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Research Article

ORGANOLEPTIC AND PHYSIC-CHEMICAL ANALYSIS OF DALU PANU GULIYA

G.U.A. Kumara

Department of Kaumarabhritya and Striroga, Gampaha Wickramarachchi Ayurveda Institue, University of Kelaniya, Yakkala, Sri Lanka.

ABSTRACT

Safety and efficacy are most important factors of the drug. Standardization is a one point of safety of the drug. Controlled trials are necessary to establish efficacy of the drug. Dalu Panu Guliya is an important traditional drug widely used for Balaroga in Sri Lankan Traditional Medical System. It is a pure herbal drug was mentioned in Sri Lankan Ayurveda Pharmacopoeia. According to the Pharmacopeia it can use for the various kind of digestive disorders like Panu Vamana, Atīsāra, Ajīrna, Agnimāndya and Udaraśūla in infants and children. There are no standard values for traditional and Ayurveda herbal drug preparations. Therefore efficacy of same drugs are variable for product to product. This study was aimed to prepare standard parameters for selected drug. The drug was prepared according to original preparation method and WHO standard methods. Then it was studied morphologically and was identified its organoleptic characters such as appearance, color, odor and taste using five senses. After that drug was analyzed by using standard methods according to the WHO guidelines and recommendations of Central Council for Research in Ayurveda and Siddha (CCRAS). As physic chemical properties moisture content, pH value, total ash values and fluid extractives values were identified. According to the findings, it was pill in appearance, dark brown color, aromatic odor and Tikta taste. Observed moisture content was 38.2015%, total ash value was 18.0930%, water soluble ash value was 9.4864%, acid insoluble ash value was 3.4080%, water extractive value was 30.7316% and ethanol extractive value was 18.8840%.

KEYWORDS: Balaroga, PanuVamana, Standardization, Traditional drug.

INTRODUCTION

Sri Lankan traditional medical system has long history. *Guli - Kalka* and *Dalu Anupana* are most prominent drugs in this system. *Dalu Paņu Guliya* is a one of them and it already was mentioned in Sri Lankan Ayurveda Pharmacopeia. According to the Ayurveda pharmacopeia it can be used for the diseases of digestive system like *Paņu Vamana*, *Atīsāra*, *Ajīrṇa*, *Agnimāndya* and *Udaraśūla* in infants and children. It is a pure herbal drug and it was included eighteen herbals. Most of them can found in easily and very common in Sri Lankan tradition. (1)

Formula of the drug

Kohomba ata mada and Kohomba dalu (Seeds and leaves of Azadirachta indica Linn.), Kumburu ata mada and Kumburu dalu (Seeds and leaves of Caesalpinia bonduc Linn.), Asamodagam (Trachyspermum involucratum Linn.), Sudulunu (Allium sativum Linn.), Kansa ata and Kansa dalu (Seeds and leaves of Cannabis sativa Linn.), Dehi dalu (Leaves of Citrus aurantifolia Linn.), Nika dalu (Leaves of Vitex negundo Linn.), Tippili (Piper longum Linn.), Sadikka and Vasavasi (Myristica fragrans Houtt.), Lunudehi ata mada (Seeds of Citrus limon Linn.), Suduru (Cuminum cymimum Linn.), Karambu (Syzygium aromaticum Linn.), Kaluduru (Nigella sativa Linn.) and Perunkayam (Ferula foetida Regel.)⁽¹⁾

Preparation base

Dehi Ambul - Juice of Citrus aurantifolia Linn.

Anupana: Dehi Ambul – Juice of Citrus aurantifolia Linn.

Dosage form: Pills

Strength: 250mg (1 *Manchadi*) **Dose:** 1-4 pills and twice a day

Standardization of herbal formulations is essential to assess quality of drugs. The quality assessment of herbal formulations is important to justify their acceptability and safety. One of the major problems faced by the Traditional and Ayurveda medical practitioners is the unavailability of unique of quality control parameters for herbal medicine and their formulations. Majority of Traditional and Traditional practitioners use traditional preparations for their treatment purposes made by them. So it is necessary to improve safety of herbal drugs by developing certain quality control parameters and by following the WHO guidelines for herbal medicines. Our ancient books has been mentioned many methods to standardize the drug and also about adulteration. Now days, old methods are necessary but there are lot of limitations to these methods due to shortage of many drugs, unavailability or limited source, adulteration, lack of knowledge of drug identification and adverse effects of drugs.

