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STANDARDIZATION OF POONARNAVASHTAK KVATHA GHANA VATI - AN AYURVEDIC FORMULATION

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ABSTRACT

Quality assurance is an integral part of all systems of medicine to ensure quality medicament. Thus, there is an urgent need to evaluate such parameters which can be adopted by the pharmaceutical industries. In the communication, attempts have been made to standardize Poonarnavashtak kwath Ghana Vati, an Ayurvedic compound formulation. Standardization and quality control of Ayurvedic formulations is necessary to ensure their quality, strength, purity and authenticity. Present work deals with physico-chemical analysis, high performance thin layer chromatography (HPTLC), microbial limit test and heavy metals analysis of Poonarnavashtak kwath Ghana Vati. The outcomes of the research confirm to the need of ensuring quality and safety of Ayurvedic medicines.

KEYWORDS: Poonarnavashtak kwath Ghana Vati, Drug standardization, HPTLC fingerprint

INTRODUCTION

In recent years, greater global interest has inclined towards non-synthetic natural drug, derived from plant sources, due to their better tolerance and negligible adverse drug reactions.[1] The World Health Organization (WHO) has also considered phytotherapy in its health programs and suggested basic guidelines and procedures for the validation of drug from plant origin both from developed western countries and developing countries like India and China.[2] Despite various efforts by WHO, there is lack of supporting studies regarding the scientific evaluation of formulation and preparation related parameters. However, India's ancient system of plant based medicine, Auyrveda is gaining recognition throughout the world and many Ayurvedic drugs are now clinically tested and accepted for manufacture.[2,3] The Ayurvedic formulations are mainly available in the form of solid dosage (Vati, Ghana and Churna), liquid dosage (Asavas, Aristhas) and semisolid dosage (Ghritas, Avlehas). All of these forms have their specific definition, method of preparation and characteristics. The method of preparation and mode of administration of the Vati is easy and it is retain potency for 3-5 yrs when kept in air tight containers while Curna and Kvatha curna retain potency for 2 yrs.[4,5] Standardization is important for ensuring of good quality products as standardized drugs of well-defined consistent quality are needed for reliable beneficial therapeutic uses. Thus, there is an urgent need to develop parameters for quality control which are cost effective and can be easily adopted by the manufactures. Efforts are being made in this area that have led to the development of analytical protocols both for single herbal drugs as well as for compound herbal formulations that can be used as valuable analytical tools in the routine standardization of Ayurvedic drugs and formulations.[6,8] Various parameters are considered to standardize these medicinal preparations as safe drugs besides adhering to quality and efficacy as per standards of the Ayurvedic formulations. As most of the tests described in ancient literature appear to be based on observation and seem subjective without valid scientific backing therefore standardization and development of reliable quality protocols for Ayurvedic formulations using modern techniques of analysis is extremely important. The study deals with Poonarnavashtak kwath Ghana Vati (GPGV),[9] a common compound preparation used for treatment of shoth, shwas, kaas, pandu.

This compound preparation is composed of eight medicinal plants ingredients,[10] like Punarnava *Boerhvia diffusa Linn* Root, *Abhaya Terminalia chebula. Retz.* Fruit, *Nimba Azadiracta indiaca. Juss* Bark, *Darvi Beberis aristata DC.* Bark,*Tikta Picrorrhiza kruraa.* Root, *Patol Tricosanthes dioica. Roxb.* Patra, *Guduchi Tinospora caordifolia Willid.* Kanda *Shunth Zingiber officinalis, Roxb* Root, *Gomutra* (Table 1). The study was carried out with the aim to develop quality standard for GPGV. The objectives included physicochemical parameters of plant drug constituents of commercial formulation procured from different Ayurvedic pharmacies; determination of the analytical values for defining the limits of heavy metals, microbial screening

