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RESEARCH ARTICLE

Standardisation and Quality Control Parameters of *Phalatrikadi Ghana Vati* – An *Ayurvedic* Formulation

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Abstract

Drug standardisation, profiling, and quality control continue to be a challenge for *Ayurvedic* medicines due to their wide range of dosage forms. Different dosage forms like decoctions and powders result in non-compliance from the patient owing to their palatability or cumbersome methods of administration. The present study aims to pharmaceutically process a traditional decoction, *Phalatrikadi Kwatha,* and standardise it into tablet form, known as *Phalatrikadi Ghana Vati* (PGV). PGV was prepared and subjected to organoleptic, physicochemical, phytochemical analysis, and HPTLC analysis in an attempt to define its quality parameters and standardisation. Distinct fingerprints of *Phalatrikadi Ghana Vati* were obtained. Out of the eight components identified, the components with Rf values 0.08, 0.74, 0.65 and 0.83 were more predominant with more percent areas 9.65%, 14.91%, 18.02%, and 40.67%, respectively Quantitative physicochemical analysis revealed loss on drying as 1.33%, ash value as 4.53%, water-soluble extractive as 15.38%, alcohol extractive as 9.63% and pH as 5.1. The study also revealed the presence of alkaloids, glycosides, flavonoids, amino acids, and saponins. Preliminary profiling of PGV exhibited striking analytical characteristics. The physicochemical parameters were in the range of a standard tablet. The quantitative physicochemical parameters and HPTLC profile can be used as a reference standard for the quality control of *Phalatrikadi Ghan Vati.*

Keywords: *Ayurveda, Bhaishajya Kalpana, Phalatrikadi Ghan Vati*, *Phalatrikadi Kwatha*, Standardisation

1. Introduction

Ayurveda, the ancient system of medicine practised in the Indian subcontinent for centuries, has a rich treasure of pharmacopoeia comprising single plant-based drugs and multi-ingredient formulations. These medicines are abundantly used to manage a wide range of diseases. However, the pharmaceutical processing and the quality control methods of *Ayurveda* medicines remain questionable. The issues of drug standardisation, its profiling or characterisation and quality control remain challenging towards global acceptance of *Ayurvedic* medicine (AyM). Hence, it becomes crucial to ensure the quality and standardisation of these formulations[1].

Different types of dosage forms have been described in the *Ayurvedic* texts. *Bhaishajya Kalpana*, a branch of Ayurvedic Pharmaceutics, lays down the guiding principles of various dosage preparations based on

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patient compliance, palatability, availability, and nature of the ailment. Pharmaceutical processing aims to transform herbal agents into potent, palatable, and easily administered dosage forms for all age groups. Current technological advances may be employed to understand the traditional concepts and make them relevant to modern health care[2].

One such dosage form is the *Kwatha churna* (coarse powder), in which a combination of dried herbs is prescribed to a patient for decoction preparation at home. Preparing *Kashaya* (decoction) at home requires adherence to a specific set of principles like the ratio of raw herbs to the amount of water, duration, quantum of heating, and most importantly, the dose of the medicine. However, many times, the patient is unaware of these principles. Moreover, in the era of ready-to-eat products, it does not seem feasible to sacredly prepare decoction every time. Therefore, in the present study, a known drug with a history of traditional use as mentioned in the *Ayurvedic* text of *Chakradatta*, *Phalatrikadi Kwatha* (PK), was standardised into tablet form to give the patient a ready-to-administer solution in a fixed dose[3,4].

2. Materials and Methods

2.1 Procurement of Raw Material

The crude herbs were procured from the local market and authenticated at the Foundation for Revitalisation of Local Health Traditions (FRLHT), Bengaluru. These herbs were cleaned and washed to remove any physical impurities using potable water, dried in a tray drier below 45°C and stored in clean and dry containers at room temperature till the preparation of *Phalatrikadi Ghan Vati* (PGV). The crude herbs used for preparing PGV are shown in Table 1 and Figure 1, along with their botanical description and properties.

