantee better clinical performance. Nano-size must be demonstrated together with appropriate release, permeation/retention and biological outcomes.

Nanoemulsion as a Carrier

Nanoemulsions are dispersed systems in which oil and water phases are stabilized by surfactants, often with a co-surfactant. Topical nanoemulsion research commonly targets small droplet sizes, physical stability and enhanced delivery of poorly water-soluble actives. The exact droplet-size range depends on the preparation method and composition; therefore, a project should report the measured value rather than assume a universal range. [13–17]

High-energy and low-energy approaches

Approach	**Principle**	**Advantages**	**Considerations**
High-energy	High shear/pressure/ ultrasonication reduces droplet size	Broadly applicable	Equipment, heat generation and energy input
Low-energy	Uses phase behavior/composition changes	Can reduce mechanical energy input	Sensitive to composition and phase behavior

Critical formulation variables

- Oil solubilization capacity for the standardized extract.
- Surfactant/co-surfactant compatibility and irritation potential.
- Water-to-oil ratio and phase behavior.
- Droplet size and polydispersity.
- Zeta potential was informative.
- Viscosity after conversion to gel.
- Physical stability under temperature and centrifugation stress.

For a botanical extract, the first development step should be solubility screening rather than immediately selecting a marketed oil. The best oil is the one that provides adequate extract solubilization while maintaining a stable and skin-compatible nanoemulsion.

Nanoemulgel Platform

A nanoemulgel is a hybrid dosage form in which a nanoemulsion is incorporated into a gel network. Reviews describe advantages including improved handling, residence time, spreadability and delivery of lipophilic compounds. Nanoemulgels have been investigated in inflammatory conditions, wound healing, infections and other dermatological applications. [13–17]

Component	**Primary function**	**Selection criterion**
Oil phase	Solubilizes hydrophobic constituents	High solubilization + skin compatibility
Surfactant	Stabilizes droplets	Low irritation + efficient emulsification
Co-surfactant	Improves interfacial flexibility/solubilization	Compatibility + safety
Aqueous phase	Continuous phase	Purity and compatibility
Gelling polymer	Provides semisolid structure	Rheology, spreadability, stability
Preservative if needed	Microbial protection	Compatibility and regulatory acceptability
pH adjuster	Skin-compatible pH	Final pH and stability

Why this platform suits T. purpurea

The plant contains multiple flavonoids and other constituents with variable polarity. A nanoemulgel can accommodate a standardized extract within a mixed oil/water environment and provide a practical semisolid dosage form. The hypothesis is especially relevant to constituents with limited aqueous solubility; however, the final extract's solubility must be measured experimentally.

Component Selection

The 2015 T. purpurea microemulsion-gel study used Captex 200 as oil, Tween 80 as surfactant and PEG 400 as co-surfactant, with the oil and aqueous phases mixed in a 1:1 ratio. Four extract concentrations were studied; F3 contained 4% w/v extract and produced the highest reported 6hour cumulative drug release (62.65%). [9]

Component	Reported 2015 microemulsion-gel precedent	Role in proposed nanoemulgel	Proposed research decision
T. purpurea extract	2–5% w/v across F1–F4	Active botanical extract	Screen 2–5% initially; optimize experimentally
Captex 200	30%	Oil phase	Screen against other skin-compatible oils
Tween 80	15%	Surfactant	Screen concentration and irritation
PEG 400	5%	Co-surfactant	Screen concentration and compatibility
Water	45–48%	Aqueous phase	q.s. after optimization
Gel polymer	Not the main variable in table	Creates nanoemulgel matrix	Screen Carbopol/HPMC or another suitable polymer

Important: the 2015 concentrations are reported values from a microemulsion-gel study and should not be copied into a new nanoemulgel as if they were optimized nanoemulgel parameters. A true nanoemulgel requires new optimization and measurement of droplet size, PDI, rheology and stability.

Formulation principle

Use the 2015 study as a starting evidence point, then perform a design-of-experiments or systematic screening approach to identify the composition that simultaneously satisfies solubilization, droplet-size, stability, viscosity, spreadability and safety requirements.

Proposed T. purpurea Nanoemulgel

The following is a research proposal rather than an experimentally validated formula.

