



STANDARDIZATION OF A SIDDHA DRUG FORMULATION PIRAṆṬAI VAṬAKAM FOR THE MANAGEMENT OF KUṬAL KIRUMIKAḷ

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ABSTRACT

Siddha system of medicine is one of the unique and ancient medical systems which is prevailing even now in India, especially in southern states. Worm infestation in children is a very common ailment that can cause mild to severe impact on them. Herein, we deal with worm infestation which is known as *KuṭalKirumikaḷ* in siddha terms. The main aim of the study is to analyze the organoleptic characters, physico-chemical characters and phytoconstituents of the trial drug *PiraṇṭaiVaṭakam*.

Key Words:

Siddha medicine, worm infestation, standardization, PLIM, organoleptic characters, physico-chemical characters, phytochemicals

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INTRODUCTION

Siddha system of medicine is one of the unique and ancient medical systems which is prevailing even now in India, especially in southern states, that too predominantly in Tamilnadu. Like every other medical system, Siddha medical system also has multi speciality fields. Pediatric care is one among it.

Worm infestation in children is a very common ailment that can cause mild to severe impact on them. The Classical Siddha text book, "PIḶḶAI PIṆI MARUTTUVAM PART – I" classifies *KuṭalKirumikaḷ* in to 27 (Twenty-seven) types. Siddha literatures describes "*KuṭalKirumikaḷ*" as a disease mainly characterised by painaround the umbilicus, gastric distension, grinding of teeth at sleep (Bruxism), Itching around anal region, vomiting, fever, tastelessness, indigestion and diarrhoea.⁽¹⁾

Though *KuṭalKirumikaḷ* is a preventable disease, it remains asymptomatic most of the time and goes unnoticed by the parents of the infected children, which may further lead to serious complications. There are numerous preparations which are effective in treating *KuṭalKirumikaḷ* mentioned in various siddha literatures. One such drug named, *Piraṇṭai Vaṭakam*⁽²⁾ (*Citta Vaṭṭiya Tiraṭṭu* – First Edition 1993; Reprinted ON 2016) is analysed in this article.

Standardization of drugs aims at purity and quality of raw drugs and finished products.

It comprises comprehensive evaluation of siddha drugs in respect of their pharmacognostical, physico-chemical and pharmacological profiles in order to study the various qualitative and quantitative characteristics of drugs. In this article, the organoleptic characters, physico-chemical characters and phytochemical analysis of the trial drug "*PiraṇṭaiVaṭakam*" for "*KuṭalKirumikaḷ*" is discussed.

MATERIALS AND METHODS

Drug Selection

Herein, the compound herbal formulation "*PiraṇṭaiVaṭakam*"⁽²⁾ for "*KuṭalKirumikaḷ*" was taken, mentioned in the classical Siddha literature "*Citta Vaṭṭiya Tiraṭṭu*" compiled by *ka nā kuppucāmimutaliyār* and *ka cu uttamarāyaṇ* published by Department of Indian medicine and Homeopathy, chennai in the year 1998, reprinted in 2009.

Ingredients of PIRAṆṬAI VAṬAKAM

The ingredients of *PiraṇṭaiVaṭakam* are mentioned in Table 1 & 2.

Table 1 Plant drugs of *Piraṇṭai Vaṭakam*

| S.no | Drug | Botanical name | Family | Parts used | Quantity |
|------|--------------------------|-----------------------------|--------------|------------|----------|
| 1 | Purified <i>Piraṇṭai</i> | <i>Cissusquadrangularis</i> | Vitaceae | Stem | 250gm |
| 2 | Purified <i>Milaku</i> | <i>Piper nigrum</i> | Piperaceae | Seed | 50 gm |
| 3 | Purified <i>Vacampu</i> | <i>Acoruscalamus</i> | Acoraceae | Root | 50 gm |
| 4 | Purified <i>Omam</i> | <i>Carumcopticum</i> | Apiaceae | Seed | 50 gm |
| 5 | Purified <i>Kaṭukkāy</i> | <i>Terminaliachabela</i> | Combretaceae | Fruit | 50 gm |

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Table 2 Mineral drug of *PiraṅṭaiVaṭakam*

| S.no | Tamil name | Scientific name | Quantity |
|------|---------------|-----------------|----------|
| 6 | Purified Uppu | Sodium chloride | 50 gm |

- Cow’s ghee – Quantity required
- Cow’s butter milk – Quantity required

Collection of Plant Materials

All the raw drugs were brought from a well reputed country shop from Tirunelveli Town.

Identification and Authentication of the Drug

The raw drugs were identified and authenticated by the HOD and lecturer of Post graduate Department of *kuḷantamaruttuvam* and HOD of Department of *kuṇapātam*, Government Siddha Medical College & Hospital, Palayamkottai. The sample specimen of each raw material is stored in the PG *kuṇapātam* department for future reference.

