

Formulation And Preliminary Evaluation of Self-Emulsifying Neem Bath Drops

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Abstract: Neem (*Azadirachta indica* A. Juss.) contains chemically diverse constituents relevant to topical and dermocosmetic research, but reproducible formulation and evidence-based safety evaluation are necessary before therapeutic claims. This preliminary study developed two nominal 10 mL self-emulsifying neem bath-drop formulations containing neem leaf extract, coconut oil, polysorbate 80, propylene glycol, glycerin, vitamin E, menthol, rose oil and rose water. Neem powder was separately macerated with water, hydroalcoholic solvent and ethanol, and the extracts were screened qualitatively for alkaloids, tannins, flavonoids and terpenoids. Formulations F1 and F2 differed mainly in polysorbate 80 (1 and 2 mL), coconut oil (1.5 and 0.5 mL) and glycerin (1 and 0.5 mL), respectively. The optimized preparation was reported to emulsify in distilled water within 32 seconds and to form a uniform milky dispersion without precipitation or phase separation after 1:100 dilution. The reported pH range was 6–7; the product was readily washable and appeared yellowish green. Hydroalcoholic extract gave positive reactions for all four tested phytochemical classes, whereas the aqueous extract lacked flavonoid and terpenoid reactions. An antimicrobial signal against *Staphylococcus aureus* and *Escherichia coli* was reported, but zone diameters, controls and replicate data were unavailable. A no-irritation statement was also recorded without sufficient ethical or methodological detail and was therefore not interpreted as proof of safety. F2 was selected provisionally because its higher surfactant and lower oil/humectant content were associated with easier dispersion and lower apparent viscosity. Confirmatory work should quantify extract markers, droplet size, viscosity, preservative efficacy, antimicrobial zones, stability and skin irritation using validated, ethics-compliant methods.

Keywords: *Azadirachta indica*; neem bath drops; self-emulsifying concentrate; polysorbate 80; phytochemical screening; topical formulation; antimicrobial screening

1. Introduction

Neem (*Azadirachta indica* A. Juss.; family Meliaceae) occupies an important place in Ayurveda and other South Asian traditional-health practices. Leaves, bark, seeds, flowers and oil have been used in preparations for hygiene and skin conditions. Modern phytochemical research has identified limonoids, flavonoids, tannins and other constituents, including nimbin, nimbidin, nimbolide, quercetin and azadirachtin-related compounds, although the relative profile differs substantially among plant parts, growing conditions and extraction methods (Alzohairy, 2016; Gupta et al., 2017; Saleem et al., 2018).

Neem has attracted dermocosmetic interest because extracts and oils have shown antimicrobial, anti-inflammatory, antioxidant and skin-conditioning activities in experimental systems. These findings provide a rationale for formulation research but do not establish that every neem product is effective or non-irritant. Botanical authentication, contaminant control, chemical standardization, dose, vehicle and exposure route



determine performance. Reviews of topical neem applications therefore emphasize both biological potential and the need for better-quality safety and efficacy evidence (Baby et al., 2022; Biswas et al., 2002).

Bath additives are diluted before contact with the skin. A poorly dispersible oil or extract can float, deposit unevenly or precipitate; a surfactant-based concentrate can improve distribution through water. Self-emulsifying systems usually combine an oil, a surfactant and often a co-solvent to form an emulsion under gentle agitation (Pouton, 1997, 2000). Polysorbate 80 is a non-ionic surfactant, propylene glycol acts as a co-solvent and humectant, coconut oil supplies an emollient phase, and glycerin improves hydration and sensory feel. In the present product, rose water is used q.s.; consequently, the final physical state must be confirmed before applying the classical term “self-emulsifying drug-delivery system.” “Self-emulsifying bath concentrate” is the more cautious description.

The original thesis described two formulations and several evaluations but contained important omissions: neem-extract quantities were absent; extraction ratio, time and yield were not specified; pH was measured only by paper; viscosity values were not provided; microbiological media were inconsistent; and animal-irritation details and ethics approval were missing. Converting such a thesis into a research paper requires distinguishing observed results from proposed or unverified procedures. The present paper therefore reports the available pilot data transparently, corrects scientific terminology where possible, and provides a confirmatory quality-control plan rather than inventing missing measurements.

