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Analytical standardisation and evaluation of Santhanathi kuligai for the treatment of Kanasuram

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Abstract

Standardisation of traditional drug is essential in order to assess the quality of drugs, based on the concentration of their active principles. As the usage of traditional medicine increases day by day it is necessary to standardise the drugs. Central council of research in siddha has given preliminary guidelines for standardizing these conventional formulations. This study is used to analyse the physicochemical characters, sterility test, heavy metal analysis, disintegration time and sophisticated instrumental analysis on santhanathi kuligai. These set of parameters were found to be sufficient to evaluate authenticity of santhanathi kuligai and can be used as reference standards for the preparation of a standardized pharmaceutical product and further quality control researchers.

Keywords: Traditional drug, Standardisation, Santhanathi kuligai.

Introduction

Siddha system is a comprehensive system that places equal emphasis on the body, mind and spirit and strives to restore the innate immunity of the individual. Health is a state of complete physical, mental, social well being and merely absence of disease or infirmity. Siddhar 'Thirumoolar' says that the medicine is to treat not only the disease but also it corrects the physical and psychological changes and to prevent the disease.In fact, the well being of children in Tamil inter wined with Tamil performed religiously help to access the growth and development of the child and help to keep the child healthy .Respiratory system is most commonly infected in children's. A major portal of entry for infectious organisms in children. Acute Respiratory infections is one among the common ailment in paediatric age group.

The ingredients of santhanathi kuligai have the property of relieving the symptoms of kanasuram without any adverse effects. For the standardisation of this drug Organoleptic properties, phytochemical screening, physicochemical parameters were done to evaluate its quality.

Materials and Methods

1. Drug selection:

The drug selection of Siddha herbal formulation 'SANTHANATHI KULIGAI' as internal medicine in treating the disease KANASURAM' in children with in the age limit of 3-12 years as given in the Siddha text book of '**PARARASASEGARA VAITHIYAM'** pg.no:914.

The preparation of any herbo formulation in *Siddha* involves the following steps:

1. Authentication of raw material
2. Purification
3. Preparation
4. Authentication of prepared drug

2. Authentication of raw material:

The raw drug has to be authenticated by the experts of Gunapadam of Government Siddha Medical College, Palayamkottai. The specimen sample of each raw material has been kept in the PG Gunapadam department individually for future reference.

3. Purification:

All drug will be purified as per clinical siddha literature

4. Preparation:

All the raw drugs are powdered and add in a kalvam and grind it with panneer to make a paste. Then it is roll into a 65 mg tablet. Dry it in a shadow light.

5. Storage of the drug:

The prepared test drug was stored in a clean, air tight glass container. The contents were inspected frequently to avoid moisture and insects.

6. Administration of the drug

Form of the medicine : Maathirai
Route of administration : Internal
Dose : 130 mg thrice a day
Adjuvant : Ilaneer
Indication : Kanasuram (fever)

7. Authentication of prepared drug:

Resulting product of preparation will be authenticated by the trained experts from the Gunapadam department of Govt. Siddha Medical College, Palayamkottai for its completion.

8. Quality assurance of prepared drug:

Quality assurance will be performed as per the PLIM (Pharmacopoeial Laboratory for Indian Medicine) guidelines and the analytical parameters are done as follows.

Methods:

1. Organoleptic character

The organoleptic characters of the sample were evaluated which include evaluation of the formulation by its colour, odour, taste, texture etc. Ten tablets were taken into watch glasses and positioned against white back ground in white tube light. Its colour was observed by naked eye and results are noted.

Colour

A sample of Mathirai were taken in watch glasses and placed against white back ground in white tube light. The Mathirai were observed for its color by naked eye.

Odour

Ten numbers of tablets were smelled individually.

2. Physiochemical analysis of tablet

Physicochemical- studies of the trial drug have been done according to WHO guidelines. Physico chemical studies like total ash, water soluble ash, acid Insoluble ash, water and alcohol soluble extract, loss on drying at 105°C and pH were done.

Solubility Test

A pinch of sample (NM) was taken in a dry test tube and to it 2 ml of the solvent was added and shaken well for about a minute and the results are observed. The test was done for solvents like distilled water, Ethanol, Chloroform and the results are observed individually.

pH value

Potentiometrically, pH value is determined by a glass and a suitable pH meter. The pH of the tablet was written in results column.

