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Standardization Of Classical Siddha Polyherbal Formulation "*Kuruthi Azhalukku Chooranam*" (For Hypertension) Through Organoleptic Character, Physicochemical, Biochemical and Heavy Metal Analysis.

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Abstract

To establish the scientific basis of analysis of "*Kuruthi Azhalukku Chooranam"*, a polyherbal formulation being used for Hypertension mentioned in a *Siddha literature "Yugi Vaithiya Sinthamani".* The global market for Siddha formulations seems remarkable but the need of the hour is to ensure the standard of preparation. Starting from Raw material to finished product the quality and purity of the product as to be ascertained. To study the physicochemical, Biochemical, and Heavy metal analysis for the drug "*Kuruthi Azhalukku Chooranam".* The drug for prepared as per the method mentioned in classical *Siddha* literature *"Yugi Vaithiya Sinthamani".* The ingredients such as Thalisapatri, Kadugu, Thiripalathy, Elam, Krambu, Jathipatri, Sarkkarai. The drug is subjected to physicochemical, Biochemical, and Heavy metal analysis. The organoleptic character of *Kuruthi Azhalukku Chooranam* was Brown in color with a characteristic odor and moderately coarse, Rough-in-touch, Free-flowing properties. Physico-chemical analysis shows the Loss on drying at 105°C (10 ± 1.47), Total Ash (11.17 ± 0.56), Acid insoluble Ash (0 ± 0), Water soluble extractive (18.47 ± 0.32), Alcohol soluble extractive (7.3 ± 0.721) and the pH value 7.5. The qualitative analysis of the sample through Biochemical analysis reveals the presence of Carbonates, Sulfates, Lead, and Arsenic. Heavy metals of lead, cadmium, arsenic, and mercury are observed below the detection limit. The preliminary safety and quality of *Kuruthi Azhalukku Chooranam* have been confirmed and authenticated through this study and this herbal-based drug improves the quality of human life.

Key words: Siddha, Standardization, Physicochemical, Kuruthi azhalukku chooranam, Biochemical, Heavy metal.

Introduction

In this modern world, all diseases are linked with the way, people lead their lives, and they are called lifestyle diseases. Over 61% of all deaths in India are due to lifestyle or non-communicable diseases. Lifestyle diseases include Atherosclerosis, Heart disease, Hypertension, stroke, Obesity, Diabetes, Colon cancer, etc. Getting away from nature causes lifestyle diseases. So getting into our nature through herbal medicine is the only best way to come out of these problems. *Siddha* system of medicine is an ancient and transcending system of medicine given by the *Siddhars* the greatest scientists in the ancient period. The basic emphasis of the *Siddha* system is to treat as well as prevent diseases by careful dieting and proper relaxation of mind to achieve a totality of health, that assures not only longevity but also immortality. Hypertension is one of the leading noncommunicable diseases that affects people worldwide. Although so many conventional drugs are available for high blood pressure in modern medicine, still people are in search of traditional herbal medicines due to their safety and efficacy. The different constituents in herbal medicine play a multitarget and synergistic role in the treatment of hypertension. Prevalence Worldwide: An estimated 1.28 billion people worldwide have hypertension, most (2/3) living in low and middle-income countries[1]. In India: The overall prevalence of hypertension in India was 29.8%. About 33% of urban and 25% rural Indians are hypertensive[2]. In Tamilnadu: An estimated 21.4% of people in Tamilnadu have hypertension. *Kuruthi azhalukku chooranam* is a *Siddha* polyherbal formulation mentioned for hypertension in classical *Siddha* literature. To standardization and documentation of the drug *Kuruthi Azhalukku Chooranam* for the management of hypertension (*Athi kuruthi azhutham*).

Materials and methods:

Selection of the drug:

The test drug *Kuruthi Azhal Chooranam* is a polyherbal formulation specifically mentioned in classical *siddha* literature *Yugi Vaithiya sinthamani (perunool 800) mudhal bhagam, Pg.no: 252,* for hypertension is supposed to possess fewer side effects with the more potent anti-hypertensive property.