The objectives were to (1) compare aqueous, hydroalcoholic and ethanolic neem-leaf extracts by qualitative phytochemical screening; (2) prepare two surfactant-based neem bath concentrates; (3) evaluate appearance, emulsification, dilution behaviour, pH, washability and preliminary biological performance; and (4) identify the analytical, microbiological, stability and ethics requirements needed for product development.

2. Materials and Methods

2.1 Study design and data provenance

This was a preliminary laboratory formulation study reconstructed from the supplied thesis text. Numerical results were retained only when explicitly reported. Missing formulation quantities and replicate-level outcomes were coded as not reported (NR). Proposed confirmatory procedures are labelled as recommendations and are not represented as experiments already performed.

2.2 Materials

Authenticated neem leaves were dried and powdered. Coconut oil, polysorbate 80 (Tween 80), propylene glycol, glycerin, vitamin E, menthol, rose oil, rose water and purified water were described as pharmaceutical, analytical or suitable cosmetic grade. The original record did not provide suppliers, batch numbers, certificates of analysis or acceptance specifications. Those details should be included in a final submission. Neem materials should be controlled for identity, foreign matter, moisture, extractable matter, microorganisms, pesticide residues, aflatoxins and toxic metals using applicable pharmacopoeial and World Health Organization methods (World Health Organization [WHO], 2011).

Table 1. Functional role and critical quality considerations for formulation components.

Material	Reported role	Important quality attributes
Neem leaf extract	Botanical active; intended antimicrobial/skin-hygiene contribution	Plant identity, solvent, dry yield, marker/fingerprint, microbes, pesticides, heavy metals and residual solvent

Material	Reported role	Important quality attributes
Coconut oil	Oil phase and emollient	Identity, fatty-acid profile, peroxide/acid value and microbial quality
Polysorbate 80	Non-ionic surfactant; promotes dilution emulsification	Compendial identity, peroxide value, water content and lot consistency
Propylene glycol	Co-solvent, humectant and possible penetration enhancer	Compendial identity and purity
Glycerin	Humectant and sensory modifier	Compendial identity, water content and impurities
Vitamin E	Antioxidant and skin-conditioning component	Tocopherol identity/potency and oxidation state
Menthol	Cooling sensory agent	Identity, optical purity where relevant and sensitization/irritation risk
Rose oil/rose water	Fragrance and aqueous vehicle	Botanical/source identity, allergen declaration, microbes and preservative status

2.3 Preparation of neem extracts

Neem powder was separately contacted with water, a hydroalcoholic solvent and ethanol at room temperature by maceration. The source stated that cold extraction was selected to reduce heat exposure of sensitive constituents. However, powder-to-solvent ratio, ethanol strength, maceration duration, agitation schedule, filtration method, concentration temperature, dry yield and storage were not recorded. These variables are essential because they determine both phytochemical recovery and the actual neem dose in the finished product.

For a reproducible confirmatory study, a pre-specified cold-maceration method should be used for each solvent. WHO describes a general cold-extractable-matter approach using accurately weighed coarsely powdered material, six hours of frequent shaking and an additional 18-hour standing period before filtration (WHO, 2011). A formulation study should additionally record extraction yield, dry residue, chromatographic fingerprint and at least one justified marker. Hydroalcoholic and ethanolic concentrates require validated residual-solvent control.

Table 2. Extraction matrix and information status.

Extract	Reported condition	Reported qualitative purpose	Critical missing record
Aqueous	Room-temperature maceration	Recover polar constituents	Drug:solvent ratio, time, yield, microbial control and storage
Hydroalcoholic	Room-temperature maceration; alcohol strength NR	Recover a wider polarity range	Alcohol percentage, time, yield, residual solvent and marker profile

Extract	Reported condition	Reported qualitative purpose	Critical missing record
Ethanollic	Room-temperature maceration; ethanol strength NR	Recover alcohol-soluble constituents	Ethanol percentage, time, yield, residual solvent and marker profile

Note. NR = not reported in the supplied thesis text.

