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Research Article

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Physio Chemical Standardization of the Siddha Formulation – Kadukkai Vadagam

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ABSTRACT

Siddha system of medicine is one among the tradition system of India. This system having lot of medicines which are prepared from raw drugs of Herbal, Metal, Mineral and Animal origins. There are so many herbal, herbo-mineral formulations are available in Siddha system of medicine to treat Bronchial asthma effectively. One of the poly herbo mineral preparations 'Kadukkai Vadagam'(KV) has been recognized as effective treatment for Swasakaasam (Bronchial asthma) mentioned in Siddha classical literature. But this drug formulation is not yet validated scientifically. In the Physiochemical analysis studies, KV has contains Total ash 15.12%, Water soluble ash 3.13%, Acid insoluble ash 0.68%, Water soluble extractive 44.00%, Alcohol soluble extractive 45.81%. Scanning Electron Microscope analysis shows that the particle size was 2 – 5 µ. ICP-OES (Inductively Coupled Plasma Optical Emission Spectroscopy) shows that the formulation is extremely safe as it contains heavy metals below detectable limits.

Keywords: Siddha Medicine; Kadukkai Vadagam; Swasakaasam; Physiochemical analysis; SEM analysis

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INTRODUCTION

Natural products, including plants, animals and minerals have been the basis of treatment of human diseases. History of medicine dates back practically to the existence of human civilization. Historically, the majority of new drugs have been generated from natural products (secondary metabolites) and from compounds derived from natural products [1,2]. The discovery of the connection between plants and health is responsible for the beginning of a new generation of treatments, including drugs derived from plants, the use of the plant itself or its parts, supplementary diets and functional foods. Nowadays the use of herbal drugs is increased to that of conventional medicine about two to third times [3]. Several drugs with Bronchial asthma action were isolated from medicinal plants for respiratory problems, such as atropine, theophylline and chromoglycates. Therefore, the Siddha system of medicine is still a valuable source of new anti- asthma therapeutics.

Today, nature has distinguished itself as a source of new active agents for a wide variety of diseases. In the past 25 years, including new drugs approved, approximately 30% are natural products or their derivatives. There are so many herbal, herbo-mineral formulations are available in Siddha system of medicine to treat Bronchial asthma effectively. As per Siddha text Swasakasam is correlated with Bronchial asthma [4]. One of the poly herbo mineral preparations 'Kadukkai Vadagam' has been recognized as an effective treatment for Bronchial asthma mentioned in

Siddha classical literature "Athmaratchamirtha Vaidhiya Saara Sangiragam (part-2)" of Kandasamy Mudaliyar [5]. It is used with increasing frequency in recent years. But this drug formulation is not yet validated scientifically. The physiochemical standardization of this drug is step by step process as per standard methods [6]. Hence, an attempt was made to find out the good possibilities of therapy and hope for further good clinical research in this area, Kadukkai Vadagam was selected for my dissertation topic to validate its therapeutic potential and safety profile through various Physio-chemical, instrumental analysis like Scanning Electron Microscope and ICP-OES. This instrumental analysis is reliable and gives faster data screening [7].

MATERIALS AND METHODS

The Ingredients of the drug are Kadukkai (Terminalia chebula), Kalluppu (Sodium chloride), Korai kizhangu (Cyperus rotandus), Kurochani omam (Hyoscyamus niger), Chukku (Zingiber officinale), Kodiveli Ver (Plumbago indica), Thippili (Piper longum), Chevuiyam (Root of Piper nigrum), Thippili moolam (Root of Piper longum), Milagu (Piper nigrum), Induppu (Sodium chloride impura), Omam (Carum copticum), Inji charu (Zingiber officinale), Elumichai charu (citrus lemon), and Butter milk. All the raw materials were identified and authenticated by the experts of Gunapadam Department, Government Siddha medical college, Arumbakkam, Chennai-106. The specimen sample of all the raw drugs have been preserved in PG Gunapadam department individually for future reference. (Reg:GSMC/PG GM/0029-43/2014-2017). All the raw materials were purified individually as per the Siddha literature [6]. After purification all the processed raw materials ground with ginger juice. This process was repeated with lemon juice and butter milk respectively and made it into pills as mentioned in text. Then the pills were carried out into following analysis.