Ingredients:

Table No: 1 Ingredients of Kuruthi Azhalukku Chooranam

S.No	Name of the drug	Scientific name	Quantity
1.	*Thalisapatri*	*Abies spectablis*	1 palam (35gm)
2.	*Kadugu*	*Brassica juncea*	1/4 palam (8.75gm)
3.	*Kadukkai*	*Terminalia chebula*	1/4 palam (8.75gm)
4.	*Neellikai*	*Phylanthus emblica*	1/4 palam (8.75gm)
5.	*Thandrikkai*	*Terminalia bellerica*	1/4 palam (8.75gm)
6.	*Elam*	*Elettaria cardamomum*	1/4 palam (8.75gm)
7.	*Krambu*	*Syzygium aromaticum*	1/4 palam (8.75gm)

8.	*Jathipatri*	*Myristica fragrans*	1/4 palam (8.75gm)
9.	*Sarkkarai*	*Saccharum officinarum*	3 palam (105gm)

Collection of the raw drug

The raw drugs *Thalisapatri (Abies spectablis), Kadugu (Brassica juncea), Kadukkai (Terminalia chebula), Neellikai (Phylanthus emblica), Thandrikkai (Terminalia bellerica), Elam (Elettaria cardamomum), Krambu (Syzygium aromaticum), Jathipatri (Myristica fragrans), Sarkkarai (Saccharum officinarum)* were bought from authenticated raw drug store, Chennai, Tamil Nadu.

Recognition and Authentication of the drug:

All drugs were recognized and authenticated by Gunapadam experts in Government Siddha Medical College, Arumbakkam, Chennai. The identified product samples were maintained in the PG Gunapadam laboratory for future reference.

Ingredients

Fig.No: 1. Ingredients of Kuruthi Azhalukku Chooranam

THALISAPATRI

Abies spectablis

THANDRIKKAI

Terminalia bellerica

KADUGU

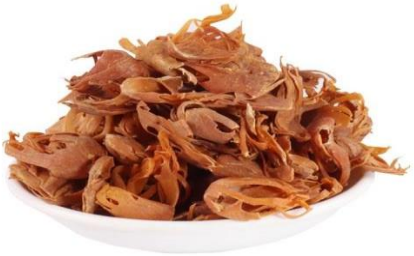
Brassica juncea

ELARISI

Elletaria cardamomum

JATHIPATRI

Myristica fragrans



NELLIKKAI

Phyllanthus emblica

KADUKKAI

Terminalia chebula

KRAMBU

Syzygium aromaticum

SAKKARAI

Saccharum officinarum

Purification of the drug:

Purification process were done as per classical *Siddha* literature (*Sarakkugalin suthi sei muraigal)*

Method of Preparation:

The above-given ingredients were taken in the mentioned quantity and pounded into fine powder. Sieved the powder in a thin cotton cloth, then stored it in a clean air-tight container named *Kuruthi Azhalukku Chooranam.*

Purification of the Chooranam:

Pittaviyal murai (Steaming process):

The *Kuruthi azhalukku chooranam* was purified by the Pittaviyal method as per Siddha literature. A mud pot was taken and it was half filled with a mixture of milk with an equal quantity of water. The mouth of

the pot was sealed with a cloth. This chooranam was placed over the cloth and tied firmly around the mouth of the mud pot by another pot. The gap between mud pots was tied with a wet cloth to avoid evaporation. The mud pot was kept on fire and boiled until the cow's milk 3 /4 part was reduced in the lower pot. The same drug was later dried and powdered then sieved again. It was used for further study.

Storage of the drug:

The prepared test drug was stored in a clean, dried, air tight container. The contents were explored frequently to avoid moisture and microbes.

Drug profile:

Route of Administration: Oral route

Dose: Mooviral alavu (800-1000mg) twice a day

Adjuvant: Luke Warm water

Indication: Kuruthi Azhal (Hypertension)

Standardization of the drug

Standardization of drugs brings the validation to be used as a medicine by subjecting the drug to many analyses and determining its quality and effectiveness. Standardization includes many studies such as its organoleptic properties, physical characteristics, and phytochemical properties and also to assess the active principles and elements present in the drug. Thus, standardization brings the safety and efficacy of the drug.