Loss on Drying

An accurately weighed 1g of Nannari mathirai was taken in a tarred glass bottle. The crude drug was heated at105ºC for 6 hours in an oven till a constant weight. The Percentage moisture content of the sample was calculated with reference to the shade dried material.

Determination of total ash

Weighed accurately 2g of Santhanathi kuligai was added in crucible at a temperature 6000C in a muffle furnace till carbon free ash was obtained. It was calculated with reference to the air-dried drug.

Determination of acid insoluble ash

Ash above obtained, was boiled for 5min with 25ml of 1M Hydrochloric acid and filtered using an ash less filter paper. Insoluble matter retained on filter paper was washed with hot water and filter paper was burnt to a constant weight in a muffle furnace. The percentage of acid insoluble as was calculated with reference to the air-dried drug.

Determination of water-soluble ash

Total ash 1g was boiled for 5min with 25ml water and insoluble matter collected on an ash less filter paper was washed with hot water and ignited for 15 min at a temperature not exceeding 4500 in a muffle furnace. The amount of soluble ash is determined by drying the filtrate.

Determination of water-soluble Extractive

5gm of air-dried drug, coarsely powered Santhanathi kuligai was macerated with 100ml of distilled water in a closed flask for twenty-four hours, shaking frequently. The Solution was filtered and 25 ml of filtrated was evaporated in a tarred flat bottom shallow dish, further dried at 1000 and weighted. The percentage of water-soluble extractive was calculated with reference to the air- dried drugs.

Determination of alcohol soluble extractive

1 gm. of air-dried drugs, coarsely powdered Santhanathi kuligai was macerated with 20 ml. alcohol in closed flask for 24 hrs. With frequent shaking. It was filtered rapidly taking precaution against loss of alcohol. 10ml of filtrate was then evaporated in a tarred flat bottom shallow dish, dried at 1000 and weighted. The percentage of alcohol soluble extractive was calculated with reference to air dried drug.

3. Disintegration test

This is the official test which testifies the time required for a tablet to disintegrate in the solution. The time required to break the tablet into fine particles. Disintegration test helps in knowing the Active Pharmaceutical Ingredients (API) solubility in the gastric fluids of the digestive system. This test is ideal for all tablets but is not performed for controlled and sustained release tablets. Temperatures are maintained accordingly for each tablet. It is calculated by the time required to dissolve the tablet in the liquid and

compared with the standard time in the pharmacopoeia [5]

Disintegration test (37± 0°C)

Disintegration is the process of breaking the tablet into the small granules and it is prior step of drug dissolution so it is the part of In-vitro- In vivo correlation so the disintegration test determines the time required to breaking the tablet and pass all the particle from mesh size 10. USP disintegration apparatus (Electrolab ED-2L) containing six glass tubes was used for the purpose. The disintegration test was performed as USP and to determine the disintegration time, one tablet of Siddha tablet was placed in each tube and the basket rack is positioned in a 1L beaker containing distilled at 37±2°C temperature. The instrument was operated with a motor driven device with 28-32 cycle/min frequency. When all the particles from all the six tubes passed from the tube mesh to the outer beaker that time was noted as disintegration time after that the average time was noted and this process was repeated for all four different brands of tablets. For the uncoated tablet the disintegration time limit is 15 minutes.

Disintegration test

Methodology

Tablets is placed basket containing medium of that stimulate the gastric content which contains sodium chloride, pepsin and hydrochloric acid. The pH is about 1.2 -1.4. The flask is cylindrical with a hemisphere bottom. The flask is maintained at 37± 0.5ºC by a constant temperature bath. The motor is adjusted to turn at the specific speed 100 RPM.

4. Atomic Absorption Spectrophotometry

Atomic absorption spectrophotometer is used in the determination of heavy metal elements and some non metal elements in the atomic state. The light of characteristic wave length emitted from a cathodic discharge lamp is absorbed when it passes through the atomic vapor generated from sample containing the element being examined atomized to the ground state. The assay of the element being examined is tested by determine the decreased degree of light intensity of radiation. Atomic absorption obeys the general rule for absorption spectrophotometry. The assay is carried out by comparing the abosorbance of the test preparation with that