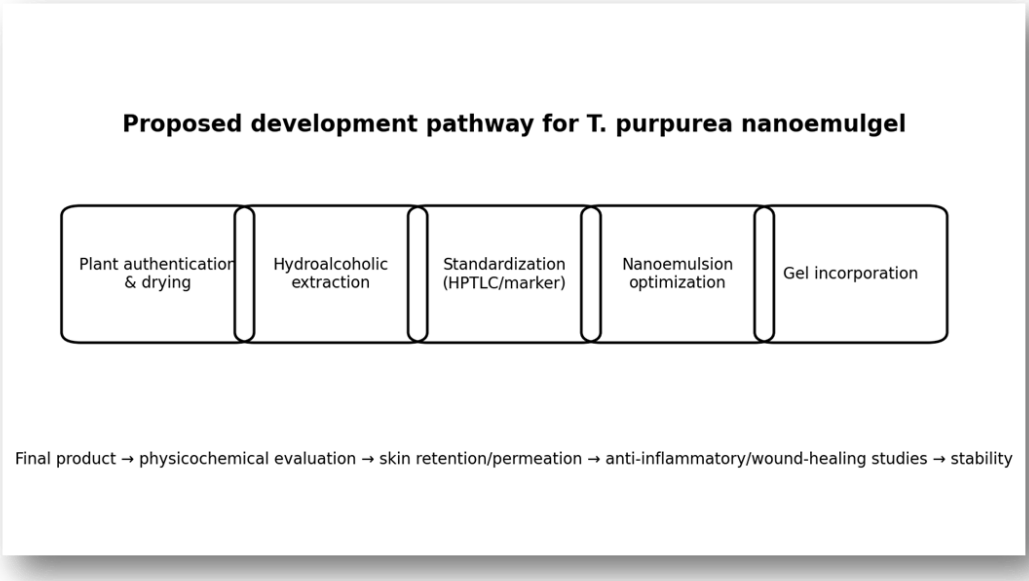
Ingredient/step	Proposed starting range or action	Scientific purpose
Standardized T. purpurea extract	2–5% w/v screening range	Provides botanical active
Oil phase	5–15% screening range	Solubilizes hydrophobic constituents
Surfactant	10–20% screening range	Stabilizes nanoemulsion
Co-surfactant	5–10% screening range	Improves interfacial flexibility/solubilization
Aqueous phase	q.s.	Continuous phase
Carbopol/HPMC or suitable gel polymer	~0.5–1.0% screening range	Provides gel structure; optimize experimentally
pH adjustment	Target skin-compatible range after testing	Patient acceptability and stability

Preservative	Only if required after compatibility/microbial assessment	Microbial protection

Target product profile

Critical quality attribute	Target direction
Appearance	Homogeneous, elegant, no phase separation
Droplet size	Nano-range; actual target defined during optimization
PDI	Low and reproducible
pH	Skin-compatible and stable
Viscosity	Spreadable semisolid suitable for topical use
Drug/marker content	Uniform and within predefined specification
In-vitro release	Reproducible and suitable for intended local action
Skin retention	Adequate local deposition with acceptable permeation
Irritation	No significant irritation in validated test model
Stability	No unacceptable change in appearance, pH, size, assay or rheology

Formulation-Development Method



Stepwise workflow

- 1. Authenticate plant material using botanical and pharmacognostic methods.
- 2. Dry under controlled conditions and mill to a uniform powder.
- 3. Prepare a reproducible hydroalcoholic extract and calculate yield.

- 4. Perform preliminary phytochemical screening and chromatographic fingerprinting.
- 5. Select quantitative marker(s), preferably supported by the literature and validated method.
- 6. Perform solubility screening of the standardized extract in candidate oils, surfactants and co-surfactants.
- 7. Construct a pseudo-ternary phase diagram or an equivalent systematic screening approach where appropriate.
- 8. Prepare nanoemulsions by an appropriate high- or low-energy method.
- 9. Measure droplet size, PDI, pH, appearance and preliminary stability.
- 10. Incorporate the optimized nanoemulsion into a gel base.
- 11. Evaluate nanoemulgel for rheology, spreadability, extrudability, assay, release and stability.
- 12. Proceed to skin permeation/retention, irritation and efficacy studies only after physicochemical acceptance.

