

IMPACT OF TWO CLASSICAL GANDHAKA SHODHANA METHODS ON THE PHARMACEUTICAL AND ANALYTICAL PROFILE OF RAJ GUTIKA: A COMPARATIVE STANDARDIZATION STUDY

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ABSTRACT

Background: In Rasashastra, Shodhana (purificatory processing) is an important Samskara (pharmaceutical processing) performed before Gandhaka is incorporated into a formulation. The processing medium and number of Dhalana cycles (melting and pouring into a liquid medium) used in Gandhaka Shodhana may influence the physicochemical and analytical characteristics of Gandhaka and the resulting formulation.

Objective: To compare Raj Gutika prepared with Godugdha Shodhita Gandhaka (TV-01) and Bhringaraja Swarasa Shodhita Gandhaka (TV-02), with emphasis on pharmaceutical processing, physicochemical quality and HPTLC fingerprinting.

Materials and Methods: Bhringaraja Swarasa and Shunthi Churna were prepared according to the methods described in Sharangadhara Samhita. Shunthi Churna and Saindhava Lavana were evaluated for quality prior to formulation. TV-01 Gandhaka underwent three Dhalana cycles in Godugdha, whereas TV-02 Gandhaka underwent seven Dhalana cycles in fresh Bhlingaraja Swarasa. Raw Gandhaka, the two Shodhita Gandhaka intermediates (TV-01 & TV-02), and the finished Raj Gutika variants (TV-01 & TV-02) were evaluated using relevant physicochemical, assay, heavy-metal and microbial parameters. The finished formulations were further assessed for organoleptic characteristics, tablet-quality parameters, qualitative phytochemical profile and HPTLC fingerprinting.

Results: From 500 g Raw Gandhaka, 387 g Godugdha Shodhita Gandhaka was obtained after three Dhalana cycles (77.40% yield), in contrast, 650 g Raw Gandhaka yielded 469 g Bhlingaraja Swarasa Shodhita Gandhaka after seven Dhalana cycles (72.15% yield). Shunthi Churna and Saindhava Lavana complied with the specified quality standards for all evaluated parameters. Sulphur assay was 94.21% in raw Gandhaka, 96.32% in TV-01 Intermediate Godugdha Shodhita Gandhaka, and 95.74% in TV-02 Intermediate Bhlingaraja swarasa Shodhita Gandhaka. Loss on drying in the raw Gandhaka and the two shodhita Gandhaka intermediates was 0.038%, 0.21%, and 0.25%, respectively. In the finished formulations, TV-02 showed higher observed LOD, pH, water-soluble extractives and alcohol-soluble extractives, total ash and acid-insoluble ash than TV-01. Both variants showed low friability, comparable hardness, and disintegration time within the stated limit. HPTLC profiles at 254nm, 366nm and 510 nm showed distinct patterns between TV-01 and TV-02, supporting their analytical differentiation.

Conclusion: The two classical Gandhaka Shodhana methods produced measurable differences in pharmaceutical and analytical profiles. The processing medium and the number of Dhalana cycles are important factors in the pharmaceutico-analytical standardization of Raj Gutika. This study doesn't isolate the individual effects of the media and dhalana cycles, and their combined influence is clear from the overall differences observed.

Keywords: Raj Gutika; Gandhaka Shodhana; Godugdha; Bhlingaraja Swarasa; pharmaceutico-analytical standardization; HPTLC Fingerprinting.

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INTRODUCTION

In Rasashastra, the quality of mineral-based formulations depends not only on the raw materials but also on the pharmaceutical processing (Samskara) steps used. Shodhana is an essential pharmaceutical process for Gandhaka, which is classically performed through controlled melting, filtration, and Dhalana into prescribed media, followed by collection, washing, drying, and powdering. The selection of the processing media and the number of Dhalana cycles are key factors

in the Shodhana of Gandhaka and influence the quality of the final product.^{1,2}

Rasa Tarangini describes Gandhaka shodhana using both Godugdha and Bhlingaraja Swarasa as processing media. The two methods differ in the processing medium and the number of Dhalana cycles used.¹

Recent studies have demonstrated measurable changes in the physical, morphological, and structural characteristics of Shodhita Gandhaka following classical Shodhana.^{2,3}

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Raj Gutika is described in Yog Chintamani (Gutikadhikara 3/1) and contains Shuddha Gandhaka, Shunthi, Saindhava Lavana, and Nimbu Swarasa used as Bhavana Dravya.⁴ In the present study, two variants of Raj Gutika were prepared using an identical formulation, with the only differences being the type of Shodhita Gandhaka employed. TV-01 incorporated Godugdha Shodhita Gandhaka, whereas TV-02 incorporated Bhringaraja Swarasa Shodhita Gandhaka. The comparison was designed to evaluate the two classical Shodhana methods while keeping all other ingredients identical.

