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ANALYTICAL EVALUATION AND DRUG SAFETY PROFILING OF KSHARAGAD

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ABSTRACT

Ayurveda, the traditional system of medicine, offers a wealth of time-tested formulations that continue to play a significant role in healthcare due to their holistic efficacy and safety. *Agad yogas*, in particular, are valued for managing toxic conditions and systemic disorders. *Ksharagad*, a classical formulation described in the *Charaka Samhita* (*Vishachikitsa Adhyaya*) and *Sushruta Samhita (Kalpa Sthana, Dundubhisvaniya Adhyaya*), is primarily based on *Palash Kshar*, an alkaline derivative of *Butea monosperma*, and incorporates *Vishaghna*, *Krimighna*, and *Rasayana dravyas* to enhance its therapeutic potential. Despite its traditional importance, systematic evaluation is essential to ensure quality, safety, and clinical reliability.This study aimed to assess the quality and safety of *Ksharagad* using modern analytical techniques. The findings provide a scientific basis for its safe therapeutic use in contemporary *Ayurvedic* practice.

KEYWORDS: *Ksharagad, Palash Kshar, Vishaghna dravyas*, Quality control, Drug safety profiling.

INTRODUCTION

The traditional *Ayurvedic* system of medicine encompasses a comprehensive pharmacopeia of therapeutic formulations that are employed for the prevention, management, and treatment of a wide range of diseases.

With the increasing global interest in *Ayurvedic* medicines, the standardization and quality control of traditional formulations have become very important. Herbal formulations may be susceptible to contamination from heavy metals, pesticide residues, and microbial organisms during cultivation, processing, and storage. Therefore, it is essential to evaluate such formulations using modern analytical techniques to ensure their safety, quality, and efficacy.[1]

The present study aims to carry out quality control and drug safety profiling of *Ksharagad* through analytical evaluation. Techniques such as Thin Layer Chromatography (TLC) for phytochemical fingerprinting, heavy metal estimation, pesticide residue analysis, and microbial contamination testing were employed to assess the quality and safety of the formulation. The findings of this study will contribute toward establishing analytical standards for *Ksharagad* and support the scientific validation and safe therapeutic use of this classical *Ayurvedic* formulation.

MATERIALS AND METHODS

The present study was designed to evaluate the **quality, safety, and standardization of *Ksharagad*** using analytical techniques. The methodology included the collection, preparation, and systematic analysis of the formulation using standard pharmacopeial and modern analytical methods.

1. **Collection and Preparation of *Ksharagad***

1. ***Palasha***

a. **Root and Seeds:** Roots and Seeds of *Palasha* were procured from Herbal Automation, Haridwar in June 2025.

b. **Flowers**: Flowers of *Palasha* were collected from Rishikul Campus, UAU, Haridwar in March 2025.

c. **Stem, Bark, and leaves;** Stem, bark and leaves were collected from Rishikul Campus, UAU, Haridwar in April 2025

2. ***Haridra, Daruharidra,*:** Rhizome of *Haridra and*

root of Daruharidra were collected from uttarkashi in March 2025.

3. ***Jatamansi, Hingu***: *Jatamansi, and Hingu* were collected from uttarkashi in June 2025.
4. ***Surasmanjari:*** Inflorescences of Tulsi (*Surasmanjari*) was collected from Rishikul Campus, UAU, Haridwar in July 2025.
5. ***Kushtha*****:** Root of *Kushtha* was collected from Dhrali village, Uttarkashi uttrakhand in June 2025.
6. ***Shweta Sariva, Krishna Sariva*** were procured from Orrisa in Aug 2025.
7. ***Laksha*** **(Resin),** ***Harenu*** **(Seed),** ***Madhuka*** **(Stem),** ***Shunti*** **(Rhizome),** ***Maricha*** **(Fruit),** ***Pippali*** **(Fruit),** ***Gairika*** **(Mineral),** ***Saindhav*** (Mineral) were procured from Herbal Automation, Haridwar in Aug 2025.

All the plants had been thoroughly washed under running water and dried in the shade.

