RESEARCH PAPER

Pharmaceutical and Analytical Characterization of Ksharagada Tablet and Ksharagada Ointment with a Preclinical Framework for Antipsoriatic Evaluation

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Abstract

Psoriasis is a chronic immune-mediated inflammatory disease in which epidermal hyperproliferation and an IL-23/IL-17-dominant inflammatory network generate well-demarcated erythematous scaly plaques. In Ayurvedic clinical reasoning, several features of plaque psoriasis are commonly compared with Kitibha Kushtha, a Vata-Kapha-predominant skin disorder. Ksharagada is a classical Agada formulation described in Charaka Samhita and later texts for disorders that include Twak-dosha. The supplied doctoral protocol proposes oral Ksharagada, a modified Ksharagada ointment, and their combination for imiquimod-induced psoriasiform inflammation. Objective: To present a source-faithful pharmaceutical and analytical research report using only the empirical data actually available in the supplied documents, and to place the planned preclinical antipsoriatic work in an evidence-based methodological framework. Materials and Methods: Primary empirical data were restricted to two laboratory quality-control certificates dated 18 March 2026. The protocol was used to reconstruct formulation procedures, planned OECD 407 repeated-dose toxicity work, and a four-group imiquimod efficacy experiment. Published literature was used only for scholarly context and was not substituted for missing study outcomes. Ksharagada tablet was yellowish, characteristically odorous and salty; total ash, water-soluble ash, acid-insoluble ash, water extractive, alcohol extractive, disintegration time, friability, hardness and pH were 3.2%, 1.1%, 0.5%, 45.32%, 17.65%, 4 min, 0.5%, 3.5 kg/cm² and 6.9, respectively. Ksharagada ointment was yellowish, characteristically odorous and smooth, with pH 6.8, good spreadability, absent rancidity, iodine value 26.21 and peroxide value 6.1; the certificate did not state units for the last two values. The listed microbiological parameters were reported as absent in both dosage forms. No numerical PASI, cytokine, histopathology or toxicity outcomes were supplied; therefore, no antipsoriatic efficacy or safety effect size was calculated. The available evidence establishes a reproducible analytical snapshot of the two formulations and supports progression to rigorously controlled preclinical testing, but it does not yet establish antipsoriatic efficacy. Reporting observed analytical data separately from prospective animal endpoints provides a more credible basis for subsequent publication and translation.

Keywords: Ksharagada; psoriasis; Kitibha Kushtha; imiquimod; Ayurvedic formulation; analytical standardization; ointment; tablet; IL-17; preclinical research

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1. Introduction

Psoriasis is a chronic, relapsing, immune-mediated inflammatory disease that affects the skin and, in a clinically important proportion of patients, joints and other organ systems. Indian epidemiological literature has reported prevalence estimates that vary by region and study design, while the broader literature consistently emphasizes the substantial physical, psychosocial and economic burden of the disease [1,2]. Plaque psoriasis is characterized by sharply demarcated erythematous plaques with silvery scale, most often on extensor surfaces and scalp, although almost any cutaneous site may be involved [2-4]. The modern understanding of psoriasis has moved from a predominantly keratinocyte-centered disorder to a systemic immune disease in which genetic susceptibility, environmental triggers, dendritic-cell activation, T-cell polarization and epidermal responses are tightly integrated [3-7].

At the molecular level, the IL-23/Th17 pathway is central to the maintenance of psoriatic inflammation. Activated dendritic cells and other innate immune populations support IL-23-dependent expansion and survival of IL-17-producing T cells. IL-17A, IL-17F, TNF and related mediators then act on keratinocytes to induce antimicrobial peptides, chemokines and additional cytokines, creating a self-amplifying inflammatory circuit [5-7]. This mechanistic framework is not merely descriptive: the clinical effectiveness of biologics

targeting TNF, IL-17 and IL-23 has provided strong causal validation for these pathways [2,7,9]. Nevertheless, long-term disease control remains challenging because treatment selection must account for disease severity, comorbidities, route of administration, cost, safety monitoring and patient preference [8,9].

Ayurveda approaches chronic skin disease through a distinct conceptual system. The supplied protocol correlates the plaque morphology and symptom cluster of psoriasis with Kitibha Kushtha, described as a Vata-Kapha-predominant condition manifesting features such as discoloration, roughness, hardness, dryness and itching. Such correlation should be interpreted as a clinical analogy rather than a claim of one-to-one nosological identity. Classical Ayurvedic categories and contemporary immunodermatological diagnoses arise from different epistemological frameworks, and translational work is strongest when each is described on its own terms while testable biological hypotheses are evaluated independently.

Ksharagada is an Agada formulation referenced in Charaka Samhita, Chikitsa Sthana 23, verses 101-104, and is also discussed in later Ayurvedic sources [28]. The protocol identifies its relevance to Twak-dosha and proposes that its Ushna, Tikshna, Lekhana, Krimighna, Kushthaghna and related properties may be pertinent to Kitibha-like pathology. Modern pharmacological literature on individual ingredients provides a plausible, but not yet formulation-specific, rationale: curcumin has immunomodulatory activity [14], Tulsi has demonstrated immunomodulatory effects in a randomized human study [15], Berberis aristata preparations have shown anti-inflammatory and antipsoriatic activity in experimental formulation research [16], and glycyrrhizin has been linked to modulation of the IL-17A/SIRT1-STAT3 pathway in a psoriasis model [17]. These observations are supportive rather than confirmatory because the pharmacology of a complex formulation cannot be inferred by simply adding the effects of its ingredients.