A comprehensive quality assessment of a herbo-mineral formulation requires evaluation of raw materials, processing steps, intermediate materials, and the final product. Physicochemical evaluation, tablet-quality assessment, microbial testing, elemental analysis, and chromatographic fingerprinting provide complementary data for assessing Ayurvedic herbo-mineral formulations. Such integrated analytical approaches have been widely used for their characterization and quality assurance.⁵⁻⁸ This integrated quality-assessment approach is consistent with the standardization and quality-assurance framework recommended by CCRAS⁹

The present study was designed to compare two classical Gandhaka Shodhana methods and to determine whether the corresponding Raj Gutika formulations could be differentiated based on pharmaceutical processing, physicochemical parameters, tablet-quality attributes, and HPTLC fingerprinting.

MATERIALS AND METHODS

Study design and raw materials

A comparative pharmaceutico-analytical design was used to compare two Raj Gutika variants (TV-01 & TV-02) prepared using two classical Gandhaka Shodhana methods. Each variant was prepared as a single **Table 1. Pharmaceutical process parameters during Godugdha Shodhana of Gandhaka (TV-01).**

Cycle	Gandhaka before Dhavana (g)	Melting duration (min)	Melting temp (°C)	Gandhaka after drying/sieving (g)	Godugdha pH before→after	Godugdha temp before→after (°C)
1st	500	5	113.8	479	6.3→6.3	62.8→63.5
2nd	479	5	113.3	444	6.3→6.6	64.6→61.2

manufacturing batch. All raw materials required for the preparation of Raj Gutika were procured & identified before processing. Applicable monographs from the Ayurvedic Pharmacopoeia of India (API) were followed for the evaluation of Gandhaka, Shunthi, and Saindhava Lavana. In contrast, the finished Raj Gutika formulations were evaluated in accordance with CCRAS guidelines.¹⁰⁻¹³ Analytical evaluation was carried out at the pre-formulation, intermediate, and finished-product stages.

Preparation of Bhringaraja Swarasa

Fresh Bhringaraja Panchanga (35 kg) was weighed, cut into small pieces, thoroughly washed, and drained. Bhringaraja Swarasa was prepared according to the Swarasa Kalpana described in Sharangadhara Samhita. The washed Bhringaraja was ground in an electric mixer-grinder to obtain a moist pulp, which was then expressed through clean muslin cloth. The collected Swarasa was transferred to a stainless-steel vessel and used fresh for Gandhaka Shodhana.¹⁴

Godugdha Shodhana of Gandhaka (TV-01)

Raw Gandhaka (500 g) was powdered and passed through sieve No. 80. Fresh Godugdha was used for each Dhavana cycle. Goghrita was used in a quantity equal to the Gandhaka taken for the respective cycle during melting. Gandhaka was gradually added to Goghrita in a cast-iron pan and heated over Mandagni until completely molten; the melting temperature and duration were recorded. The molten Gandhaka was filtered through clean muslin cloth into Godugdha. The solidified Gandhaka was recovered, washed repeatedly with warm water, dried, powdered in Khalva Yantra, and sieved before the next cycle. The procedure was repeated for three Dhavana cycles. Godugdha pH and temperature were recorded before and after Dhavana, together with cycle-wise Gandhaka weights as process-control observations (Rasa Tarangini 8/7-10).¹

Cycle	Gandhaka before Dhavana (g)	Melting duration (min)	Melting temp (°C)	Gandhaka after drying/sieving (g)	Godugdha pH before→after	Godugdha temp before→after (°C)
3rd	444	6	115.5	387	6.3→6.7	64.3→62.3



Figure 1. Preparation of Godugdha Shodhita Gandhaka (TV-01):

Aamlasara Gandhaka ,Godugdha ,melting with temperature monitoring , filtration through muslin Bhringaraja Swarasa Shodhana of Gandhaka (TV-02)

Raw Gandhaka (650 g) was finely powdered and passed through sieve No. 80. Fresh Bhringaraja Swarasa was used for each Dhalana cycle. Before each Dhalana, its pH and temperature were recorded. The inner surface of the cast-iron pan was lightly smeared with Goghrita; Gandhaka was gradually added to the pan and heated over Mandagni until completely molten, and the melting temperature and duration were recorded. The molten Gandhaka was subjected to Dhalana into fresh **Table 2. Pharmaceutical process parameters during Bhringaraja Swarasa Shodhana of Gandhaka (TV-02).**