2.4 Formulation composition

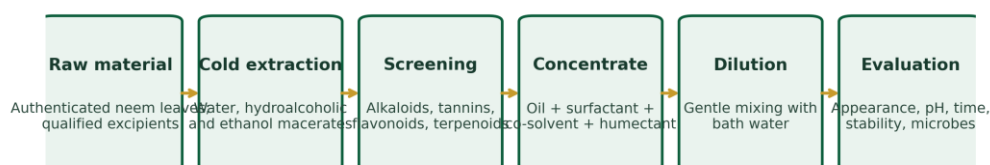
Two nominal 10 mL formulations were described. F2 contained twice the polysorbate 80 of F1 and one-third of the coconut oil, while glycerin was halved. The neem-extract quantity was absent from both columns; rose water was added q.s. and rose oil was measured as drops. Because extract quantity and density were not reported, a true mass balance and active concentration cannot be calculated.

Table 3. Source-reported composition of nominal 10 mL neem bath-drop formulations.

Ingredient	F1	F2	Function/data note
Neem extract	NR	NR	Essential missing active quantity and extract identity
Polysorbate 80	1.0 mL	2.0 mL	Non-ionic surfactant
Propylene glycol	2.0 mL	2.0 mL	Co-solvent/humectant
Glycerin	1.0 mL	0.5 mL	Humectant/soothing agent
Coconut oil	1.5 mL	0.5 mL	Oil phase/emollient
Vitamin E	0.05 mL	0.05 mL	Antioxidant
Rose oil	2 drops	2 drops	Fragrance; convert to mass for reproducibility
Menthol	0.2 g	0.2 g	Cooling agent; confirm complete solubilization
Rose water	q.s. to 10 mL	q.s. to 10 mL	Aqueous vehicle; preservative status not reported

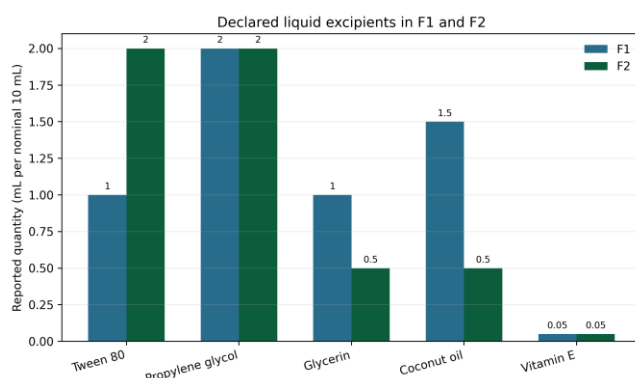
Note. The missing neem-extract amount prevents reproduction. “q.s.” means quantity sufficient. Use mass-based manufacturing records in future batches.

Development pathway for a self-emulsifying neem bath concentrate



Critical gaps to verify: extract ratio/yield, neem-extract dose in F1/F2, calibrated pH/viscosity, antimicrobial zones, controls and ethics approval.

Figure 1. Development and evaluation workflow.



Neem-extract quantity was not reported; rose water was q.s. Rose oil (2 drops) and menthol (0.2 g) are excluded because their units differ. Bars are compositional declarations, not replicate data.

Figure 2. Comparison of declared liquid excipients in F1 and F2.

2.5 Method of preparation

1. A measured quantity of neem extract was placed in a clean, dry vessel; the amount and extract identity must be recovered from the batch record.
2. Coconut oil and vitamin E were mixed to form the initial oily phase. Menthol should be dissolved in a compatible phase and its complete solubilization documented.
3. Polysorbate 80 was incorporated gradually with continuous stirring, followed by propylene glycol and glycerin.
4. Rose oil was added and the mixture was stirred until macroscopically uniform.
5. Rose water was added slowly with continued mixing to the nominal final volume. Mixing speed, time and temperature were not reported and should be standardized.
6. The product was transferred to an airtight amber container for evaluation. Future batches should record theoretical yield, actual yield, fill mass and container-closure specifications.