The attached doctoral protocol advances this translational question by proposing three intervention strategies oral Ksharagada tablet, topical Ksharagada ointment and their combination—in an imiquimod (IMQ)-induced psoriasiform model. IMQ is widely used to induce psoriasis-like skin inflammation in mice and is mechanistically relevant because its phenotype depends strongly on IL-23/IL-17 signaling [10]. The protocol additionally plans repeated-dose safety assessment according to OECD Test Guideline 407, together with PASI-like scoring, inflammatory cytokines and histopathology. These choices are conceptually appropriate for an early preclinical program, provided that the study design, dosing, blinding, randomization, humane endpoints and statistical analysis are finalized before experimentation [10-12].

A central challenge in converting a doctoral protocol into a research paper is the distinction between planned work and completed work. The supplied materials contain verified laboratory analytical certificates for the tablet and ointment, but they do not contain numerical animal efficacy results, individual animal records, cytokine concentrations, histopathology scores, hematology, biochemistry or toxicity outcomes. A publication-quality manuscript must not create those data. Accordingly, the present paper is deliberately structured as a pharmaceutical and analytical characterization study accompanied by a preclinical framework. Its results section reports only observed analytical findings, while the animal component is described as prospective methodology. This source-faithful approach preserves scientific integrity and avoids the common but serious error of presenting protocol expectations as experimental findings.

2. Literature Review

2.1 Contemporary pathobiology and treatment of psoriasis

Psoriatic plaques arise from a dynamic interaction between cutaneous immune cells and keratinocytes. Genetic risk is distributed across numerous loci, including pathways related to antigen presentation, NF-kappaB, interferon signaling and the IL-23 receptor axis [5,6]. Environmental triggers such as infection, trauma, medications, stress and metabolic factors can influence disease expression. Histologically, established plaques typically show acanthosis, altered keratinocyte differentiation, parakeratosis, vascular changes and a mixed inflammatory infiltrate. Modern reviews emphasize that psoriasis is not simply a disorder of accelerated epidermal turnover; epidermal hyperplasia is maintained by reciprocal immune-epithelial signaling [2-7].

The treatment landscape spans topical corticosteroids, vitamin D analogues and keratolytic approaches for limited disease; phototherapy for selected patients; conventional systemic agents such as methotrexate, cyclosporine and retinoids; targeted oral small molecules; and biologic therapies directed against TNF, IL-17, IL-12/23 or IL-23 [2,8,9]. These options can produce substantial disease control, but long-term management is individualized. Cost, monitoring burden, pregnancy potential, infection risk, metabolic and hepatic comorbidity, patient adherence and access to specialty care all influence therapeutic choice [8,9]. This continuing therapeutic complexity provides a rational setting for investigating standardized traditional formulations as adjunctive or exploratory candidates, but such candidates require the same principles of quality control, toxicology and reproducible efficacy assessment applied to other interventions.

2.2 Kitibha Kushtha and the translational rationale for Ksharagada

The protocol conceptualizes Kitibha Kushtha as predominantly involving Vata and Kapha, with Twak, Rakta, Mamsa and Lasika considered relevant Dushya and with Rasa/Rakta-vaha Srotas implicated in disease progression. The proposed Samprapti-vighatana of Ksharagada includes Vata-Kapha shamana, Deepana-Pachana, Srotoshodhana, Rakta-prasadana, Lekhana/Rukshana and Kandughna/Twak-prasadana

actions. From a modern experimental perspective, these terms do not constitute surrogate biomarkers. Their scientific value lies in generating hypotheses—for example, whether the formulation reduces erythema and scaling, normalizes epidermal thickness, lowers inflammatory cytokines or modifies oxidative stress. The protocol's planned PASI-like scoring, IL-1, IL-17 and IL-23 measurements, and histology can therefore serve as operational endpoints without claiming that a cytokine directly represents a Dosha or Dhatu.

Classical Ksharagada is prepared around Palasha Kshara with a multi-ingredient herbal-mineral matrix [28]. Recent pharmaceutical studies have independently revisited its manufacturing and analytical profile. Manuprasad and colleagues described a modern pharmaceutical preparation process for Ksharagada and documented changes in pH through stages of Kshara preparation [25]. More recently, Gohil and colleagues reported pharmaceutico-analytical and pharmacognostic standardization of Ksharagada, emphasizing raw-drug authentication, physicochemical testing and chromatographic profiling [27]. These publications support the broader need for batch-specific standardization before biological testing; they do not substitute for the analytical certificate of the formulation evaluated in the present source set.

2.3 Pharmacological plausibility of representative ingredients

The supplied synopsis specifies a 17-ingredient Ksharagada formulation comprising Palasha (*Butea monosperma*), Gairika (red ochre), Haridra (*Curcuma longa Linn.*), Daruharidra (*Berberis aristata DC*), Surasamanjari/Tulsi (*Ocimum sanctum Linn.*), Madhuka/Yashtimadhu (*Glycyrrhiza glabra Linn.*), Laksha (*Laccifer lacca*), Saindhava (rock salt), Bahlika (*Crocus sativus Linn.*), Jatamansi (*Nardostachys jatamansi*), Hingu (*Ferula narthex*), Shweta Sariva (*Hemidesmus indicus*), Krishna Sariva (*Ichnocarpus frutescens*), Kushtha (*Saussurea lappa*), Shunthi (*Zingiber officinale*), Maricha (*Piper nigrum*) and Pippali (*Piper longum*). The most defensible modern interpretation is not that every constituent is antipsoriatic, but that selected ingredients have independent evidence for anti-inflammatory, antioxidant, immunomodulatory, antimicrobial or skin-related activities.

