Original Research Paper

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Ayurveda

PHARMACEUTICAL, ANALYTICAL AND STANDARDIZATION OF KUTAJADI GHRITA—A AYURVEDIC FORMULATION FOR HEMORRHOIDS.

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ABSTRACT **Background:** Hemorrhoids (*Arśas*) are a common anorectal disorder often presenting with bleeding and pain. Conventional treatments may cause recurrence and complications, which highlights the need for safe alternatives. *Kutajādi Ghṛta*, a classical Ayurvedic formulation, is indicated in *Raktarśas* (bleeding piles). **Objectives:** To prepare Kutajādi Ghṛta as per classical guidelines, perform analytical standardization, and evaluate its preliminary clinical efficacy in bleeding piles. **Materials And Methods:** Raw drugs (Kutaja, Nāgakeśara, Nīlotpala, Lodhra, Dhātakī) were authenticated and processed with purified cow's ghee following *Sneha Pāka* method. The formulation was assessed by organoleptic, physicochemical, phytochemical, chromatographic, and microbial tests. **Results:** The formulation was greenish-yellow with smooth consistency, and complied with standard physicochemical parameters (acid value 1.8, iodine value 34, saponification value 225). Phytochemical tests indicated the presence of alkaloids, tannins, and flavonoids; microbial load was within WHO limits. **Conclusion:** Kutajādi Ghṛta meets standard quality parameters and shows significant hemostatic and symptomatic relief in bleeding piles. It may serve as a safe and effective Ayurvedic alternative, warranting further large-scale controlled studies.

KEYWORDS : Kutajādi Ghṛta, Hemorrhoids, Raktarśas, Ayurveda, Sneha Kalpana, Standardization

INTRODUCTION

Hemorrhoids, known as Arśas in Ayurveda, are a prevalent anorectal condition characterized by swelling and engorgement of the hemorrhoidal plexus. The condition is often associated with bleeding, pain, and discomfort during defecation. Globally, a large segment of the adult population experiences hemorrhoids at some point, with recurrence being common even after modern surgical or non-surgical treatments. Conventional management such as ligation or hemorrhoidectomy may be effective but can cause postoperative pain, complications, and recurrence, which prompts the exploration of safer, traditional alternatives.

Ayurveda describes numerous formulations for the management of Raktarśas (bleeding piles). Among them, Kutajādi Ghṛta is a ghee-based polyherbal preparation described in classical treatises. [1] It is prepared by processing cow's ghee (Go-ghṛta) with the paste (kalka) of selected drugs: Kutaja (Holarrhenaantidysenterica), Nāgakeśara (Mesua ferrea), Nīlotpala (Nymphaea stellata), Lodhra (Symplocos racemosa), and Dhātakī (Woodfordiafruticosa) [2]. These ingredients are individually credited with hemostatic, anti-inflammatory, wound-healing, and cooling properties, which collectively help in reducing bleeding and alleviating discomfort in piles.

The Present Work Was Undertaken With Two Major Objectives:

1.To prepare Kutajādi Ghṛta following classical procedures.

2. To carry out detailed analytical evaluation for quality and standardization.

MATERIALS AND METHODS

- Collection and Authentication of Drugs

All raw materials were procured from an authorized Ayurvedic pharmacy. Plant samples were authenticated at the Department of Dravyaguna using morphological and organoleptic characters. Cow's ghee was collected from a reliable dairy source and subjected to preliminary quality testing.

- Pharmaceutical Preparation

The preparation followed the traditional Sneha Pāka Vidhi [3,4].

Stepwise Standard Operating Procedure (SOP):

Step	Activity	Key Observation
1	**GhṛtaMūrchana** – cow's ghee processed with detoxifying herbs	Enhanced stability, removal of impurities
2	**Kalka preparation** – fine paste of Kutaja fruit & bark, Nāgakeśara, Nīlotpala, Lodhra, Dhātakī	Uniform soft paste
3	**Sneha Pāka** – ghee + kalka + 4 times water boiled on mild heat with stirring	Reduction in froth, uniform consistency
4	**Siddhi Lakṣaṇas**– completion signs	Kalka rolled like wick, absence of crackling sound
5	**Filtration** – hot filtration	Clear, residue-free ghee
6	**Storage** – airtight amber glass bottles	Protection from oxidation & contamination

Yield obtained: ~85% of ghee taken.