2.6 Qualitative phytochemical screening

Each extract was screened for four phytochemical classes using conventional colour or precipitation reactions: Dragendorff's reagent for alkaloids, ferric chloride for tannins/phenolics, alkaline reagent followed by dilute acid for flavonoids, and the Salkowski reaction for terpenoids. A positive alkaloid result was an orange precipitate;



tannins produced dark blue/green/black colour; flavonoids produced yellow colour that changed after acidification; and terpenoids produced a reddish-brown interface. Qualitative tests are presumptive and cannot identify individual molecules or compare concentration without chromatographic confirmation (Kokate et al., 2010).

2.7 Physicochemical evaluation

Appearance, colour, odour, clarity, homogeneity, precipitation and creaming were assessed visually after 24 hours at room temperature. For self-emulsification, 1 mL concentrate was introduced into 100 mL distilled water at 37 °C under mild agitation, and the time to a macroscopically uniform emulsion was recorded. Dilution stability was assessed at 1:100 after 24 hours for precipitation, cracking and phase separation. The source measured a 1% v/v dilution with pH paper. A calibrated pH meter, defined equilibration time and triplicate readings are required for publication-quality measurement.

Washability was evaluated by applying the diluted or neat product to skin and rinsing with water, followed by assessment of residual oiliness. Viscosity was discussed in the thesis, but no instrument, spindle, speed, temperature or values were given. Accordingly, viscosity was not included as a numerical result. Future evaluation should include rheological conditions, density, refractive index where relevant, droplet size and polydispersity after dilution, centrifugation stress, freeze–thaw cycles and longer-term storage.

2.8 Antimicrobial and skin-compatibility evaluation

The source described an agar-well diffusion study against *Staphylococcus aureus* and *Escherichia coli* at 37 °C for 24 hours but referred inconsistently to MacConkey, nutrient and unspecified inoculated agar. MacConkey agar is selective for Gram-negative enteric organisms and is not an appropriate common diffusion medium for both species. Because strain identifiers, inoculum standardization, well diameter, sample concentration, positive/negative controls, replicates and zone diameters were absent, the result was classified only as an unquantified antimicrobial signal.

A confirmatory assay should use a validated common medium such as Mueller–Hinton agar for non-fastidious *S. aureus* and *E. coli*, reference strains (for example, ATCC 25923 and ATCC 25922), a 0.5 McFarland inoculum, standardized agar depth and wells, a formulation-base control, solvent control and appropriate positive antimicrobial control. Zone diameters should be reported in millimetres as individual replicates and mean $\pm$ standard deviation. Broth microdilution can then estimate minimum inhibitory concentration. The base formulation must be tested because surfactant, menthol or fragrance may contribute activity or diffusion effects.

The thesis also stated that the formulation caused no erythema or oedema after application to shaved animal skin. Species, sex, sample size, dose, area, exposure, scoring times, control, protocol and institutional animal ethics approval were not provided. The statement was therefore not treated as validated safety evidence. Future development should prioritize an accepted in-vitro reconstructed human epidermis method such as OECD Test Guideline 439; any human patch study requires prior ethics approval and informed consent (Organisation for Economic Co-operation and Development [OECD], 2021).

2.9 Statistical analysis

No inferential statistics were applied because the supplied record contained no replicate-level dataset. Confirmatory batches should be prepared independently at least three times. Numerical attributes should be reported as mean $\pm$ standard deviation with individual values. Formulation effects may be assessed by an appropriate parametric or non-parametric comparison after checking assumptions, while time-dependent stability should be modelled with batch and storage condition. Prespecified acceptance criteria are preferable to significance testing alone.

3. Results

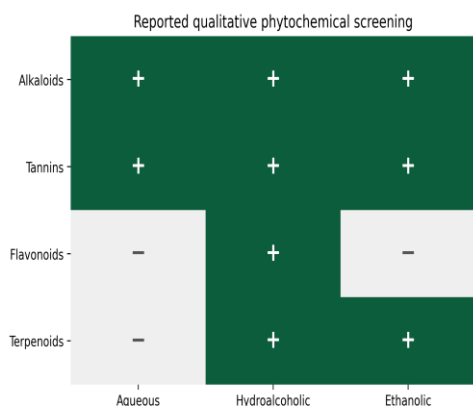
3.1 Phytochemical profile

Alkaloid and tannin reactions were reported in all three extracts. The aqueous extract was negative for flavonoids and terpenoids, whereas the hydroalcoholic extract was positive for all four classes. The final thesis summary recorded ethanolic extract as positive for alkaloids, tannins and terpenoids but negative for flavonoids. This final value conflicts with the detailed procedure text, which described a yellow flavonoid reaction. The inconsistency requires review of laboratory photographs or bench sheets before submission.