Drug Identification and Authentication

All collected ingredients of *Kshar Agad* were identified and authenticated by the experts of the Dravyaguna Department at Rishikul Campus, Haridwar (UAU).
Ref. no – DG/RC/UAU-276

Preparation of *Ksharagad*

The preparation of *Ksharagad* was divided into two main steps: **(1) Preparation of *Kshara*** and **(2) Preparation of *Ksharagad Churna*.**

1. **Preparation of *Kshara*[2]**-Following *Sushruta Saṁhita* (*Sutrasthana* 11th *Adhyaya* – "*Kṣara Karma Vidhi Adhyaya*"). *Palasha Kshara* was prepared in three phases:

a. **Ash Preparation:** Dried *Palasha Panchanga* (≈9 kg) was cleaned, coarsely powdered, and incinerated to obtain whitish-grey ash.

b. ***Kshara Jala*****:** 910 g of ash was mixed with six times its weight in water, allowed to settle for 24 hours, and filtered 21 times through muslin cloth to obtain clear *Kshara Jala.*

c. ***Kshara*** **Formation:** The filtrate was heated to evaporate water, yielding 90 g of *Kshara*.

2. **Preparation of *Ksharagad Churna***

All ingredients, except *Palash panchang* were individually coarsely powdered, sieved (No. 80), and mixed with Palasha Kshara. The final churna weighed 1,583 g, with a minimal loss of 17 g during processing, and was stored in an airtight container for further analysis.

ORGANOLEPTIC ANALYSIS

Using pharmacognostical methods, the prepared formulation was evaluated organoleptically by visual and sensory examination with the naked eye. Parameters such as appearance, color, odor, taste, touch, and texture were observed. The results of the organoleptic evaluation of ***KsharAgad*** are presented below.

Appearance- Dry, slightly coarse powder
Colour – Light brown color
Odour – Earthy with hint of pungency.
Taste – Slightly bitter and earthy.

Soxhlet Extraction Method

For the extraction process, distilled water and ethanol were used as solvents, resulting in the preparation of two types of extracts.

Aqueous extract
Alcoholic (ethanolic) extract
Procedure of Aqueous and Ethanolic Extraction

Figure 1.a: Soxhlet heat extraction.

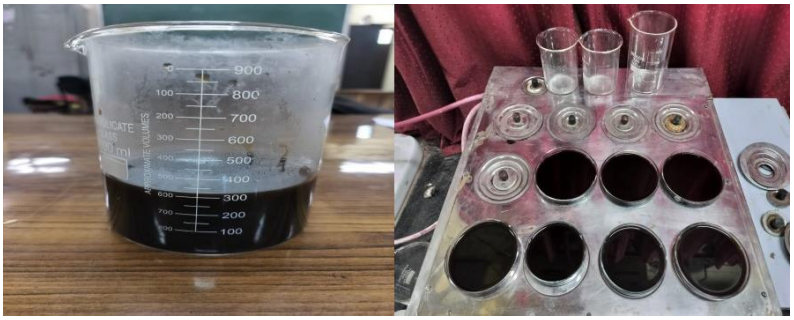


Figure 1.b: Water Bath.

Figure 1.c: Final prepared Aqueous extract and Ethanolic extract.

Aqueous Extraction
For the aqueous extraction, **100 g of the powdered drug** was placed in the Soxhlet extraction chamber and **200 ml of distilled water** was added. An additional **250 ml of distilled water** along with a few **glass beads** were placed in the round-bottom flask. The entire apparatus was then assembled and connected to a **heating mantle**.

The temperature was maintained at **80°C**, which is below the boiling point of water, and the extraction process was carried out continuously for **five consecutive days**. After completion of the extraction, the contents collected in the round-bottom flask were transferred to a **petri dish** and allowed to evaporate on a **water bath for 1–2 days**. The residue obtained was then **dried at room temperature** and preserved for further analysis.[2]

Ethanolic Extraction
For the ethanolic extraction, **100 g of the powdered drug** was placed in the Soxhlet extraction chamber. The chamber was filled with **100 ml of ethanol**, while an additional **250 ml of ethanol** along with a few **glass beads** were added to a round- bottom flask. The entire assembly was connected to a **heating mantle** to maintain continuous extraction. The temperature was maintained at **60°C**, which is below the boiling point of ethanol, and the extraction process was carried out continuously for **five consecutive days**. After completion of the

extraction, the contents collected in the round-bottom flask were transferred to a **petri dish** and allowed to evaporate on a **water bath for 1–2 days**. The remaining residue was further dried at **room temperature.**[3]