Cy cle	Gand haka before Dhala na (g)	Melti ng durat ion (min)	Melt ing tem p (°C)	Gandha ka after drying/si eving (g)	Swarasa pH before→ after	Swarasa temp before→ after (°C)
1st	650	5	110. 0	638	6.9→7.0	39.2→3 9.2
2nd	638	5	112. 3	618	6.9→7.3	32.0→3 5.0
3rd	618	5	113. 0	595	6.9→7.3	30.8→3 5.0
4th	595	6	114. 6	582	6.9→7.2	25.3→3 6.9



Figure 2. Preparation of Bhringaraja Swarasa: weighing, cutting, washing of fresh Bhringaraja Panchanga, grinding and expression through muslin

cloth , Dhalana , washing , drying, final powering using Khalva yantra and representative measurements of Godugdha pH and temperature before and after Dhalana .

Bhringaraja Swarasa. The pH and temperature of the Swarasa were again recorded after Dhalana. The solidified Gandhaka was recovered by filtration through clean muslin cloth, washed with warm water, dried, powdered in Khalva Yantra, and passed through sieve No. 80. The procedure was repeated for seven Dhalana cycles using fresh Bhringaraja Swarasa for each cycle. Cycle-wise weights and process observations were recorded (Rasa Tarangini 8/21-22).¹

Cy cle	Gand haka before Dhala na (g)	Melti ng durat ion (min)	Melt ing tem p (°C)	Gandha ka after drying/si eving (g)	Swarasa pH before→ after	Swarasa temp before→ after (°C)
5th	582	6	110. 5	575	6.9→7.4	34.0→3 5.1
6th	575	6	112. 9	532	6.9→7.7	36.3→3 9.9
7th	532	6	106. 7	469	6.9→7.7	34.7→3 5.9

cloth, collection of expressed Swarasa, and pH measurement.

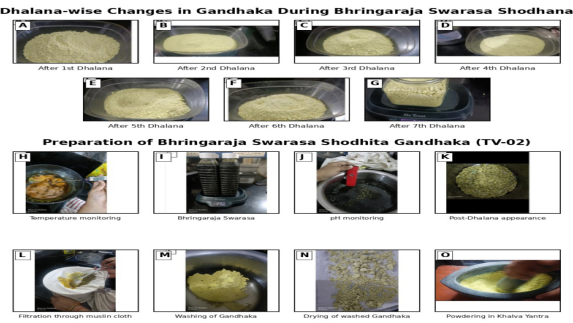


Figure 3. Bhringaraja Swarasa Shodhana of Gandhaka (TV-02), showing Dhalana-wise changes and representative process steps including

temperature and pH monitoring, filtration through muslin cloth, washing, drying and final powdering using Khalva Yantra.

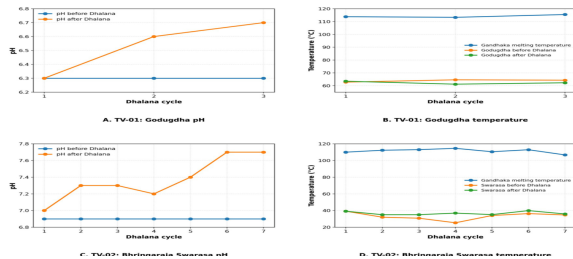


Figure 4. A&B- Cycle-wise changes in godugdha pH and temperature across dhalana cycles during shodhana of Gandhaka (TV-01)

C&D- Cycle-wise changes in Bhringaraj Swarasa pH and temperature across dhalana cycles during shodhana of Gandhaka (TV-02)

Preparation of Shunthi Churna

Shunthi Churna was prepared according to the Churna Kalpana described in Sharangadhara Samhita. Shunthi was cleaned, then broken into smaller pieces using Ulukhalva Yantra. The pieces were powdered using an

electric mixer-grinder and passed through sieve No. 80. Coarse fibrous particles retained on the sieve were reground and sieved again. The prepared Churna was mixed uniformly and stored in clean, dry, airtight containers.¹⁴

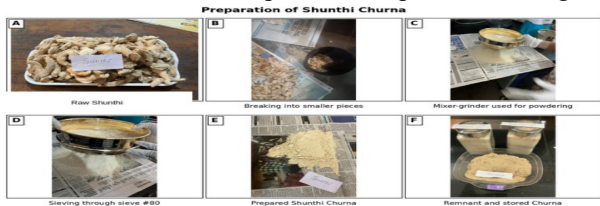


Figure 5. Preparation of Shunthi Churna: Shunthi, size reduction using Ulukhalva Yantra, powdering using an electric mixer-grinder, sieving through sieve No. 80, prepared Shunthi Churna and stored Churna.

Preparation of Raj Gutika
Two Raj Gutika batches (TV-01& TV-02) were prepared according to Yog Chintamani (Gutikadhikara 3/1), Table 3. Composition of Raj Gutika variants (TV-01 and TV-02).