and development of high performance thin layer chromatography (HPTLC) finger print profile as a rapid analytical tools for authentication of commercial samples. From ancient time, all Ayurvedic preparations have their traditional methods of preparation, mode of administration, dose and time duration on the basis of traditional knowledge on medicine by local peoples or Vaidyas. Due to the advent of commercialization longer shelf life has become the need of hour, especially for the preparation of Kvatha (decoction) which are highly perishable. Even though preservatives and additives are considered to be inert, one cannot expect the same result as that of freshly prepared Kwatha. Kvatha (decoction) Kalpana is one amongst the basic preparations in herbal pharmaceutics. Marketing these formulations is not possible because of its shorter shelf life and hence Poonarnavashtak kwath is converted to Poonarnavashtak kwath Ghana Vati (solidified aqueous extract) form by using the method of Anukta paribhasha explained in the classical texts of Ayurveda.[11] Converting Kvatha into different dosage forms like Ghana Vati, (solidified aqueous extract) Arishta (self-generated alcoholic liquid) may help to increase the shelf life without much change in the property of the particular formulation.[12] This form of drug is easy to take, storage, transport, easily absorbed, and have longer shelf life (2-5 yrs) with enhance therapeutic action and fewer side effects.

These types of drugs are very pure, safe, good quality and traditionally have strong faith and acceptability. Poonarnavashtak kwath Ghana Vati is widely used in traditional practices to maintain for treatment of shoth, shwas, kaas, pandu.[13]

MATERIALS AND METHODS

Preparation of the Poonarnavashtak kwath Ghana Vati

The authenticated crude drugs were crushed to a coarse powder separately (180 µm IS sieve or old sieve number 85 and then mixed thoroughly with equal proportion of each ingredients and 8 parts of water in a stainless steel container and then continuous mild heat was supplied until it was reduced to one-fourth of its initial quantity. During the heating process, continuous stirring was done to facilitate the evaporation and avoid any deterioration due to burning of materials. After a desirable reduction in volume was achieved, the Kwath was filtered through single folded cotton cloth and collected in a separate vessel.[14,15]

Table 1:

Sr. No.	Drug Name	Latin name	Part use	Proportion of ingredient
1	*Punarnava*	*Boerhvia diffusa Linn*	Root	1part
2	*Abhaya*	*Terminalia chebula*	Fruit	1part
3	*Nimba*	*Azadiracta indiaca*	Bark	1part
4	*Darvi*	*Beberis aristata DC*	Bark	1part
5	*Tikta*	*Picrorrhiza kruraa*	Root	1part
6	*Patol*	*Tricosanthes dioica. Roxb.*	leaves	1part
7	*Guduchi*	*Tinospora caordifolia Willid*	stem	1part
8	*Shunth*	*Zingiber officinalis, Roxb*	Root	1part

Poonarnavashtak kwath ingredients

Kwath was boiled again over slow fire on a gas stove, maintaining the temperature between 90 °C and 95 °C till a semisolid consistency is obtained. As the water evaporates, the viscosity of the extract increases, resulting in Ghana16 form. Then, the Ghana was mixed with the Curnas of Poonarnavashtak (up to 10 % of extract) further forming a solid mass.

The solid mass (Ghana) was forced through a number of,[16] sieve and granules were prepared and then dry the rounded Vatis in a tray-dryer at a temperature not exceeding 50 °C to 60 °C for 10 to 12 h. The formulation was then compressed in a single punch press with a target weight of 250 mg. Stored Vatis in containers and packed them in air-tight condition to protect them from light and moisture.[17-18]

Physicochemical and quantitative parameters

Organoleptic characters, average weight loss on drying at 105 °C and physicochemical analysis of all the samples were carried out. Quantitative analyses for friability test and disintegration time were checked in triplicate according to the prescribed Standard methods in Indian Pharmacopoeia.[18]

High Performance Thin Layer Chromatography (HPTLC) profile

For HPTLC,[19,20] 0.25 g of each dried samples and powdered Ghana Vati macerated with 10 mL ethanol were taken. Filtered each of the extracts and combines together. Added 5 g of anhydrous sodium sulphate, kept it for 10 min, filtered and concentrated. HPTLC of extracts of all the samples were carried out on silica gel 60 F254 pre-coated plates. Toluene: Ethyl acetate: Methanol: Water (5: 3.5: 1: 0.5) were used as mobile phase. The plate was developed and visualized under ultraviolet at 366 nm, visible light and after spraying with 5 % methanolic- sulphuric acid reagent followed by heating at 105 °C for 5 min.

