

A Study on the Standardization and Quality Evaluation of Panchabhautika Medicines for Amlapitta

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Abstract

Amlapitta, a common gastrointestinal disorder in Ayurveda, arises due to the vitiation of Pitta Dosha and impairment of Agni, presenting with symptoms such as indigestion, nausea, sour belching, and burning sensation, and correlates with gastroesophageal reflux disease. The present study evaluates the quality of Panchabhautika medicines prescribed in Amlapitta. Various herbal, herbo-mineral, and mineral drugs procured from a good manufacturing practice-certified pharmacy were assessed using Ayurvedic Pharmacopoeia of India (API)-recommended physicochemical and analytical parameters, including moisture content, ash values, extractive values, hardness, disintegration time, pH, elemental analysis, and phytochemical screening. The findings demonstrate significant variation in quality attributes influencing therapeutic action: mineral-based formulations such as *Shouktika Bhasma* and *Laghusutashekhara Rasa* exhibit rapid disintegration and alkaline nature, providing quick symptomatic relief, whereas herbal and herbo-mineral formulations such as *Phalatrikadi Guggulu*, *Gokshuradi Guggulu*, and *Paripathadi Kaadha* show higher extractive values and phytochemical richness, supporting sustained therapeutic effects and mucosal protection. All formulations comply with acceptable quality standards as per API guidelines. The study establishes that Panchabhautika-based interventions adopt a holistic approach by addressing both the root pathology (Agnimandya and vitiated Pitta) and clinical manifestations of *Amlapitta*. It contributes to the development of standardized quality control parameters and supports the integration of classical Ayurvedic principles with modern analytical methods, thereby strengthening evidence-based Ayurvedic practice.

Key words: Ayurvedic Pharmacopoeia of India guidelines, evidence-based validation, panchabhautika medicines, phytochemical screening

INTRODUCTION

One of the most common ailments in Ayurveda is “Amlapitta.” It happens due to the vitiation of Pitta and Agni. “Amlapitta” is not individually mentioned in Sushruta Samhita and Ashtanga Hrudaya, but mentioned indirectly under the title of Grahani (IBS) in Charaka Samhita^[1] (the triad of ayurveda), but disorders having similarity with symptomatology are seen. When Pitta becomes vitiated specifically, when it abandons its natural pungent nature and turns acidic, the disease named Amlapitta manifests, which involves *Annavahasrotas*.^[2] It is characterized by symptoms^[3] such as *avipaka* (indigestion), *klama* (fatigue), *utklesha* (nausea), *tikta-amlā udgaar* (bitter and sour belching), *gaurava*

(heaviness), *hrit-kantha daha* (sensation of burning in the throat and chest), and *aruchi* (anorexia). In the present era, it can be correlated to gastroesophageal reflux disease (GERD).^[4] Amlapitta happens due to Nidana sevana, vitiation of pitta pradhanatridoshas, causing Agnimandya. In this state, the excessive sourness of the digestive juices makes the Ahara Rasa excessively sour (*Vidagdha*). Through this mechanism, *Amashaya* gets weakened, and Amlapitta

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develops. According to classical literature, Amlapitta falls under the category of disorders of Annavaahasrotas, mainly due to mandagni followed by *vidagdha* Pitta.^[5] Line of treatment (chikitsa siddhanta) includes *Pitta shamana*, *agnideepana*, *amapachana*, etc. Among many drugs used in clinics, herbo-mineral formulations such as *Kamadugdha Rasa*.^[6] Besides, formulations such as *Sutashekhara Rasa*, *Pravala Panchamrita*, *Shankha bhasma*, and various other kalpanas are often prescribed according to symptoms. In recent years, in regions of Maharashtra, there has been a growing trend toward a therapeutic approach based on Panchabhautikatwa. Over the past few years, a trend has emerged toward a more basic use of Ayurveda in the diagnosis and treatment of diseases based on Panchabhautikatwa. In the case of Amlapitta, emphasis is given on the predominance of Teja and Ap Mahabhuta^[3] and its treatment using Panchabhautika medicines to restore balance. Understanding disease pathology and the action of drugs forms an important part of this method. While the use of Panchabhautika medicines has been on the rise, standardization and quality control (QC) of such medicines are still lagging.

Hence, the objective of the present study is to list the drugs, based on the Panchabhautika protocol, prescribed for the treatment of Amlapitta and to evaluate their quality. By integrating classical Ayurvedic practices with modern quality assessment techniques, this study will contribute to evidence-based Ayurvedic practice.

MATERIALS ANDMETHODS

Material

Medicines procured from a good manufacturing practice-certified Ayurveda Pharmacy, Ayurveda Samshodhanalaya Sangli, Maharashtra.