This sequence separates extract standardization from formulation optimization, which improves scientific reproducibility.

Characterization

Test	**What it measures**	**Importance**
Appearance/homogeneity	Physical uniformity	Detects instability and aggregation
pH	Acid/base condition	Skin compatibility and stability
Viscosity/rheology	Flow and structural behavior	Controls spreadability and residence
Droplet size	Mean nanoemulsion droplet diameter	Core nanoemulsion quality attribute
PDI	Distribution breadth	Indicates size uniformity
Zeta potential	Interfacial charge	Supportive stability indicator
Assay/marker content	Amount of standardized extract/marker	Dose consistency
In-vitro release	Release through membrane	Compares formulations
Ex-vivo permeation/retention	Skin delivery behavior	Direct topical performance
FTIR/DSC if appropriate	Compatibility/physical state	Supports formulation compatibility
Centrifugation/freeze-thaw	Stress stability	Early instability screening
Long-term/accelerated stability	Changes over storage	Shelf-life development

Reported T. purpurea microemulsion-gel precedent

The 2015 study reported optimized formulations with pH values around 6.70–7.22 and viscosities around 370–412 cps, and F3 showed 62.65 ± 0.35% cumulative release at 6 hours. These are historical data for that specific microemulsion-gel formulation, not target specifications for the proposed nanoemulgel. [9]

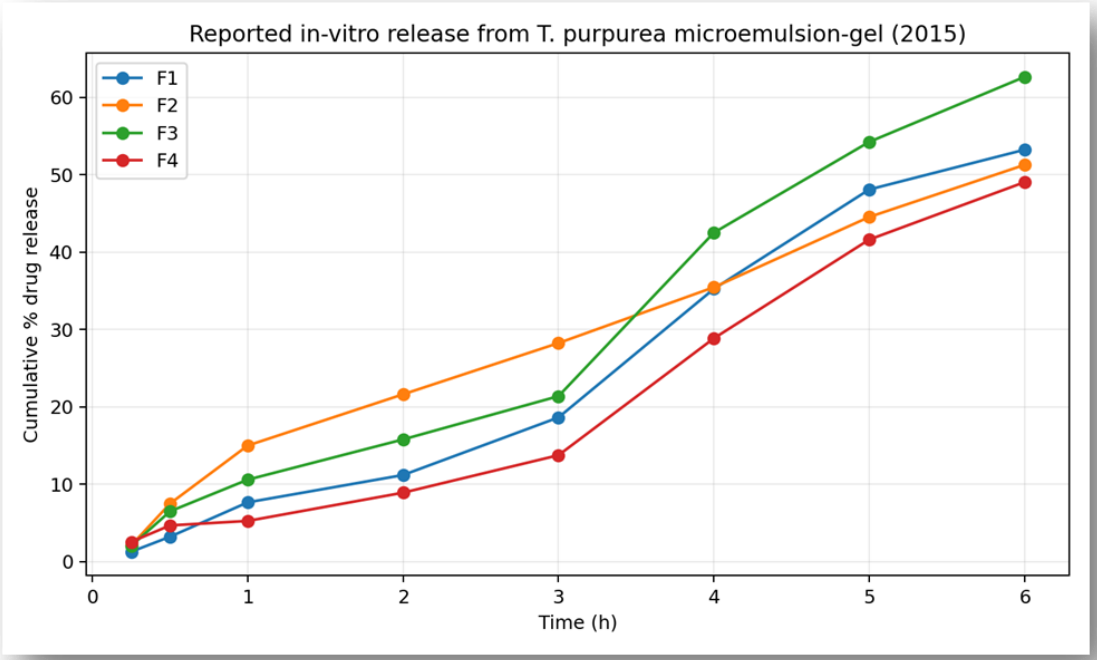


Figure 4. Replotted from reported 2015 release values in [9]; values are not new experimental results.

Biological Evaluation

In-vitro screening

- Cytocompatibility/viability of the final formulation in a relevant skin-cell model.
- Inflammatory mediator assays appropriate to the selected model.
- Antioxidant assays as supportive, not standalone, evidence.
- Antimicrobial testing only where infection-related rationale is part of the study.
- Scratch/wound-closure assay where appropriate and scientifically justified.