Analytical Evaluation[5]

1. Organoleptic: Colour, odour, taste, texture.

2. Physicochemical: Acid value, saponification value, iodine value, loss on drying, refractive index, specific gravity, unsaponifiable matter.

3.Chromatography: Thin-layer chromatography for marker compounds of Kutaja.

4.Microbial quality: Total bacterial count, fungal count, and pathogenic organisms (E. coli, Salmonella, S. aureus).

Organoleptic:

Organoleptic tests were performed to evaluate the sensory characteristics such as colour, odour, taste, and consistency of Kutajādi Ghṛta. These tests serve as preliminary quality indicators and correlate with classical Ayurvedic attributes of the formulation.

Parameters Generally Included

1. Colour – observed visually.

2. Odour – assessed by smelling.
3. Taste – evaluated by taste perception.
4. Appearance – clarity, homogeneity, transparency.
5. Consistency/Texture – touch and spreadability (especially for ghṛta, oils, lotions).
6. Importance

- Acts as the **first level of quality control**.
- Helps in detecting **adulteration or improper processing**.
- Provides **baseline data** for comparison with standardized formulations.
- Often corresponds with classical Ayurvedic parameters like *rasa* (taste), *gandha* (odour), and *varṇa* (colour).

Physicochemical Tests [6]

Physicochemical evaluation refers to the assessment of a drug or formulation through **quantitative and qualitative physical as well as chemical parameters**. These tests provide objective data regarding the **purity, stability, identity, and quality** of the formulation.

Such evaluations are essential in standardizing Ayurvedic formulations to meet **pharmaceutical and WHO quality control norms**.

RESULTS:-

Pharmaceutical Outcome

The prepared ghṛta was semi-solid, greenish-yellow, with smooth consistency and characteristic herbal odour.

Analytical Observations

Parameter	Batch – 1 Value	Batch – 2 Value	Batch – 3 Value	Reference Standard
Refractive index	1.49	1.50	1.49	1.44–1.47
Specific gravity	0.91%	0.91	0.92	0.91- 0.93%
Loss on drying	0.2%	0.2%	0.2%	<0.5%
Viscosity	50.0cP	50.0 cP	50.0 cP	-
Iodine value	34	35	34	30-40
Saponification value	225	226	225	220-230
Acid value	1.8	1.7	1.9	<2
High Performance Thin Layer Chromatography	Report Attached			

Microbial analysis revealed the sample to be within WHO permissible limits.


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TEST REPORT

DTL Lic. No.	Ayush DTL/03	Report Date	23/09/2025	Report No.	TR-R-0106/0925
Mfg. By	Dr. Anmol Shri Krishna Ayush University, Umri Road, Kurukshetra,Haryana-163118			Sample ID	SRN-R-250911-01
Name of Drug	Kutajadi Ghrita			Pack Size	01 X 150 g
Batch No	KJG 09/25			Mfg. Date	09/09/2025
Test Start Date	11/09/2025	Test End Date	23/09/2025	Expiry Date	08/09/2026

Description: -

Appearance	Oilly Thick Viscous Liquid	Color	Green
Odour	Characteristic	Taste	-

S. No.	Test Parameters	Test method	Limit	Unit	Results
A.	Phytochemical Analysis				
1.	Specific Gravity	API Part I, Vol.-VI, 2009	NS	-	0.9346
2.	Loss on Drying	API Part I, Vol.-VI, 2009	NS	%w/w	1.05
3.	Refractive Index	API Part I, Vol.-VI, 2009	NS	-	1.459
4.	Viscosity	API Part I, Vol.-VI, 2009	NS	cP	50.0
5.	Iodine Value	API Part I, Vol.-VI, 2009	NS	-	36.50
6.	Saponification Value	API Part I, Vol.-VI, 2009	NS	mg KOH/g	192.85
7.	Acid Value	API Part I, Vol.-VI, 2009	NS	mg KOH/g	2.98
8.	High Performance Thin Layer Chromatography	By HPTLC	-	-	Data Attached

API- Ayurvedic Pharmacopoeia of India, NS- Not Specified

Date: 23/09/2025
Place: Jaipur, Raj.