2.2 Preparation of *Phalatrikadi Ghana Vati* (Tablets)

2.2.1 Preparation of Decoction

After cleaning, washing and drying, the eight authenticated raw herbs, as shown in Table 1, were comminuted separately into a coarse powder. Then, following the general principles for the preparation of decoction as mentioned in the Ayurvedic texts, the coarse powder was mixed thoroughly with eight parts of potable water in a stainless steel container. The mixture was kept on a gas burner, and constant moderate heat was applied until it was reduced to one-fourth of the initial volume. During this process, the boiling contents were stirred continuously to avoid burning and deterioration of the material. Once the desired decrease in volume was attained, the decoction was strained into a separate container through a triple-layered muslin cloth.

2.2.2 Preparation of Ghana (Solid Extract)

The filtrate was kept over a gas burner and heated again, maintaining the temperature below 95°C. The process resulted in the evaporation of liquid, thus increasing the viscosity and forming a semi-solid extract, at which point the heating was turned off. This semi-solid extract thus obtained is termed *Ghana* in *Ayurveda* parlance. This *Ghana* was mixed with a fine powder of the same contents (equal to 10% of extract), resulting in a solid mass as shown in Figure 2[5,6].

Table 1. Formulation composition of *Phalatrikadi Ghan Vati*

S. No.	Botanical Name	Sanskrit Name	Part Used	Ratio
1	*Emblica officinalis* Gaertn. *(= Phyllanthus emblica* L)	*Amalaki*	Pericarp	1 Part
2	*Terminalia chebula* Retz.	*Haritaki*	Pericarp	1 Part
3	*Terminalia bellerica* Roxb.	*Bibhitaki*	Pericarp	1 Part
4	*Adhatoda vasica* Nees.	*Vasa*	Whole plant	1 Part
5	*Tinospora cordifolia* Miers.	*Guduci*	Stem	1 Part
6	*Picrorrhiza kurroa* Royale ex Benth.	*Katuka*	Root	1 Part
7	*Andrographis panniculata* Nees.	*Kalmegha*	Whole plant	1 Part
8	*Azadirachta indica* A. Juss.	*Nimba*	Stem bark	1 Part

Figure 1. Raw material used for the pharmaceutical processing of *Phalatrikadi Ghana vati*.