Organoleptic properties:

The state, nature, odor, feel, flow property, physical appearance, and taste were noted from the prepared drug *Kuruthi Azhalukku Chooranam*.

Physicochemical analysis[6,7]:

Percentage Loss on Drying

The test drug was accurately weighed in an evaporating dish. The sample was dried at 105℃ for 5 hours and then weighed.

Determination of Total Ash

The test drug was accurately weighed in a silica dish and incinerated in the furnace at a temperature of 400℃ until it turned white in color which indicates the absence of carbon. The percentage of total ash will be calculated according to the weight of the air-dried drug.

Determination of Acid Insoluble Ash

The ash obtained by the total ash test will be boiled with 25 ml of dilute hydrochloric acid for 6 mins. Then the insoluble matter is collected in a crucible and will be washed with hot water and ignited to constant weight. The percentage of acid-insoluble ash will be calculated according to the weight of air-dried ash.

Determination of Alcohol Soluble Extractive

The test sample was macerated with 100 ml of Alcohol in a closed flask for twenty-four hours, shaking frequently for six hours, and allowing it to stand for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat-bottomed shallow dish, and dry at 105℃, to constant weight and weight. Calculate the percentage of alcohol-soluble extractives regarding the air-dried drug.

Determination of Water Soluble Extractive

The test sample was macerated with 100 ml of chloroform water in a closed flask for twenty-four hours, shaking frequently for six hours, and allowing it to stand for eighteen hours. Filter rapidly, taking precautions against loss of solvent, evaporate 25 ml of the filtrate to dryness in a tared flat-bottomed

shallow dish, and dry at 105°C, to constant weight and weight. Calculate the percentage of water-soluble extractives regarding the air-dried drug.

pH determination

The required quantity of test sample was admixed with distilled water and subjected to screening using a pH meter.

Biochemical analysis:

5 gm of *Kuruthi Azhalukku Chooranam* was dissolved with 50 ml of distilled water. Boiled well for 10 minutes and cooled. Filtered the extract and made up to 100 ml with distilled water. This preparation was used for the qualitative analysis of acidic/ basic radicals and biochemical constituents in it.

Analysis of Specific Acid Radicals:

Test for Carbonates:

1 ml of the test solution was added with 1 ml of concentration (conc.) HCl. The formation of brisk effervescence indicates the presence of carbonates.

Test for chlorides

2 ml of test solution was added with about 1 ml of silver nitrate solution. The appearance of a White precipitate indicates the presence of chlorides.

Test for sulfates

1 ml of the test sample was added to dilute H2SO4 till effervescence ceased followed by this about 1 ml of barium chloride solution was added. The appearance of a white precipitate indicates the presence of sulfates.

Test for sulfides

1 ml of the test sample about 2 ml of HCl was added with slight warming of the mixture. The formation of colorless gas with the smell of rotten eggs indicates the presence of sulfides.

Test for phosphates

2 ml of test solution treated with 2 ml of Ammonium molybdate solution followed by the addition of 2 ml of concentrated nitric acid. The formation of yellow precipitate Indicates the presence of phosphates.

Test for Fluoride and Oxalate

2 ml of the test solution about 2 ml of dil acetic acid and 2 ml of Calcium chloride solution was added. The formation of a white precipitate Indicates the presence of Fluoride/ Oxalate

Test for Borates

2ml of the test solution was added with sulphuric acid and 95% alcohol followed by exposure to flame. The appearance of green flame Indicates the presence of Borates.

Test for Nitrates

0.5 ml of test solution heated with copper turning followed by the addition of sulphuric acid. The appearance of reddish-brown gas Indicates the presence of Nitrates.

Analysis of Specific Basic Radicals:

Test for Lead

1 ml of the test solution added with 2 ml of potassium chromate solution. The formation of a yellow precipitate indicates the presence of lead.

Test for Arsenic

1 ml of the test solution added with 2 ml of 10% (2N) sodium hydroxide (NaOH) solution. The formation of a brownish-red precipitate indicates the presence of Arsenic.