Physico-Chemical Analysis

One Physicochemical studies like total ash, water insoluble ash, acid Insoluble ash, loss on drying at 105°C and pH were done at Siddha Central Research Institute, Chennai [8].

Organoleptic Evaluation

The Organoleptic characters of the sample were evaluated which include evaluation of the formulation by its colour, odour, size etc [9,10].

Colour examination
Ten tablets were taken into watch glasses and positioned against white back ground in white tube light. Its color was observed by naked eye and the results were noted.

Odour examination
Ten numbers of tablets were smelled individually. The time interval among two smelling was kept two minutes to overturn the effect of previous smelling. Odour of Kadukkai Vadagam was noted.

Size examination
The diameter of ten tablets was measured by Vernier caliper. The mean value of diameter was noted.

Solubility test
A pinch of the sample KV was taken in a dry test tube and shaken well with distilled water. A little amount of the sample KV is shaken well with conc. Hcl and then conc. H_2SO_4. The solubility was observed.

Determination of total ash
About 2 g of the ground drug KV was accurately weighed in a silica dish and incinerated at a temperature not exceeding 450° until it was free from carbon, cooled and weighed. The percentage of ash with reference to the air-dried drug was calculated [11,12].

Determination of water soluble ash
Total ash was heated up to 600°C with 25 ml of distilled water for 10 minutes. The residue was ignited in the furnace to get a constant weight and the weight was calculated.

Determination of acid insoluble ash

The ash obtained was boiled for 5 minutes with 25 ml of dil. Hcl and insoluble matter was collected in an ash-less filter paper, washed with hot water and put up in flames to constant weight. The percentage of acid-insoluble ash with reference to the air dried drug was noted.

Determination of moisture content (Loss on Drying)

This procedure was done to determine the amount of volatile matter in the drug. A sample of 10 gram of the drug KV was placed in a tarred evaporating dish after accurately weighting without preliminary drying. The dish was dried at a temperature of 105°C for about 5 hours and again weighed. The drying and weighing procedure was repeated again and again until the difference between two successive weights was not more than 0.25%. And the weight was calculated [13].

pH value

Potentiometrically pH value was determined by a glass electrode and a pH meter. The pH of the *KV* was noted

Tablet disintegration test

Each *KV* was placed in each of the six tubes of the basket present in the disintegration apparatus. The apparatus was operated by using water as the immersion fluid maintained at 35-39 °C. At the end of the 30 min, the basket is lifted from the fluid and the state of the tablet is observed. The disintegration time of *KV* was recorded [14,15].

INSTRUMENTAL ANALYSIS

The drug (*Kadukkai Vadagam*) sample was analysed by the Inductively Coupled Plasma Optical Emission Spectroscopy (ICP-OES) to detect the trace elements and other elements quantitatively [10]. The digested sample solution was shifted into plastic containers and labelled properly. It was completed in Bio-chemistry lab, Govt. Siddha Medical College, Chennai-106.

In scanning electron microscope (SEM) high-energy electron beam is focused through a probe towards the sample material [10]. This study gives the information about the sample and it includes external morphology, texture, its crystalline structure, chemical composition and it displays the shape of the sample (Figures 1 and 2).

RESULTS

by condensation reaction. The curcumin analogues synthesized were subjected to *in vitro* antioxidant activity test (Tables 1-4).

Table 1: Organoleptic characterization of *Kadukkai Vadagam*

S.No	Parameter		Results
1.	Colour		Dark Brown
2.	Odour		Citrus smell
3.	Taste		Sour in taste
4.	Sense of touch		Hard
5.	Size		1 cm
6.	Solubility		
	i	Distilled water	Soluble
	ii	Benzene	Soluble
	iii	Chloroform	Soluble
	iv	Carbon tetra chloride	Soluble
	v	Xylene	Soluble

	vi	Petroleum ether	Soluble
	vii	Propylene glycol	Not Soluble

Table 2: Physiochemical analysis

S.No	Parameter	Result
1.	PH	3.93
2.	Total Ash	15.12%
3.	Acid Insoluble ash	0.68%
4.	Water soluble ash	3.13%
5.	Loss on drying at 105^{0}C	14.22%
6.	Water soluble Extractive	44.00%
7.	Alcohol soluble Extractive	45.81%
8.	Disintegration time	24 min