Purification of the Raw Drugs

Purification of raw drugs was done as per classical *Siddha* literature. (3)

Preparation of the Trial Drug PIRAṅṬAI VAṬAKAM

The nodes and fibres of raw material 1 are removed and fried in Ghee. Raw materials 2 to 6 were grinded into fine powder and sieved separately. Then the mixture of powders and raw material 1 were grinded and made into a semi dry paste by mixing with Butter milk. Then it was made into a pill weighing 4.4 gm and dried in shade.(2)The end product was kept in the air tight container and labelled as *PiraṅṭaiVaṭakam(PiV)*.

The medicine was prepared in *kuṇapātam* lab of GSMCH, Palayamkottai after proper purification. The prepared medicine was also authenticated by the Head of the Department.

Administration of the Trial Drug

Form of the medicine: *māttirai*

Route of administration: Oral

Dose: 4.4gm. 1 tab in divided doses, thrice a day

Adjuvant: Water

Indication: “*KuṭalKirumikaḷ*” (Worm infestation)

Table 3 Traditional test for pill

| S. 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 | + |

Organoleptic Characters

The organoleptic characters of the powdered sample of the trial drug were evaluated which comprises evaluation of the formulation by its texture, odor, consistency, flow property, etc. The analysis was done by Noble research solutions Pvt. Ltd., Chennai, India.

Physicochemical Analysis of PIRAṅṬAI VAṬAKAM

Physiochemical studies of the powdered trial drug have been done according to PLIM guidelines for standardization and evaluation of Indian medicine. The analysis such as solubility test, loss on drying, determination of total ash, water soluble ash, acid insoluble ash, water and alcohol soluble extract were done at Noble research solutions Pvt. Ltd., Chennai, India.

Each analysis was done three times and the mean value was calculated.(4,5)

Percentage Loss on Drying

Test drug was accurately weighed in evaporating dish. The sample was dried at 105°C 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 °C until it turns white in colour 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 105°C, 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 105°C, to constant weight and weigh. Calculate the percentage of water-soluble extractive with reference to the air-dried drug.

Solubility test

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

Phytochemical Screening Analysis of PIRAṅṬAI VAṬAKAM

The phytochemical screening test was carried out for the extract of *PiraṅṭaiVaṭakam* as per the standard procedure by the experts of biochemistry department, Government *Siddha* medical college, Palayamkottai.

Preparation of The extract

5 gm of the drug was weighed accurately and placed in a 250 ml clean beaker. Then 50 ml of distilled water is added and dissolved well. Then it is boiled well for about 10 minutes. It is cooled and filtered in a 100 ml volumetric flask and then it is made to 100 ml with distilled water. This fluid is taken for analysis.

Test for Calcium

2 ml of the above prepared extract is taken in a clean test tube. To this add 2 ml of 4 % Ammonium oxalate solution. Formation of white coloured precipitate indicates the presence of Calcium.

Test for Sulphate

2 ml of the extract is added to 5 % Barium chloride solution. Formation of white coloured precipitate indicates the presence of Sulphate.

Test for Chloride

The extract is treated with Silver nitrate solution. Formation of white coloured precipitate indicates the presence of Chloride.

Test for Carbonate

The substance is treated with concentrated HCl. Formation of brisk effervescence indicates the presence of Carbonate.

Test for Starch

The extract is added with weak iodine solution. Formation of blue colour indicates the presence of Starch.

Test for Ferric Iron

The extract is acidified with Glacial acetic acid and Potassium ferrocyanide. Formation of blue colour indicates the presence of Ferric Iron.

Test for Ferrous Iron

The extract is treated with Concentrated Nitric acid and Ammonium thiocyanate solution. Formation of blood red colour indicates the presence of Ferrous Iron.

Test for Phosphate

The extract is treated with Ammonium molybdate and concentrated nitric acid. Formation of Yellow coloured precipitate indicates the presence of Phosphate.

Test for Albumin

The extract is treated with Eshbach's reagent. Formation of Yellow coloured precipitate indicates the presence of Albumin.

Test for Tannic Acid

The extract is treated with Ferric chloride. Formation of blue-black coloured precipitate indicates the presence of Tannic acid.

Test for Unsaturation

Baeyer's Test: Potassium permanganate solution is added to the extract. If it gets decolourised, it indicates the presence of unsaturated compounds.

Test for the reducing sugar

5 ml of Benedict's qualitative solution is taken in a test tube and allowed to boil for 2 minutes and add 8 – 10 drops of the extract and again boil it for 2 minutes. If it gets any colour, it indicates the presence of reducing sugar.