Test for Mercury

1 ml of the test solution added with 2 ml of 10% (2N) sodium hydroxide (NaOH) solution. The formation of a yellow precipitate indicates the presence of mercury.

Test for Copper

1 ml of the test solution added with 1 ml of Ammonium hydroxide (NH4OH) solution. The formation of a blue precipitate indicates the presence of copper.

Test for Ferric

1 ml of test solution and about 2 ml of potassium ferrocyanide was added. The formation of a blue precipitate indicates the presence of ferric.

Test for Ferrous

1 ml of test solution, and about 1 ml of potassium ferricyanide solution were added. The formation of a blue precipitate indicates the presence of ferrous.

Test for Zinc

1 ml of the test solution added with 2 ml of sodium hydroxide (NaOH) dropwise until indication appears. The formation of a white precipitate indicates the presence of Zinc.

Test for Silver

1 ml of the test solution was added with 1 ml of conc. HCL followed by the appearance of a curdy white precipitate. Boil the precipitate with water. It does not dissolve. Add NH4OH solution in it and add 1 ml dilute HNO3. The formation of a curdy white precipitate indicates the presence of silver.

Test for Magnesium

1 ml of the test solution added with 2 ml of sodium hydroxide (NaOH) dropwise until indication appears. The formation of a white precipitate indicates the presence of Magnesium.

Heavy metal analysis[8]:

The total heavy metal content of the sample was performed by Atomic Absorption Spectrometry (AAS) Model AA 240 Series. To determine the heavy metals such as mercury, arsenic, lead, and cadmium concentrations in the test item. Sample Digestion - The test sample was digested with 1mol/L HCl for determination of arsenic and mercury. Similarly, for the determination of lead and cadmium, the samples were digested with 1 mol/L of HNO3.

Standard preparation: As & Hg- 100 ppm sample in 1 mol/L HCl

Cd & Pb- 100 ppm sample in 1 mol/L HNO3

Result

Organoleptic properties:

Fig.No:2. Prepared form of Kuruthi Azhalukku Chooranam

Table no:2. Organoleptic characters of Kuruthi Azhalukku Chooranam

State	Solid
Nature	Moderately Coarse
Odour	Pleasant smell
Touch	Rough
Flow Property	Free Flowing
Appearance	Brownish
Taste	Hot spiciness

Solubility:

Table no:3. Solubility Profile of Kuruthi Azhalukku Chooranam

S.No	Solvent Used	Solubility / Dispersibility
1	Chloroform	Insoluble
2	Ethanol	Soluble
3	Water	Soluble
4	Ethyl acetate	Insoluble
5	DMSO	Soluble

Physicochemical analysis:

Table no:4. Physicochemical analysis of Kuruthi Azhalukku Chooranam

S.No	Parameter	Mean (n=3) SD
1.	Loss on Drying at 105 °C (%)	10 ± 1.47
2.	Total Ash (%)	11.17 ± 0.56
3.	Acid insoluble Ash (%)	0 ± 0
4.	Water soluble Extractive (%)	18.47 ± 0.32
5.	Alcohol Soluble Extractive (%)	7.3 ± 0.721
6.	pH	7.5

Biochemical analysis of kuruthi azhalukku chooranam

Table no:5. Results of Test for acid radicles

S.No	Specific radical	Observation	Test report
1	Test for Carbonates	Presence of brisk effervescence	Positive
2	Test for chlorides	Absence of White precipitate	Negative
3	Test for Sulfates	The presence of white precipitate	Positive
4	Test for Sulfides	Absence of rotten egg smell	Negative
5	Test for Phosphates	Absence of yellow precipitate	Negative
6	Test for Fluoride and Oxalate	Absence of white precipitate	Negative
7	Test for Borates	Absence of green flame	Negative
8	Test for Nitrates	Absence of reddish brown color	Negative

