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Quality Control Analysis of Devadarvydi Kashaya Choorna – A Traditional Formulation of Shwasa Therapy

Shivaprasad Sharma Thanugula[1*], Kirankumar V Mutnali[2], Giridhar Vedantam[3]
[1]Clinical Research officer, Department of MCH Transitional Health Science & Technology Institute, Autonomous body of Ministry of Science, NCR Biotech Science Cluster, 3rd Milestone,Faridabad – Gurugram, Haryana, India
[2]Principal & Professor, Department of Kayachikitsa, KLE Ayurveda Medical college, Chikodi, Karnataka, India
[3]Reader, Department of Dravya Guna, KAHER's Shri. BMK Ayurveda Mahavidyalaya, PGStudies and Research Centre, Shahapur, Belagavi, Karnataka, India

Corresponding Author
Email: spsharmadr22@gmail.com

ABSTRACT

***Background**: Medicinal herbs have served the health requirements of civilization since time immemorial. It is imperative to know that the herbs are liable to be subjected to ambient physiochemical influencing parameters viz. sunlight, soil, fertilizers and pesticides. Quality control and standardization also ensures uniformity and reliability. Devadarvyadi kashaya churna (DDKC) is a poly-herbal formulation widely used in kasa and shwasa.*
***Objective:** To set the uniformity and quality of DDKC by assessing three different market samples of the same.*
***Materials and methods**: The formulation ingredientsof DDKC from three different market sources were subjected to analysis consisting of evaluation of organoleptic, physiochemical, phytochemical parameters and thin layer chromatography examination. Further mean, standard deviation and range were calculated.*
***Results**: The standardization and quality control parameters were comparable in the entire threesamples.*
***Conclusion**: The mean obtained from the results can be set as standard reference value for further preparations of DDKC combination.*
***Key words:** Devadarvyadi kashaya churna, organoleptic, physio-chemical, phyto-chemical parameters, Shwasa, Standardization, Bronchial Asthma.*

INTRODUCTION

Mankind has held faith in Ayurvedic science since time immemorial but the major stumbling block in its wide-spread acceptance in the contemporary world is lack of quality control and standardization. The maintenance of bio-equivalence is of paramount importance as it directly influences the response of an individual to the treatment administered. Establishment of right quality control and standardization sets a mark and identity for a drug thereby maintaining uniformity in bioequivalence [1]. With the changing time trends and booming of Ayurvedic medicine, WHO took a a step ahead recommending the incorporation of herbal medicines into national health care programs on grounds of their feasibility, safety and hands down accessibility [2]. It's the evidence based clinical trials and documentation that carries more weightage in terms of reliability, acceptability and uniformity. Their conductance however demands the drug to pass through process of authentication, standardization at the level of cultivation, identification, processing pharmacological evaluation and quality control

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parameters for wide spread application.
Bronchial Asthma (BA) is escalating world-wide and has become a chronic disease that needs more attention and cases are rising at the rate of 50% every decade. Globally around 300 million people suffer with BA and 2,50,000 annual deaths are attributed to it [3]. In India it is estimated that around 15 to 20 million people are asthmatics and it is seen as one of the leading causes of morbidity and financialexpensiveness in urban India [4].

Shwasa (Bronchial Asthma) is a disease of Pranavaha Srotas (respiratory system) that emerges due to disturbance in Vata and Kapha Dosha stemming out from Pitta Sthana (lower GI). Tamaka Shwasa is one variety among five types of Shwasa. It is characterized by difficulty in breathing, cough, wheeze, chest tightness etc. The disease is curable if it's newly originated otherwise, it is yapya (manageable). Tamaka shwasa is further classified into pratamaka and santamaka by doshic association.

The treatment of Tamaka Shwasa primarily composed of the therapies and medications that are vata and kapha pacifying, hot in potency and vatanulomaka (that ease movement of vata dosha in its natural direction). Approach to the case for selection of therapy (bio-purification or palliative) is based on the strength of the patient. Patients with good strength are recommended bio-purification therapies like Vamana (Therapeutic emesis), Virechana (purgation) and Niruha Basti (Medicated Enema) where as those with poor strength are recommended to opt for palliative therapy.

