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A REVIEW OF CLASSICAL AND MODERN PARAMETERS FOR STANDARDIZATION OF SNEHA KALPANA

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ABSTRACT

Ayurveda has a long and strong heritage use of various formulations i.e. S*waras, kalka, kwath, Hima, Phanta, Guti, Vati, Asava, Arishta, Sneha Kalpana* to treat various disease. Among these *Sneha Kalpana i*s one which is in vogue since *samhit*a period. Concept of medicated *Tail and Gruta* is well established in *Ayurveda under Sneha Kalpana*. *Sneha Kalpana* is used to extract fat soluble active principles. It is only *kalpana* which is used through all four modes of administration i.e. *Pana, abhyanga, nasya and basti*. *Sneha Kalpana* has longer shelf life compare to other formulations. Here it will be explored in details and its standardization technique will be elaborated. The classical *siddhi lakshanas* and modern standardization aspects regarding this formulation such as organoleptic parameters, physicochemical parameters [specific gravity, viscosity, refractive index, rancidification, iodine value, acid value, saponification value, free fatty acids, peroxide value] Analytical parameters [Thin layer chromatography, High performance thin layer chromatography] have been explained in brief.

KEYWORDS: *Sneha Kalpana, standardization, Analytical parameters.*

INTRODUCTION

Ayurvedic preparations are typically based on complex herbal compounds, minerals and metal substances. This science is divided into two branches as *Rasshastra and bhaishajya kalpana. Bhaishajya* means medicine, *kalpna kalpana* means forms. *Bhaishajya kalpana* includes panchvidh kashya *kalpana* i.e. *swaras, kalka, kwath, Hima, phanta. Bhaishajya kalpana* also includes preparation of various forms of medicine i.e. *churna, vati, guti, ghruta paka, Tail paka, lepa, Asav, Arishta, etc.*[1] *sneha kalpna* is used to prepare medicated Tail and ghrita which can be used externally and internally. *Sneha kalpna* is used to extract active principles from fat soluble drugs, also increased permeability.

In *sharangdhar samhita* completion test for medicated oil/ghee types of *sneha paka, mrudu, madhya, and khar paka a*nd duration of process as per variation in type and preparation are discussed elaborately, Which may be applied during preparation of these *sneha kalpna.*[2] For *sneha paka* some *sneha Siddhi lakshana* are important such as *sneha kalka* attains perfect shape when rolled between fingers i.e. *vartivat snehakalka angulya vimardita.* If part of kalka is put on fire no sound is produced i.e. *shabdahino agninikshipta.* Foam appears in *Tail paka,* disappear in *ghruta paka* i.e. *fenodgam Tail, fenashanti ghruta*. Desired color, odor, and taste of ingredients become appreciable after completion of *sneha paka* i.e. *Gandhavarna rasadinam samptao.*[3] These parameters of completion test and other measures may also be used as distinguish criteria for quality control of products.

Different Analytical parameters including organoleptic characters i.e. Ph, specific gravity, Refractive index, Rancidity, viscosity, Iodine value, Peroxide value, free fatty acid, Acid value, saponification, Thin layer chromatography, High performance thin layer chromatography will be evaluated as per API*(Ayurvedic* pharmacopoeia of India). All the parameters were found to be within the reference standards and can be used for studies of identity and purity of drug.[4]

AIM AND OBJECTIVES

Aim

To review the classical and modern standards parameters of Sneha Kalpana.

Objectives

1) To review the importance and application of standardization techniques of Sneha Kalpana.
2) Compilation of standard analytical values of *sneha kalpna* as per source of *sneha kalpna.*

MATERIALS AND METHODS

In the present study material related to Analytical standardization according to classical was collected from ancient a*yurvedic* classics books such as *sharangdhar samhita, charak samhita,* and modern parameters from pharmacopeial standards of ayurvedic formulations, a manual of pharmacopoeia, *ayurvedic* formulary of india. The research article related to study was collected from authenticated sources like google scholar articles and pubmed.