Ingredient	TV-01	TV-02
Godugdha Shodhita Gandhaka	100 g	—

differing only in the type of Shodhita Gandhaka used. Nimbu Swarasa was used as Bhavana Dravya and added gradually during Mardana; approximately 450 mL was used in each batch. The resulting cohesive mass was manually rolled into uniform Gutikas, shade-dried, and stored properly.⁴

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Ingredient	TV-01	TV-02
Bhringaraja Swarasa Shodhita Gandhaka	—	100 g
Shunthi Churna	200 g	200 g

Ingredient	TV-01	TV-02
Saindhava Lavana	100 g	100 g
Nimbu Swarasa	~450 mL consumed	~450 mL consumed



Figure 6. Principal Ingredients, processing media, and batch-wise weighing of Raj Gutika ingredients for TV-01 and TV-02.



Figure 7. Pharmaceutical preparation of Raj Gutika, showing initial mixing, Mardana with Nimbu Analytical evaluation of Shunthi Churna and Saindhava Lavana

The prepared Shunthi Churna and procured Saindhava Lavana were evaluated at Cognosmed Laboratories Pvt. Ltd., Patna, India, before formulation. The prepared Shunthi Churna was tested for loss on drying at 105°C, pH of a 10% aqueous solution, water-soluble extractive, alcohol-soluble extractive, total ash, acid-insoluble ash, HPTLC identification, qualitative phytochemical constituents, Pb, Cd, As and Hg, total microbial count and total yeast and mould count. HPTLC documentation used TLC Silica Gel 60 F254 plates (10 × 10 cm), ethanol as the sample solvent and 10 µL per track applied as 6-mm bands using CAMAG Linomat 5; densitometric records were obtained at 250, 366 and 510 nm.

Swarasa, shade drying, and finished TV-01 and TV-02 Gutikas.

Saindhava Lavana was evaluated for loss on drying, sodium, chloride, solubility in water, chemical identification, sodium chloride assay, Pb, Cd, As and Hg, total microbial count and total yeast and mould count. Limits and analytical methods were reported as stated in the laboratory reports.

Analytical evaluation of raw and Shodhita Gandhaka
Raw Gandhaka, Godugdha Shodhita Gandhaka (TV-01 intermediate) and Bhringaraja Swarasa Shodhita Gandhaka (TV-02 intermediate) were evaluated at Cognosmed Laboratories Pvt. Ltd., Patna, India. Parameters included loss on drying at 105°C, solubility, carbonaceous matter, volatile impurities, sulphur assay by gravimetric method, Pb, Cd, As, and Hg, total microbial count, and total yeast and mould count. API

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procedures were followed where applicable; solubility, carbonaceous matter, and volatile impurities were evaluated using the laboratory methods CML/STP/041, CML/STP/039, and CML/STP/040, respectively.

Analytical evaluation of finished Raj Gutika

Organoleptic assessment included colour, odour, taste, appearance, shape and surface texture. Physicochemical evaluation included loss on drying at 105°C, pH of a 10% aqueous preparation, water-soluble extractive, alcohol-soluble extractive, total ash and acid-insoluble ash. Tablet evaluation included average weight, friability, hardness, and disintegration time. Qualitative phytochemical screening, heavy-metal analysis and microbial testing were performed at Cognosmed Laboratories Pvt. Ltd., Patna, India. Heavy-metal analysis included Pb, Cd, As, and Hg; microbial quality was assessed as total aerobic microbial count (TAMC) and total yeast and mould count (TYMC).

HPTLC fingerprinting

HPTLC was performed using a CAMAG system with TLC Silica Gel 60 F254 plates (10 × 10 cm). Ethanol was used as the sample solvent; 10 µL per track was applied as 6-mm bands with CAMAG Linomat 5 on three tracks. Densitometric scanning was performed with a CAMAG TLC Scanner at 254nm, 366nm, and 510 nm at 20 mm/s using a slit dimension of 4.00 × 0.30 mm. Rf values and relative peak areas were compared. As authenticated reference standards were not used; therefore, the detected peaks were retained as unassigned comparative peaks.

Statistical handling

Analytical parameters were available as single-batch observations rather than independently replicated batch means. The comparisons were therefore descriptive, and statistical tests or inferential p-values were not applied.