Test for Amino Acid

One or two drops of the extract is placed on a filter paper and dried well. After drying, 1% Ninhydrin is sprayed over the filter paper and again dried. If it gets violet colour, it indicates the presence of Amino acid.

Test for Zinc

The extract is treated with Potassium Ferrocyanide. Formation of white coloured precipitate indicates the presence of Zinc.

RESULTS AND DISCUSSION

Organoleptic characters

The powdered trial drug *PiraṅṅaiVaṅakam* is soft, fine, non-free flowing, dark-greenish and aromatic in nature. Table 4.

Table 4 Organoleptic characters

| State | Solid |
|---------------------|-------------------|
| Nature | Fine |
| Odor | Aromatic |
| Touch / Consistency | Soft |
| Flow Property | Non- free flowing |
| Appearance | Dark greenish |

Physicochemical analysis: (Table 5A & 5B)

Loss on drying

Moisture content of the drug reveals the stability and its shelf-life. Low moisture content could get maximum stability and better shelf-life. Loss on drying of *PiraṅṅaiVaṅakamis* 6.94±1.24.

Total ash

Ash value constitutes the inorganic residues obtained after combustion of the drug. It is a parameter to assess the degree of purity of the given drug. The total ash value of *PiraṅṅaiVaṅakam* is 34.3±0.95 which denotes the low amount of inorganic content.

Acid insoluble ash

The acid insoluble value indicates the amount of siliceous matter present in the plant. Acid insoluble ash value of *PiraṅṅaiVaṅakam* is 1.57±0.55 which indicates the high quality of the drug.

Alcohol soluble extractive value/Water soluble extractive value

Extractive values are used to evaluate crude drugs by using different solvents to assess quality, purity and to detect adulteration due to exhausted and incorrectly processed drugs. Lower value indicates exhausted drugs. Alcohol and water-soluble extractive value of *Piraṅṅai Vaṅakamis* 9.20 ± 0.09 and 25.8 ± 1.65 respectively.

Solubility

Solubility is one of the factors that controls the bioavailability of a drug. It helps in determining the form of the drug and processing of its dosage form. Poor solubility and low permeability attributes to low oral bioavailability. PiV is soluble in major solvents and partially soluble in some solvents which indicates the increased bioavailability of the drug.

Table 5A Physicochemical analysis of *PiraṅṅaiVaṅakam*

| S.No | Parameter | Mean (n=3) SD |
|------|--------------------------------|---------------|
| 1. | Loss on Drying at 105 °C (%) | 6.94 ± 1.24 |
| 2. | Total Ash (%) | 34.3 ± 0.95 |
| 3. | Acid insoluble Ash (%) | 1.57 ± 0.55 |
| 4. | Alcohol Soluble Extractive (%) | 9.20 ± 0.09 |
| 5. | Water soluble Extractive (%) | 25.8 ± 1.65 |

Table 5B Physicochemical analysis of *Piraṅṭai Vaṭakam*- Solubility Profile

| S.No | Solvent Used | Solubility / Dispersibility |
|------|---------------------------|-----------------------------|
| 1 | Chloroform | Insoluble |
| 2 | Ethanol | Partially Soluble |
| 3 | Water | Soluble |
| 4 | Ethyl acetate | Insoluble |
| 5 | Dimethyl sulfoxide (DMSO) | Soluble |

Phytochemical analysis

The phytochemical analysis of *PiraṅṭaiVaṭakam* reveals the presence of Calcium, Sulphate, Chloride, Starch, Tannic acid, Unsaturated compounds and Amino acid. (Table 6)

Table 6 Phytochemical analysis of *Piraṅṭai Vaṭakam*

| S.No. | Phytochemicals | Result |
|-------|-----------------------|---------|
| 1. | Calcium | Present |
| 2. | Sulphate | Present |
| 3. | Chloride | Present |
| 4. | Carbonate | Absent |
| 5. | Starch | Present |
| 6. | Ferric Iron | Absent |
| 7. | Ferrous Iron | Absent |
| 8. | Phosphate | Absent |
| 9. | Albumin | Absent |
| 10. | Tannic acid | Present |
| 11. | Unsaturated compounds | Present |
| 12. | Reducing sugar | Absent |
| 13. | Amino acid | Present |
| 14. | Zinc | Absent |

CONCLUSION

Organoleptic property of *PiraṅṭaiVaṭakam* reveals its soft, fine, non-free flowing, dark-greenish and aromatic nature which justifies purity and quality of the finished formulation. The physico-chemical and phytochemical results of *PiraṅṭaiVaṭakam* denotes the safety and potent therapeutic activity of the pill. But, *PiraṅṭaiVaṭakam* still have to go through animal study and clinical trials in future so as to ensure its efficacy.

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