Table no:6. Results of Test for Basic radicles

S.No	Specific radical	Observation	Test report
1	**Test for Lead**	Presence of yellow precipitate	Positive
2	**Test for Arsenic**	Presence of brownish red precipitate	Positive
3	**Test for Mercury**	Absence of yellow precipitate	Negative
4	**Test for Copper**	Absence of blue precipitate	Negative
5	**Test for Ferric**	Absence of blue precipitate	Negative
6	**Test for Ferrous**	Absence of blue precipitate	Negative
7	**Test for Zinc**	Absence of white precipitate	Negative
8	**Test for Silver**	Absence of curdy white precipitate	Negative
9	**Test for Magnesium**	Absence of white precipitate	Negative

Heavy metal analysis:

Table no:7. Heavy metal analysis of Kuruthi Azhalukku Chooranam

Name of the Heavy Metal	Absorption Max A max	Result Analysis	Maximum Limit
Lead	217.0 nm	0.517	10 ppm
Arsenic	193.7 nm	0.761	3 ppm
Cadmium	228.8 nm	BDL	0.3 ppm
Mercury	253.7 nm	BDL	1 ppm

BDL- Below Detection Limit

Discussion

The organoleptic parameters of *Kuruthi Azhalukku Chooranam* were brown in color with a pleasant odor, moderately coarse, rough in touch, and free-flowing properties (Table 2). Solubility: Here, the drug is highly soluble in water, ethanol, and DMSO; which means increased bioavailability and therapeutic effect (Table 3).

Physico-chemical analysis: Loss on drying: This Chooranam showed the loss on drying at 105°C of 10%, Low moisture content of the prepared drug. The moisture content of the drug indicates stability and shelf life. High humidity can negatively affect the active ingredients of the medicine. Thus, maximum stability and longer shelf life can be achieved with low humidity. Thus, the stability and longer shelf life of chooranam were much better. Total ash: The total ash value determines the amount of minerals and earth substances in the medicine. The total ash content of this Chooranam is 11.17%, which determines the absence of inorganic content. Acid insoluble ash: Acid-insoluble ash content of this Chooranam is 0%. It indicates the absence of silicon-containing substance in the sample. It indicates that the preparation is free from contaminants like sand or dust. Water-soluble extractive: It is a fraction of the total ash value that indicates drug dispersion. Here, the water-soluble extraction value of this Chooranam was 18.47%, indicating easy facilitation of diffusion and osmotic mechanism. Alcohol-soluble extractive: Alcohol-soluble extracts are useful for evaluating drug quality and purity. Here, the alcohol-soluble extract value of this drug is 7.3%. The result revealed that the drug is of good quality and purity and does not require that Chooranam is not adulterated in the crude drug. pH: This drug has a pH of 7.5 (alkaline). A greater amount of the alkaline drug is ionized in nature. This is the reason for better absorption of alkaline drugs from the small intestines[3] (Table 4).

Biochemical Analysis Tests for acid radicals show that carbonate and sulfate are present. Test for basic radicals shows that Lead and Arsenic are present (Table 5&6).

Heavy metals are known to be slowly excreted by the kidneys, which can cause adverse effects in humans even at very low concentrations. Heavy metals can disrupt the normal functioning of the central nervous system, liver, lungs, heart, kidneys, and brain, and cause serious health problems such as kidney damage, symptoms of chronic toxicity, and kidney failure[4,5].

Results of the present investigation have clearly shown that the sample has no traces of heavy metals such as mercury and cadmium as the sample is evident the presence of lead and arsenic at 0.517 and 0.761 ppm as listed in the table (Table 7). Heavy metals of lead, cadmium, arsenic, and mercury are observed below the detection limit. Here, the test drug *Kuruthi Azhalukku Chooranam* does not contain heavy metals, which indicates the safety of the drug.

Conclusion

From the results, the purity and quality of the formulation *Kuruthi azhalukku chooranam* was proven. Here, its physicochemical, biochemical parameters, and heavy metal analysis were done, and they showed positive results in the management of hypertension. So, the *Kuruthi Azhalukku Chooranam* can be used for the treatment of hypertension. Furthermore, extensive preclinical and clinical studies are needed to prove its effectiveness in treating hypertension. Through such studies, the effectiveness of this *Chooranam* may reduce the morbidity and mortality rate of hypertension worldwide.

Declaration by Authors:

Ethical approval: Approved

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