Ethical statement

The overall thesis protocol received approval from the Institutional Ethics Committee of Government Ayurvedic College, Patna. The present article reports only the pharmaceutical preparation and laboratory

Table 4. Analytical quality profile of Shunthi Churna and Saindhava Lavana

Material	Parameter	Result	Stated limit	Unit
Shunthi Churna	Loss on drying at 105°C	5.71	NMT 8	% w/w
Shunthi Churna	pH (10% aqueous solution)	4.73	4-7	-
Shunthi Churna	Water-soluble extractive	16.04	NLT 10	% w/w
Shunthi Churna	Alcohol-soluble extractive	8.21	NLT 3	% w/w
Shunthi Churna	Total ash	5.04	NMT 6	% w/w

analytical components; no human participants or experimental animals were involved in the work presented here.

RESULTS

Pharmaceutical process outcomes

From 35 kg fresh Bhringaraja Panchanga, 10.6 L Swarasa was obtained, corresponding to the 30.29% process yield documented in the study. In TV-01, 500 g Raw Gandhaka yielded 387 g Godugdha Shodhita Gandhaka after three Dhalana cycles (77.40% recovery; 22.60% recorded processing loss). In TV-02, 650 g Raw Gandhaka yielded 469 g Bhringaraja Swarasa Shodhita Gandhaka after seven Dhalana cycles (72.15% recovery; 27.85% recorded processing loss). From 978 g raw Shunthi, 848 g fine Shunthi Churna was obtained (86.71% recovery). From 400 g of Raj gutika formulation ingredients, the final Raj Gutika yield was 351 g (87.75%) for TV-01 and 346 g (86.50%) for TV-02.

Analytical profile of Raj gutika ingredients

The analytical results for Shunthi Churna and Saindhava Lavana are summarized in Table 4. For Shunthi Churna, loss on drying was 5.71%, pH 4.73, water-soluble extractive 16.04%, alcohol-soluble extractive 8.21%, total ash 5.04%, and acid-insoluble ash 0.78%, all within the stated limits. HPTLC identification documentation was generated, and the qualitative Phytochemical screening indicated the presence of tannins, alkaloids, saponins, protein, phenolic compounds, glycosides, flavonoids, and steroids. Pb was 0.001 ppm, while Cd, As, and Hg were below detection limits; total microbial count was 1200 CFU/g, and total yeast and mould were absent. Saindhava Lavana showed loss on drying of 4.21%, sodium 35.18%, chloride 60.24%, and sodium chloride assay 95.42%; it was soluble in water, and all values complied with the laboratory chemical identification test. Pb, Cd, As, and Hg were below detection limits (BDL); total microbial count was <100 CFU/g, and total yeast and mould (TYMC) were absent.

Material	Parameter	Result	Stated limit	Unit
Shunthi Churna	Acid-insoluble ash	0.78	NMT 1.5	% w/w
Shunthi Churna	Identification by HPTLC	Data attached	-	-
Shunthi Churna	Lead	0.001	NMT 10	Ppm
Shunthi Churna	Cadmium	BDL	NMT 0.3	Ppm
Shunthi Churna	Arsenic	BDL	NMT 3	Ppm

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Material	Parameter	Result	Stated limit	Unit
Shunthi Churna	Mercury	BDL	NMT 1	Ppm
Shunthi Churna	Total microbial count	1200	NMT 100000	CFU/g
Shunthi Churna	Total yeast & mould	Absent	NMT 1000	CFU/g
Saindhava Lavana	Loss on drying at 105°C	4.21	NMT 7	% w/w
Saindhava Lavana	Sodium	35.18	NLT 35	% w/w
Saindhava Lavana	Chloride	60.24	NLT 58	% w/w
Material	Parameter	Result	Stated limit	Unit
Saindhava Lavana	Arsenic	BDL	NMT 4	Ppm
Saindhava Lavana	Mercury	BDL	NMT 1	Ppm

BDL: below detection limit; NLT: not less than; NMT: not more than. Stated limits are reproduced from the laboratory reports.

Analytical profile of raw and Shodhita Gandhaka

The analytical profiles of raw and shodhita Gandhaka are summarized in Table 5. Loss on drying was 0.038% in raw Gandhaka, 0.21% in Godugdha Shodhita Gandhaka and 0.25% in Bhringaraja Swarasa Shodhita Gandhaka; all values within the specified limit NMT 0.5% limit. Sulphur assay was 94.21%, 96.32% and 95.74%, respectively, and all values were within the specified limit NLT 90%. Solubility characteristics were unchanged across the three samples: the material was reported as insoluble in water and acids and soluble in carbon disulphide. Carbonaceous matter and volatile impurities were absent. Pb values were 1.03ppm, 1.06ppm and 1.08 ppm, respectively, below the stated 10 ppm limit; Cd, As and Hg were below detection limits in all three samples. Total microbial count was <100 CFU/g and total yeast and mould (TYMC) were absent in all three samples.