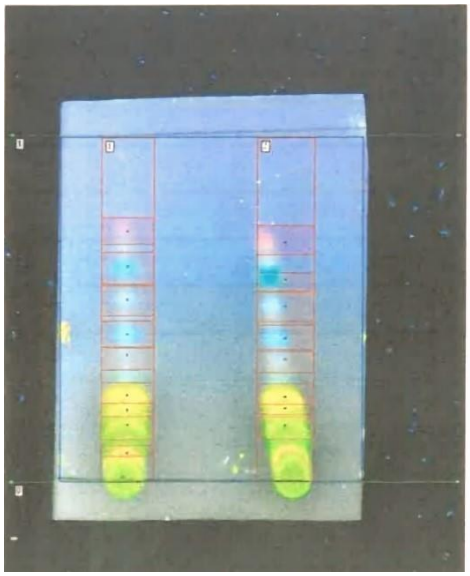
Safety Profile Analysis of *Ksharagad*

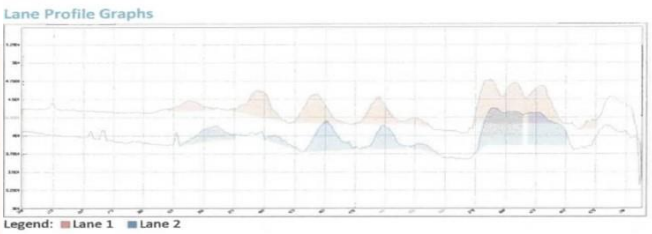
To ensure the safety and quality of the prepared formulation, safety evaluation was carried out by analyzing **TLC, heavy metals, pesticide residues, and microbial contamination**. The analyses were performed according to standard pharmacopoeial guidelines.

Thin Layer Chromatography (TLC)

Methodology -Thin Layer Chromatography was performed using a **silica gel– coated glass plate** as the stationary phase. The plate was activated at **105 °C** in a laboratory oven. Small spots of the drug extract were applied about **1 cm above the base** using a capillary tube. The plate was then placed in a developing chamber containing the mobile phase mixture of **chloroform: methanol: ethyl acetate (51.01: 39.00: 9.99)**. The solvent moved upward by capillary action, separating the components based on their affinity for the stationary and mobile phases. After development, the plate was removed, dried, and the separated spots were visualized. The **Rf value** was calculated using the formula.[4]

Rf = Distance traveled by solute / Distance traveled by solvent.





Lanes

ID	Width	Bands	Volume	Displayed Volume	Notes
1	75	9	43377525	433.77	
2	81	8	37119627	371.18	

Bands

Lane ID	Band ID	Rf	Area	Volume	Displayed Volume	Notes
1	1	0.723	3000	2363775	23.64	
1	2	0.621	3600	5711400	57.11	
1	3	0.525	3375	6155700	61.56	
1	4	0.425	2925	4824375	48.24	
1	5	0.365	2475	1023900	10.24	
1	6	0.25	2325	7821600	78.22	
1	7	0.208	1500	6979350	69.79	
1	8	0.165	2550	7726950	77.27	
1	9	0.085	1200	770475	7.7	
2	1	0.688	3564	3685419	36.85	
2	2	0.583	2268	827334	8.27	
2	3	0.506	3564	6329907	63.3	
2	4	0.413	2997	4192479	41.92	
2	5	0.354	2592	888084	8.88	
2	6	0.244	2511	6703479	67.03	
2	7	0.212	1215	5329395	53.29	
2	8	0.162	2673	9163530	91.64	

Microbial Contamination Analysis

Microbial contamination analysis was performed to evaluate the microbiological safety and sterility of the samples using the agar plate method under aseptic conditions. Nutrient agar medium was prepared and sterilized in an autoclave at 121 °C for 15 minutes. The sterilized medium was cooled to 45–50 °C and poured into sterile Petri plates inside a laminar airflow cabinet, where it was allowed to solidify. For sample preparation, 1 mL of aqueous and ethanolic extracts was diluted with 9 mL of sterile normal saline. Then, 0.1 mL of the diluted sample was spread evenly on the surface of the agar plate using a sterile L-shaped spreader. The inoculated plates were incubated at 37 °C for 24–48 hours.[5]

Heavy Metal Analysis by ICP–MS

Heavy metal analysis of Ksharagad was carried out using Inductively Coupled Plasma–Mass Spectrometry (ICP–MS) in accordance with the permissible limits prescribed in the *Ayurvedic Pharmacopoeia of India (API)*.[6] Approximately 0.5–1 g of the powdered sample was accurately weighed and subjected to acid digestion using a mixture of concentrated nitric acid and hydrochloric acid until a clear solution was obtained.[7] The digested sample was filtered and diluted to the required volume with deionized water.