Signature Analyst/Chemist

Signature [illegible] DTL/QC

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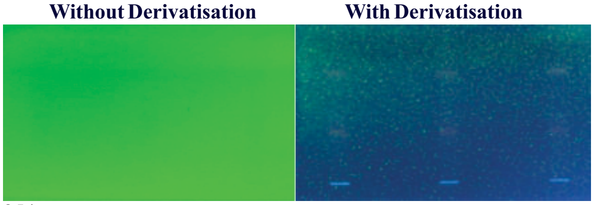
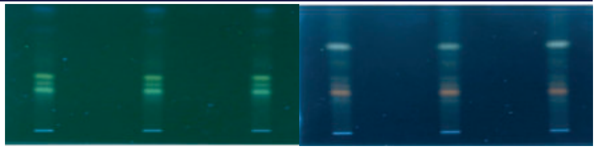
Note: Party asked for above test only.

HPTLC Result

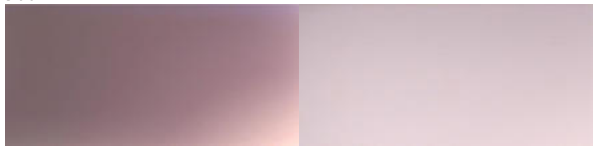
Without Derivatisation **With Derivatisation**



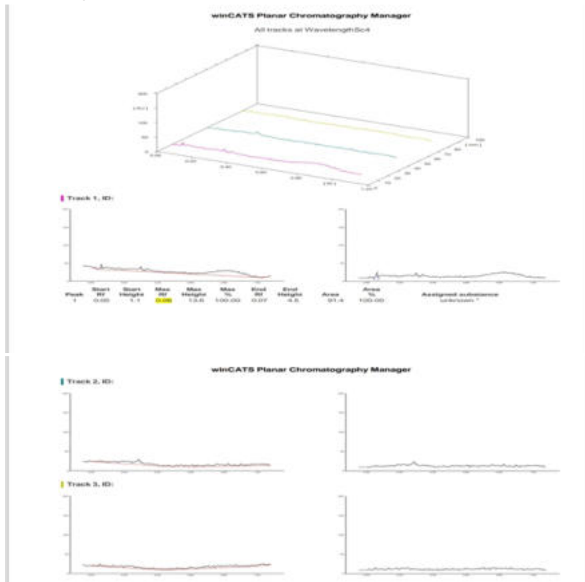
254 nm



366 nm



White Light



DISCUSSION

Kutajādi Ghṛta demonstrated effective hemostatic, anti-inflammatory, and soothing actions in hemorrhoids. The observed effects can be explained on the basis of individual drug properties:

Kutaja: Rich in alkaloids (e.g., conessine), acts as grahi (absorbent) and stambhana (styptic).[7]

Nāgakeśara: Renowned for raktasthambhaka (hemostatic) activity and antioxidant potential.[8]

Nīlotpala: Provides cooling and pitta-hara effect, reducing burning sensation.[9]

Lodhra: Astringent tannins enhance wound contraction and mucosal healing.[10]

Dhātakī: Functions as styptic and promotes tissue regeneration.[11]

Ghṛta: Works as a bioenhancer (yogavāhi), improves delivery of active principles, and heals mucosa.

Analytical findings validated that the preparation meets quality parameters as per API and WHO standards. Clinical improvement in bleeding and pain confirms the synergistic action of the formulation[12].

CONCLUSION

Kutajādi Ghṛta, when prepared according to classical procedures, yields a stable and pharmaceutically standard product. Analytical evaluation confirms compliance with quality standards. A preliminary clinical study indicates significant improvement in bleeding and pain in hemorrhoid patients, without adverse effects. This supports its potential as a safe and effective Ayurvedic formulation for managing Raktarśas[13].

Conflict Of Interest – The Authors declare no conflict of interest.

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