Ex-vivo / in-vivo screening

- Skin permeation and retention using a validated membrane/skin model.
- Dermal irritation/sensitization assessment using an ethically and scientifically appropriate method.
- Animal wound-healing models only after appropriate approval and study design.
- Histopathology and biochemical markers to support mechanism.
- Pharmacokinetic/systemic exposure assessment if systemic absorption is plausible.

Endpoint	**Example readout**	**Decision**
Inflammation	Edema, cytokines, histology	Supports/does not support anti-inflammatory hypothesis
Wound healing	% contraction, epithelialization,	Supports repair activity
	hydroxyproline	
Skin delivery	Amount retained/permeated	Defines local vs systemic delivery
Safety	Erythema/edema/cell viability	Accept/reformulate
Stability	Size, PDI, pH, assay over time	Shelf-life suitability

A formulation should progress only when the evidence supports the next stage. This staged design reduces the risk of interpreting a good-looking gel as therapeutically effective without biological confirmation.

Safety, Quality and Standardization

Safety is a central issue for Tephrosia species because the genus contains biologically active rotenoids and other compounds. A 2012 rodent study reported that an extract was well tolerated up to 2000 mg/kg in its acute oral toxicity model, with additional subacute observations at lower doses. This information is supportive background, but oral systemic safety cannot substitute for topical irritation, sensitization and dermal exposure studies. [18]

Quality-control framework

Stage	Recommended control
Raw material	Botanical identity, voucher specimen, moisture, foreign matter
Powder	Microscopy, ash/extractive values where relevant
Extract	Yield, phytochemical profile, microbial limits
Chemical standardization	HPTLC/HPLC fingerprint; marker quantitation
Nanoemulsion	Droplet size, PDI, pH, appearance, physical stability
Nanoemulgel	Viscosity, spreadability, assay, release, microbial quality
Finished product	Stability, irritation, preservative effectiveness where applicable

Rutin has been proposed as an important quality-control marker in HPTLC-chemometric work, with β-sitosterol and lupeol also contributing to the marker panel. A fingerprint plus quantitative marker approach is preferable to relying on a single constituent alone. [11]

Regulatory perspective

The development pathway should follow the applicable institutional, pharmacopoeial, animalethics and regulatory requirements for herbal topical products. Claims should be limited to the evidence actually generated.

Limitations

- Much of the pharmacological evidence is preclinical and uses different plant parts, extracts, doses and routes.
- The anti-inflammatory literature is not completely consistent across models.
- Plant chemistry varies with geography, season, plant part and extraction solvent.
- Published topical formulation evidence is mainly a microemulsion-gel study rather than a validated T. purpurea nanoemulgel.
- Nanoemulgel advantages described in the literature are largely platform-level evidence and cannot be assumed for every botanical extract.
- Topical safety, sensitization and long-term stability of a standardized T. purpurea nanoemulgel require direct evaluation.
- Human clinical studies are needed before therapeutic claims for inflammatory skin disorders can be made.

How these limitations affect the proposed project

The project should prioritize reproducibility and direct evidence. A standardized extract should be prepared first, followed by a controlled formulation screen and then biological evaluation of the finished nanoemulgel. This order prevents formulation variables and plant-material variability from becoming confounded.

Avoidable reporting errors

- Do not call a microemulsion gel a nanoemulgel without measuring nanoscale droplets.
- Do not claim 'clinically proven' from animal wound-healing studies.
- Do not treat antioxidant assay results as direct anti-inflammatory efficacy.

- Do not copy a published formula without re-optimization and compatibility testing.
- Do not omit botanical authentication or chemical standardization.