The prepared solution was analyzed by ICP–MS for the estimation of heavy metals, namely lead (Pb), arsenic (As), cadmium (Cd), and mercury (Hg).[8,9] Calibration was performed using certified reference standard solutions of known concentrations. The concentration of each metal was expressed in mg/kg and compared with the permissible limits specified in API guidelines to assess the safety of the formulation.[10]

Pesticide Residue Analysis

For the determination of pesticide residues, 5 g of powdered plant material was accurately weighed and transferred into a clean extraction flask. The sample was extracted with 50 mL of acetone according to standard procedures described in the *Ayurvedic Pharmacopoeia of India* and WHO guidelines. The mixture was mechanically shaken for 30 minutes to ensure complete extraction of pesticide residues. The extract was filtered through Whatman No. 1 filter paper to remove particulate matter and subsequently subjected to clean-up

using a column packed with activated charcoal or silica gel to eliminate interfering substances.

The purified extract was concentrated to 5–10 mL under reduced pressure using a rotary evaporator at 40–45 °C. Standard pesticide solutions of known concentrations (1, 5, and 10 ppm) were prepared for calibration. The sample extract was analyzed using Gas Chromatography (GC) coupled with an Electron Capture Detector (ECD) for sensitive detection and quantification of pesticide residues.[4,5] Quantification was performed by comparing the chromatographic peak areas of the sample with those of the standard solutions.

OBSERVATIONS AND RESULTS

Table 1: Findings of Heavy Metal Estimation.

Heavy Metals by ICP-MS	RESULTS	UNITS	SPECIFICATIONS
Lead (as Pb)	0.137	mg/kg	NMT 10.0
Arsenic (as As)	BLQ(LOQ0.1)	mg/kg	NMT3.0
Cadmium (as Cd)	BLQ(LOQ0.1)	mg/kg	NMT0.3
Mercury (as Hg)	-	mg/kg	NMT 1.0

Table 2: Findings Of Pesticide Residue Analysis.

TEST PARAMETERS	RESULTS	UNITS	SPECIFICATIONS
Alachlor	BLQ (LOQ-0.1)	mg/kg	NMT 0.02
Aldrin & Dieldrin	BLQ (LOQ-0.1)	mg/kg	NMT 0.05
Azinphos- Methyl	BLQ (LOQ-0.1)	mg/kg	NMT1.0
Brompropylate	BLQ (LOQ-0.1)	mg/kg	NMT3.0
Chlordane Oxythlordane	BLQ (LOQ-0.1)	mg/kg	NMT0.05
Chlorfenvinphos	BLQ (LOQ-0.1)	mg/kg	NMT0.5
Chlorpyrifos	BLQ (LOQ-0.1)	mg/kg	NMT0.2
Chlorpyrifos- Methyl	BLQ (LOQ-0.1)	mg/kg	NMT0.1
Cypermethrin	BLQ (LOQ-0.1)	mg/kg	NMT1.0
DDT	BLQ (LOQ-0.1)	mg/kg	NMT1.0
Deltamethrin	BLQ (LOQ-0.1)	mg/kg	NMT 0.5
Diazinon	BLQ (LOQ-0.1)	mg/kg	NMT0.5
Dichlorvos	BLQ (LOQ-0.1)	mg/kg	NMT 1.0
Dithiocarbamates	BLQ (LOQ-0.1)	mg/kg	NMT 2.0
Endosulfan	BLQ (LOQ-0.1)	mg/kg	NMT3.0
Endrin	BLQ (LOQ-0.1)	mg/kg	NMT 0.05
Ethion	BLQ (LOQ-0.1)	mg/kg	NMT 2.0
Fenitrothion	BLQ (LOQ-0.1)	mg/kg	NMT 0.5
Fenvalerate	BLQ (LOQ-0.1)	mg/kg	NMT 0.05
Fonofos	BLQ (LOQ-0.1)	mg/kg	NMT 0.05
Heptachlor	BLQ (LOQ-0.1)	mg/kg	NMT 0.05
Hexachlorobenzene	BLQ (LOQ-0.1)	mg/kg	NMT 0.1
Hexachlorocyclohexane isomer	BLQ (LOQ-0.1)	mg/kg	NMT 0.3
Malathion	BLQ (LOQ-0.1)	mg/kg	NMT 1.0
Methidathion	BLQ (LOQ-0.1)	mg/kg	NMT 0.2
Parathion	BLQ (LOQ-0.1)	mg/kg	NMT 0.5
Parathion- Methyl	BLQ (LOQ-0.1)	mg/kg	NMT 0.2
Permethrin	BLQ (LOQ-0.1)	mg/kg	NMT 1.0
Phosalone	BLQ (LOQ-0.1)	mg/kg	NMT 0.1
Piperonylbutoxide	BLQ (LOQ-0.1)	mg/kg	NMT 3.0
Pirimiphos methyl	BLQ (LOQ-0.1)	mg/kg	NMT 4.0
Pyrethrins	BLQ (LOQ-0.1)	mg/kg	NMT 3.0
Quintozene	BLQ (LOQ-0.1)	mg/kg	NMT 1.0

