Research Article

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PROCESS STANDARDISATION OF KARA SOODA SATHU PARPAM: A SIDDHA HERBO MINERAL DRUG

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ABSTRACT
This study aims to document the step wise procedures carried out in the preparation of a Siddha herbo mineral formulation, Kara soda sathu parpam. The purified ingredients were ground with lemon juice and made into pellets and subjected to pudam with Karchuuna moosai (crucible made of limestone). The calcinized pellets were ground to fine powder and stored in an air tight glass container. The used quantity of raw materials and the quantity after purification and the end product quantification is documented and compared. It was noted that the loss percentage in the preparation of this drug was more and hence careful administration of pudam and number of varattis should be strictly adhered. The raw material should be taken in larger quantities to reduce loss percentage. It can be concluded that identification of raw materials, purification process, SOP of drug preparation, Final product analysis etc. need to be followed while preparing a drug. This may lead to large scale preparation of the same with GMP standards.
Keywords: Siddha, Herbo mineral, Validation, Documentation

INTRODUCTION

The traditional systems of medicine have become significantly more popular all over the globe because of the curative property, less toxic and minimal side effects. It is more widely used for the human ailments from time immemorial. It has been estimated that 70-80 % of world's population relies on traditional healthcare. The mode of preparation and plant used in traditional medicine varies from place to place. In addition acceptance of traditional medicines, especially herbal medicines in the developed world is sharply increasing[1-3]. Among the traditional systems of medicine in India, Siddha medicine uses more of herbal, mineral and animal products as raw materials in various formulations. The herbs are dispensed in the form of Decoctions, Karkam, Choornam, Pills, Lehyams, Nei, and Manappagu etc. Other forms of drugs include Parpam, Chendooram, Chunnam, Pathangam, Kattu, Kalangu etc. In contrary to Ayurveda, Siddha formulations over cede the use of herbo mineral and herbo metallic preparations. The usage of these medicines especially the dosage, mode of administration etc. are well documented in traditional literature. To meet the global standards, medicines under the Indian systems of medicine (ISM) are required to be manufactured in sanitized environment following Good Manufacturing Practices (GMP) norms, duly laid down by the Government of India. There are several forms of medications in Siddha system of medicine. They are broadly classified into 32 internal and external therapies. Among the medications, parpams and chendoorams especially made up of metals are widely used in this system. In the traditional literature various steps have been mentioned to convert a metal to its compound form so that it can be used as a medicine with a particular anupanam and hence reducing the toxicity and enhancing the absorption rate of the drug. The end product, which is the final drug made out of metals and minerals has a unique chemical nature in its own, which differs from drug to drug. Standardisation is a measurement for ensuring the quality and is used to describe all measures which are taken care during the manufacturing process and quality control leading to reproducible quality. Standard is a numerical value which quantifies a parameter and thus denotes the quality and purity of material, thereby enhancing its efficacy. Quality control is not only a laboratory procedure, but also the procedures through which a raw material is transformed to a drug and the finished product till it is used by the patient. Need for standardisation:

- Global acceptance
- Documentation
- Reproducibility
- Industrial scale production
- Prevent adulteration and contamination
- Assess the quality of raw material and finished product
- Estimate the amount of active principle
- Achieve batch to batch consistency of finish product

Here an attempt was made to study the process standardisation of a Siddha herbomineral drug Kara Sooda Sathu Parpam (KSSP), used in the treatment of Kalladaippu noi (Urolithiasis). The study was focussed in the following steps;

- Procurement of raw materials
- Authentication of raw materials
- Purification of raw materials
- Preparation of the drug

MATERIALS AND METHODS

Ingredients of Kara soodasathuparpam

- Fried Vengaram (Borax / Sodium bi borate)
- Karpoora silasathu (Gypsum)
- Vediuppu (Potassium nitrate / salt petre)
- Chitrandathol (Egg shell of *Gallus domesticus*)
- Palagarai (*Cyprea moneta*.Linn)
- Padigaaram (Alum / Alumen)
- Lemon juice (*Citrus limon*)

Procurement of raw materials

The mineral drugs were procured from market sample at Govindhasamy chetty store, Chennai, India and egg shell was procured from Institute of Poultry Production and Management, Madhavaram milk colony.