Berberis aristata has particular relevance because a transferosomal gel containing its extract was evaluated for anti-inflammatory and antipsoriatic activity, supporting the plausibility of topical delivery of Berberis-derived constituents [16]. Glycyrrhizin from Glycyrrhiza species has shown mechanistic effects on psoriasis-related pathways, including suppression of IL-17A-associated responses and modulation of the SIRT1-STAT3 axis [17]. These studies provide a more specific link to psoriatic biology than generic antioxidant claims, but formulation-level pharmacokinetics, concentration and interaction effects remain unknown.

Other constituents contribute a broader anti-inflammatory rationale. Saussurea lappa/costus has a long history of use and a phytochemical literature describing sesquiterpene lactones and diverse pharmacological effects [18]. Ginger is widely recognized for anti-inflammatory actions mediated through eicosanoid and cytokine pathways [19]. Piper nigrum and piperine have shown antioxidant effects in experimental oxidative-stress models [20]. Nardostachys jatamansi contains sesquiterpenoids with experimentally demonstrated anti-inflammatory activity in cell systems [21], while Crocus sativus constituents have been reviewed for immunoregulatory effects involving NF-kappaB and cytokine pathways [22]. HPTLC fingerprinting of Hemidesmus indicus has also been reported and is relevant to botanical identity and standardization [23].

These ingredient-level data should be handled conservatively. Extract chemistry depends on plant identity, geographic source, harvesting, processing and solvent conditions. A compound present in an isolated extract may be present at a very different concentration in a classical multi-ingredient preparation. Kshara processing may further alter the chemical environment, while the ointment manufacturing process changes the delivery matrix. Therefore, the correct sequence is to authenticate raw materials, standardize the finished product, document chemical fingerprints and then assess the whole formulation experimentally. WHO guidance on herbal quality control emphasizes identity, physicochemical parameters, contaminants and appropriate analytical methods as foundational steps [13,30].

2.4 Quality control of the tablet dosage form

For a complex Ayurvedic tablet, organoleptic characteristics, ash values, extractive values, pH, disintegration, friability and hardness collectively describe different aspects of formulation quality. Ash values reflect inorganic residue under defined test conditions and can assist in detecting unusual contamination or processing variation, while acid-insoluble ash is particularly useful as an indicator of siliceous or earthy matter. Water- and alcohol-soluble extractive values provide broad estimates of the proportion of constituents extractable in solvents of differing polarity. These tests are non-specific: they do not identify active molecules, but they are valuable for batch comparison when performed under standardized methods [13,29].

Disintegration, friability and hardness address the mechanical behavior of tablets. A tablet must be strong enough to withstand handling yet capable of breaking down appropriately after administration. Because the supplied certificate does not state the exact analytical method, acceptance specification, number of replicates or instrument model, the present manuscript reports the values descriptively without declaring pharmacopoeial compliance. This distinction is important: a measured value can be authentic while the evidence required to claim compliance with a particular monograph remains incomplete.

2.5 Quality control of the ointment dosage form

Topical semisolid preparations require a different analytical focus. Appearance, odor, texture, pH and spreadability influence usability and consistency. Rancidity, peroxide value and iodine value provide information relevant to the condition of lipid components. Peroxide value is commonly used as an indicator of primary lipid oxidation, whereas iodine value reflects unsaturation; however, interpretation requires the analytical method, units and matrix-specific specification. The supplied report provides numerical values but does not state the units for iodine and peroxide values. They are therefore preserved exactly as reported and are not compared with an external limit.

Microbiological quality is critical for both oral and topical formulations. The certificates state that total viable count, Enterobacteriaceae, total fungal count, Escherichia coli, Salmonella, Staphylococcus aureus and Pseudomonas aeruginosa were absent. This is reassuring within the context of the report, yet 'absent' should not be equated with absolute sterility because the report does not provide the culture method, sample size, detection limit or acceptance criteria. WHO guidance recommends defined microbiological methods and limits appropriate to the product category [13,30].

2.6 Imiquimod-induced psoriasiform inflammation as a preclinical model

Topical imiquimod produces a rapid psoriasiform dermatitis in susceptible laboratory rodents, characterized by erythema, scaling, epidermal hyperplasia and inflammatory infiltration. The model has mechanistic relevance because it activates innate pathways and depends substantially on IL-23/IL-17 signaling [10]. It is therefore suitable for screening anti-inflammatory interventions that may affect pathways also involved in human psoriasis. Nevertheless, it is an acute inducible model and cannot reproduce the full genetic, chronic, systemic and comorbid spectrum of human psoriasis. The protocol's planned interpretation should remain at the level of 'antipsoriatic-like activity in an IMQ model' rather than direct proof of clinical efficacy.

A related Indian study developed an imiquimod-induced psoriatic-like inflammatory model in rats and demonstrates local experience with standardized induction and lesion assessment [11]. In the supplied protocol, 5% IMQ cream is proposed for dorsal application for seven days, followed by ten days of intervention. A four-group efficacy design is described: IMQ control, IMQ plus oral Ksharagada, IMQ plus Ksharagada ointment, and IMQ plus the combination. The proposed oral dose is 260 mg/kg based on a body-surface-area conversion calculation in the protocol. This is a testable regimen, but the final protocol should also pre-specify the IMQ amount per unit area, sex-stratified randomization, blinding of lesion scoring, rescue/humane endpoints and whether treatment overlaps with or follows IMQ exposure.