Research Gaps

Gap	**Why it matters**	**Recommended study**
Plant-specific nanoemulgel data	Direct evidence is limited	Develop and optimize T. purpurea nanoemulgel
Standardized extract specification	Batch variability can change outcomes	Validate HPTLC/HPLC fingerprint + marker assay
Mechanistic skin studies	Systemic animal studies do not define skin mechanisms	Use keratinocyte/immune-cell models
Dermal retention vs permeation	Local action is the intended goal	Perform ex-vivo skin deposition studies
Long-term stability	Botanical constituents may oxidize/degrade	ICH-aligned stability program as applicable
Toxicological profile of final formulation	Extract safety does not equal finished-product safety	Irritation, sensitization and systemic exposure studies
Clinical evidence	Animal data cannot establish human efficacy	Pilot controlled clinical study after preclinical package

Central research question

Can a chemically standardized T. purpurea extract be incorporated into a physically stable, skincompatible nanoemulgel that increases local skin deposition and demonstrates reproducible anti-inflammatory and/or wound-healing activity compared with a conventional extract gel or ointment?

Secondary questions

- Which plant part and extraction solvent give the most reproducible phytochemical profile?
- Which marker panel best predicts batch consistency?
- Which oil/surfactant/co-surfactant system gives the best extract solubilization with acceptable irritation?
- Does nanoemulsification improve skin retention relative to a conventional gel?
- Which biological endpoints respond to the final formulation?

Future Research Roadmap

Phase	**Work package**	**Expected output**
Phase I	Authentication + extraction + phytochemical fingerprint	Standardized T. purpurea extract
Phase II	Solubility and excipient screening	Candidate nanoemulsion composition
Phase III	Nanoemulsion optimization	Stable nanoscale dispersion
Phase IV	Gel incorporation and rheology optimization	Topical nanoemulgel prototype
Phase V	Physicochemical characterization	CQAs and release profile
Phase VI	Ex-vivo skin retention/permeation	Local-delivery evidence
Phase VII	Safety + biological efficacy	Preclinical proof-of-concept
Phase VIII	Stability and scale-up	Robust formulation process
Phase IX	Clinical development if justified	Human evidence

Conclusion

Tephrosia purpurea (L.) Pers. has a substantial ethnomedicinal and pharmacological literature, with reported flavonoids, rotenoids, chalcones, sterols and other constituents. Experimental studies provide evidence for antioxidant, antimicrobial, anti-inflammatory and wound-healing activities, although the strength and directness of evidence differ among models and preparations. [2–8,20–23]

For topical development, the most relevant evidence is the combination of direct wound-healing studies using topical preparations and the 2015 microemulsion-gel study of T. purpurea extract. The latter demonstrated that a plant extract can be incorporated into a topical microemulsion-gel and evaluated for pH, viscosity, spreadability, antimicrobial activity and in-vitro diffusion. [5,7,9]

Nanoemulgel technology offers a logical next-generation platform because it combines a nanoemulsion's ability to handle poorly water-soluble compounds with a gel's topical usability. Current reviews support investigation of nanoemulgels for inflammatory and dermatological applications. [13–17]

However, a T. purpurea nanoemulgel should be presented as a proposed research formulation unless new experimental evidence demonstrates its performance. The recommended development pathway is: authenticated plant → standardized extract → excipient/solubility screening → nanoemulsion optimization → gel incorporation → physicochemical characterization → skin retention/permeation → safety → efficacy → stability.