Material	Parameter	Result	Stated limit	Unit
Saindhava Lavana	Solubility	Soluble in water	-	-
Saindhava Lavana	Identification (chemical method)	Complies	-	-
Saindhava Lavana	Sodium chloride assay	95.42	NLT 93	% w/w
Saindhava Lavana	Lead	BDL	NMT 12	Ppm
Saindhava Lavana	Cadmium	BDL	NMT 4	Ppm

Material	Parameter	Result	Stated limit	Unit
Saindhava Lavana	Total microbial count	<100	NMT 1000	CFU/g
Saindhava Lavana	Total yeast & mould	Absent	NMT 100	CFU/g

limit NLT 90%. Solubility characteristics were unchanged across the three samples: the material was reported as insoluble in water and acids and soluble in carbon disulphide. Carbonaceous matter and volatile impurities were absent. Pb values were 1.03ppm, 1.06ppm and 1.08 ppm, respectively, below the stated 10 ppm limit; Cd, As and Hg were below detection limits in all three samples. Total microbial count was <100 CFU/g and total yeast and mould (TYMC) were absent in all three samples.

Parameter	State d limit	Raw Gandhaka	TV-01 Shodhita Gandhak a	TV-02 Shodhita Gandhak a
Loss on drying at 105°C (% w/w)	NMT 0.5	0.038	0.21	0.25
Solubility	–	Insoluble in water/acids ; soluble in carbon disulphide	Same as raw Gandhaka	Same as raw Gandhaka
Carbonaceous matter	Absent	Absent	Absent	Absent
Volatile impurities	Absent	Absent	Absent	Absent
Sulphur, gravimetric (% w/w)	NLT 90	94.21	96.32	95.74
Lead (ppm)	NMT 10 ppm	1.03	1.06	1.08

*Stated specifications were reproduced from the analytical laboratory reports.

Organoleptic and physicochemical profile of Raj Gutika

Both finished Raj Gutika variants were brownish-yellow in colour, TV-01 appeared slightly darker than TV-02. Both exhibited a characteristic aromatic in odour, pungent and salty taste, spherical shape and smooth surface texture. TV-02 showed higher observed values for all six measured physicochemical parameters (Table 6 and Figure 8). TV-02 showed an LOD of 8.09%, exceeding the specified NMT 8% limit, whereas the corresponding value for TV-01 was 6.03%. The remaining physicochemical parameters of both variants were within the specified limits.

Parameter	State d limit	Raw Gandhaka	TV-01 Shodhita Gandhak a	TV-02 Shodhita Gandhak a
Loss on drying at 105°C (% w/w)	NMT 0.5	0.038	0.21	0.25
Cadmium (ppm)	NMT 2 ppm	BDL	BDL	BDL
Arsenic (ppm)	NMT 1 ppm	BDL	BDL	BDL
Mercury (ppm)	NMT 1 ppm	BDL	BDL	BDL
Total microbial count (CFU/g)	NMT 1000	<100	<100	<100
Total yeast & mould (CFU/g)	NMT 100	Absent	Absent	Absent

Table 6. Physicochemical profile of Raj Gutika.

Parameter	TV-01	TV-02	Stated specification
Loss on drying (% w/w)	6.03	8.09	NMT 8%
pH	3.00	4.28	2–5
Water-soluble extractive (% w/w)	32.82	35.79	NLT 20%

**Stated specifications were reproduced from the analytical laboratory reports.*

Parameter	TV-01	TV-02	Stated specification
Alcohol-soluble extractive (% w/w)	10.86	13.32	NLT 5%*
Total ash (% w/w)	23.24	25.28	NMT 30%
Acid-insoluble ash (% w/w)	1.64	1.72	NMT 5%*

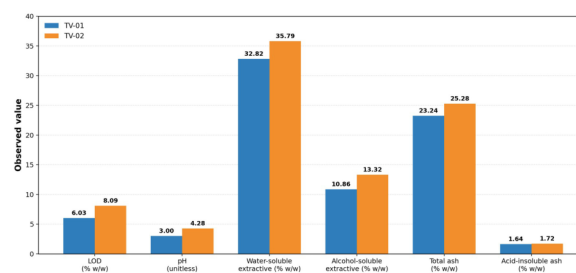


Figure 8. Comparative physicochemical profile of TV-01 and TV-02. The x-axis represents physicochemical parameters and numerical values are displayed above the bars.

Tablet quality of Raj Gutika variants

Both Raj Gutika variants had an average weight of 700 mg and hardness of 3 kg/cm². Friability was 0.21% for

Parameter	TV-01	TV-02	Stated specification
Average weight	700 mg	700 mg	±2.5%
Friability	0.21%	0.23%	NMT 1%

Qualitative phytochemical, microbial and elemental observations

Tannins, alkaloids, saponins, carbohydrates, flavonoids and steroids were detected in both finished formulations, whereas proteins and starch were not detected. Pb, Cd, As, and Hg were below detection limits in both finished formulations. TAMC was 800 CFU/g for TV-01 and 900 CFU/g for TV-02, while yeast and mould were not detected in either formulation.