2.7 Safety assessment before efficacy interpretation

Traditional use does not remove the need for systematic toxicology, especially for a multi-component formulation that includes an alkaline Kshara component and a mineral ingredient. OECD Test Guideline 407 provides a standardized framework for repeated 28-day oral toxicity testing in rodents and includes clinical observations, body weight, food consumption, hematology, clinical chemistry, necropsy, organ weights and histopathology [12]. The supplied protocol plans vehicle control and Ksharagada dose groups, plus recovery groups, with doses of 200, 400 and 1000 mg/kg/day. The protocol uses more animals per group than the minimum stated in the current OECD 407 summary; final numbers remain subject to ethics approval and power considerations.

Independent Ksharagada toxicology has recently been reported in Wistar rats. Manuprasad and colleagues evaluated acute and 28-day repeated oral exposure and reported no mortality at high acute doses, while noting biochemical changes at higher repeated doses despite generally unremarkable vital-organ histopathology [26]. This finding is relevant because it argues against assuming that 'no visible toxicity' is sufficient. The proposed study should retain comprehensive biochemical and histological monitoring and should establish a clearly defined no-observed-adverse-effect level rather than relying only on survival or gross behavior. Related experimental work on another Ayurvedic Agada formulation illustrates how traditional antidotal formulations can be evaluated with modern hematological and tissue endpoints [24].

2.8 Complete constituents and translational rationale

Protocol ingredient	Botanical/material identity in synopsis	Rationale/status in this manuscript	Interpretive caution/source note
Palasha	*Butea monosperma*	Kshara source; protocol constituent	Complete formulation ingredient specified in synopsis.
Gairika	Red ochre	Mineral constituent	Non-botanical material; included because it is one of the 17 protocol ingredients.

Protocol ingredient	Botanical/material identity in synopsis	Rationale/status in this manuscript	Interpretive caution/source note
Haridra	*Curcuma longa Linn.*	Representative anti-inflammatory/immunomodulatory rationale [14]	Ingredient-level evidence does not establish whole-formulation efficacy.
Daruharidra	*Berberis aristata DC*	Representative topical anti-inflammatory/antipsoriatic rationale [16]	Delivery system and concentration differ from Ksharagada ointment.
Surasa manjari (Tulsi)	*Ocimum sanctum Linn.*	Representative immunomodulatory rationale [15]	The cited study was in healthy volunteers, not psoriasis.
Madhuka (Yashtimadhu)	*Glycyrrhiza glabra Linn.*	Representative psoriasis-pathway rationale [17]	Marker concentration in finished Ksharagada is unknown.
Laksha	*Laccifer lacca*	Classical constituent (lac/resin material)	Non-plant biological material; retained as specified in the synopsis.
Saindhava	Rock salt	Mineral/salt constituent	Non-botanical material; retained as specified in the synopsis.
Bahlika	*Crocus sativus Linn.*	Representative immunoregulatory rationale [22]	Classical-name/botanical mapping should be authenticated before experimental use.
Jatamansi	*Nardostachys jatamansi*	Representative anti-inflammatory rationale [21]	Ingredient-level evidence requires formulation-level confirmation.
Hingu	*Ferula narthex*	Protocol constituent	Botanical identity should be authenticated with the raw material.
Shweta Sariva	*Hemidesmus indicus*	Identity/standardization and anti-inflammatory rationale [23]	Useful for botanical identity/fingerprint; not therapeutic proof for the whole formulation.
Krishna Sariva	*Ichnocarpus frutescens*	Protocol constituent	Distinct Sariva variant listed separately in the synopsis.

Protocol ingredient	Botanical/material identity in synopsis	Rationale/status in this manuscript	Interpretive caution/source note
Kushtha	*Saussurea lappa*	Representative phytochemical/pharmacological rationale [18]	Botanical identity should be voucher-authenticated.
Shunthi	*Zingiber officinale*	Representative broad anti-inflammatory rationale [19]	Not specific to psoriasis.
Maricha	*Piper nigrum*	Representative antioxidant rationale [20]	Does not establish clinical antipsoriatic activity.
Pippali	*Piper longum*	Protocol constituent	Ingredient-specific evidence was not separately relied on in this manuscript.

Table 1. Complete 17-ingredient composition of Ksharagada as specified in the supplied synopsis, with botanical/material identities and the evidence status used in this manuscript. The list includes non-botanical materials (Gairika, Saindhava and Laksha) because they are integral constituents of the classical formulation.

3. Materials and Methods

3.1 Study design and data-source hierarchy

This manuscript was constructed as a source-grounded pharmaceutical and analytical study with a prospective preclinical component. Two categories of source material were distinguished before analysis. Category A comprised empirical observations that had actually been generated: two analytical laboratory quality-control reports dated 18 March 2026, one for Ksharagada Vati/tablet and one for Ksharagada ointment. Category B comprised planned methods contained in the doctoral protocol: raw-material procurement and authentication, formulation procedures, repeated-dose toxicity testing and IMQ-induced efficacy assessment. Only Category A values were treated as study results. Category B information was used to describe methods and future endpoints and was never converted into numerical outcomes.

The source protocol was prepared under the Faculty of Ayurveda, Mahatma Gandhi Ayurved College, Hospital & Research Centre, Salod (H), Wardha, for a PhD project in Agadtantra. The analytical reports were issued by the analytical laboratory of Cotex Laxmi Healthcare Private Limited/Mahatma Gandhi Ayurved College, Hospital & Research Centre, Salod (H), Wardha, to the investigator. The laboratory certificate itself, rather than extrapolated literature values, was treated as the primary source for finished-product quality-control data.

