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FORMULATION AND EVALUATION OF *KALYANAKA KSHARA*: AN AYURVEDIC COMPOUND FORMULATION

Suddala Anitha [1]*, G Babu [2], Charde Vaibhav [3], KMVD Prasad [4], PVNR Prasad [5]

[1] Assistant Professor, Department of Prasuti Tantra and Stree roga, Dr NRS. Government Ayurvedic College, Vijayawada, Andhra Pradesh, India

[2] Assistant Director In-charge, Central Ayurveda Research Institute (CARI), Gwalior Road, Jhansi, Uttar Pradesh, India

[3] Research officer (Ayurveda), Central Ayurveda Research Institute (CARI), Gwalior Road, Jhansi, Uttar Pradesh, India

[4] Ex. Principal, HOD, Department of Shalya Tantra. Dr NRS. Government Ayurvedic College, Vijayawada, Andhra Pradesh, India

[5] Professor, PG Department of Rasa Shastra & Bhaishajya Kalpana, Dr NRS. Government Ayurvedic College, Vijayawada, Andhra Pradesh, India

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***Corresponding author**
E-mail: dranitha2005@gmail.com

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ABSTRACT

Background: Ayurveda utilises different forms of herbs in therapeutics. *Kshara* is one such form. The material destroys or cleans the excessive/morbid *doshas* (*Ksharanat Kshananat va Kshara)*. They are considered *anushastra's* (para-surgical instruments). *Kshara's* (alkaline substances) are more suitable and can be used where *shastra chikitsa* (surgery) is contraindicated. *Kshara* (alkaline substances) is the best drug for internal and external use. Considering the quick action, lesser dose, and more comprehensive action, an attempt is made to formulate and standardise the product, as there is insufficient data regarding its standardisation. Objective: To formulate and standardise the *Kalyanaka Kshara*. Methods: All ingredients were taken per the reference *Ashtanga Hridaya chikitsa sthana, Kalyanaka Kshara*. All the Raw materials like plants, animals, and mineral drugs were collected from the local market of Jhansi, Uttar Pradesh. And by the *sharava samputa* (earthen pot) method, three different samples (KK1, KK2, and KK3) of *Kalyanaka Kshara* were prepared. Result: Physicochemical changes in each sample, organoleptic characters of the product yield were observed. The standard values of *Kalyanaka Kshara* are alkaline with pH 10.01, loss on drying (% w/w) 0.47, total ash value (% w/w) 55.5, acid insoluble ash value (% w/w) 0.93 water extractive value (% w/w) 62.55, alcohol extractive value (% w/w) 38.54. Conclusion: On behalf of each sample's pharmaceutical and physicochemical analysis, there are no considerable changes in any of the KK1, KK2, and KK3 samples, and encouraging results were observed. The developed SOP and physicochemical parameters can be adopted as pharmacopeial standards.

Keywords: *Kalyanaka Kshara*, physicochemical, Standardization, Standard operating procedure.

INTRODUCTION

Ayurveda utilises different forms of herbs in therapeutics. *Kshara* is one such form. *Kshara* is an alkaline substance obtained by processing the ash of drugs. It is a commonly used clinically but less explored dosage form. *Acharya Sushruta* defines it as the material which destroys or cleans the excessive/ morbid *doshas* (*Ksharanat Kshananat va Kshara)*. [1] They are considered *anushastra's* (para-surgical instruments).[2] *Kshara's* are more suitable and can be used where *Shastra Chikitsa* (surgical treatment) is contraindicated or where we cannot use surgical instruments, e.g., in *marmas* (vital parts), for women, children, etc. *Kalyanaka Kshara* (KK) is a potent Ayurvedic herbomineral preparation used in the management of several disorders like *Udavarta* (reverse movement of *Vata*), *Vibandha* (constipation), *Arshas* (haemorrhoids), *Gulma* (abdominal lump), *Pandu* (anaemia), *Udara* (disorders of abdomen/enlargement of the abdomen), *Krimi* (helminthiasis /worm infestation), *Mutrasanga* (urinary obstruction). KK is one among such formulations that aim to correct *agni*, which enables the proper formation of stool and easy defecation. [3,4] *Kshara* is the best drug for internal and external use, considering the lesser dose and quick and wider action of KK. [5,6]

In the current situation, Good Manufacturing Processes are necessary to meet global standards. [7] It can provide quality assurance and reproducibility of the drug. Hence standardisation of the process is mandatory to keep the quality and efficacy of the product. [8] To develop a Standard Operating Procedure (SOP) for preparing *Kalyanaka Kshara*, three samples, KK1, KK2, and KK3 processed. [9] Physicochemical assessments like organoleptic characters, pH, loss on drying, acid insoluble ash solubility, PSA, heavy metal analysis, etc., were done. Here an attempt is made to standardise the product as there is insufficient data regarding its standardisation.

