

STANDARDIZATION OF SIDDHA DRUG FORMULATION *AKKARA NEI* FOR THE MANAGEMENT OF *VAAI AKKARAM*

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Abstract

Siddha system of medicine is the most popular traditional system of followed by the people of Tamil Nadu nowadays. Today's children are the future citizens of a nation. To have a better nation, healthy citizens can contribute a lot. The text book dealing with pediatrics in Siddha system is called balavagadam. In Balavagadam the *Akkaram* is one of the *Agakkarana noi*. *Vaai Akkaram* is one of the type of *Akkaram*. In Siddha system the disease *Vaai Akkaram* due to excess heat production in moolam and affect the oral cavity to induced ulceration. Drug standardization is very much essential nowadays to prove the therapeutic efficacy of siddha medicine as per PLIM guidelines. Both qualitative and quantitative study of the compound drug is considered as a great tool to access the medicine therapeutic standard worldwide. This research article will help to provide details of information about the organoleptic characters, biochemical and physicochemical analysis of the compound herbal ingredients of *Akkara nei*.

KEYWORDS: Siddha system, *Vaai Akkaram*, Oral ulceration, *Akkara Nei*, biochemical analysis.

INTRODUCTION:

Siddha system of medicine is one of the versatile system of medicine which is being commonly practiced in Tamil Nadu and Sri Lanka. The term AKKARAM is one of the diseases more common in children which is being mentioned in the classical siddha textbooks that occur in also all age group. In the siddha literature “PARARASASEKARAM” mentioned about the type of Akkaram, THE VAAI AKKARAM is one among of them, mentioned in paediatric age group with the presenting symptoms of ulceration in the mouth, Blisters in the mouth, Common cold, Loss of appetite, Fever with chills, Puffiness of face and swelling of oral cavity. Some of the symptoms mentioned in the above said literature for VAAI AKKARAM can be correlated with STOMATITIS in Western Bio – Medicine.

STOMATITIS is a condition with the presenting symptoms of swelling and redness inside the mouth, or individual painful sores that makes uncomfortable for a person to eat, swelling and ulceration over the oral cavity, or blisters in the mouth, Dysgeusia (alterations in taste) *Akkara nei* is used for treating these symptoms and this *nei* has been prepared under the strict standards and parameters given by PLIM Guidelines. This article can also be used as an initiative for research areas for identifying Organoleptic, Biochemical and Physicochemical properties respectively.

2.MATERIALS AND METHODS:

2.1 Drug Selection:

The siddha formulation drug *Akkara Nei* selected from the *Pararasasaekaram vaithiyam moolamum uraiyum part-1* pg.no. -806 and this medication is indicated for treating stomatitis called *Vaai Akkaram*.

2.2 Ingredients of AKKARA NEI:

This poly herbal formulation contains raw drugs and the ingredients of the drug and its quantity are listed below Table 1