3.2 Pharmaceutical preparation of Ksharagada tablet

The protocol-derived manufacturing sequence begins with Palasha (Butea monosperma) Kshara preparation. The Palasha plant material is burned in open air to obtain ash. The ash is soaked in approximately four to six times its quantity of water, stirred and allowed to settle. The supernatant alkaline liquid is filtered through clean cloth and the filtrate is gently evaporated to obtain Kshara. Fresh Kshara is then dissolved in water to prepare an alkaline liquid extract. The remaining powdered ingredients are prepared as fine Churna, mixed in the specified proportions and incorporated into the Kshara solution. Continuous trituration is performed until a thick paste-like mass forms. The mass is subsequently shade-dried and shaped into Gutika/tablets, which are stored in airtight containers. The protocol does not provide a completed batch manufacturing record with exact yield, in-process temperatures, mixing time or tablet weight for the batch represented by the 2026 analytical certificate; those variables should be included in future GMP-style documentation.

3.3 Preparation of Ksharagada ointment

The modified ointment procedure described in the protocol converts the classical formulation into a topical semisolid. Palasha Kshara solution is prepared from ash and water. Kalka of the other ingredients is combined with Kshara Jala and sesame oil, using the protocol's ratio of Kshara Jala 16 parts, Kalka 1 part and sesame oil 4 parts. The mixture is heated gently with continuous stirring until the aqueous phase evaporates and the medicated oil remains, after which it is filtered. Separately, an ointment base comprising beeswax, white soft paraffin and liquid paraffin is melted in a water bath at approximately 60-70°C. Warm Ksharagada Taila is gradually incorporated into the molten base with continuous stirring. The preparation is then cooled while stirring to promote uniformity, filled into suitable containers while semisolid and stored away from direct light. Because the final analytical report does not specify the batch formula or excipient quantities, the manuscript does not infer them beyond the protocol description.

3.4 Analytical evaluation

The analytical certificate for Ksharagada tablet listed organoleptic tests (colour, odour and taste), physicochemical tests (total ash, water-soluble ash, acid-insoluble ash, water extractive value, alcohol extractive value, disintegration time, friability, hardness and pH) and microbiological parameters. The certificate for Ksharagada ointment listed colour, odour and texture; pH,

spreadability, rancidity, iodine value and peroxide value; and the same microbiological panel. The source protocol additionally proposes HPTLC as a phytochemical parameter, but no HPTLC chromatogram, Rf table, densitogram or marker quantification was included in the supplied results. Consequently, HPTLC is discussed as an appropriate future standardization step [13,23,27] but is not reported as a completed result.

All analytical values were transcribed exactly from the certificates. No unit was added where the certificate did not provide one. In particular, the iodine value (26.21) and peroxide value (6.1) for the ointment are reported without invented units. Similarly, the microbiological result 'Absent' is retained as a categorical laboratory finding and not converted to a colony-forming-unit value. No acceptance limit was imposed retrospectively because the certificates did not identify the analytical standard or product-specific specification used.

3.5 Prospective repeated-dose toxicity study

The protocol proposes a 28-day repeated-dose oral toxicity study using albino mice, informed by OECD Test Guideline 407 [12]. Planned groups include vehicle control (0 mg/kg/day), Ksharagada 200 mg/kg/day, 400 mg/kg/day and 1000 mg/kg/day, with recovery control and recovery high-dose satellite groups. Oral gavage once daily is proposed, using distilled water as vehicle and a dosing volume of 10 mL/kg. The protocol proposes daily clinical observation, twice-daily mortality/morbidity checks, weekly body weight and food consumption, functional/neurological observations, hematology, serum biochemistry, urinalysis, gross necropsy, organ weights and histopathology. These are prospective procedures; no toxicity dataset was provided for this manuscript.

3.6 Prospective IMQ-induced efficacy study

For efficacy, the protocol proposes 24 albino mice, equally distributed by sex, aged approximately 6-8 weeks and weighing about 20-30 g. Animals are to be housed under controlled temperature, humidity and a 12-hour light-dark cycle with standard food and water. The planned induction procedure is daily topical application of 5% imiquimod cream to dorsal skin for seven days [10,11]. Thereafter, treatment is planned for days 8-17. Group A (n=6) serves as IMQ positive control; Group B (n=6) receives IMQ plus oral Ksharagada at 260 mg/kg; Group C (n=6) receives IMQ plus topical Ksharagada ointment; Group D (n=6) receives the oral and topical formulations in combination. The protocol labels topical dosing as local application but does not provide a mass-per-area dose; this should be standardized before study initiation.

The principal disease endpoint proposed is a PASI-like assessment of the psoriasiform patch. The protocol additionally proposes histopathological examination and measurement of inflammatory biomarkers including IL-1, IL-17 and IL-23, with blood collection after final treatment. For a publication-grade experiment, the PASI-like scoring rubric should be explicitly adapted for mice, ideally scoring erythema, scaling and thickness independently with blinded observers. Histology should include predefined measures such as epidermal thickness and inflammatory-cell infiltration, and cytokine assays should specify matrix, kit, calibration range and normalization strategy.

3.7 Statistical analysis

For the completed analytical dataset, the available certificates provide single reported values rather than replicate measurements; therefore, inferential statistical tests were not appropriate. Results were summarized descriptively and plotted as reported. The protocol states that future animal data will be expressed as mean ± SEM and analyzed by Student's t test and ANOVA as required. A more rigorous final analysis plan should use one-way or two-way ANOVA according to the time structure of the endpoint, followed by a multiplicity-adjusted post-hoc comparison; repeated PASI measurements should be analyzed with a repeated-measures or mixed-effects model. Assumptions of normality and variance should be assessed, and nonparametric alternatives prespecified. Effect sizes and confidence intervals should accompany P values.