Heavy Metal Analysis

The test consists of two consecutive operations: preparation of the test solution, and the colour development by reaction with hydrogen sulfide, followed

by comparison of the colour obtained with that produced with standard lead solution.

The reaction with hydrogen sulfide is carried out by mixing the test solution with freshly prepared hydrogen sulfide TS. The comparison of the colour thus obtained is carried out either by directly comparing the coloration of the liquid in suitable comparison tubes (Method A) or by comparing the intensity of coloration of spots obtained by filtering the liquid using an appropriate apparatus (Method B).

Method A is generally applicable only when the amount of heavy metals in the weight of test substance used exceeds 5 µg*;* for amounts of 2-5 µg of heavy metals Method B should be used. The standard lead solution used in the test; dilute lead PbTS contains 10 µg of lead in 1 mL. When 0.1 mL of this solution is employed to prepare the standard for comparison with a solution of 1 g of the substance being tested, the standard solution thus prepared contains 1 µg of Pb and represents the equivalent of 1 µg of lead per g of the substance tested.

Microbial Contaminations

Petri plates, micro tips, nutrient agar medium (2.6 gms of nutrient broth + 4gms of agar agar in 200ml distilled water) was sterilized in autoclave at 121°C at 15psi for 15mins. The sterilized apparatus were taken to laminar hood. The weighed triturated powder of Ghana pills, ghanawati pills and tablets respectively were dispersed in petri plate containing nutrient medium. (*Malassezia furfur*) was used as positive control and one petri plate kept as negative control. The plates were incubated at 37°C for 24hrs to see numbers of colony forming units.

RESULTS AND DISCUSSION

Standardization and quality control of Ayurvedic formulations is necessary to ensure their quality, strength, purity and authenticity. Present work deals with organoleptic, physico-chemical analysis, high performance thin layer chromatography (HPTLC), microbial profile and heavy metals analysis of Poonarnavashtak Kvatha Ghana Vati.

Table 2:

Parameters	GPGV-I	GPGV-II	GPGV-III	Mean	SD
Total Ash %	14.17	14.21	13.89	14.09	0.17
Acid Insoluble Ash %	1.6	1.7	1.4	1.56	0.152
Water Soluble Extract %	21.92	21.96	20.59	21.9	0.77
Alcohol Soluble Extract %	3.52	3.83	3.39	3.58	0.22
pH	5.99	6.10	5.87	5.98	0.11
Moisture content (%)	5.89	4.56	4.78	5.07	0.71
Hardness	5	5	6	5.333	0.577
Uniformity (%)	12.825	12.900	12.419	12.710	0.250
Friability	0.290	0.302	0.300	0.297	0.0064
Disintegration Time	106 mins	95 mins	112 mins	104.3 mins	8.62

Preparation, organoleptic and analysis studies of GPGV were carried out in three different bathes individually with exactly identical conditions and the results obtained were expressed as Mean ± Standard Deviation (SDV) of three observations. (Table 2)

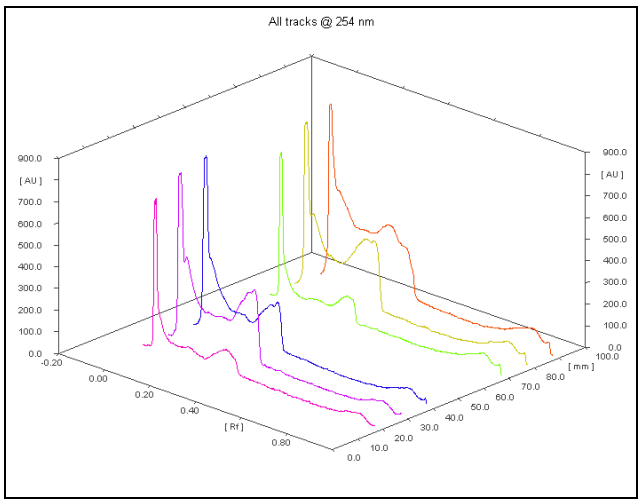
Rasakriya converts kwath into Ghana by boiling of kwath over mandagani. The reaction was carried out till it reaches to a thick consistency i. e. semisolid form by evaporation to remove watery portion. Total weight of Ghana was found to be 470 ± 20 g. The yield was found to be 22.5% (w/w) as compared to the total raw material taken. Further, Ghana was triturated in gomutra. It has been reported that, gomutra was found to be used as a vehicle as reported in the sharangdhar sanhita.