Table 1

| S.NO | NAME | BOTANICAL NAME | FAMILY | PART USED | QUANTITY |
|------|----------------------|-----------------------------------|---------------|----------------|----------|
| 1. | <i>Omam</i> | <i>Carum copticum</i> | Apiaceae | Seed | 10g |
| 2. | <i>Narjeeragam</i> | <i>Cuminum cyminum</i> | Apiaceae | Seed | 10g |
| 3. | <i>Karujeeragam</i> | <i>Nigella sativa</i> | Ranunculaceae | Seed | 10g |
| 4. | <i>Kadukkai</i> | <i>Terminalia chebula</i> | Combretaceae | Ripened fruit | 10g |
| 5. | <i>Thippili</i> | <i>Piper longum</i> | Piperaceae | Seed | 10g |
| 6. | <i>Lavagam</i> | <i>Syzygium aromaticum</i> | Myrtaceae | Dry flower bud | 10g |
| 7. | <i>Kostam</i> | <i>Costus speciosus</i> | Zingiberaceae | Root | 10g |
| 8. | <i>Elam</i> | <i>Elettaria cardomomum</i> | Zingiberaceae | Fruit | 10g |
| 9. | <i>Nellikai</i> | <i>Phyllanthus emblica</i> | Euphorbiaceae | Dry fruit | 10g |
| 10. | <i>Senchandhanam</i> | <i>Pterocarpus santalinus</i> | Fabaceae | Wood | 10g |
| 11. | <i>Vendhaiyam</i> | <i>Trigonella foenum –graecum</i> | Fabaceae | Seed | 10g |
| 12. | <i>Thandrikaai</i> | <i>Terminalia bellerica</i> | Combretaceae | Ripened fruit | 10g |
| 13. | <i>Adhimadhuram</i> | <i>Glycyrriza glabra</i> | Fabaceae | Root | 10g |
| 14. | <i>Masikai</i> | <i>Quercus infectoria</i> | Fagaceae | Gall | 10g |
| 15. | <i>Karporavalli</i> | <i>Anisochilus carnosus</i> | Lamiaceae | Dry leaf | 10g |
| 16. | <i>Cow's Ghee</i> | - | - | - | 1.5lit |

2.3 COLLECTION OF RAW DRUG:

The raw drugs were brought from a well reputed raw drug store in Tirunelveli town.

2.4 IDENTIFICATION AND AUTHENTICATION OF THE DRUG:

The raw drugs were identified and authenticated by the Head of the Department of Post graduate department of Gunapadam, Government Siddha Medical College, Palayamkottai. The sample of each raw drug is stored in the PG Department of Gunapadam for the future reference.

2.5 PURIFICATION OF THE RAW DRUG:

Purification of raw drugs were done as per classical Siddha literature.

சுத்தி முறைகள்

| | |
|--------------|--|
| திப்பிலி | பழச்சாற்றில் ஊறவைத்து எடுத்து கழுவி வைத்து கொள்ளவும். |
| சீரகம் | உலர்த்தி பின் சிறுக வறுத்து எடுத்து கொள்ளவும். |
| கருஞ்சீரகம் | கருஞ்சீரகத்தை உலர்த்தி பின் சிறுக வறுத்து எடுத்து கொள்ளவும். |
| ஓமம் | நன்கு வறுத்து எடுத்து கொள்ளவும். |
| செஞ்சந்தனம் | கட்டையை வெயிலில் காய வைத்து எடுத்து கொள்ளவும். |
| கடுக்காய் | கொட்டையை நீக்கி எடுத்து கொள்ளவும். |
| நெல்லிக்காய் | கொட்டையை நீக்கி எடுத்து கொள்ளவும். |
| தான்றிக்காய் | கொட்டையை நீக்கி எடுத்து கொள்ளவும். |
| இலவங்கம் | மொக்குகளை நீக்கி வறுத்து எடுத்து கொள்ளவும். |
| ஏலம் | வெயிலில் காயவைத்து எடுத்து கொள்ளவும். |
| கோட்டம் | தூயநீரில் கழுவி மேற்தோல் சீவி காயவைத்து எடுத்து கொள்ளவும். |
| மாசிக்காய் | வெயிலில் உலர்த்தி பொடித்து கொள்ளவும். |
| வெந்தயம் | நன்கு வறுத்து எடுத்து கொள்ளவும். |
| அதிமதுரம் | தூயநீரில் கழுவி மேற்தோல் சீவி காயவைத்து எடுத்து கொள்ளவும். |
| கற்பூரவள்ளி | இலைகளை தூய துணியால் துடைத்து காம்பு, நரம்புகளை நீக்கி கொள்ளவும். |

2.6 PREPARATION OF THE TRIAL COMPOUND DRUG *AKKARA NEI*:

The above mentioned drugs are powdered, taken and boiled in cow's ghee until it attains its consistency it is heated. Allow it to cool and store it in airtight container.