Aim and objectives: To develop quality control parameters and standardise the drug *Kalyanaka Kshara* as per textual specifications.

MATERIALS AND METHODS

Collection and authentication the raw drugs used in the formulation were procured from the local market of Jhansi (Table 1) and were authenticated at the Botany Section of Central Ayurveda Research Institute (CARI), Gwalior road, Jhansi. (F.No. 4-5/CARI/ 2022/Tech/Pharm/35). Pharmacognostic and physicochemical analyses were done at CARI, Jhansi, as mentioned in Ayurvedic pharmacopoeia of India (API). [10] The

quality control (QC) parameters of single drugs include total ash (ta),[11] acid insoluble ash (aia), [12] water soluble extractive (wse), alcohol soluble extractive (ase) [13] and high-performance thin layer chromatography (HPTLC). [14] Fresh gomutra was collected. *Tila taila* (sesamum oil) was analysed with parameters like refractive index (RI), acid value (AV), saponification value (SV), and Iodine value (IV). [14]

Table 1: Raw drugs used in the preparation of *Kalyanaka Kshara*

Raw Drugs	Botanical name/Scientific Name	Part Used	Quantity
Shunthi	*Zingiber officinale* Roscoe	Rhizome	1 Part
Maricha	*Piper nigrum* Linn.	Fruit	1 Part
Pippali	*Piper longum* Linn.	Fruit	1 Part
Saindhav Lavana	Rock Salt	-	1 Part
Sauvarchala Lavana	Black Salt	-	1 Part
Bida Lavana	Black Salt	-	1 Part
Haritaki	*Terminalia chebula* Linn.	Fruit pericarp	1 Part
Bibhitaki	*Terminalia bellirica* Linn.	Fruit pericarp	1 Part
Amalaki	*Emblica officinalis* Linn.	Fruit pericarp	1 Part
Danti	*Baliospermum montanum* Linn.	Root	1 Part
Bhallataka	*Semecarpus anacardium* Linn.	Fruit	1 Part
Chitraka	*Plumbago zeylanica* Linn.	Root	1 Part
Tila taila	*Sesamum indicum* oil	Expressed oil	1 Part
Gomutra	Cow urine		1 Part

Amalaki (*Emblica officinalis* Linn.) Fruit pericarp

Haritaki (*Terminalia chebula* Linn.) Fruit pericarp

Bibhitaki (*Terminalia bellirica* Linn.) Fruit pericarp

Shunthi (*Zingiber officinale* Roscoe) Rhizome

Pippali (*Piper longum* Linn.) Fruit

Maricha *(Piper nigrum* Linn.) Fruit

Danti *(Baliospermum montanum* Linn.) Root

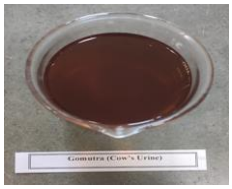
Chitraka *(Plumbago zeylanica* Linn.) Root

Bhallataka (*Semecarpus anacardium* Linn.) Fruit

Saindhav Lavana (Rock Salt)

Sauvarchala Lavana (Black Salt)

Bida Lavana (Black Salt)



Gomutra (Cow urine)

Tila Tail (*Sesamum Indicum* Oil)

Figure 1: Raw material used in the preparation of *Kalyanaka Kshara.*

Triphala (Amlaki, Haritaki, Bibhitaki)

Amalaki Choorna
***(Emblica officinalis* L.)**

Haritaki Choorna
***(Terminalia chebula* L.)**

Bibhitaki Choorna
(*Terminalia bellirica* L.)