3.8 Ethical and reporting considerations

The protocol states that animal work is contingent on institutional animal ethics approval. The final study should comply with applicable Indian animal-experimentation requirements, the 3Rs (replacement, reduction and refinement), and humane endpoints. Randomization and outcome-assessor blinding should be documented. The manuscript also identified internal protocol inconsistencies that require resolution before experimentation: one section describes a three-parallel-arm design, whereas the efficacy table contains four groups; the overall study duration is stated as 18 days, while another line mentions sacrifice after six weeks. These discrepancies were not silently corrected in the present paper; the four-group, 18-day efficacy schedule was used only because it is the most detailed operational table, and the inconsistency is retained as a limitation requiring protocol amendment.

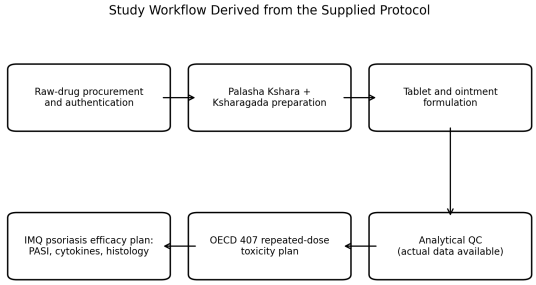

Figure 1. Workflow derived from the supplied protocol. "Actual data available" refers only to the finished-product analytical certificates; toxicity and efficacy blocks remain prospective.

3.9 Prospective efficacy-group structure

Group	n	Induction	Intervention	Dose/route	Planned treatment period
A	6	5% IMQ	Positive control	Local IMQ only	Protocol days 8-17 after induction
B	6	5% IMQ	Ksharagada tablet	260 mg/kg, oral	Days 8-17
C	6	5% IMQ	Ksharagada ointment	Local application; quantity not specified	Days 8-17
D	6	5% IMQ	Tablet + ointment	260 mg/kg oral + local application	Days 8-17

Table 2. Four-group efficacy design as specified in the detailed protocol table; these are planned groups, not completed results.

4. Results

4.1 Source integrity and availability of results

The empirical dataset comprised the two laboratory reports received on 18 March 2026. The tablet certificate covered 50 units, and the ointment certificate covered 50 g of product. No individual replicate values, raw instrument outputs or chromatographic records were attached. Therefore, the results below represent the laboratory-reported batch values exactly as supplied. The preclinical animal experiment remains prospective in the available documents; there are no authentic PASI trajectories, cytokine concentrations, histopathology scores, body-weight changes, hematology results or toxicity findings to report.

Formulation identity used for interpretation of results.

The analytical results below relate to the Ksharagada dosage forms described in the supplied study materials. For compositional context, the synopsis specifies 17 constituents: Palasha, Gairika, Haridra, Daruharidra, Surasamanjari, Madhuka, Laksha, Saindhava, Bahlika, Jatamansi, Hingu, Shweta Sariva, Krishna Sariva, Kushtha, Shunthi, Maricha and Pippali. This composition is protocol-derived and should not be interpreted as an independent chromatographic confirmation of each constituent in the tested batch.

4.2 Organoleptic and physicochemical profile of Ksharagada tablet

The Ksharagada tablet was reported as yellowish in colour, with characteristic odour and salty taste. Total ash was 3.2%, water-soluble ash 1.1% and acid-insoluble ash 0.5%. The water extractive value was 45.32%, substantially greater numerically than the alcohol extractive value of 17.65%. These values are best interpreted as a batch fingerprint under the unspecified laboratory method rather than as direct measures of therapeutic constituents. The high relative water extractive fraction is compatible with a formulation containing numerous polar plant constituents and salts, but no chemical identification can be inferred from the extractive result alone.

The tablet disintegration time was reported as 4 minutes, friability as 0.5%, hardness as 3.5 kg/cm² and pH as 6.9. Together, these observations indicate a mechanically coherent tablet that disintegrated rapidly in the test used by the laboratory. However, the certificate does not identify the compendial apparatus, medium, temperature, number of tablets tested or acceptance criterion, and therefore the values should not be described as formal pharmacopoeial compliance. The pH value is close to neutral and contrasts with the alkaline character expected during early Palasha Kshara preparation, illustrating that the finished multi-ingredient dosage form cannot be characterized solely by the chemistry of Kshara.

4.3 Organoleptic and physicochemical profile of Ksharagada ointment

The ointment was yellowish, had characteristic odour and a smooth texture. Its pH was 6.8 and the laboratory reported 'Good Spreadability.' Rancidity was reported as absent. Iodine value was 26.21 and peroxide value was 6.1. Because the certificate did not state units or analytical methods for iodine and peroxide values, these values are intentionally presented without units and without comparison to a specification. They provide a useful batch-level analytical record that can be compared with future batches only if the same validated method is applied.

The ointment result is pharmaceutically relevant because a topical product must combine chemical stability, acceptable texture and practical application characteristics. A pH of 6.8 is compatible with a near-neutral semisolid environment, while the qualitative spreadability result suggests that the prepared base could be distributed on a surface without obvious handling difficulty. Yet spreadability was not reported numerically, so it cannot be statistically compared or correlated with rheology. Future work should measure spreadability using a specified method and should add viscosity/rheology, phase-separation testing, accelerated stability and content/fingerprint analysis.