The *sparsha* of all three batches were *shlakshna*. The colour (*roopa*) was blackish brown. Taste (*rasa*) was *katu, tikta, kashaya (bitter)* due to the ingredients used in the preparation were having almost same *rasa*. All the three batches were gomutra gandhi due to trituration with gomutra.

The total ash value of GPGV was 14.09 ± 0.17; Acid insoluble ash value was 1.56 ± 0.15. Water soluble extractive value was 21.9 ± 0.77 and alcohol soluble extractive value was observed to be 3.58 ± 0.22. This studies showed that, the extraction of GPGV was more in the water than the alcohol. The pH of the GPGV was found to be 5.98 ± 0.11 suggestive of its acidic nature. The moisture content of the GPGV was 5.07 ± 0.71, which was in normal limits. For hardness, the mean value was observed as 5.33 ± 0.58. The uniformity of the GPGV was 12.27 ± 0.25. The average weight was ranged in between 230 mg to 370 mg. The amount of total tablets obtained was calculated as 1556. It was also necessary to assess the tendency of the tablet of breaking while handling and transportation. The values for friability and disintegration time were calculated as 0.297 ± 0.006 and 104.3 ± 8.42 mins respectively.

Table 3: HPTLC chromatogram of GPGV in comparison with PSK.

Track no.	Substance	Concentration (ppm)	Applied volume
2	Ghanavati	5000	10µl
3	PSK 1	50000	20µl
4	PSK 2	50000	20µl
7	Ghanavati	5000	10µl
8	Water extract 1	50000	20µl
9	Water extract 2	50000	20µl



The tracks selected for study were track no. 2 and 3 respectively for PSK and GPGV.values described in (Table 3, 4) Values obtained at 254nm were,

Table 4:

Track no.	Substance
2	Ghanavati
3	PSK 1

Table 5:

Tract no	Peak no	Max Rf
2	3	0.31
3	3	0.32

The tracks selected for study were track no. 2, 3 and 4 respectively for GPGV, PSK values described in (Table 6). Values obtained at 254nm.

Table 6:

Track no.	Substance
2	GPGV
4	PSK

Table 7:

Tract no.	Peak no.	Max Rf
2	6	0.85
3	6	0.99
4	6	0.99

The tracks selected for study were track no. 2, 3 and 4 respectively for GPGV, GHANA and PSK values described in (Table 7) Values obtained at 254nm.

Table 8:

Track no.	Substance
2	GPGV
3	Ghana
5	PSK

Table 9:

Tract no.	Peak no.	Max Rf
3	3	0.27
5	3	0.28

The tracks selected for study were track no 3 and5 respectively for GPGV, PSK and Fresh gomutra values described in table. Values obtained at 254nm

Table 10:

Track no.	Substance
2	GPGV
3	PSK
4	Fresh gomutra

Table 11:

Trak no.	Peak no.	Max Rf
1	5	0.85
2	5	0.60
3	5	0.79
4	5	0.84

These are the significant values which are to be considered for HPTLC analysis.

Petri plates, micro tips, nutrient agar medium (2.6 gms of nutrient broth + 4gms of agar agar in 200ml distilled water) was sterilized in autoclave at 121°C at 15psi for 15mins. The sterilized apparatus were taken to laminar hood. The weighed triturated powder of Ghana pills were dispersed in petri plate containing nutrient medium. (*Malassezia furfur*) was used as positive control and one petri plate kept as negative control. The plates were incubated at 37°C for 24hrs to see numbers of colony forming units.