Procedure

Method (direct calibration method) Prepare not less than 3 reference solutions of the element being examined of different concentrations, covering the range the reference preparation recommended by the instrument manufacturer and add separately the correspond ingredients as that for the test solution and prepare the blank solution with the correspond ingredients. Measure the absorbance of the blank solution and each reference solution of different concentrations separately, record the readings and prepare a calibration curve with the average value of 3 readings of each concentration on the ordinate and the corresponding concentration on the abscissa. Prepare a test solution of the substance being examined as specified in the monograph, adjust the concentration to fall within the concentration range of the reference solution. Measure the absorbance 3 times, record the readings and calculate the average value. Interpolate the mean value of the readings on the calibration curve to determine the concentration of the element. When used in the test for impurities, prepare two test preparations of the same concentration as specified in the monograph. To one of the test preparation add an amount of the reference substance equivalent to the limit of the element specified inthe monograph. Proceed as directed above and measure this solution to give an appropriate reading a; then measure the test preparation without the addition of the reference substance under the same condition and record the reading b; b is not greater than (a-b).

i) Determination of lead

Measure accurately 1 ml of the test solution and its corresponding reagent blank solution respectively, add 1 ml of solution containing 1%

$NH_4H_2PO_4$ and 0.2% Mg $(NO_3)_2$, shake well, pipette accurately10-20 µl to determine their absorbance according to the above method of "Preparation of calibration curve". Calculate the content of lead (Pd) in the test solution from the calibration curve.

ii) Determination of cadmium

Pipette accurately 10-20 µl of the test solution and its corresponding reagent blank solution respectively, determine their absorbance according to the above method of "Preparation of calibration curve" (If interference occurs, weigh accurately respectively 1 ml of the standard solution, blank solution and test solution, add 1 ml of a solution containing1% NH4H2PO4 and 0.2% Mg (NO3)2, shake well, determine their absorbance according to the method above, calculate the content of Cd in the test solution from the calibration curve.

iii) Determination of arsenic

Pipette accurately 10 ml of the test solution and its corresponding reagent blank solution respectively, proceed as described under "Preparation of calibration curve" beginning at the words "add 1 ml of 25%potassium iodide solution". Calculate the content of As in the test solution from the calibration curve.

Heavy metal analysis by AAS

Standard: Hg, As, Pb and Cd – Sigma

Methodology

Atomic Absorption Spectrometry (AAS) is a very common and reliable technique for detecting metals and metalloids in environmental samples. The total heavy metal content of the sample was performed by Atomic Absorption Spectrometry (AAS) Model AA 240 Series. In order to determination the heavy metals such as mercury, arsenic, lead and cadmium concentrations in the test item.

Sample Digestion

Test sample was digested with 1mol/L HCl for determination of arsenic and mercury. Similarly, for the determination of lead and cadmium the sample were digested with 1mol/L of HNO3.

Standard reparation

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

5. Sterility test:

Test sample was inoculated in sterile petri dish to which about 15 mL of molten agar 45^oC were added. Agar and sample were mixed thoroughly by tilting and swirling the dish. Agar was allowed to completely gel without disturbing it. (about 10 minutes). Plates were then inverted and incubated at 37^o C for 24-48 hours and further extended for 72 hrs for fungal growth observation. Grown colonies of organism was then counted and calculated for CFU.

Sterility test by pour plate method

Objective

The pour plate techniques were adopted to determine the sterility of the product. Contaminated / un sterile sample (formulation) when come in contact with the nutrition rich medium it promotes the growth of the organism and after stipulated period of incubation the growth of the organism was identified by characteristic pattern of colonies. The colonies are referred to as Colony Forming Units (CFUs).

Results and Discussion

Percentage Loss on Drying

Test drug was accurately weighed in evaporating dish. The sample was dried at 105^oC for 5 hours and then weighed.

Determination of Total Ash

Test drug was accurately weighed in silica dish and incinerated at the furnace a temperature 400 ºC until it turns white in color which indicates absence of carbon. Percentage of total ash will be calculated with reference to the weight of air-dried drug.

Determination of Acid Insoluble Ash

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

Determination of Alcohol Soluble Extractive

Test sample was macerated with 100 ml of Alcohol in a closed flask for twenty-four hours, shaking frequently during 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 105ºC, to constant weight and weigh. Calculate the percentage of alcohol-soluble extractive with reference to the air-dried drug.

Determination of Water Soluble Extractive

Test sample was macerated with 100 ml of chloroform water in a closed flask for twenty-four hours, shaking frequently during six hours and allowing it to stand and 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 105ºC, to constant weight and weigh. Calculate the percentage of water-soluble extractive with reference to the air-dried drug

Disintegration test

Based on the experiment it was observed that the start of disintegration time of tablet varying from 40 mins to 50 mins. Further test formulation took average of 2 hrs for completion of 100 % disintegration.