Trikatu (Shunti, Pippali, Maricha)

Shunthi Choorna
(*Zingiber officinalis)*

Pippali Choorna
(*Piper longum*)

Maricha Choorna
***(Piper nigrum* L.)**

Tripatu (Trilavana)

Saindhav Lavan (black salt)

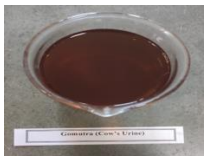
Sauvarchala Lavan (black salt)

Vida Lavan (black salt)

Danti Choorna
***(Baliospermum montanum* L.)**

Chitraka Choorna
***(Plumbago zeylanica*)**

Bhallataka Choorna
(*Semecarpus anacardium*)



Gomutra (cows' urine)

Mixing with Tila tail and Gomutra

Mixing of Triphala, Trikatu, Tripatu, Danti, Chitraka, Bhallataka

Homogenous mixture of Kalyanaka Kshara

KK sarava samputi, sandhi bandhana

Kalyanaka kshara

Figure 2: Raw material used in preparing *Kalyanaka Kshara.* and procedure.

Preparation of Kalyanaka Kshara (KK)

All the raw drugs used in *Kalyanaka Kshara* (KK) with their scientific name, useful parts, and ratios are mentioned in Table 1. *Shodhana* (purification) of *Chitraka* (*Plumbago zeylanica* L.) [15] and *Bhallataka* (*Semecarpus anacardium* L.) [16] were done as per classical methods. *Chitraka shodhana* (purification method) used churnodaka (lime water). Three batches of KK were prepared by adopting *puta* (heating up to 1000 ^{0}C to prepare ash) method by following good manufacturing practices (GMP) norms. [17] (Classical method using earthen pots subjected to specific heat). The ingredients *Triphala* (equal quantity of *Terminalia chebula* L., *Terminalia bellirica* L. *Emblica officinalis* L.), *Trikatu* (equal quantity of *Zingiber officinale* Roscoe, *Piper nigrum* L., *Piper*

longum L.), [18] *Tripatu* (equal quantity of salts like *saindhav lavana*, (rock salt), *sauvarchala lavana* (black salt), *bida lavana* (*black salt)*, *Danti* (*Baliospermum montanum* L.), purified *Bhallataka* (*Semecarpus anacardium* L.) and purified *Chitraka* (*Plumbago zeylanica* Linn.) were taken in equal amount, coarsely powdered and were mixed uniformly. *Tila taila* (oil of *Sesamum indicum*) and *gomutra* (cow's urine) were added as required to form a homogenous mixture. The mixture of all the above drugs was transferred into a *sharava samputa* (earthen pot) and closed with another *sharava samputa* (earthen pot), sandhi *bandhana* (closure of joints) done with mud smeared seven layers of cotton clothes and dried and placed in *gajaputa* (heat of amount of thousand cow dung's cake) (1000 ^{0}C), then allowed for *swanga sheeta* (self-cooling) and the product was collected in the next day. Finally, the content was tightly packed in a closed container to protect it from light and moisture. The same SOP (standard operating procedure) was adopted for preparing three batches of KK and labelled as KK1, KK2, and KK3. [19-20]

OBSERVATIONS AND RESULT

Organoleptic evaluation: All three batches have the same odour, colour, taste and touch. i.e., faint odour, blackish colour with a salty taste and refined in nature.

Physicochemical evaluation: pH value of a given sample expresses the degree of acidity or alkalinity of the sample. The alkalinity of the drug indicates the site of absorption and action of the drug. Acid insoluble ash value helps detect the presence of silica and oxalates in the drugs. This test measures the amount of ash insoluble in dilute HCl. As per API, the acid insoluble ash of KK is less than 1% (Table 2).[21] Loss on drying is a widely used test method to determine the moisture content of the sample, although occasionally, it may refer to the loss of volatile matter from the sample. It is an important parameter to be assessed for *Kshara*, as it is hygroscopic due to the presence of alkaline compounds. The lesser the LOD value more stable the *Kshara* is. As per API, the LOD value is less than 6%. Here all the samples had LOD values within normal limits.

Table 2: Physicochemical Characters of three different batches of *Kalyanaka Kshara*

Physicochemical Parameter	Batch I	Batch II	Batch III
pH (10 % Solution)	10.01	10.00	10.25
Loss on Drying (% w/w)	0.47	0.48	0.47
Total Ash Value (% w/w)	55.50	55.5	55.25
Acid Insoluble Ash Value (% w/w)	0.93	0.69	0.97
Water Extractive Value (% w/w)	62.55	62.54	62.84
Alcohol Extractive Value (% w/w)	38.54	37.26	38.97
Test for Heavy Metals (ppm) (Pb, Cd, Hg, As)	Complies as per API	Complies as per API	Complies as per API

KK1 KK2 KK3

Figure 3: Prepared samples of three different batches of *Kalyanaka Kshara.*

Microbiological Analysis: The microbiological analysis of three samples, KK1, KK2 and KK3, was done in which the microbial load was observed to be less than the permissible limit. Also found that the total bacterial count was 1×10^1 CFU/gram. and total fungi or yeast count 2×10^2 CFU/gram, Test for specific organisms like *S.aureus* absent, *Pseudomonads Sp.* absent, *Salmonella Sp* absent, *E. coli* absent.