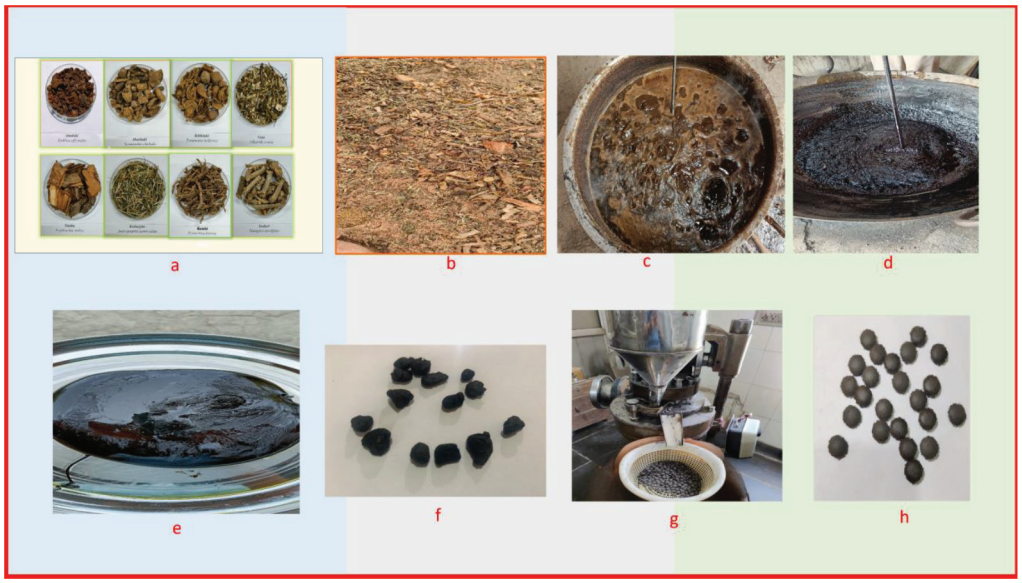

Figure 2. Sequential representation of the unit process of pharmaceutical preparation of *Phalatrikadi Ghana vati*; **(a).** Ingredients of PGV, **(b).** Coarse powder of ingredients, **(c).** Coarse powder is boiled with eight times of potable water till one-fourth of volume reduction to form decoction, **(d).** Decoction is filtered and further reduced to a semi-solid consistency known as *ghana*, **(e).** and **(f).** *Ghana* is further dried to form granules for tablet compression, **(g).** Tablet compression, **(h).** Final product.

2.2.3 Preparation of PGV (Tablets)

The solid mass thus obtained was further dried and granulation was done in multi-mill through a number 8 sieve. These granules were dried in a hot air oven at 45ºC for 12 hours. Later, they were passed through a sieve size 16 to obtain uniform granules. The granules were mixed with talc and magnesium stearate as glidant and lubricant, respectively. These granules were then compressed in a tablet press with a target weight of 500mg (±5mg) using a die-punch set (12mm)[7].

2.2.4 Preformulation Analysis[7,8]

The granules of PGV were subjected to pre-formulation analysis, and angle of repose, bulk density (ρb), tapped density (ρt), Carr's index and Hausner's ratio were assessed before punching them into tablets.

2.2.5 Physicochemical and Quantitative Analysis[9]

Phalatrikadi Ghana vati (PGV tablets) were subjected to analysis on the following parameters:

1. Organoleptic parameters: *Rupa* (colour), *Rasa* (taste), *Gandha* (odour) and *Sparsha* (touch).
2. Physicochemical parameters: Loss on drying at 110°C, pH of 5% aqueous solution, ash value, acid-insoluble ash, water-soluble extractive and methanol soluble extractive.
3. Quantitative tests for tablets: Weight variation, disintegration time, tablet hardness test and, friability.
4. Qualitative tests for alkaloids, glycosides, flavonoids, amino acids, steroids, saponins and tannins were conducted on both alcohol and water extract[10,11].
5. Analysis for microbiological contamination.
6. Chromatographic analysis: High-Performance Thin Layer Chromatography (HPTLC).
7. Heavy metal analysis for mercury (Hg), lead (Pb), cadmium (Cd) and arsenic (As) was performed through Microwave Plasma Atomic Emissions Spectrometer (MP-AES).

3. Results

The organoleptic characters of PGV were assessed as given in Table 2. It was found that PGV was brown in colour and astringent in taste. It had a characteristic odour due to the specific properties of its constituents and was round and smooth in touch.

The pH of PGV was 5.1, the loss on drying at 105 °C was 1.33%, and the total ash value was 4.53%. The water-soluble extractive was reported to be 15.38%, while the alcohol extractive value was 9.63%. The average weight of the tablet was 500 ± 0.5% mg. The disintegration time was 4.2 minutes, and the hardness of the tablet was 3.5kg/cm^2 as shown in Table 3.

The samples under study were also evaluated for microbiological contamination as per the standard procedure mentioned in the Ayurvedic Pharmacopoeia of India. These were found to be free from contamination and showed no viable microbiological growth, as shown in Table 4. The qualitative analysis of the alcohol extract of PGV revealed the presence of alkaloids, glycosides, flavonoids and amino acids, as shown in Table 5. Likewise, the water extract showed the presence of saponins, alkaloids, glycosides, flavonoids, and amino acids.

The final product, i.e. PGV was also subjected to heavy metal analysis for mercury (Hg), lead (Pb), cadmium (Cd) and arsenic (As) as per Ayurvedic Pharmacopoeia. It was performed using Agilent Technology 4210 MP-AES. None of the heavy metals were detected in the sample as shown in Table 7.