HPTLC fingerprinting

HPTLC plate images recorded at 254nm and 366 nm are presented in Figure 9, while the corresponding densitometric profiles obtained at 254nm, 366nm and 510 nm are shown in Figure 10. The chromatographic

Table 8. Comparative HPTLC fingerprint of TV-01 and TV-02.

TV-01 and 0.23% for TV-02. The Disintegration time was shorter in TV-01 (5 min 15 s) than in TV-02 (8 min 26 s); both values were within the specified NMT 30 min limit (Table 7).

Table 7. Tablet-quality parameters of Raj Gutika.

Parameter	TV-01	TV-02	Stated specification
Hardness	3 kg/cm ²	3 kg/cm ²	NLT 2 kg/cm ²
Disintegration time	5 min 15 s	8 min 26 s	NMT 30 min

patterns of TV-01 and TV-02 differed across the evaluated wavelengths (Table 8). At 254 nm, TV-01 showed two peaks, with a predominant peak at R_f 0.62 (86.58%), whereas TV-02 showed a predominant low-R_f peak at R_f 0.02 (86.19%). At 366 nm, TV-01 showed two peaks at R_f 0.57 (23.79%) and R_f 0.65 (76.21%), with the latter being predominant. TV-02 showed one to three peaks across the three tracks, predominantly in the low-R_f region (R_f 0.02–0.05). At 510 nm, TV-01 showed a predominant peak at R_f 0.65 (93.50%), whereas TV-02 showed a single detected peak at R_f 0.03 (100%). As authenticated reference standards were not used, the detected peaks were not assigned to specific compounds.

Detection	TV-01	TV-02
254 nm	Rf 0.50 (13.42%); 0.62 (86.58%)	Rf 0.02 (86.19%); 0.78 (13.81%)
366 nm	Rf 0.57 (23.79%); 0.65 (76.21%)	Track 1: 0.02 (100%); Track 2: 0.04 (84.50%), 0.77 (15.50%); Track 3: 0.05 (60.77%), 0.80 (21.50%), 0.84 (17.72%)

Detection	TV-01	TV-02
510 nm	Rf 0.50 (6.50%); 0.65 (93.50%)	Rf 0.03 (100%)

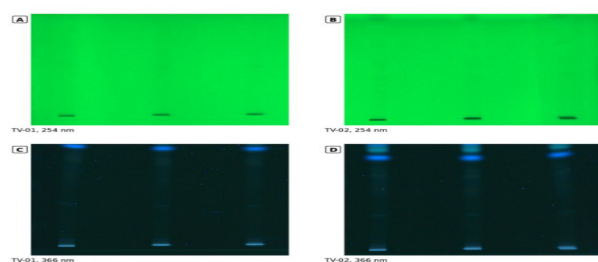


Figure 9. HPTLC plate images of TV-01 and TV-02 recorded at 254 and 366 nm.

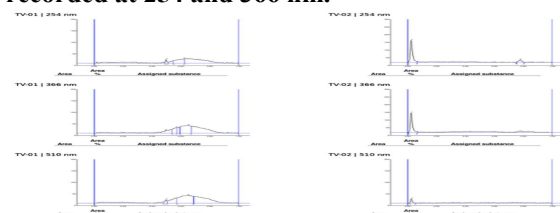


Figure 10. HPTLC densitometric profiles of TV-01 and TV-02 recorded at 254, 366 and 510 nm using CAMAG winCATS.

DISCUSSION

The present study compared two complete classical Gandhaka Shodhana methods rather than treating Shodhana as a single generic purification step. TV-01 and TV-02 differed in both the processing medium and the prescribed number of Dhalana cycles; therefore, the observed differences represent the overall effect of complete classical procedures and cannot be attributed to the processing medium alone.¹⁻³

Godugdha Shodhana yielded 77.40% recovered Gandhaka after three Dhalana cycles, whereas the Bhringaraja Swarasa Shodhana yielded 72.15% recovered Gandhaka after seven dhalana cycles. The lower cumulative recovery in TV-02 occurred in a procedure involving greater number of repeated handling steps, including melting, transfer, washing, drying, powdering, and sieving. As the material lost during the procedure was not chemically characterized, these

values should be interpreted as process recovery rather than evidence of chemical degradation.