Among palliative therapy, there are innumerable multidimensional dosage forms and formulations that are currently adopted in the management *viz*., *churna (*powders*)*, *avaleha (*electuary*)*, *sneha (*oils*)*, *vati*/*gut (*tablets*)*, *rasa oushadhi (*herbo mineral preparations*)*, *kashaya (*Decoctions) *kalpana* (formulations) etc. Author of Yogaratnakara claims *Devadarvyadi kwatha churna* (DDKC) to eliminate Tamaka Shwasa once for all and the same kashaya formulation is selected for present study [5]. Ingredients of devadarvyadi kashaya are *Devadaru [6]* (Cedrus deodara Roxb), *Vacha [7]* (*Acorus calamus* Linn), *Kantakari [8]* (*Solanum xanthocarpum* Schrad & Wall), *Shunthi[9]* (*Zingiber* officinale Roxb), *Katphala [10]* (*Myrica nagi* Thumb) and *Pushkaramula [11]* (*Innula recemosa* hook.f). All of these ingredients have Katu and Tikta rasa, katu vipaka pacify kapha, vata, Kasa and Shwasa. The individual drugs of the formulation have proven pharmacological action of anti-inflammatory activity, mast cell stabilization, brono-dilation, mucolysis and expectoration all of which are beneficial in BronchialAsthma.

Since, Ayurveda uses medicinal herbs as raw material, it is liable to be subjected to influencing factors from environment viz sunlight, soil, fertilizers, insecticides and other local factors including weeds. Adulteration and improper identification resulting in substitutions are other unchecked parameters influencing the final product. This might result in substantial discrepancy in the efficacy from different manufactures. Hence it becomes important to have stringent quality control and standardization protocol.

The DDKC formulation is not available in the API. Hence, in the present study, an attempt is made to set a mark of parameters for further reference purposes by evaluating DDKC formulation from three different market sources. It consisted of determination of organoleptic, physiochemical, phytochemical parameters and thin layer chromatography examination. Furthermean, standard deviation and range were calculated.

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MATERIALS AND METHODS

Procurement of Plant Material:

The individual herbs mentioned in *yogaratnakara* for the final formulation of *Devadarvyadi kashaya* were procured from three different market sources. One from GMP certified KLE Pharmacy coded sample 1. Sample 2 and sample 3 were collected from recognized market sources from Belagavi and Hyderabad respectively. Authentication of herbs was done by department of Central Research Facility (CRF) of Shri B M Kankanawadi Ayurveda Mahavidyalaya, Post Graduate Studies and Medical Research Centre, Belagavi. The individual drugs used have been enlisted in (Table 1).

Table 1: Devadarvyadi Kashaya Churna Individual Drug List [6-11]

S. No	Ingredients	Botanical name	Family	Part used	Proportion
1	*Devadaru*	*Cedrus deodara* Roxb	Pinaceae	Heartwood	1 part
2	*Vacha*	*Acorus calamus Linn*	Acoracea	Stem	1 part
3	*kaṇṭhakāri*	*Solanum xanthocarpum Schrad & Wall*	Solanaceae	Stem	1 part
4	*śoṇṭhi*	*Zingiber officinale Roxb*	Zinzibaracea	Rhizome	1 part
5	*Katphala*	*Myrica nagi Thumb*	Myricaceae	Bark	1 part
6	*Pushkaramoola*	*Innula recemosa hook.f*	Asteraceae	Whole plant	1 part

Preparation of DDKC: There is collection of the individual ingredients in the proportionate quantity in equal parts, coarsely powdered with mesh size 40, homogenously mixed and stored in air tight container. The standard protocol guidelines mentioned in AFI are strictly adhered to and preparation was done accordingly.

The drugs were submitted to the Central Research Facility for further evaluation of Organoleptic, Physiochemical and Preliminary phytochemical analysis. The obtained parameters were compared and mean taken.