DISCUSSION

No clear description is available regarding the preparation of *Kalyanaka Kshara*; an attempt has been made to standardise the *Kalyanaka Kshara*. In the present study, the preparation of three samples *Kalyanaka Kshara* (KK1, KK2 and KK3), was carried out as per reference of *Ashtanga Hridaya Arsha chikisthadhya*. [5] the ingredients were taken as per (Table 1). *Shodhana* (purification) of *Chitraka* (*Plumbago Zeylanica* L.) and *Bhallataka* (*Semecarpus anacardium* Linn.) was done as per classical methods. *Chitraka shodhana* (purification method) used churnodaka (lime water). Three batches of KK were prepared by adopting the *gaja puta* (heating to 1000 ^{0}C to prepare ash using 1000 cow dung cakes) method by following good manufacturing practices (GMP) norms.

Organoleptic characteristics of KK1 (*Kalyanaka Kshara* first sample), KK2 (*Kalyanaka Kshara* second sample) and KK3 (*Kalyanaka Kshara* third sample) were like delicate touch, blackish in colour, salty in taste, with faint odour shows reproductivity in terms of physical characteristics. It is crucial to store samples in an air-tight glass jar container as the finished product shows hygroscopic nature. The material absorbs moisture during storage. In conjunction with a suitable temperature, moisture will activate enzymes and give suitable conditions for the proliferation of living organisms. Hence, the moisture content may affect the quality of the drug. [22]

After the preparation of *Kalyanaka Kshara*, the physicochemical evaluation and particle size analysis (PSA) was carried out. In the physicochemical characterisation, the pH was noted as 10 above comes under the high alkaline range. A sample's pH value expresses the degree of acidity or alkalinity of a sample solution. KK1, KK2, and KK3 samples have pH 10.01, 10.00 and 10.25,

respectively. The alkalinity of the drug indicates the site of absorption and action of the drug. (Table 2)

Acid insoluble ash value helps detect the presence of silica and oxalates in the drugs. This test measures the amount of ash insoluble in dilute HCl. As per API, the acid-insoluble ash of *Kalyanaka Kshara* is said to be less than 1%. In the *Kshara* prepared, KK1, KK2 and KK3 values are 0.93%, 0.69% and 0.97%, respectively.

Loss on drying is a widely used test method to determine the moisture content of the sample, although occasionally, it may refer to the loss of volatile matter from the sample. It is an important parameter to be assessed for *Ksharas*, as it is hygroscopic due to the presence of alkaline compounds. The lesser the LOD value more stable the *Kshara* is. As per API, the LOD value is less than 6%. Here all the samples had LOD values within normal limits. KK1, KK2 and KK3 were 0.47,0.48,0.47 respectively.

A larger surface area allows the increase in surface area to volume ratio, thus increasing the surface area available for solvation. When the particle size of a drug is decreased, the reduced particle size enhances the bioavailability of the drug. [23] Here it was found that prepared KK1, KK2 and KK3 were having particle size with mean diameter of 51.441 microns, 51.882 microns, 52.035 microns respectively. Particle size determines bioavailability; hence lesser the particle size more available the drug will be. As *Ksharas* are dosage forms having minimal dose, they should have lesser PSA values. In ICP-OES, heavy metal analysis, arsenic, cadmium mercury and lead were within less than permissible limits in samples KK1, KK2 and KK3. The study shows the reproducibility of its manufacturing method so that SOP can be used for further preparation. Microbiological studies show safety and contamination-free, so safe to administer internal or local drug applications. [24]

CONCLUSION

The study shows that there is no significant difference among the three different batches of *Kalyanaka Kshara*. *Gaja puta* was used as a standard procedure for the preparation and obtained the highest alkaline pH, i.e. 10. Considering these facts, we can conclude that this method is better for *Kalyanaka Kshara* preparation. The study will be helpful to future researchers in the standardisation of *Kalyanaka Kshara.* The developed Standard Operative Procedures (SOPs) and physicochemical parameters can be adopted as in-house/pharmacopeial standards.

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