Table 4. Reported qualitative phytochemical reactions of neem-leaf extracts.

Test/class	Aqueous	Hydroalcoholic	Ethanolic	Interpretive note
Dragendorff / alkaloids	+	+	+	Orange reaction reported; hydroalcoholic response described as weak
Ferric chloride / tannins	+	+	+	Dark coloration reported in all extracts
Alkaline reagent / flavonoids	–	+	–*	*Final summary negative; detailed narrative described ethanolic yellow colour
Salkowski / terpenoids	–	+	+	Brown/reddish-brown interface reported in alcohol-containing extracts

Note. Qualitative symbols do not indicate concentration. Chromatographic fingerprints and replicates are needed.



*+ and –" represent qualitative reactions only. The source narrative described the ethanolic flavonoid test as positive, whereas the final summary table recorded it as negative; the summary value is plotted pending verification.

Figure 3. Qualitative phytochemical profile reported for the three neem extracts.

3.2 Formulation and dilution performance

The freshly prepared concentrate was described as clear to slightly translucent and yellowish green with a characteristic neem odour. No visible precipitation or creaming was observed after 24 hours. On addition to water, the optimized formulation produced a uniform milky emulsion within 32 seconds. The 1:100 dilution remained free of visible precipitation, cracking or phase separation over the reported 24-hour observation period. The pH was reported as 6–7 by paper. The product was easily removed by water without a marked oily residue.

F2 was selected as the preferred formula in the thesis. Its compositional distinction was a higher polysorbate-80 level and lower coconut-oil and glycerin levels than F1. These changes are mechanistically consistent with easier aqueous dispersion and lower apparent thickness, but comparative emulsification times, viscosity values and droplet-size data were not available. Therefore, F2 optimization should be considered provisional rather than statistically demonstrated.

Table 5. Available preliminary evaluation results and evidence status.

Attribute	Source-reported observation	Evidence strength / qualification
Appearance	Yellowish-green, clear to slightly translucent liquid	Descriptive; lighting, replicate batches and photographs not standardized
Homogeneity/24-hour appearance	No visible precipitation or creaming	Short-term visual observation only
Self-emulsification	Uniform milky emulsion in 32 seconds	Numerical time reported; formulation identity, replicate number and variability not stated
Dilution stability	Good at 1:100; no separation after 24 hours	Qualitative; no droplet-size or turbidity measurement
pH	6–7	Indicator paper only; calibrated triplicate measurement required
Washability	Easily removed; little oily residue	Qualitative sensory observation
Viscosity	F2 described as lower than F1	No instrument or numerical values; not verifiable
Antimicrobial activity	Activity reported against <i>S. aureus</i> and <i>E. coli</i>	No zones, controls, strain IDs or replicates; signal only
Skin irritation	No visible irritation reported	Protocol and ethics information absent; not accepted as proof of safety