Figure 1. Preparation of DDKC

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Analytical Study

The analytical study was done in the laboratory of department of Central Research Facility (CRF) of Shri B M Kankanawadi Ayurveda Mahavidyalaya, Post Graduate Studies and Medical Research Centre, Belagavi. It consisted of assessment of organoleptic parameters, preliminary phytochemical investigations encompassing Molisch's test, fehling's test, Benedict's test, Barfoed test, Bial's test, orcimol' test, selwinoff's test, millon's test, ninhydrin's test, Salkowsky's test, Baljet's test, Borntragers's test, foam test, sulphuric acid test, dragendroff'stest and Lead acetate test; physicochemical analysis included Loss on dryng, ash value, water and alcohol soluble extract by following standard procedure. For the Thin layer chromatography (TLC), the stationary phase consisted of 5% water extract of DDKC was spotted on pre coated silica gel GF_{254} plates. The mobile phase consisted of Toluen: ethyl acetateof 7:3 ratio. The plates were kept in TLC chamber and run. The spots were visualsed after placing them in UV chamber under white light where the short wave of wave length 254nm and long wave 355nm. the number of spots were identifying with naked eye visualization. The R_f values were calculated.

RESULTS

Organoleptic Study

The organoleptic characters were assessed for Taste, Smell, Color and Touch and the observations noted in table 2.

Table 2. Showing Organoleptic Characters

Sl.no	CHARACTER	SAMPLE1	SAMPLE 2	SAMPLE 3
1	Taste	Astringent	Astringent	Astringent
2	Odour	Aromatic	Aromatic	Aromatic
3	Color	Light brown	Light brown	Light brown
4	Touch	Coarse	Coarse	Coarse

Physicochemical Study

The parameters of physicochemical tests for all three different samples were assessed, the mean of the values was taken and the standard deviation and range were calculated and tabulated in Table 3.

Table 3: Physicochemical Study

S.no.	Test %	Sample 1	Sample 2	Sample 3	Mean	Standard deviation	Range
1	Loss on Drying	11.283	11.324	6.28	9.627	2.899	6.28-11.324
2	Ash Value	4.968	4.987	5.075	5.013	0.058	4.968-5.075
3	Acid insoluble ash	0.876	0.897	1.317	1.03	0.248	0.876-1.317
4	Water soluble extract	14.456	19.7	17.20	17.118	2.622	14.456-19.7
5	Alcohol soluble extract	9.771	6.076	5.60	7.149	2.283	5.60-9.771

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Phytochemical Analysis

The Phytochemical tests for various functional group and glycoside were conducted and the results have been mentioned in Table 4.

Table 4: Phytochemical Tests

TEST	Sample 1		Sample 2		Sample 3	
	Water	Akcohol	Water	Alcohol	Water	Alcohol
Carbohydrates	+ve	+ve	+ve	+ve	+ve	+ve
Reducing sugars	+ve	+ve	+ve	+ve	+ve	+ve
Monosacharides	+ve	+ve	+ve	+ve	+ve	+ve
Pentose sugar	-ve	-ve	-ve	-ve	-ve	-ve
Hexose	-ve	-ve	-ve	-ve	-ve	-ve
Protiens	-ve	-ve	-ve	-ve	-ve	-ve
Aminoacids	-ve	-ve	-ve	-ve	-ve	-ve
Steroids	+ve	+ve	+ve	+ve	+ve	+ve
Flavonoids	+ve	+ve	+ve	+ve	+ve	+ve
Alkaloids	-ve	-ve	-ve	-ve	-ve	-ve
Tanins	+ve	+ve	+ve	+ve	+ve	+ve
Cardiac glycosides	-ve	+ve	-ve	+ve	-ve	+ve
Anthraquinone glycosides	-ve	-ve	-ve	-ve	-ve	-ve
Saponine glycosides	+ve	-ve	+ve	-ve	+ve	-ve

TLC: The chromatogram of KLE Pharmacy sample showed 11 spots in short and long waves each; 7 and 12 in short and long wave respectively of market sample 1; 3 and 4 in short and long wave respectively of market sample 2. The R_f values were recorded under mentioned in Table 5.