Table 1 represents the quality evaluation in physicochemical parameters of Panchabhautik medicines used in Amlapitta as per the Panchabhautik protocol recommended by Ayurvedic Pharmacopoeia of India (Part-II).

Methods

Physicochemical analysis was performed as per the API-standard physicochemical, elemental, and phytochemical tests to establish their quality and standardization of selected medicine dosage forms.

RESULTS

Table 2 represents the quality evaluation in physicochemical parameters of the *Phalatrikadi Guggulu* tablet protocol recommended by the Ayurvedic Pharmacopoeia of India (Part-II).

Table 1: Physicochemical parameters selected for quality evaluation of Panchabhautik medicines

S. No.	List of medicine	Quality evaluation parameters
1.	Phalatrikadiguggulu ^[7]	Description, moisture content, ash value, acid-insoluble ash, water-soluble extractive, alcohol soluble extractive, hardness, disintegration time, friability.
2.	Gokshuradiguggulu ^[8]	Description, moisture content, ash value, acid-insoluble ash, water-soluble extractive, alcohol soluble extractive, hardness, disintegration time, friability and alcoholic extract.
3.	Shuddhagiri ^[9]	Description, moisture content, ash value, acid-insoluble ash, water-soluble extractive, alcohol soluble extractive, hardness, disintegration time, friability and alcoholic extract
4.	Laghusutashekhara rasa ^[10]	Description, moisture content, ash value, acid-insoluble ash, water-soluble extractive, alcohol soluble extractive, hardness, disintegration time and friability.
5.	Rajaniyoga ^[11]	Description, moisture content, ash value, acid-insoluble ash, water-soluble extractive, alcohol soluble extractive, hardness, disintegration time, friability.
6.	Haralu ^[12]	Description, moisture content, ash value, acid-insoluble ash, water-soluble extractive, alcohol soluble extractive, hardness, disintegration time and friability.
7.	Vidangadikshara ^[13]	Description, pH, sodium, potassium.
8.	Pittadamanachurna ^[14]	Description, moisture content, ash value, acid-insoluble ash, water-soluble extractive, alcohol soluble extractive.
9.	Shouktikabhasma ^[15]	Description, pH loss of ignition, pH, calcium and potassium.
10.	Paripathadikaadha ^[16]	Description, pH, total solids, carbohydrates, reducing sugar, monosaccharides, pentose sugar, non-reducing sugar, hexose sugar, proteins, amino acids, steroids, flavonoids, alkaloids, tannins.
11.	Jatamamsi ^[17]	Description, foreign matter, ash value, acid insoluble ash, water soluble extractive, alcohol soluble extractive, alcoholic extract

Table 3 represents the quality evaluation in physicochemical parameters of the *Gokshuradi Guggulu* tablet protocol recommended by the Ayurvedic Pharmacopoeia of India (Part-II) and quantification of calcium and total flavonoids.

Table 4 represents the quality evaluation in physicochemical parameters of the *Shuddha Girija* tablet protocol recommended by the Ayurvedic Pharmacopoeia of India (Part-II).

Table 5 represents the quality evaluation in physicochemical parameters of the *Laghusutashekhara rasa tablet* protocol recommended by the Ayurvedic Pharmacopoeia of India (Part-II).

Table 6 represents the quality evaluation in physicochemical parameters of the *Rajaniyoga* tablet protocol recommended by the Ayurvedic Pharmacopoeia of India (Part-II).

Table 2: Physicochemical analysis of *Phalatrikadi Guggulu* tablet

Description	Results
QC parametrs	Color: Dull greyish, Odor: Faint, Taste: Bitter
Moisture content	10.816%
Ash value	28.903%
Acid-insoluble ash	5.868%
WSE	32.924%
ASE	10.221%
Hardness	5 kg/cm
Disintegration time	35 min
Friability	0.002%

QC: Quality control, WSE: Water soluble extractive, ASE: Alcohol soluble extractive

Table 3: Physicochemical analysis of *Gokshuradiguggulu* tablet

Description	Results
QC parametrs	Color: Light brown, Odor: Characteristic, Taste: Bitter
Moisture content	10.753%
Ash value	30.087%
Acid-insoluble ash	6.395%
WSE	16.909%
ASE	7.828%
Hardness	6 kg/cm
Disintegration time	27 min
Friability	0.026%
Flame photometry	
Calcium	104.54 ppm
Total flavonoid content	(3.02±0.80) mg QE/g of extract

QC: Quality control, WSE: Water soluble extractive, ASE: Alcohol soluble extractive, QE: Quercetin equivalent

Table 7 represents the quality evaluation in physicochemical parameters of the *Haralu Guggulu* tablet protocol recommended by the Ayurvedic Pharmacopoeia of India (Part-II).