There are different newer techniques to standardize raw materials and finished products. This can be achieved only if herbal products are evaluated and analyzed using sophisticated modern techniques standardization such as UV visible, TLC, HPTLC, GCMS, Spectrofluorometric and other methods as Phyto-chemical constituents, Fingerprinting content, appearance, pH,

viscosity, refractive index, saponification value and spread ability etc. (2)

According to the CCRAS recommendations, following analytical tests should apply standardization of Vati, Varti and Guggulu (Pills). Those are Organoleptic characters, Identification, Hardness, Disintegration time, Melting temperature, Uniformity of weight, Loss on drying at 105°C, Total ash/Acid insoluble ash, resin content (For Guggulu), Water soluble/Alcohol soluble extractive. Test for heavy toxic materials. Microbial contamination and Shelf life. Therefore in this study Extractive values in different solvents, Total Ash value, Acid insoluble Ash value and Water soluble Ash value, Moisture content (loss on drying), pH values (1% and 10% solutions), Fluorescence analysis (TLC finger print) were analyzed as per the standard methods for the selected drug. (3,4)

Any researches related to the safety and efficacy of the *Dalu Paṇu Guliya* didn't have conducted. So, standardization of this drug is a very important thing.

Aims and objectives

This is an individual drug analysis. Therefore can't prepare the standard parameters. This study was aimed to prepare the standard parameters for the preparation of the selected drug via further analysis. (Because this a preliminary study.)

METHODOLOGY

There were three main steps in the methodology. Those were identification of the drug formula, preparation of the drug according to the pharmacopeia and organoleptic and physic chemical analysis of the drug according to the WHO guidelines.

Identification of the drug formula: Main ingredients of the drug was mentioned in Sri Lankan Ayurveda Pharmacopeia, Volume 1. All the ingredients were herbal and those should be taken in dry form. Drug preparation base was juice of *Citrus medica* Linn. Dosage form was pill and strength was 250mg.

Preparation of the drug

All the ingredients were collected at raw material was authenticated from Botany unit in Bandaranaike Memorial Ayurveda Research Institute. Foreign materials were removed manually. Then the sand and remaining foreign materials were removed by washing with water. After that the raw materials were dried under the sunlight separately. Dried raw materials were separately ground and powdered as fine powder by using grinding machine. After that was obtained juice from the *Citrus medica Linn*. All the powders of ingredients were mixed together and ground with juice of *Citrus medica Linn*. by using grinding stone. Finally the pills were prepared by pills preparing machine at Ayurveda Drug Co-operation.

Pharmacognostic study of the drug

There are two types of analytical study. Those are identification of organoleptic characters Determination of physicochemical parameters. Prepared Dalu Paņu Guliya was studied morphologically and was identified its organoleptic characters such as appearance, color, odor and taste using five senses. The herbal drugs were standardized according to WHO guidelines and other pharmacopoeial procedures. Physicochemical standardization which includes Extractive values in different solvents, Total Ash value, Acid insoluble Ash value and Water soluble Ash value, Moisture content (loss on drying), pH values (1% and 10% solutions), Fluorescence analysis (TLC finger print) were analyzed as per the standard methods. (Anonymous, 1998; Khandelwal 2007, WHO, 2011)

Pharmacognostic study was done in Bandaranaike Memorial Ayurvedic Research Institute (BMARI), Maharagama in Sri Lanka.

RESULTS OF DRUG ANALYSIS

Determination of Moisture content of the drug

Loss on dying is the loss of mass expressed as percent w/w. About 2g of dug 2 samples of each powder was accurately weighed in a dried and tared flat weighing disk and dried at 105° C for 5hrs. Percentage was calculated with reference initial weight.

Table 1: Moisture content	(Loss on drying) of <i>Dalu I</i>	Paņu Gu	liya
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			Loss on drying						
Drug	Samples	Initial	Sample	Final Weight	Final Weight	Final Weight	Constant	Percentage of Loss on drying	
	Š	Weight (g)	Weight (g)	(g) After 5hrs	(g) After 2hrs	(g) After 1hr	Weight (g)	(W/w %)	
01	1	73.3458	2.0919	74.5755	74.5787	74.5912	74.5912	40.4608	
02	2	83.0775	2.0557	84.3472	84.3604	84.3681	84.3681	37.2185	
03	3	72.0530	2.0972	73.3541	73.3663	73.3758	73.3758	36.9254	
				Mean	Value 38.2015 ±	1.5			

Determination of Total Ash value of the drug

1g of powdered material was placed in a suitable tared crucible of silica previously ignited and weighed. The powdered drug was spread into an even layer and weighed accurately. The material was incinerated by gradually increasing the heat, not exceeding 450°C until free from carbon, cooled in desiccators, weighed and percentage ash was calculated by taking in account the difference of empty weight of crucible &that of crucible with total ash.