Table 5: The Chromatogram of KLE Pharmacy samples

R_f	Sample 1	Sample 2	Sample 3
Short wave	0.03,0.06,0.12,0.16,0.21,0.26, 0.38,0.53,0.75,0.84,0.86	0.13, 0.3, 0.43, 0.5, 0.55 ,0.66, 0.77	0.52, 0.76, 0.82
Long wave	0.04, 0.06, 0.13, 0.21, 0.24, 0.35, 0.37,0.47, 0.52, 0.80, 0.88.	0.16,0.3,0.37,0.45,0.55,0.61.0.63, 0.67,0.75,0.8,0.86,0.92	0.047,0.54,0.71,0.823

Fig. 1 Sample 1 TLC

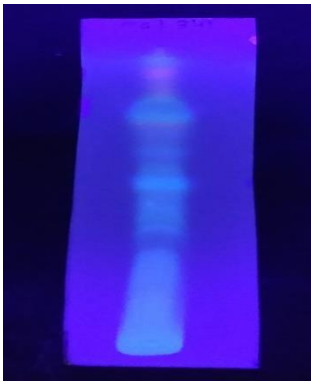

Fig. 2 Sample 2 TLC

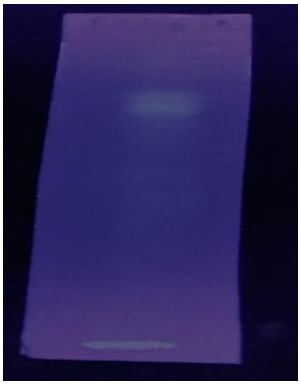

Fig. 3 Sample 3 TLC

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DISCUSSION

The Polyherbal compound DDKC is widely used for treatment of respiratory ailments in Ayurveda. This works evaluates the quality control parameters of DDKC. There are no set standard parameters promising uniform bioequivalence.

An attempt to solve this issue is done here. The formulation of devadarvyadi kashaya churna was prepared in accordance with the guidelines mentioned by AFI. Three market samples of the ingredients were procured, analyzed and interpretation of results done to set quality control and standardization parameters. The organoleptic characters are imparted by the intrinsic properties of the ingredients. The three samples were consistent in the results.

Physico chemical property, the ash value is measure of inorganic substances and is directly proportional to it. It governs the authenticity and purity of the drug. The mean obtained was 5.013%. The acid insoluble ash measures the proportion of sample which remains un hydrolyzed by 72% sulphuric acid and is not volatilized on incineration. The mean was noted to be 1.03%. The moisture content is directly related to loss on drying. The lower values of moisture content have negative influence for growth of microorganisms. Sample3 showed values significantly lower than the others. The mean for LOD was 9.627%. The assessment was done for solubility in water (mean 17.118%) and alcohol (mean 7.149%) which stipulates the amount of active constituent and bioavailability. It was noted that solubility was more in water which implies higher bioavailability in aqueous medium.

The phytochemical test was done on water soluble and alcohol soluble extract of devadarvyadi kashaya churna of all the three samples. The tests revealed the presence of carbohydrates, reducing sugars, monosaccharaides, steroids, flavonoids and tannins. The results were consistent with all the samples. The cardiac glycosides were present in alcohol soluble extract of KLE and second market sample, water and alcohol soluble extract of market sample one. The saponine glycosides were present in the water-soluble extract of all three samples. The chromatogram of KLE pharmacy sample showed 11 spots in short and long waveseach; 7 and 12 in short and long wave respectively of market sample 1; 3and 4 in short and long wave respectively of market sample 2. The number of spots is a depiction of number of active principles present the sample 1 and sample 2 apparently have a higher number of active principles than sample three as evidenced by the results. however, the intensity showed inconsistent results especially when it came to sample no. 3. The R_f values are differing in the all the samples implying inconsistency of the active ingredients.

CONCLUSION

In the present study, the organoleptic, physiochemical phytochemical and chromatographic parameters were assessed for three different samples**.** The results were comparable with slight variations which are negligible; hence the mean was obtained and taken as the final value. These values can be considered as a possible standard reference values. These set of values can be retained while manufacturing further formulation of devadarvyadi kashaya churna. As it was mentioned earlier the major stumbling block in the widespread acceptance ofAyurvedic medicine was the lack of standardization and quality control parameters. It is the need of the hour to convert it into a stepping stone by carrying out similar studies with high-end equipment that comes with a weighted assurance.

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