Table 8 represents the quality evaluation in physicochemical parameters of the *Vidangadiksharachoorna* protocol recommended by Ayurvedic Pharmacopoeia of India (Part-II) and quantification of sodium and potassium.

Table 9 represents the quality evaluation in physicochemical parameters of the *Pittadamana churna* protocol recommended by the Ayurvedic Pharmacopoeia of India (Part-II) and quantification of calcium.

Table 10 represents the quality evaluation in physicochemical parameters of the *Shouktika Bhasma* Powder protocol recommended by Ayurvedic Pharmacopoeia of India (Part-II) and quantification of calcium and potassium.

Table 11 represents the quality evaluation in physicochemical parameters of *Paripathadi Kaadha liquid* protocol

Table 4: Physicochemical analysis of *Shuddha Girija* tablet

Description	Results
QC parametrs	Colour: Brownish, Odour: Characteristic, Taste: Tasteless
Moisture content	3.865%
Ash value	72.740%
Acid-insoluble ash	8.387%
WSE	2.766%
ASE	3.583%
Hardness	7kg/cm
Disintegration time	5 min
Friability	0.236%

QC: Quality control, WSE: Water soluble extractive, ASE: Alcohol soluble extractive

Table 5: Physicochemical analysis of *Laghusutashekhara Rasa* tablet

Description	Results
QC parametrs	Colour: Dull brownish Odour: aromatic Taste: Spicy
Moisture content	7.038%
Ash value	43.578%
Acid-insoluble ash	28.785%
WSE	9.221%
ASE	6.183%
Hardness	4 kg/cm
Disintegration time	02 min
Friability	0.002%

QC: Quality control, WSE: Water soluble extractive, ASE: Alcohol soluble extractive

Table 6: Physicochemical analysis of *Rajaniyoga* tablet

Description	Results
QC parameters	Color: Brownish, Odor: Faint, Taste: Tasteless
Moisture content	6.116%
Ash value	47.308%
Acid-insoluble ash	26.393%
WSE	10.918%
ASE	6.991%
Hardness	8 kg/cm
Disintegration time	16 min
Friability	0.001%
QC: Quality control, WSE: Water soluble extractive, ASE: Alcohol soluble extractive	

Table 7: Physicochemical analysis of *Haralu Guggulu* tablet

Description	Results
QC parameters	Color: Off-white, Odor: Aromatic, Taste: Tasteless
Moisture content	5.379%
Ash value	62.020%
Acid-insoluble ash	7.382%
WSE	5.393%
ASE	1.740%
Hardness	5 kg/cm
Disintegration time	3 min
Friability	0.018%
QC: Quality control, WSE: Water soluble extractive, ASE: Alcohol soluble extractive	

Table 8: Physicochemical analysis of *Vidangadiksharachoorna*

Description	Results
QC parameters	Color: Blackish, Odor: Strong, distinct, Taste: Bitter
pH	6.84
Flame photometry	
Sodium	12,13,312 ppm
Potassium	1382.5
QC: Quality control	

recommended by Ayurvedic Pharmacopoeia of India (Part-II), Phytochemical screening and quantification of total flavonoids.

Table 12 represents the quality evaluation in physicochemical parameters of the Jatamamsi Rhizome protocol recommended by the Ayurvedic Pharmacopoeia of India (Part-I).

Table 9: Physicochemical Analysis of *Pittadamanachurna*

Description	Results
QC parameters	Color: Reddish-brown, Odor: Faint, Taste: Tasteless
Moisture content	4.028%
Ash value	53.346%
Acid-insoluble ash	47.742%
WSE	3.424%
ASE	2.552%
Flame photometry	
Calcium	229.40 Pm
QC: Quality control, WSE: Water soluble extractive, ASE: Alcohol soluble extractive	

Table 10: Physico-chemical analysis of *Shouktika Bhasma* powder

Description	Results
QC parameters	Color: Greyish-white, Odor: Faint, Taste: Tasteless
pH	11.77
Loss of ignition	37.212%
Flame photometry	
Calcium	16,633 ppm
Potassium	21.45 ppm
QC: Quality control	