Picture 1- Sample Description



2.7 ADMINISTRATION OF THE DRUG:

Form of the Medicine: Nei

Route of Administration: Oral

Dose: 1.5ml-3ml (Twice a Day after food)

Indication: *Vaai akkaram*

2.8 ORGANOLEPTIC CHARACTERS:

State, Nature, Odor, Consistency, Flow Property, Appearance of the Drug and Solubility of the drug were noted. The Organoleptic Character analysis was done by Noble Research Solutions Pvt. Ltd., Chennai, India

2.9 PHYSICOCHEMICAL ANALYSIS OF *AKKARA NEI*:

Physiochemical analysis includes Sample Description, Solubility Test, Determination of iodine value, Determination of Saponification value, Determination of viscosity value, Determination of refractive index, Determination of weight per ml, Acid value, Peroxide value. The analysis were done at Noble research solutions Pvt. Ltd., Chennai, India. Each analysis is done three times and the mean value is calculated.

Determination of Iodine value

About 20 gm of test sample was transferred into Iodine flask. To which 10 ml of chloroform was added and warmed slightly and cooled for 10 minutes. Followed by this about

25 ml of Wiji's solution was added in the same flask and shaken well. The flask was allowed to stand for 30 mins and refrigerated for an hour. About 10 ml of KI solution was added to this and titrated against 0.1 N Sodium thiosulphate solutions until the appearance of yellow colour. 1 ml of starch indicator was added and again titrated against the sodium thiosulphate solution from the burette. Disappearance of blue colour indicates end point. Repeat the above procedure without taking sample and note the corresponding reading for blank titration.

Determination of saponification value

About 2 gm of test sample was transferred into the round bottomed flask. To this about 20 ml of 0.5 N alcoholic KOH solutions was added to the round bottomed flask. Repeat the same procedure without taking the sample for blank titration. Reflux both sample and blank round bottomed flasks for 1 hour. After reflux, allow both the round bottomed flasks to cool. Titrate the samples using 0.5 N HCl with phenolphthalein indicator. The disappearance of pink indicates the end point.

Determination of Viscosity value

Viscosity determination were been carried out using Ostwald viscometers. Measurement of viscosity involves the determination of the time required for a given volume of liquid to flow through a capillary. The liquid is added to the viscometer, pulled into the upper reservoir by suction, and then allowed to drain by gravity back into the lower reservoir. The time that it takes for the liquid to pass between two etched marks, one above and one below the upper reservoir, is measured.

Determination of Refractive Index

Determination of RI was carried out using Refractometer.

Determination of Weight per ml

Weight per ml was determined using the comparative weight calibration method, in which the weight of 1ml of the base of the formulation was calculated and then weight of 1 ml of finished formulation were been calculated. The difference between weight variations of the base with respect to finished formulation calculated as an index of weight per ml.

Acid Value

Accurately 5 g of test sample was weighed and transferred into a 250 mL conical flask. To this, a 50 mL of neutralized alcohol solution was added. This mixture was heated for 10

min by heating mantle. Afterwards, the solution was taken out after 10 min and 1 or 2 drops of phenolphthalein indicator was added. This solution was titrated against KOH solution from the burette. The appearance of pink color indicated the end point. The volume of consumed KOH solution was determined and the titration of test sample was carried out in triplicate and the mean of the successive readings was used to calculate the acid-value of the respective sample by following expression.