SEM (Scanning Electron Microscope with Energy Dispersive X-Ray Analysis)

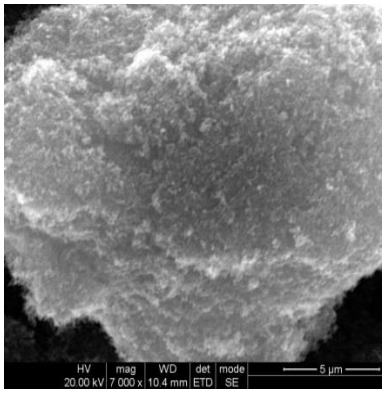

Figure 1: Shows particle size of the *KV* in SEM analysis

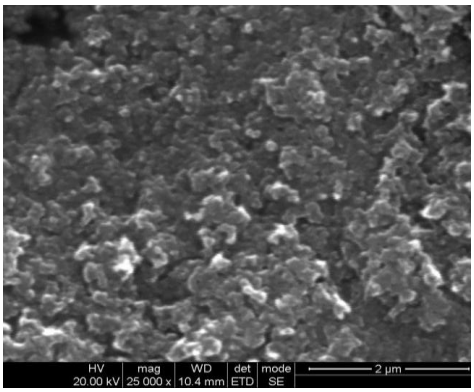

Figure 2: SEM images shows the partical size of *KV is 2 – 5*µ

ICP-OES (Inductively Coupled Plasma Optical Emission Spectroscopy)

The drug (Kadukkai Vadagam) sample was analysed by the Inductively Coupled Plasma Optical Emission Spectroscopy (ICP-OES). The result of ICP-OES is given on the Table 3.

Table 3: ICP-OES of Kadukkai Vadagam

S. no	Elements	Wavelength (nm)	*Kadukkai Vadagam 100 mg*
1	Al	396.152	BDL
2	As	188.979	BDL
3	Cd	228.802	BDL
4	Cu	327.393	BDL
5	Hg	253.652	BDL
6	K	766.491	53.820 mg/L
7	Na	589.592	04.300 mg/L
8	Ni	231.604	BDL
9	Pb	220.353	BDL
10	P	213.617	225.740 mg/L
11	Al	396.152	BDL
12	As	188.979	BDL
13	Cd	228.802	BDL
14	Cu	327.393	BDL

BDL: Below Detectable Limit
%=10000 ppm,
1ppm=1/1000000 or 1 ppm=0.0001%
The toxic metals and the permissible limits

Table 4: The toxic metals and the permissible limits

Heavy metals	WHO and FDA limits
Arsenic (As)	10 ppm
Mercury (Hg)	1 ppm
Lead (Pb)	10 ppm
Cadmium (Cd)	0.3 ppm

DISCUSSION

The pH of KV is weak acidic in nature. Being weak acidic, the drug is more readily absorbed in an acid medium like stomach which enhance the bio availability of the drug. Total ash value will determine the amount of minerals and earthy materials present in the drug. The quality of the drug is better if the acid insoluble ash value is low. The water

soluble ash value which represents easy facilitation of diffusion and osmosis mechanism. Loss on Drying indicates the amount of volatile substance and moisture present in the drug. This also indicates the stability and shelf life of the drug. Being a Vadagam, without incineration process, the moisture content is slightly high. The less value of moisture content could prevent bacterial, fungal or yeast growth [16,17]. The SEM reveals the micro size particle of the sample can be easily manipulated to achieve both passive and active drug targeting. ICP-OES reveals high concentration of Phosphorous in Kadukkai Vadagam. It also possess Na and K. Phosphorous is also used in treating Bronchial asthma with symptoms of accumulation of mucus in the bronchi, dyspnoea and the sensation of heat in the chest, aetiology being temperature changes in atmosphere. Bichromate form of potassium relieves hyper production of mucus [18].

CONCLUSION

The ingredients of the trial drug was identified and authenticated by the experts of Gunapadam Department. By the classical methods, ingredients of the trial drug Kadukkai Vadagam were purified and the drug was prepared. In the purification process toxins were eliminated and increase its efficacy. In the grinding process, particle size of the drug became into nano particle for its better bio availability.

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