In the present formulation, the microbial count was within permissible limits, which indicates the proper hygiene norms followed during the preparation of formulation and packing of prepared products.

No colony forming units were seen in case of Ghana and ghanawati pills and tablets.

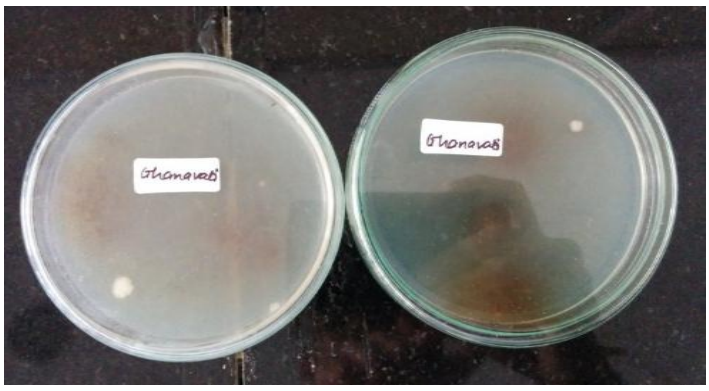


Fig. 1:

The test consists of two consecutive operations: preparation of the test solution, and the colour development by reaction with hydrogen sulfide, followed by comparison of the colour obtained with that produced with standard lead solution.

The reaction with hydrogen sulfide is carried out by mixing the test solution with freshly prepared hydrogen sulfide TS. The comparison of the colour thus obtained is carried out either by directly comparing the coloration of the liquid in suitable comparison tubes (Method A) or by

comparing the intensity of coloration of spots obtained by filtering the liquid using an appropriate apparatus (Method B).

Method A is generally applicable only when the amount of heavy metals in the weight of test substance used exceeds 5 µg*;* for amounts of 2-5 µg of heavy metals Method B should be used.

The standard lead solution used in the test; dilute lead PbTS contains 10 µg of lead in 1 mL. When 0.1 mL of this solution is employed to prepare the standard for comparison with a solution of 1 g of the substance being tested, the standard solution thus prepared contains 1 µg of Pb and represents the equivalent of 1 µg of lead per g of the substance tested.

Heavy metals were not detected in the analysis, thus showing the purity of the prepared products. The limit test for heavy metals is provided to demonstrate that the content of metallic impurities that are coloured by hydrogen sulfide does not exceed the heavy metals limit given in the individual monograph in terms of micrograms of lead per gram of the test substance.

CONCLUSION

The Ayurvedic system of medicines is prevalent in India since the Vedic period and as early as the dawn of human civilization. Though, Ayurveda has undergone many changes in the course of its long history, it still remains the mainstay of medical relief to a large section of population of the nation. Due to urbanization and dwindling of forests, the Vaidyas by and large is no longer a self-contained unit collecting and preparing his own medicines as before. He has now to depend on the newly developed agencies like one collecting and supplying the crude drugs and the other undertaking mass production of medicines in the Ayurvedic pharmaceutical units run on the commercial scale. The standardization of such formulation is need of the hour for wider acceptability. Hence, the organoleptic, physicochemical parameters, quantitative analysis, HPTLC fingerprint profiles, heavy metals and microbial profiles together may be used for quality evaluation and the standardization of compound formulations. From ongoing observations it can be concluded that the distinguishing band in the HPTLC profiles may be utilized as marker parameters for monitoring the quality of the formulation. The data generated indicates genuineness, purity and safety of the finished product and can be useful as diagnostic tool for standardization of same drugs.