References

1. Kew Science. Plants of the World Online: Tephrosia purpurea (L.) Pers. Accepted name, taxonomy, distribution and morphology.
2. Rao AS, Yadav SS, Singh P, Nandal A, Ganaie SA, et al. A comprehensive review on ethnomedicine, phytochemistry, pharmacology, and toxicity of Tephrosia purpurea (L.) Pers. Phytotherapy Research. 2020;34(8):1902-1925. DOI: 10.1002/ptr.6657.
3. Khatun A, Rahman M, et al. Ethnopharmacology, phytochemistry and pharmacology of Tephrosia purpurea. Chinese Journal of Natural Medicines. 2014;12(1):1-7. DOI: 10.1016/S1875-5364(14)60001-7.
4. Agnihotry VK, Sharma SP, Agnihotri N, Saxena RC. Chemical constituents of Tephrosia purpurea family: Leguminosae. International Journal of Chemical Sciences. 2011;9(3):10451052.
5. Lodhi S, Pawar RS, Jain AP, Singhai AK. Wound healing potential of Tephrosia purpurea (Linn.) Pers. in rats. Journal of Ethnopharmacology. 2006;108(2):204-210. DOI: 10.1016/j.jep.2006.05.011.
6. Shenoy S, Shwetha K, Prabhu K, Maradi R, Bairy KL, Shanbhag T. Evaluation of antiinflammatory activity of Tephrosia purpurea in rats. Asian Pacific Journal of Tropical Medicine. 2010;3(3):193-195. DOI: 10.1016/S1995-7645(10)60007-7.
7. Lodhi S, et al. Effects of flavonoids from Martynia annua and Tephrosia purpurea on cutaneous wound healing. Journal of Ayurveda and Integrative Medicine. 2016.
8. Kumar R, et al. Determination of flavonoids, polyphenols and antioxidant activity of Tephrosia purpurea: a seasonal study. Chinese Herbal Medicines. 2016.
9. Vaidya VR, Mahendrakuar CB, Bhise KS. Formulation Development and Evaluation of Microemulsion Gel System of Extract of Tephrosia purpurea for Topical Use. Journal of Current Pharma Research. 2015;5(4):1640-1646.
10. Sandhya S, Venkata Ramana K, Vinod KR. Pharmacognostical Standardization of Tephrosia purpurea Pers Root. Ancient Science of Life. 2010;30(1):1-6.
11. Katakam S, Sharma P, Anandjiwala S, Sharma S, Shrivastava N. Investigation on apposite chemical marker for quality control of Tephrosia purpurea (L.) Pers. by means of HPTLCchemometric analysis. Journal of Pharmaceutical and Biomedical Analysis. 2019.
12. Mansour M, et al. Phytochemical Analysis and Profiling of Antioxidants and Anticancer Compounds from Tephrosia purpurea (L.) subsp. apollinea. Molecules. 2023;28(9):3939.
13. Choudhury H, Gorain B, Pandey M, et al. Recent Update on Nanoemulgel as Topical Drug Delivery System. Journal of Pharmaceutical Sciences. 2017;106(7):1736-1751. DOI:
14. 10.1016/j.xphs.2017.03.042.
15. Sengupta P, Chatterjee B. Potential and future scope of nanoemulgel formulation for topical delivery of lipophilic drugs. International Journal of Pharmaceutics. 2017;526(1-2):353-365. DOI: 10.1016/j.ijpharm.2017.04.068.
16. An Overview of Nanoemulgels for Bioavailability Enhancement in Inflammatory Conditions via Topical Delivery. 2023.
17. Nanoemulgel: A Novel Nano Carrier as a Tool for Topical Drug Delivery. Pharmaceutics. 2023;15(1):164. DOI: 10.3390/pharmaceutics15010164.

18. Jacob S, Nair AB. Nanoemulgels as Advanced Topical Drug Delivery Systems: Mechanistic Insights and Therapeutic Applications in Skin Disorders, Infections, Wound Healing, and Cancer. Pharmaceuticals. 2026;19(2):247. DOI: 10.3390/ph19020247.
19. Acute and subacute oral toxicity evaluation of Tephrosia purpurea extract in rodents. 2012.
20. Dalwadi PP, Patel JL, Patani PV. Tephrosia purpurea Linn (Sharpunkha, Wild Indigo): A Review on Phytochemistry and Pharmacological Studies. Indian Journal of Pharmaceutical and Biological Research. 2014;2(1):108-121.
21. Natural Products from the Genus Tephrosia. 2013.
22. Determination of polyphenols and free radical scavenging activity of Tephrosia purpurea linn leaves. 2010.
23. Praveena R, Amarnath S, Jegadeesan M. Anti-inflammatory activity of Tephrosia purpurea root. International Journal of Pharmacognosy and Phytochemical Research. 20112012;3(4):9394.
24. Vedica RS, Kori ML. Investigations on flavonoid rich extracts of Martynia annua Linn. and Tephrosia purpurea Linn. for Anti-inflammatory and Antihemorrhoidal effects in rats. International Journal of Pharmaceutical Sciences and Drug Research. 2022.
25. Dubey G. Development, Characterization, and Isolation of Alkaloidal Fraction from Tephrosia purpurea and Evaluate its Wound Healing Activity. International Journal of Pharmaceutical & Biological Archive. 2018;9(2).
26. Wikimedia Commons. File: Tephrosia purpurea.jpg. Photograph by Dr. Subhransu, CC BYSA 3.0.