The granules of PGV before compression were subjected to pre-formulation analysis, and the values were found to be in the acceptable range as shown in Table 6. A preliminary HPTLC profile of PGV tablets was developed and the densitogram is demonstrated in Figure 3. The tablets were subjected to HPTLC analyses using CAMAG Linomet 5. A syringe size of 100 µl using methanol as a solvent with a speed of 150 nl/s and a pre-dosage volume of 0.2 µl was applied. The HPTLC fingerprint scanned at wavelength 254nm using toluene: ethyl acetate (7:3 v/v) as mobile phase and scanning speed of 20 mm/s revealed the presence of eight polyvalent phytoconstituents with corresponding Rf values of -0.01, 0.08, 0.12, 0.24, 0.55, 0.65, 0.74 and 0.83 (Figure 3).

4. Discussion

The present work deals with the modification of the dosage form of a traditional *Ayurvedic* formulation, PK,

Table 2. Organoleptic identification of the *Phalatrikadi Ghan vati*

S. No.	Description	Result
1	Colour	Brownish
2	Taste	Astringent
3	Odour	Characteristic
4	Appearance	Biconvex discoid and smooth

Table 3. Physicochemical evaluation of *Phalatrikadi Ghana vati*

S. No.	Description	Result
1	Weight variation	0.5%
2	Loss on drying at 105°C	1.33%
3	Total ash	4.53%
4	Acid insoluble ash	0.5%
5	Water soluble extractive	15.38%
6	Alcohol extractive value	9.63%
7	pH	5.1
8	Disintegration test	4.2 min
9	Hardness test	3.5 kg/cm^2

Table 4. Results of microbiological evaluation of *Phalatrikadi Ghana vati*

S. No.	Description	Result	Limits
1	Total viable count	Within permissible limits	10^5 CFU/g
2	Enterobacteriaceae	Absent	NA*
3	Total fungal count	Within permissible limits	10^3 CFU/g
4	*E. coli*	Absent	Absent
5	*Salmonella*	Absent	Absent
6	*Staphylococcus aureus*	Absent	Absent
7	*Pseudomonas aeruginosa*	Absent	Absent

* Limits not mentioned in Ayurvedic Pharmacopoeia of India.

into standardised *Ghana vati* (tablet form) and analyses its quality control parameters. *Ghana* is a second derivative dosage form of decoction, where water-soluble plant metabolites are extracted by employing the decoction process and further reheated to obtain a concentrated semi-solid form. This semi-solid mass is then dried at 50ºC.

The wet granulation method was adopted to convert solid mass into tablet form. Gum Acacia was added as a binding agent up to 2%, i.e. 110gm, along with 550gms (10%) powder of PK[5,12]. The addition of a binder in herbal tablets facilitates initial granule formation by imparting cohesiveness. It also ensures that the tablet remains intact after compression with desirable hardness[13]. The granules were dried in a hot air oven at 45 ºC for 12 hours to prevent microbial proliferation. The granules were mixed with 1% talc and magnesium stearate as glidant and lubricant, respectively. The pre-formulation (pre-compression) parameters indicate a good flow of granules aiding in optimum compression in the tablets. These granules were subsequently compressed in a tablet press with a die-punch set (12mm) to a desired weight of 500mg. The tablets were smooth in texture and the surface was uniform without any cracks. It is one of the primary characteristics for assessing the quality of herb-based tablets. If the powder is not fine or the granules are not uniform, the tablets may not be compressed uniformly, resulting in cracks on the surface. The colour of the tablets was brown, the taste was astringent and it had a characteristic odour. It could probably be due to the specific properties of herbal ingredients present in the tablets.

Table 5. Results of phytochemical evaluation of *Phalatrikadi Ghana vati*

S. No.	Parameter	Name of Test	Chemical Used	Test Result	
				Alcohol Extract	Water Extract
1	Alkaloids	Dragendorff's test	Bismuth subnitrate, tartaric acid, potassium iodide.	Present	Present
2	Glycosides	Keller–kiliani test	Glacial acetic acid, Ferric chloride, H_2SO_4	Present	Present
3	Flavonoids	Ferric chloride reagents	Ferric chloride.	Present	Present
4	Amino Acids	Ninhydrin test	Ninhydrin reagents, n-butanol (heat).	Present	Present
5	Steroids	Salkowaski reaction	Chloroform (2ml), H_2SO_4 (2ml)	Absent	Absent
6	Saponin	Foam test	$CHNaO_3$	Absent	Present
7	Tannins	Ferric chloride reagents	Ferric chloride	Present	Present