Table 2: Total Ash Value of Dalu Paņu Guliya

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50		Total Ash Value								
Drug	Initial	Sample	Final Weight	Final Weight	Final Weight	Constant	Percentage of Total			
Ω	Weight (g)	Weight (g)	(g) after 5hrs	(g) after 2hrs	(g) After 1hr	Weight (g)	Ash (W/w %)			
A	11.7951	1.5030	12.0704	12.0655	12.0656	12.0656	17.9973			
В	12.5333	1.5041	12.8105	12.8075	12.8073	12.8073	18.2167			
С	10.8662	1.5046	11.1390	11.1375	11.1376	11.1376	18.0380			
D	11.3575	1.5041	11.6341	11.6308	11.6309	11.6309	18.1770			
E	23.5917	1.5077	23.8673	23.8645	23.8646	23.8646	18.1004			
F	22.5846	1.5048	22.8575	22.8560	22.8559	22.8559	18.0290			
			Mean	Value 18.0930	± 0.07					

Determination of Water soluble Ash Value of the drug

The ash obtained as above was boiled for 5min with 25ml of dilute Water; the insoluble matter was hot water and collected on an ash less filter paper, washed with ignited to constant weight. The percentage of water-insoluble ash with reference to the air-dried drug was calculated.

Table 3: Water soluble Ash Value of Dalu Paņu Guliya

	Water soluble Ash		soluble Ash					
Drugs	Total Ash	Water Soluble Ash	Percentage of Water soluble Ash (W/W %)					
A	0.2705	0.1427	9.4943					
В	0.2740	0.1405	9.3411					
С	0.2714	0.1448	9.6238					
	Mean Value 9.4864 ± 0.15							

Determination of Acid Insoluble Ash Value of the drug

The ash obtained as above was boiled for 5min with 25ml of dilute hydrochloric acid; the insoluble matter was hot water and collected on an ash less filter paper, washed with ignited to constant weight. The percentage of acid-insoluble ash with reference to the air-dried drug was calculated.

Table 4: Acid Insoluble Ash Value of Dalu Panu Guliya

	Acid Insoluble Ash						
Drugs	Total Ash	Acid Insoluble Ash	Percentage of Acid insoluble Ash (W/W %)				
D	0.2734	0.0551	3.6633				
E	0.2729	0.0394 DAPI	2.6132				
F	0.2713	0.0594	3.9474				
	Mean Value 3.4080 ± 0.53						

• Determination of PH value at temperature

The pH of different formulations in 1% w/v and 10%w/v of water soluble portions were determined using pH meter.

Table 5: PH value of Dalu Panu Guliya

Sample No.	Formulations	P ^H Value at Temperature			
Sample No.	rormulations	1% Solution	10% Solution	4 Pills	
01	VVK Sample-1	7.25 at 34.2°C	7.05 at 34.4°C	7.02 at 34.0°C	
02	VVK Sample-2	7.25 at 34.2°C	6.09 at 34.1°C	7.35 at 34.1°C	

Determination of Water Extractive value of the drug

2.5g of coarsely powdered air-dried drug was macerated with 50ml of water in a closed flask for twenty-four hours, shaking frequently during six hours and allowed to stand for eighteen hours. It was then filtered rapidly, taking precautions against loss of solvent. 25ml of the filtrate was evaporated to dryness in a tared flat bottomed shallow dish at 105°C to constant weight and weighed. The percentage of water-soluble extractive was calculated with reference to the air-dried drug and is represented as % value.

Table 6: Water Extractive Value of Dalu Panu Guliva

Table 0. Water Extractive value of Duta Fund dullyu						
	Water Extractive Value					
Drugs	Solvent	Initial Weight	Amount of	Final Weight	Extractive Value	
		of Sample (g)	Solvent (ml)	of Sample (g)	(%)	
Sample 1	Water	2.5000	50	0.3973	31.7840	
Sample 2	Water	2.5001	50	0.4723	37.7825	
Sample 3	Water	2.5013	50	0.283	22.6282	
Mean Value 30.7316 ± 5.4						

• Determination of Ethanol Extractive value of the drug

2.5g of coarsely powdered air-dried drug was macerated with 50ml of alcohol in a closed flask for twenty-four hours, shaking frequently during six hours and allowing standing for eighteen hours. It was then filtered rapidly; taking precautions against loss of solvent. 25ml of the filtrate was evaporated to dryness in a tared flat-bottomed shallow dish at 105°C to constant weight and weighed. The percentage of alcohol-soluble extractive was calculated with reference to the air-dried drug and is represented as % value.