Sterility test:

Observation

No growth was observed after incubation period. Reveals the absence of specific pathogen

Traditional test for pill:

Sl. No	Character	Inference
1.	Non sticky on rolling	+
2.	No cracks over the surface after drying	+
3.	Shall be rolled uniformly over the plane surface	+
4.	Shining surface	+

Physicochemical Evaluation

Sample Description

State	Solid
Nature	Smooth Surface
Odor	Strongly Aromatic
Touch / Consistency	Hard solid
Flow Property	Free flowing
Appearance	Dark Brownish

Solubility Profile

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

Final Test report

S.No	Parameter	Mean (n=3) SD
1.	***Loss on Drying at 105 °C (%)***	4.16 ± 0.60
2.	***Total Ash (%)***	0.24 ± 0.017
3.	***Acid insoluble Ash (%)***	0.14 ± 0.02
4.	***Alcohol Soluble Extractive (%)***	7.99 ± 1.45
5.	***Water soluble Extractive (%)***	15.95 2.45

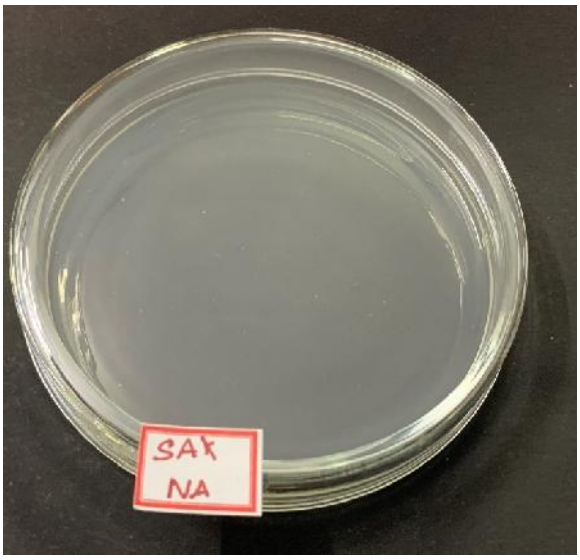
Result analysis on disintegration time test of the sample THM

Tablet	Start of disintegration	25% disintegration	50% disintegration	100% disintegration
Tablet 1	40 mins	1 hr 5 mins	2hr 50mins	2 hr 40mins
Tablet 2	50 mins	1 hr 35 mins	2 hr 45 mins	3 hr 15mins
Tablet 3	45 mins	1 hr 20 mins	2 hr 30 mins	2 hr 50 mins

Test report for heavy metal:

Name of the Heavy Metal	Absorption Max Λ max	Result Analysis
Lead	217.0 nm	35.65
Arsenic	193.7 nm	12.95
Cadmium	228.8 nm	3.45

Sterility test by pour plate method



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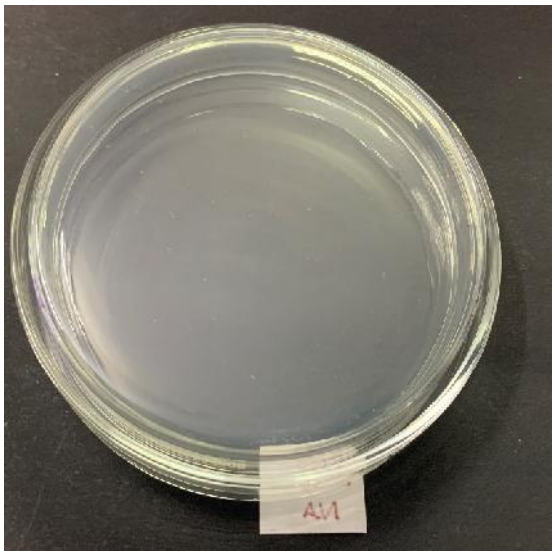

No growth / colonies was observed in any of the plates inoculates with the test sample.

Test	Result	Specification	As per AYUSH/WHO
Total Bacterial Count	Absent	NMT 10^5CFU/g	As per AYUSH specification
Total Fungal Count	Absent	NMT 10^3CFU/g	

Conclusion

All these parameters can be utilised for the overall quality check over its preparation and formulation.

These set of parameters presented in this paper can be used as reference standards. The application of high technology oriented advanced techniques will serve as a rapid and unmabiguous tool in the herbal research thereby benefiting the entire pharmaceutical industry.

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