4.4 Microbiological findings

For both dosage forms, the report listed total viable count, Enterobacteriaceae, total fungus count, E. coli,

Salmonella, Staphylococcus aureus and Pseudomonas aeruginosa as absent. This is a favorable categorical finding for the tested samples. Because the analytical report does not provide quantitative limits of detection, inoculum/sample mass, incubation conditions or the compendial method, the most accurate statement is that the listed organisms/parameters were not detected according to the laboratory report. The data do not justify the stronger term 'sterile.'

4.5 Graphical representation of authentic analytical data

Figures 1-4 visualize only the values appearing in the certificates. Figure 1 shows the percentage-based tablet parameters and makes the contrast between extractive values and ash/friability parameters readily visible. Figure 2 shows the tablet's disintegration time, hardness and pH, with an explicit warning that the values use different units and should not be compared as a common quantitative scale. Figure 3 depicts the ointment's pH, iodine value and peroxide value without inventing missing units. Figure 4 presents the categorical microbiological findings for both formulations. Figure 5 is a conceptual three-dimensional schematic of the dual oral/topical strategy and is not an experimental image or result. Figure 6 summarizes the protocol workflow and visually separates completed analytical QC from prospective toxicity and efficacy experiments.

4.6 Preclinical efficacy and toxicity outcomes

No authentic preclinical outcome data were present in the supplied files. Consequently, no claim can be made regarding reduction in erythema, scaling, thickness, total PASI-like score, IL-1, IL-17, IL-23, C-reactive protein, epidermal thickness or any other efficacy variable. Similarly, no NOAEL, organ-toxicity profile or safety conclusion can be assigned to the 2026 study batch. Published Ksharagada toxicology [26] and ingredient studies [14-22] are discussed as external evidence only; they are not merged with the present dataset.

4.7 Tablet analytical results

Domain	Parameter	Reported result
Organoleptic	Colour	Yellowish
Organoleptic	Odour	Characteristic
Organoleptic	Taste	Salty
Physicochemical	Total ash	3.2%
Physicochemical	Water-soluble ash	1.1%
Physicochemical	Acid-insoluble ash	0.5%
Physicochemical	Water extractive value	45.32%
Physicochemical	Alcohol extractive value	17.65%
Performance	Disintegration time	4 min
Performance	Friability	0.5%
Performance	Hardness	3.5 kg/cm²
Physicochemical	pH	6.9

Table 3. Ksharagada tablet quality-control results transcribed from the supplied analytical certificate dated 18 March 2026.

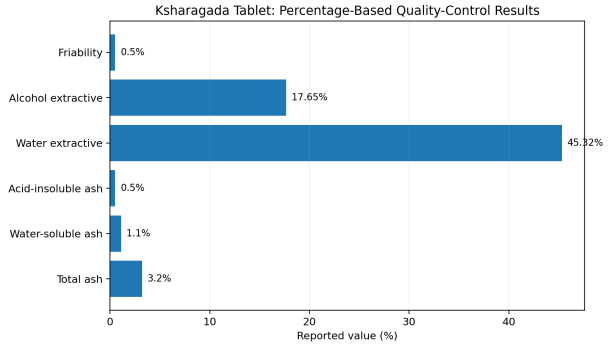

Figure 2. Authentic percentage-based tablet quality-control values from the analytical certificate.

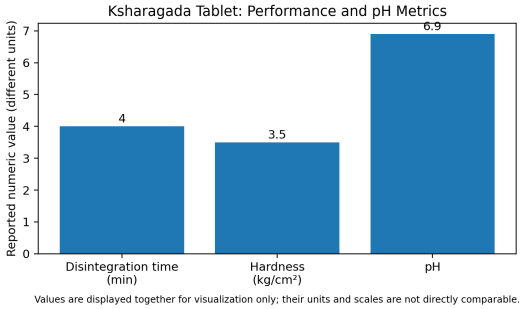

Figure 3. Authentic tablet disintegration, hardness and pH results. The plotted metrics have different units and are not directly comparable.

4.8 Ointment analytical results

Domain	Parameter	Reported result
Organoleptic	Colour	Yellowish
Organoleptic	Odour	Characteristic
Organoleptic	Texture	Smooth
Physicochemical	pH	6.8
Physical	Spreadability	Good spreadability
Stability	Rancidity	Absent
Lipid-quality index	Iodine value	26.21 (unit not stated)

Domain	Parameter	Reported result
Lipid-quality index	Peroxide value	6.1 (unit not stated)

Table 4. Ksharagada ointment quality-control results transcribed from the supplied analytical certificate dated 18 March 2026.

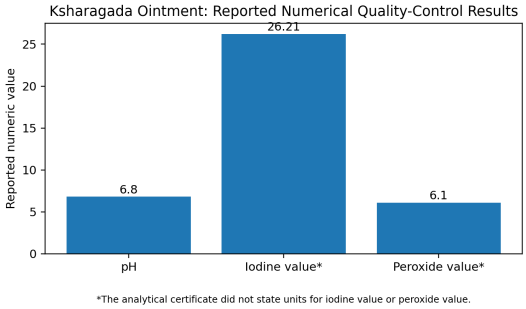

Figure 4. Authentic numerical ointment quality-control values. Units were not provided for iodine or peroxide value in the source certificate.

4.9 Microbiological findings

Parameter	Tablet	Ointment
Total viable count	Absent	Absent
Enterobacteriaceae	Absent	Absent
Total fungal count	Absent	Absent
E. coli	Absent	Absent
Salmonella	Absent	Absent
S. aureus	Absent	Absent
P. aeruginosa	Absent	Absent

Table 5. Microbiological findings reported by the analytical laboratory. "Absent" is reproduced verbatim and should not be interpreted as proof of sterility without method/detection-limit information.