DISCUSSION

Amlapitta is a disorder of vitiated Pitta Doshas. The analysis of medicine prescribed in Amlapitta as per the Panchabhautik Siddhanta-based protocol is discussed below. Overall, *Phalatrikadi Guggulu* has a moderate level of stability as it also contains large amounts of soluble extractives, which make for great bioavailability. As *Phalatrikadi Guggulu* has a disintegration time of 35 min, this suggests the product will provide a longer duration of action. In addition, when treating Amlapitta, this product will act on Agni (digestive fire) for a longer period of time to aid in the digestion of Ama (toxic metabolic waste), as well as providing a calming effect to the heat energy (Pitta) generated in the metabolism. *Gokshuradi Guggulu* contains calcium and flavonoids (acting as an antioxidant) to provide protection to the mucosal lining of the gut; therefore, it has the ability to decrease inflammation and acidity through both its instantaneous (27 min) and long-term disintegration time. *Shuddha Girija* has a large amount of minerals with a very fast (5-min) disintegration time, indicating that this herb can work quickly, neutralizing acid and providing symptomatic relief in acute Amlapitta. *Laghushutashekhara Rasa* is mineral-oriented in composition and has a fast (2-min) disintegration time, allowing for immediate relief of symptoms associated with

Table 11: Physicochemical analysis of *Paripathadi Kaadha* liquid

Description	Results
QC parametrs	Color: Dark-brown Odor: aromatic Taste: Sweet
pH	3.39
Total solids	59.884%
Phytochemical screening	
Carbohydrates	Positive
Reducing sugar	Positive
monosaccharides	Positive
Pentose sugar	Negative
Non-reducing sugar	Positive
Hexose sugar	Positive
Proteins	Negative
Amino acids	Negative
Steroids	Negative
Flavonoids	Positive
Alkaloids	Negative
Tannins	Positive
Test for glycosides	
Cardiac glycosides	Positive
Anthraquinone glycosides	Negative
Saponin glycosides	Negative
Total Flavonoid content	(110.99±0.70) µ QE/mL of sample

QC: Quality control, QE: Quercetin equivalent

Table 12: Physicochemical analysis of *Jatamamsi* rhizome

Description	Results
QC parameters	Color: Reddish-brown, Odor: Strongly aromatic, Taste: Acrid
Foreign matter	Nil
Ash value	6.653%
Acid-insoluble ash	2.914
WSE	12.872
ASE	7.120
Alcohol extract	(3.41±0.82) mg QE/g Extract

QC: Quality control, WSE: Water soluble extractive, ASE: Alcohol soluble extractive, QE: Quercetin equivalent

acidity, burning and regurgitation. *Rajani Yoga* provides an average disintegration time (16 min) for stabilization of the balance of digestive processes, controlling Pitta and therefore has the capacity to regulate and stabilize digestion. *Haralu Guggulu* has a large amount of minerals and a fast (3-min) disintegration time, meaning it can quickly relieve symptoms of Amlapitta; nevertheless, its lack of extractive properties may limit its ability to restore digestion in the long run. Vidangadi

Kshara is weakly acidic; however, it supports digestion (Agni deepana) and helps digest Ama. In addition, it contains various electrolytes and may support metabolic processes; however, it should be taken with caution. *Pittadamana Churna* has a mineral-based composition and a significant amount of ash (50%) and is directed toward pacifying Pitta and managing acidity in chronic Amlapitta. *Shouktika Bhasma* is highly alkaline and calcium-rich, acting as a potent natural antacid.^[18] This medicine. *Paripathadi Kaadha* is rich in phytochemicals such as flavonoids and tannins. Helps reduce inflammation, protect gastric mucosa, and support long-term healing. *Jatamamsi* is a nervine and adaptogen that reduces stress-related.^[19] Pitta aggravation. Supports digestion and addresses the psychosomatic aspect of Amlapitta.

CONCLUSION

The current study shows that Panchabhautika medicines used for Amlapitta vary significantly in their physical and chemical properties, which affects their therapeutic effects. The quality evaluation parameters indicate that these formulations meet acceptable standards based on API guidelines, ensuring they are safe, stable, and effective. Mineral-based formulations like *Shouktika Bhasma* and *Laghusutashekhara Rasa* provide quick relief due to their alkaline nature and rapid disintegration. In contrast, herbal and herbo-mineral formulations such as *Phalatrikadi Guggulu*, *Gokshuradi Guggulu*, and *Paripathadi Kaadha* support long-term management by enhancing digestion, reducing inflammation, and restoring mucosal integrity. The study also points out that Panchabhautika-based treatment takes a holistic approach by targeting both the underlying issues (*Agnimandya* and vitiated Pitta) and the symptoms of Amlapitta. However, standardization and QC are essential to ensure consistency and reliability in these formulations. In summary, combining traditional Ayurvedic principles with modern quality evaluation methods strengthens evidence-based practice and promotes the effective use of Panchabhautika medicines in treating Amlapitta.

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