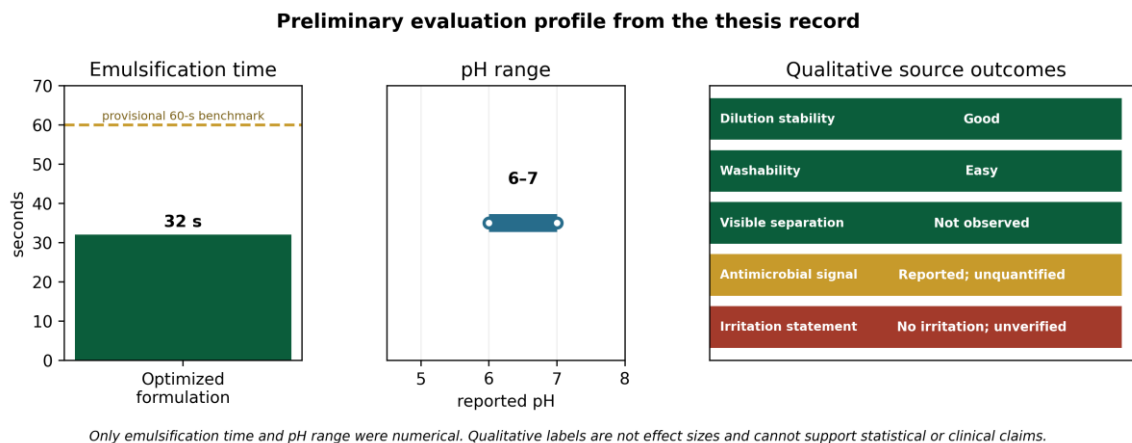


Figure 4. Preliminary physicochemical and qualitative evaluation profile.

3.3 Antimicrobial and irritation observations

The thesis stated that measurable inhibition zones were present against *S. aureus* and *E. coli*, but no diameters were included. The formulation itself contains multiple components that may affect growth or diffusion; without a base control, activity cannot be attributed specifically to neem. The result is therefore hypothesis-generating only. Similarly, the statement of no visible redness, swelling or irritation cannot be evaluated in the absence of animal and ethics information. Neither observation supports a clinical efficacy or safety claim in its present form.

4. Discussion

4.1 Influence of extraction solvent

The broader positive profile of the hydroalcoholic extract is plausible because mixed water–alcohol systems can recover constituents across a wider polarity range than water alone. However, qualitative colour reactions are vulnerable to interference, especially in dark botanical extracts. The apparent absence of aqueous flavonoids or terpenoids may reflect concentration below visual detection rather than true absence. Conversely, a positive reaction does not establish the identity or biological relevance of a constituent. Thin-layer chromatographic fingerprinting, total phenolic/flavonoid assays and a stability-indicating marker method would materially strengthen the study.

The extract incorporated into F1 and F2 must be identified. If hydroalcoholic extract was selected because it produced all four reactions, its final alcohol level and residual-solvent status need control. If an aqueous extract was used, microbial preservation becomes particularly important. A bath product containing botanical extract and rose water presents a microbial-growth risk unless the formulation is self-preserving or contains a validated preservative system. A challenge test is therefore more informative for product safety than an assay showing that the product can inhibit selected test organisms.

4.2 Formulation interpretation

F2 contains a larger surfactant-to-oil ratio than F1. This change can lower interfacial tension and accelerate dispersion, while the lower glycerin and coconut-oil content can reduce bulk viscosity. The reported 32-second emulsification and stable milky appearance are consistent with this rationale. Nevertheless, a milky dispersion is a macro- or fine emulsion by appearance; it is not evidence of a microemulsion or nanoemulsion. Those terms require droplet-size data and appropriate physical characterization (Date & Nagarsenker, 2007; Pouton, 1997).



The presence of rose water in the concentrate raises a classification issue. Classical self-emulsifying systems are usually essentially anhydrous oil/surfactant/co-solvent mixtures that emulsify after encountering water. If substantial rose water is already present, the product may instead be a concentrated oil-in-water emulsion that undergoes further dilution. This distinction affects stability mechanisms, preservative requirements and labelling but not the practical goal of uniform bath-water dispersion. The manuscript therefore uses functional, not nanoscale, terminology.

Polysorbate 80 at 20% v/v in nominal F2 is high enough that skin compatibility and sensory acceptability must be tested at the actual in-use dilution as well as in concentrate-contact scenarios. Menthol and rose fragrance can also irritate or sensitize some users. “Herbal” and “natural” do not guarantee safety, and the finished product must be evaluated as a mixture rather than inferred from neem alone.

4.3 Interpretation of pH, washability and stability

A reported pH of 6–7 is near neutral and may be compatible with a rinse-off use, but skin compatibility cannot be concluded from pH alone. Paper provides only coarse resolution and can be affected by colour. A calibrated meter should be used on a defined dilution because concentrate and bath-water pH may differ. Good washability and absence of visible separation are useful early formulation attributes, yet 24-hour visual stability is insufficient for shelf-life assignment. At minimum, three pilot-scale batches should be evaluated under real-time and accelerated conditions for appearance, odour, pH, viscosity, marker content, phase behaviour, droplet size, microbial limits and packaging compatibility.