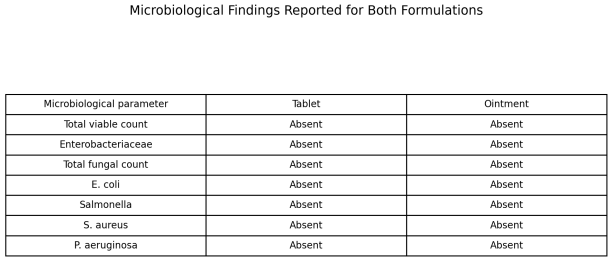

Figure 6. Categorical microbiological findings in the supplied tablet and ointment certificates.

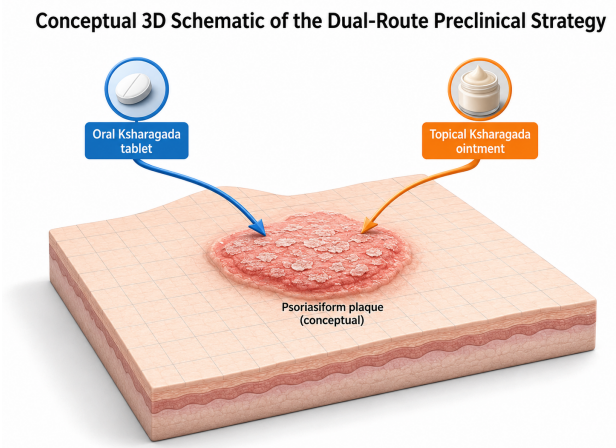

Figure 6. Conceptual 3D schematic of oral and topical intervention routes in the planned psoriasiform model. This is an explanatory illustration, not an experimental or histological image.

5. Discussion

The most important finding of this source-grounded study is not a therapeutic effect but the establishment of a transparent analytical baseline for two dosage forms intended for later biological testing. The tablet and ointment had clearly documented organoleptic, physicochemical and microbiological attributes, and the certificates permit exact reporting of those attributes. This is a necessary step in herbal and herbo-mineral research because a biological result is difficult to interpret if the identity and quality of the administered material are not characterized [13,29,30]. Batch documentation is particularly important for Ksharagada because its manufacturing process involves an alkaline Kshara stage followed by incorporation of numerous plant and mineral components.

The tablet profile shows a combination of low ash fractions relative to the much larger water extractive value, together with a smaller alcohol extractive value. These measurements should be treated as fingerprint descriptors rather than proxies for active concentration. Extractive values can be affected by particle size, extraction time, solvent composition and drying conditions. If subsequent biological experiments produce a meaningful effect, reproducibility will depend on demonstrating that future batches share a comparable analytical fingerprint. HPTLC or another chromatographic method is therefore a high-priority addition. The protocol already proposes HPTLC, and published Ksharagada standardization studies likewise emphasize chromatographic and physicochemical evaluation [23,25,27]. A well-defined fingerprint could also help identify whether the process produces consistent marker bands across batches.

The near-neutral pH of the finished tablet (6.9) and ointment (6.8) is noteworthy because Kshara processing is alkaline. A recent pharmaceutical analysis of Ksharagada reported higher pH during early Palasha Kshara preparation followed by a lower pH in the final formulation [25]. The exact values from that external

study should not be used to validate the present batch because the manufacturing details and analytical methods differ, but the direction of change provides a plausible explanation for why a finished Ksharagada product need not remain strongly alkaline. Neutralization can occur through dilution and interaction with the complex ingredient matrix. This is a hypothesis that could be tested by monitoring pH at each manufacturing stage in future batches.

The tablet disintegration time of 4 minutes and friability of 0.5% suggest useful dosage-form characteristics, while hardness of 3.5 kg/cm² indicates a defined mechanical resistance. These measurements are practically valuable for handling and administration. Still, declaring the tablet 'standard' requires more than three performance measures. A full quality profile would ideally include average weight and weight variation, dimensions, moisture content, uniformity of dosage units where applicable, microbial limits using a specified method, chromatographic identity and stability testing. For a complex traditional formulation, content uniformity may need to be operationalized through selected markers rather than a single active ingredient.

6. Conclusion

Ksharagada tablet and Ksharagada ointment were successfully represented by authenticated laboratory quality-control data from the supplied 18 March 2026 reports. The tablet was yellowish, characteristically odorous and salty, with total ash 3.2%, water-soluble ash 1.1%, acid-insoluble ash 0.5%, water extractive 45.32%, alcohol extractive 17.65%, disintegration time 4 minutes, friability 0.5%, hardness 3.5 kg/cm² and pH 6.9. The ointment was yellowish, characteristically odorous and smooth, with pH 6.8, good spreadability, absent rancidity, iodine value 26.21 and peroxide value 6.1; the source report did not state units for the latter two results. The listed microbiological parameters were reported as absent in both formulations. These findings provide a useful batch-specific analytical baseline. The attached protocol supplies a plausible preclinical framework using OECD 407 safety testing and a four-group IMQ-induced psoriasiform model with oral, topical and combined intervention. However, the supplied files do not contain completed animal outcomes, and therefore no conclusion of antipsoriatic efficacy, cytokine modulation, histological improvement or NOAEL can presently be made. The scientifically appropriate next step is to complete standardized chemical fingerprinting, resolve protocol inconsistencies, execute randomized and blinded safety/efficacy experiments, and report the resulting data with full statistical transparency.

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