Table 6. Pre-compression tests of *Phalatrikadi Ghana vati*

S. No.	Parameter	Result
1	Angle of repose	31.29
2	Bulk density	0.76g/ml
3	Tapped density	0.83g/ml
4	Carr's index	25%
5	Hausner's ratio	1.14

Table 7. Heavy metal analysis of *Phalatrikadi Ghana vati*

S. No.	Parameter	Limit	Result
1	Mercury (Hg)	1 ppm	Below detection limit
2	Lead (Pb)	10 ppm	Below detection limit
3	Arsenic (As)	3 ppm	Below detection limit
4	Cadmium (Cd)	0.3 ppm	Below detection limit

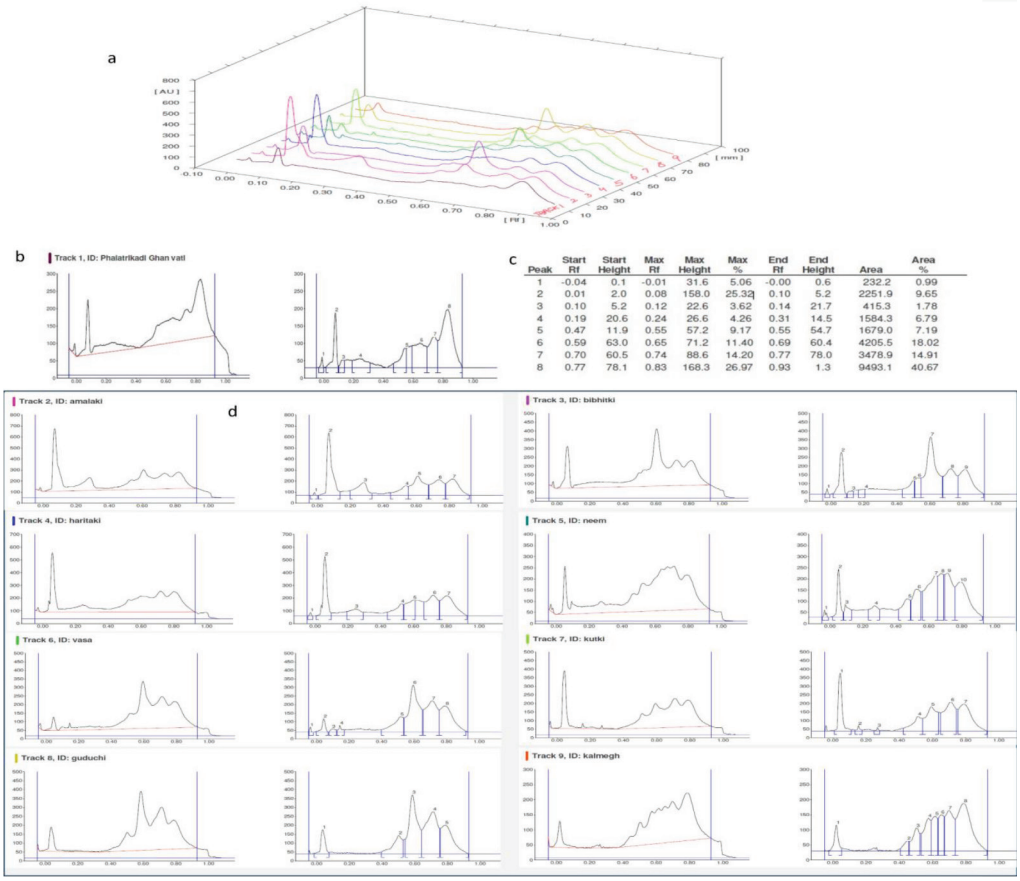

Figure 3. **(a).** Densitogram of developed TLC plate under 254nm. The tracks correspond to the tracks identified in Figure 3 (b) and (d); **(b).** Densitogram and HPTLC Profile corresponding to Track ID 1 in Figure 3(a) of prepared medicine PGV at 254nm; **(c).** Corresponding Rf values and height-area calculation results of PGV at 254nm; **(d).** Densitogram corresponding to Figure 3(a) of individual formulation ingredients of PGV.