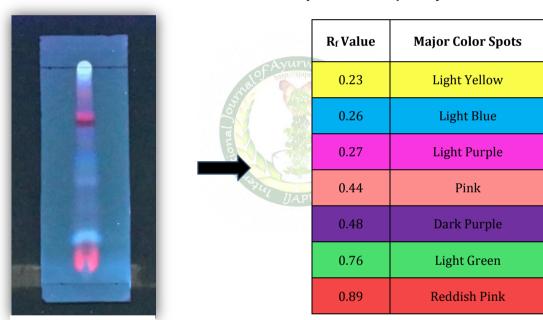
Table 7: Ethanol Extractive Value of Dalu Paņu Guliya

	Ethanol Extractive Value						
Drugs	Solvent	Initial Weight	Amount of	Final Weight	Extractive		
	Solvent	of Sample (g)	Solvent (ml)	of Sample (g)	Value (%)		
Sample 1	Ethanol	2.5015	50	0.2521	20.1560		
Sample 2	Ethanol	2.5009	50	0.2402	19.2160		
Sample 3	Ethanol	2.5000	50	0.2160	17.2800		
	Mean Value 18.8840 ± 1.06						

• Fluorescence analysis (TLC Finger-print) of the drug

The fluorescents analysis of powder sample treated with different chemical reagents. The color of the extracts from organic and inorganic solvent were observed both under ordinary and UV light (254nm), (356nm) in a UV chamber. There is little difference between extracts and the light sources. It can be as a diagnostic tool for testing the adulteration. 1mg of powdered drugs of both formulations was exposed to ultraviolet at wave length of reagents.

Table 8: Fluorescence analysis of Dalu Paņu Guliya



TLC Finger-print

Toluene: Ethyl Acetate 3.5: 1.5 (Under UV light 365nm)

Determination of Organoleptic characters

Powder of the drug was studied morphologically and identified its Appearance, Color, Odor and Taste using five senses. **Table 9: Organoleptic Characters of** *Dalu Panu Guliya*

	Sample Formulations		Appearance Color		Taste	Odor
Ī	01	Dalu Paņu Guliya	Pill	Dark Brown	Tikta	Aromatic

DISCUSSION

In field of drug research there is large scope for Ayurveda researchers and can play the lead role in production of standardized safety and more efficacy Ayurveda and Traditional drug formulations. This can be achieved only if the herbal products are evaluated and analyzed using sophisticated modern techniques. These guidelines for the assessment of herbal medicines are intended to facilitate the work of regulatory authorities,

scientific bodies and registration of such products. The advancement of analytical techniques will serve as a rapid and specific tool in the herbal research, thereby, allowing the manufacture to set quality standards and specifications so as to seek marketing approval from regulatory authorities for therapeutic efficacy, safety and self-life of the herbal drug.

Now a day's Ayurveda and Traditional practitioners are totally depends upon mediators for drug collection. Proper identification of drug, adulteration and availability are major problems faced by herbal industry. Actual availability of drug and finished products which are available in market. Some practitioners prepare their own medicines, so raw drugs used and quality of product which is prepared differs and it is questionable. So it is necessary to conduct uniform rules for preparing drug.

CONCLUSION

According to the findings, it can concluded that *Dalu Paṇu Guliya* is a pill in appearance, dark brown color, aromatic odor and *Tikta* taste. Observed moisture content should be 38.2015%, total ash value should be 18.0930%, water soluble ash value should be 9.4864%, acid insoluble ash value should be 3.4080%, water extractive value should be 30.7316% and ethanol extractive value should be 18.8840%.

SUGGESTIONS AND RECOMMENDATIONS

To make same samples according to the methods in the text and conduct above same manner to analyze the drug.

Then prepare a WHO standard value for the standardization and overall therapeutic effect of pill can be evaluated by using animal and clinical studies as well as laboratory investigations.

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*Address for correspondence Dr G.U.A. Kumara

Department of Kaumarabhritya and Striroga, Gampaha Wickramarachchi Ayurveda Institue, University of Kelaniya, Yakkala, Sri Lanka.

Email: guakumara@gmail.com

Ph: +94 716 774 587 +94 767 677 458