REFERENCES

1. Kimmatkar N, Thawani V, Hingorani L & Khiyani R, Efficacyand tolerability of Boswellia serrata extract in treatment of osteoarthritis of knee a randomized double blind placebo controlled trial, Phytomedicine, 2003; 10: 3-7.
2. Goldfrank L, Lewin N, Flomenbaum N & Howland MA, Thepernicious panacea: Herbal medicine, Hops Phys, 1982; 18: 64-87.
3. Vulto AG & Singh PAGM, Drugs used in non-orthodox medicine, In: Meyler's Side Effects of Drugs, 11th edn, (Elsevier, Amsterdam), 1988; 999-1005.
4. Anonymous, The Ayurvedic Formulary of India, 1st edn, Part- III, (Government of India, Ministry of Health and Family Welfare, The Controller of Publications, New Delhi), 2011; 3: 115, 231-238.
5. Anonymous, The Gazette of India, Notification No. GSR764 (E), 2009.
6. Tiwari AK, Dwivedi N & Tripathi MK, Scientific evaluation and standardization of the Ayurvedic compound formulation Yavanyadi curna, Indian J Tradit Knowle, 2015; 14(4): 544-549.
7. Tiwari Ashok Kumar, Dwivedi Neelesh & Tripathi Manoj Kumar, Scientific Evaluation of Darvyadi Kvatha Curna-A Classical Ayurvedic Compound Formulation, Indian J Nat Prod Resour, 2015; 6(4): 314-319.
8. Tiwari Ashok Kumar, Dwivedi Neelesh, Tripathi Manoj Kumar & Tripathi Sharda Prasad, Standardization and quality control of Darvyadi Pravahi Kvatha-An Ayurvedic formulation, Indian J Tradit Knowle, 2016; 16(4): 554- 558.
9. Anonymous, The Ayurvedic Formulary of India, 1st edn, Part-II, (Government of India, Ministry of Health and Family Welfare, The Controller of Publications, New Delhi), 2000; 75: 171.
10. Sharangdhar samhita, Prof. K.R. Srikantha Murthy, Chaukhambha orientalia, Varanasi, Reprint, 2012; 56, 57.
11. Liju BS, Seema MB & Ravi Mandugaru, Comparative AntipyreticEffect of Nagaradi Kwatha, Ghana Vati and Arishta in Wistar Albino Rats, J Ayu Med Sci, 2016; 1(2): 86-9.
12. Vagbhata, Astanga Hrudaya with Sarvangasundara commentary of Arunadatta and Ayurvedarasayana commentary of Hemadri, edited by Hari Sadhashiva Shashtri Paradkara, 1st edn, Varanasi: Chaukhambha Suraabhrati Prakashan, 2014.
13. Sharangdhar samhita, Prof. Dr. Ravindra Angadi, Chaukhambha orientalia, Varanasi, Reprint-Madhyamkhanda, 2012; 2/76.
14. Anonymous, Pharmacopoeial Standards for Ayurvedic Formulations, (Government of India, Ministry of Health & Family Welfare. The Controller of Publications, Delhi), 1987; 456-457, 491-494.
15. Baragi UC, Baragi PC, Vyas MK & Shukla VJ, Standarization and quality control parameters Dashanga kwatha Ghana tablet: An ayurvedic formulation, Int J Ayur Res, 2014; 2(1): 42-47.
16. Trikamji AY, Sidha Yoga Sangraha, 11th edn, Baidyanath Ayurveda Bhawan, Nagapur, 2000; 4.
17. Anonymous, The Ayurvedic Pharmacopoeia of India (Formulations), 1st edn, Part-II, Vol. II-III, (Government of India, Ministry of Health and

Family Welfare, The Controller of Publications, New Delhi), 2010; 104: 116, 159- 180, 263.
18. Anonymous, Laboratory Guide for the Analysis of Ayurveda and Siddha Formulation, (Government of India, Ministry of Health and Family Welfare, New Delhi), 2010; 27, 63-66, 103-117.
19. Wagner H & Bladt S, Plant Drug analysis of thin layer Chromatography atlas, (Springer Germany), 1996; 147-174.
20. Wall PE, Thin-Layer Chromatography, Modern Practical Approach Series, (The Royal Society of Chemistry, Thomas Graham House Cambridge, UK), 2005.