Acid value = Titter Value X 0.00561X 1000 / Wt of test sample (g)

Peroxide value

5 g of the substance being examined, accurately weighed, into a 250-ml glass-stoppered conical flask, add 30 ml of a mixture of 3 volumes of glacial acetic acid and 2 volumes of chloroform, swirl until dissolved and add 0.5ml volumes of saturated potassium iodide solution. Allow to stand for exactly 1 minute, with occasional shaking, add 30 ml of water and titrate gradually, with continuous and vigorous shaking, with 0.01M sodium thiosulphate until the yellow colour almost disappears. Add 0.5 ml of starch solution and continue the titration, shaking vigorously until the blue colour just disappears (a ml). Repeat the operation omitting the substance being examined (b ml). The volume of 0.01M sodium thiosulphate in the blank determination must not exceed 0.1 ml.

$$\text{Peroxide value} = 10 (a - b)/w$$

3. PHYTOCHEMICAL SCREENING ANALYSIS OF AKKARA NEI

The Phytochemical screening analysis was carried out for the extract of *Akkara nei* as per the standard procedure by the experts of Biochemistry Department of Government Siddha Medical College, Palayamkottai.

Preparation of the Extract

5 grams 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

2ml 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 colored precipitate indicates the presence of Calcium.

Test for Sulphate

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

Test for chloride

The extract is treated with Silver nitrate solution. Formation of White colored 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 color indicates the presence of Starch.

Test for Ferric Iron

The extract is acidified with Glacial acidic acid and potassium ferrocyanide. Formation of Blue color indicates the ferric iron.

Test for Ferrous Iron

The extract is treated with Concentrated Nitric acid and Ammonium thiocyanate solution. Formation of Blood red color indicates the presence of ferrous iron.

Test for Phosphate

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

Test for Albumin

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

Test for Tannic Acid

The extract is treated with Ferric Chloride. Formation of Blue- black colored indicates the presence of Tannic acid.

Test for Unsaturation

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

Test for Reducing Sugar

5 ml of Benedicts qualitative solution is taken in a test tube and allowed to boil for 2 minutes and add 8-10 drops of the extract again boil it for 2 minutes. If it gets any color, 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 color, it indicates the presence of Amino acid.

Test for Zinc

The extract is treated with Potassium Ferrocyanide. Formation of white colored precipitate indicates the Presence of Zinc.

RESULTS AND DISCUSSION:

ORGANOLEPTIC CHARACTERS:

Table 2

| State | Liquid |
|--------------|----------------|
| Nature | Viscous |
| Odor | Characteristic |

| | |
|---------------|--------------|
| Touch | Greasy |
| Flow Property | Free flowing |
| Appearance | Yellowish |

SOLUBILITY PROFILE:

Table 3

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

PHYSICOCHEMICAL ANALYSIS:

Table 4

| S.No | Parameter | AKN |
|------|--|--------|
| 1 | Viscosity at 50oC (Pa s) | 61.98 |
| 2 | Refractive index | 1.88 |
| 3 | Weight per ml (gm/ml) | 1.32 |
| 4 | Iodine value (mg I ₂ /g) | 76.84 |
| 5 | Saponification Value (mg of KOH to saponify 1gm of fat) | 177.63 |
| 6 | Acid Value mg KOH/g | 1.009 |

| | | |
|---|-------------------------|------|
| 7 | Peroxidase Value mEq/kg | 1.74 |
|---|-------------------------|------|

BIOCHEMICAL ANALYSIS:

The biochemical analysis of *Akkara nei* reveals the presence of **Sulphate, Chloride, Starch, Tannic acid, Unsaturated Compound and Amino acid.**

Table 5

| S.NO | PHYTOCHEMICALS | RESULT |
|------|------------------------------|----------------|
| 1. | Calcium | Absent |
| 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 characters of *Akkara nei* reveals that the drug is liquid, greasy, viscous, free flowing, yellowish color and strong characteristic. The Biochemical analysis of *akkara nei* reveals the presence of **Sulphate, Chloride, Starch, Tannic acid, Unsaturated Compound and Amino acid.** Many research shows that the tannic acid will prevent stomatitis. So, I concluded that the presence of tannic acid in the medicine had significant anti-inflammatory

property. Physicochemical and biochemical property of *Akkara nei* reveals that the drug is safety and effective. Further, preclinical and clinical trials should be done in future to know the value of the drug.

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