The pH of the tablets was weak acidic as shown in Table 3. When a weakly acidic drug is given orally, most of it remains un-ionized in the stomach, favouring diffusion through the gastric mucosa, but short transit time limits the absorption. The small intestine's large surface area and more permeable membranes favour drug absorption primarily in the lower GI tract. The weak acids, despite their ability as un-ionized drugs to readily cross membranes, are also absorbed faster in the intestine than in the stomach. Hence, it can be inferred that being a weak acid, absorption of PGV primarily starts in the stomach but is enhanced in the small intestine[14–16].

Loss on drying at 105 °C was 1.33%, which showed minimal moisture content in the prepared PGV. Minimal moisture content increases the stability and shelf life of the medicine. The absence of moisture also prevents the deterioration and growth of microorganisms. This finding also substantiates the absence of any microbiological organisms in the sample, as shown in Table 4. The total ash of the test sample was found to be 4.53%w/w. Higher ash value may indicate the presence of high inorganic substances, additives, contamination, substitution or adulteration in preparing the drug formulation. Ash value was found low, indicating low inorganic substances or additives in the test drug.

The extractive values are another important quality control parameter for herbs-based tablets. Various components have their solubility in different media. In the present study, PGV was prepared as a water extract, adding 10% powder of the same contents. The water-soluble extractive value was 15.38% and the alcohol-soluble extractive was 9.63%. Currently, there are no pharmacopeial standards for *Ghan vati*. Hence these values can be considered as a reference for further studies on the physicochemical parameters of *Ghan vati*.

Qualitative tests were performed to detect the presence of functional groups responsible for the expression of therapeutic actions of the herbal products. The presence of various phytochemicals like phenols and flavonoids plays a role in protecting the human body from Reactive Oxygen Species (ROS) induced damage by interrupting its chain reaction in cellular mechanisms[17]. In the present study, alkaloids, glycosides, flavonoids and amino acids were determined qualitatively, whereas steroids and tannins were absent. The presence of these different functional groups can explain the biological effects of the PGV[3,18]. Heavy metals were not detected, thus confirming the quality control and safety profile of the sample.

HPTLC is becoming a critical and indispensable analytical technique for the standardisation of herbal drugs. A unique identification of the product can obtained by optimising the HPTLC[19]. *Ayurveda* formulations are composed of multiple herbal ingredients possessing a cocktail of numerous phytoconstituents. It is very tedious work to identify all the compounds in such a multi-ingredient formulation. Here, out of the eight components identified, the components with Rf values 0.08, 0.74, 0.65, and 0.83 were more predominant with more per cent area 9.65%, 14.91%, 18.02% and 40.67% respectively. The highest concentration of the phytoconstituents in PGV was found at Rf value 0.83, corresponding with the highest percentage area under the peak of 40.67%. The densitogram of individual ingredients of the drug corresponds to that of PGV as shown in Figure 3.

Based on the data generated in this study, future work can be undertaken for quantitative estimation of alkaloids. Moreover, the HPTLC profile can be compared against marker compounds for individual ingredients of the formulation composition. A more detailed analysis of the phytoconstituents can be conducted using higher techniques like liquid chromatography-mass spectrophotometry. However, the outcome from this evaluation can be considered as a reference standard for further quality control studies.

5. Conclusion

The present study reveals that optimum quality control parameters were adopted for manufacturing PGV. The analyses were carried out as per pharmacopoeial principles and the absence of any microbes and heavy metals in the finished product indicates the purity of the final product. The HPTLC profile of the sample under study can be considered a prefatory tool to ascertain the genuineness and authenticity of *Phalatrikadi Kwatha* in tablet form. All the physicochemical parameters of PGV, like loss on drying, ash value, water-soluble and alcohol-soluble extractive values, pH and HPTLC profile, can be used as standard for future reference.

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