Authentication of raw materials

Authentication of botanical

The lemon used for grinding was authenticated by the Asst. Professor, Dept of medicinal botany, National institute of Siddha, Chennai, India

Authentication of minerals

The minerals Borax, Gypsum, Alum, Potassium nitrate were authenticated by Professor, Dept of Geology, University of Madras, Guindy campus, Chennai, India based on their macroscopic and microscopic characteristics.

Authentication of animal products

The shell of *Cyprea moneta* was authenticated by officer in charge, Marine Biology Regional Centre, Zoological Survey of India, Santhome high road, Chennai, India. The Egg shell of Gallus domesticus was procured from Institute of Poultry Production and Management, Madhavaram milk colony, Chennai, India and authenticated by Professor and Head of the same Institute.

Purification of raw materials

Purification of Vengaram (Borax)

Weighed amount of vengaram was fried in an earthen pot

Purification of Karpoora silasathu (Gypsum)

Weighed Karpoora silasathu was boiled in tender coconut water, washed and dried

Purification of Vediuppu (Potassium nitrate)

Known quantity of the salt is dissolved in water and egg white yolk was added while boiling and the impurities removed and filtered. The filterate was dried and the salt was recovered. The process was repeated seven times.

Purification of Chitrandathol (Egg shell)

Egg shells were soaked and boiled in water containing Kariuppu (Sodium chloride)

Purification of Palagarai (*Cyprea moneta*)

The shells were soaked in lemon juice and washed and dried

Purification of Padigaram (Alum)

Known quantity of Alum was dissolved in water and heated, impurities removed by filteration and the salt is recovered by drying[4]

Method of preparation of the drug

The purified ingredients were ground with lemon juice and made into pellets and subjected to pudam with Karchuuna moosai (crucible made of limestone). The calcinized pellets were ground to fine powder and stored in an air tight glass container.[5]

Route of administration: Oral
Dosage of medicine: 1 -1 ½ panavedai (488-732 mg)
Duration of treatment: 45 days.
Anupaanam: Tender coconut water, Lemon juice.
Indications: Kalladaippu, Neeradaippu, Neerchurukku, Sadhaiadaippu

RESULTS

Authentication of Palagarai

Two different market samples in the name of palagarai were procured and given for authentication. One sample was identified as *Cyprea annulus* and the other as *Cyprea moneta*. *Cyprea annulus* has a golden ring on the dorsal surface and *Cyprea moneta* has stripes on the dorsal surface (Figure 16 and Figure 17).

Purification of the Ingredients

Palagarai after purification was pure white in colour and it lost its lustre. Padigaram changed to light yellow in colour after purification process. Vengaram turned to light weight ball like structure and became more voluminous. Vediuppu turned comparatively bright after purification. Egg shell got cleaned off the membranes and other organic matter after purification.

Preparation of limestone moosai

The earthen vessel was coated with limestone to a thickness of 1 cm, dried and used for pudam.

Preparation of KSSP

It was noted that the loss percentage in the preparation of this drug was more and hence careful administration of pudam and number of varattis should be strictly adhered. The raw material should be taken in larger quantities to reduce loss percentage.

Table 1: Ingredients and quantity used in the preparation of KSSP asgiven in Siddha literature

S. No.	Tamil name	Scientific name	Quantity	Quantity in g
1	Vengaram	Borax/ Sodium bi borate	½ palam	17.5
2	Karpoorasilasathu	Gypsum	½ palam	17.5
3	Vediuppu	Potassium nitrate/ Salt petre	½ palam	17.5
4	Chitrandathol	Egg shell of *Gallus domesticus*	½ palam	17.5
5	Padigaram	Alum/ Alumen	½ palam	17.5
6	Palagarai	Shell of *Cypreamoneta*	½ palam	17.5
7	Pazhachaaru	Juice of *Citrus limon*	Essential quantity	-

Table 2: Purification of Palagarai

Sample no	Quantity of raw material (g)	Lemon juice used (ml)	Soaking time (h)	Weight after purification (g)	Loss of weight (g)
1	100	100	24	98	2
2	100	100	24	97	3

Table 3: Purification of Vengaram

Sample no	Quantity of raw material (g)	Weight after purification (g)	Loss of weight (g)
1	100	53	47
2	100	58	42