Pre-formulation analytical testing documented the quality of the common formulation ingredients used in both variants. The measured physicochemical, elemental and microbial parameters of Shunthi Churna and Saindhava Lavana were within the stated laboratory limits. Shunthi Churna additionally underwent HPTLC identification documentation and qualitative phytochemical screening, which indicated presence of tannins, alkaloids, saponins, protein, phenolic compounds, glycosides, flavonoids and steroids. These findings provide an analytical baseline for the common input materials before comparison of the two Gandhaka Shodhana methods.

Evaluation of the intermediate Gandhaka provided an important analytical link between the pharmaceutical procedure and the finished formulation. Sulphur assay

was 94.21% in raw Gandhaka, 96.32% after Godugdha Shodhana and 95.74% after Bhringaraja Swarasa Shodhana. Loss on drying remained below the stated 0.5% limit in all three Gandhaka samples, carbonaceous matter and volatile impurities were absent, Pb remained below the stated limit, whereas Cd, As and Hg were below detection limits. These observations were based on single laboratory values and were not statistically established. Previous work has likewise reported measurable changes in processed sulphur following classical Shodhana.^{2,3}

Cycle-wise pH and temperature recording added process-control information to the pharmaceutical documentation. Godugdha remained at pH 6.3 before Dhalana and reached 6.7 after the third cycle, whereas fresh Bhringaraja Swarasa was recorded at pH 6.9 before each cycle and increased to as high as 7.7 after Dhalana. These observations are descriptive process records; the two procedures also differed in the number of Dhalana cycles and other procedural variables.

The finished Raj Gutika variants were comparable in gross organoleptic characteristics and basic tablet integrity but differed in the measured physicochemical parameters. TV-02 showed higher observed values of LOD, pH, water-soluble extractive, alcohol-soluble extractive, total ash and acid-insoluble ash, whereas TV-01 had a shorter disintegration time. The TV-02 LOD of 8.09% exceeded the stated NMT 8% specification. This slightly higher LOD may be attributed to greater retention of residual moisture and plant derived constituents. However, as only a single manufacturing batch was evaluated this interpretation remains tentative and should be confirmed in independently prepared batches.

HPTLC showed differences between the two finished formulations. At 254 nm, the predominant peaks occurred at R_f 0.62 in TV-01 and R_f 0.02 in TV-02, and differences were also observed at 366nm and 510 nm. Since authenticated reference standards were not used, the detected peaks were not assigned to specific compounds. Nevertheless, the observed chromatographic patterns provide comparative fingerprint profiles of the two Raj Gutika variants. Comparable herbo-mineral standardization studies have combined chromatographic, physicochemical and elemental approaches for characterization and quality assurance.⁵⁻⁸

Both formulations showed low friability, comparable hardness and disintegration time within the stated limit. Pb, Cd, As and Hg were below detection limits in the finished formulation; TAMC was 800 CFU/g in TV-01 and 900 CFU/g in TV-02, while yeast and mould (TYMC) were not detected. These results indicate satisfactory control of the measured quality and contamination parameters in the tested formulations, but they do not constitute a complete toxicological safety assessment. Similar qualitative phytochemical profiles despite distinct HPTLC fingerprinting indicate that qualitative phytochemical screening and

chromatographic fingerprinting provide complementary information.

The principal limitations of the study include the use of a single manufacturing batch of each formulation, the difference in the number of Dhalana cycles between the two classical procedures, and the absence of authenticated reference standards for HPTLC peak assignment were additional limitations. Future studies should include independently replicated batches prepared; when the specific objective is to isolate the effect of the processing medium, a matched-cycle or factorial design would be appropriate. Marker-based HPTLC/HPLC and complementary techniques such as XRD, FTIR or SEM-EDS may further characterize process-related changes in Gandhaka and their persistence in Raj Gutika.

CONCLUSION

This study provides a comparative pharmaceutico-analytical profile of Raj Gutika prepared using two classical Gandhaka Shodhana methods (TV-01 & TV-02). **Godugdha Shodhana yielded 77.40% Shodhita Gandhaka after three Dhalana cycles, whereas Bhringaraja Swarasa Shodhana yielded 72.15% after seven Dhalana cycles.** Intermediate-material testing showed sulphur assays of 96.32% and 95.74% in TV-01 and TV-02 Shodhita Gandhaka, respectively, compared with 94.21% in raw Gandhaka, while **the reported heavy-metal and microbial parameters remained within the stated limits.** The finished formulations were comparable in basic tablet quality but differed in physicochemical values, disintegration behavior, and HPTLC fingerprinting. **The processing medium and the number of Dhalana cycles should be considered together** during pharmaceutico-analytical evaluation of Raj Gutika. **Further studies using independently replicated batches are required** to establish reproducibility and evaluate the contribution of individual process variables.

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