Abbrevations; - NS; Not specified, BLQ ; Below Limit of quantification, LOQ; - Limit of quantification, NMT; Not more than

RESULT SUMMARY

The analytical evaluation of *Ksharagad* demonstrated satisfactory quality and safety parameters. Thin Layer Chromatography (TLC) showed clear separation of phytochemical constituents in the solvent system of chloroform : methanol : ethyl acetate, with distinct spots on the silica gel plate and characteristic Rf values indicating the presence of multiple compounds and

confirming the chemical profile of the formulation. Microbial contamination analysis revealed that microbial growth was either absent or within acceptable limits after incubation, suggesting that the sample was microbiologically safe and prepared under hygienic conditions. Heavy metal analysis indicated that the detected level of lead (0.137 mg/kg) was well below the permissible limit, while arsenic and cadmium were below the limit of quantification and mercury was not detected, confirming compliance with API safety standards.

Furthermore, pesticide residue analysis showed that all tested pesticides were below the limit of quantification, indicating the absence of significant pesticide contamination in the formulation. Overall, these findings confirm the purity, safety, and acceptable quality profile of the prepared *Ksharagad*.

DISCUSSION

The present investigation was undertaken to examine the safety-related analytical profile of *Ksharagad*, a classical *Ayurvedic* formulation, through multiple modern analytical approaches. In traditional herbal preparations, variability in raw drug quality and possible environmental contamination remain important concerns that may influence the overall safety of the final product.

In this study, a multi-parameter evaluation approach was adopted, including heavy metal analysis, pesticide residue screening, microbial load assessment, and chromatographic profiling. Together, these parameters provide a broad understanding of both chemical integrity and microbiological safety of the formulation. The absence of significant contamination across all tested parameters suggests that appropriate care was taken during selection, processing, and handling of raw materials.

The heavy metal and pesticide residue results further indicate that the formulation remained within acceptable safety limits, reflecting good agricultural and manufacturing practices. Similarly, the microbiological findings support that the preparation and storage conditions were adequate to prevent microbial proliferation. The chromatographic profile also indicated a consistent phytochemical pattern, suggesting uniformity in the composition of the formulation.

Overall, the results reflect that *Ksharagad* maintains a reliable safety profile when prepared under controlled and hygienic conditions, reinforcing its suitability for internal therapeutic use within *Ayurvedic* practice.

CONCLUSION

The present study provides an analytical evaluation of *Ksharagad* prepared according to classical *Ayurvedic* principles, integrating traditional pharmaceutical procedures with modern scientific testing. The formulation demonstrated acceptable physicochemical characteristics along with a consistent phytochemical profile.

Safety assessments revealed that heavy metals were within permissible limits, pesticide residues were not detected, and microbial load remained within acceptable standards. These findings collectively indicate that the formulation is free from significant toxic or contaminant-related risks under the studied conditions.

Overall, *Ksharagad* exhibits a satisfactory safety profile and chemical consistency, supporting its suitability for therapeutic application in *Ayurvedic* practice when prepared and handled under appropriate conditions. The study also highlights the value of employing modern analytical tools alongside classical methods to better understand and evaluate traditional formulations.

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