Table 4: Purification of Karpoorasilasathu

Sample no	Quantity of raw material (g)	Quantity of tender coconut water (ml)	Weight after purification (g)	Loss of weight (g)
1	100	300	97	3
2	100	300	98	2

Table 5: Purification of Padigaram

Sample no	Quantity of raw material (g)	Quantity of water (ml)	Weight after purification (g)	Loss of weight (g)
1	100	500	55	45
2	100	500	48	52

Table 6: Purification of Egg shell

Sample no	Quantity of raw material (g)	Weight after purification (g)	Loss of weight (g)
1	140	125.5	14.5
2	140	122	18

Table 7: Purification of Vediuppu (Processing for 7 times)

Sample no	Quantity of raw material (g)	Quantity of water (ml)	Weight after purification (g)	Loss of weight (g)
1	100	200	99	1
	99	200	85	14
	85	170	73	12
	73	140	58	15
	58	120	48	10
	48	100	39	9
	39	80	35	4

Table 8: Batch wise details of preparation of KSSP

Batch	Quantity of each ingredient (g)	Quantity of lemon juice (ml)	Hours of grinding	Weight of pellets before pudam (g)		No of varatti	Weight of pellets after pudam (g)	Weight of Parpam (g)
KSSP1	17.5	80	5	96		15	63	60
KSSP2	17.5	35	4	93.45		12	62	58.5
KSSP3	35	35	4	101.2		12	65	63
KSSP4	35	65	5	197	97	12	52	50.25
					95	12	51	50
KSSP5	52.5	120	4	313	156	15	110.25	109
					157	15	92.5	90

Figure 1: Karpoora silasathu before purification

Figure 2: Karpoora silasathu after purification

Figure 3: Padigaram before purification

Figure 4: Padigaram after purification

Figure 5: Palagarai before purification

Figure 6: Palagarai after purification

Figure 7: Vediuppu before purification

Figure 8: Vediuppu after purification

Figure 9: Vengaram before purification

Figure 10: Vengaram after purification

Figure 11: Chitrandathol before purification

Figure 12: Chitrandathol after purification

Figure 13: Pellets in limestone moosai before pudam

Figure 14: Pellets in limestone moosai after pudam

Figure 15: The drug Kara soda sathuparpam

Figure 16: The dorsal and ventral surface of *Cyprea annulus*

Figure 17: The dorsal and ventral surface of *Cyprea moneta*

DISCUSSION

Drug is a substance used as a medicine. They are used in their raw state directly or after they are undergone some processes or modifications. It may be of plant or animal or metal and mineral origin[6-8]. WHO has also recently recognized the inevitability of the use of alternate system of medicine for certain conditions such as cancer, skin diseases and multiple sclerosis etc for which no definite solutions are available in allopathic system[9]. For the acceptance of these drugs, a minimum level of quality control is required. But when the question of bulk production, marketing and distribution to the public arises, to ensure uniformity and quality control it becomes an imperative need. Hence the need for standardization includes study from cultivation of the plant to clinical application which involves various disciplines. From the step of authentication to the preparation of the drug it is very important to document each process which will be much helpful for future researchers and physicians. The literature references and the changes that have been made during the preparation of the drug play an important role in repeatability of the process of drug preparation. Here it has been focussed on the quantity of raw material used and the yield of the final product obtained. It has been attempted to prepare the drug in different ratios of raw material and the yield have been studied. It is well understood that the use of more amount of raw material reduces the loss percentage. As far as mineral drug preparation, the method of purification and the season of preparation are notable. It is ideal to prepare this drug (KSSP) during early summer and during summer season. During other seasons the pellets may dry in the day time under sunlight and starts melting during night hours even when kept air tight. It is said that it is the nature of salts added. Hence the juice added to grind the raw materials and the duration of grinding should be minimal.

CONCLUSION

When proper care is given in each step right from authentication to the final product development, it will pave way to standardisation of ISM drugs. Standardisation is needed both in the traditional methodology as given in literature and by scientific methods too. It can be concluded that identification of raw materials, purification process, SOP of drug preparation, final product analysis etc. need to be followed while preparing a drug. This will lead to large scale preparation of the same with GMP standards.

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