4.4 Antimicrobial evidence and safety boundaries

Neem extracts can inhibit both Gram-positive and Gram-negative organisms in vitro, but activity varies by solvent, concentration and strain (Biswas et al., 2002; Ugwu, 2019). Agar diffusion is especially sensitive to how an oily or surfactant-rich formulation moves through the gel. A small zone may represent poor diffusion rather than lack of activity, while surfactant can create a zone unrelated to the botanical. Controls and a dilution-based MIC method are therefore essential. No claim of infection prevention or treatment is justified from the present “yes/no” observation.

The source irritation statement presents a more serious reporting issue. Animal experiments require prospective ethics review, humane design, complete methods and individual observations. Without those elements, the result should be removed from a submission or clearly excluded from the evidence. OECD TG 439 reconstructed-human-epidermis testing provides an animal-free route for irritation hazard identification and should be considered before any human acceptability work. A subsequent supervised patch study would still require institutional ethics approval, informed consent and adverse-event procedures.

4.5 Strengths, limitations and confirmatory development plan

The study’s strengths are the comparison of three extraction solvents, rational variation of surfactant and oil levels, a simple in-use dilution test, and attention to washability. Its main limitations are missing extract dose and yield, absence of batch replication, incomplete rheology, approximate pH, no droplet-size characterization, unquantified antimicrobial results, and inadequate irritation/ethics documentation. The supplied reference list also included secondary and difficult-to-verify sources; the present paper prioritizes traceable reviews, standards and primary methods.

Table 6. Recommended confirmatory study sequence.

Stage	Minimum design	Decision output
Extract standardization	Authenticated leaves; specified solvent ratio/time; $n \geq 3$ extraction batches; yield and chromatographic fingerprint	Select extract on reproducibility and marker recovery, not qualitative colour alone
Mixture optimization	Defined neem dose; mass-based F1/F2 manufacture; phase/mixture design across surfactant:oil ratios	Identify a robust composition with acceptable dilution, viscosity and sensory properties
Physical characterization	Calibrated pH; viscosity with full settings; density; droplet size/PDI; turbidity; centrifugation and dilution robustness	Quantitative finished-product specifications
Microbiological quality	Microbial limits and preservative-efficacy/challenge testing	Demonstrate product preservation during shelf life and use
Antimicrobial screening	MHA and broth dilution with reference strains, base/solvent/positive controls and ≥ 3 independent runs	Zones and MIC with confidence intervals; attribute activity appropriately
Skin compatibility	OECD TG 439 or justified validated alternative, followed if appropriate by ethics-approved human patch work	Evidence-based irritation classification and use warnings
Stability	At least three batches in intended package under real-time/accelerated conditions	Shelf life based on physical, chemical and microbiological acceptance criteria

A confirmatory formulation record should express all components by mass, state the exact extract dry-equivalent per millilitre and define the in-use dose, such as drops per litre of bath water. This enables exposure assessment and reproducibility. Packaging should limit light and oxidation, include a calibrated dropper, and carry warnings for eye contact, ingestion, children, allergy and discontinuation if irritation occurs.

5. Conclusion

Two nominal self-emulsifying neem bath concentrates were prepared using polysorbate 80, coconut oil, propylene glycol, glycerin, vitamin E, menthol, rose oil and rose water. The hydroalcoholic neem extract produced the broadest qualitative phytochemical profile. The optimized preparation was reported to form a uniform milky dilution within 32 seconds, remain visually stable at 1:100 dilution for 24 hours, have a pH range of 6–7 and wash readily from skin. F2 was provisionally preferred because its higher surfactant and lower oil/humectant content were consistent with faster dispersion and lower apparent viscosity. However, missing neem dose, extract yield,

replicate data, calibrated pH, quantitative viscosity, antimicrobial zones, controls and irritation/ethics details prevent strong efficacy or safety conclusions. The product should therefore be described as a promising preliminary bath concentrate rather than a validated antimicrobial or therapeutic preparation. Standardized extract chemistry, quantitative physical characterization, microbial preservation, controlled antimicrobial testing, validated irritation assessment and multi-batch stability are required before publication-ready claims or product development.

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