Sneha kalpna may be defined as a pharmaceutical process to prepare oleaginous medicament from the substance like *kalka, kwath or drava dravya* taken in specific proportion and by subjecting them to unique heating pattern and duration to fulfill certain pharmaceutical parameters, according to need of therapeutics.[5]

METHODOLOGY

Sneha Kalpana prepares in 3 phases.

1) *Tail Murchana*
2) *Tail paka*
3) *Paka siddhi*

1) Method of *Murchana*

Tila Tail is warmed and cooled down. *kalka* is added slowly and gently to the vessel containing oil. Water is added on constant stirring. *Taila Paka* is carried in *mandagni* for 3 days. After *Taila pakasiddhi* oil is filtered and collected in glass vessels.

2) Sneha paka

This second phase and important one. Specified amount of liquid and *kalka* are added to oil base and subjected to moderate heat till liquid portion evaporates.

3) Paka siddhi pariksha

It is third phase where desired quality of oil may be obtained.

Sneha paka siddhi lakshna

- *Vartivat snehakalka angulya vimardit.*
- *Shabdahino agninikshiptha.*
- *Fenoudgam: Taila, fenashanti :sarpi*
- *Gandhavarna rasadinam samptao.*

Modern Analytical parameters/classification of Analytical parameters

According to API and CCRAS following standardization parameters are elaborated.

1) As per pharmaceutical guidelines for analysis of *ayurvedic* formulations following analytical parameters must be tested for *Sneha Kalpana.*[6]

a) Organoleptic parameters

1. Color
2. Odor
3. Taste

b) Physicochemical parameters

1. Rancidification
2. Viscosity
3. Refractive index
4. Iodine value
5. Acid value
6. Saponification value
7. Free fatty acid
8. Peroxide value

c) Analytical (phytochemical)

1. Thin layer chromatography
2. High profile thin layer chromatography.

OBSERVATIONS

Table No. 1: Classical parameters.[7]

Sr.no	Name of parameters	Inference
1	***Vartivat snehakalka angulya vimardit***	*Sneha kalka* attains perfect shape when rolled between fingers
2	***Shabdahino Agni nikshipta***	If part of *kalka* is put into fire no sound is produced indicating loss of moisture in it
3	***Fenoudgam Taila fenashanti sarpi***	Foam appears in *Taila* and disappears in ghruta paka during completion of preparation
4	***Gandhavarna rasadinam sampatao* (Color, odor, taste)**	Desired color, odor and taste of the ingredients become appreciable as the preparations properly boiled and completed

Table No. 2: Modern Parameters.

Sr no.	Name of parameters	Inference	Significance
1	Rancidity[8]	Rancidity is odor process that is accompanied by the formation of the unpleasant odor, taste in fat and oils due to action of moisture and air	It indicates the degree of deterioration and decomposition, which is criterion to judge the quality or purity of drug sample
2	Viscosity	It is a liquid property that measures its frictional resistance (resistance of flow)	It is standardization parameters for quality control of any liquid. Estimation of flow property, consistency and stability of liquid semi-liquid and semisolid products.
3	Refractive index[9]	It is the ratio of velocity/speed of light in a vacuum or air to that in the substance.	Most commonly used to measure the concentration of solute in an aqueous solution. it is a fundamental physical property of a substance used to identify a particular substance, confirm its purity and its concentration.
4	Iodine value[10]	The number of grams of iodine absorbed by 100 gm. Of sample material when determined by using Iodine mono-chloride solution	It measures the amount of unsaturation (number of double bonds) in fat/ oil. Higher the iodine number ,more unsaturated fatty acid bonds are present in fat, decreases it's stability.
5	Acid value	The number of milligrams of potassium hydroxide required to neutralize the free fatty acids present in one gram of fat.	Estimation of acid value which is criterion to judge the quality and purity of drug sample. Tool for standardization of sample.
6	Saponification value	The number of milligrams of potassium hydroxide required to neutralize the fatty acids present in 1gm of sample.	Evaluation of average/mean molecular weight of ghruta and oils. Higher saponification value explicates the high amount of low molecular weight fatty acids. Higher the saponification value more easily absorb Tail by external application due to low molecular weight of fatty acids.
7	Free fatty acids	The free fatty acids content is expressed as oleic acid equivalents. It is a relative measure of Rancidity as free fatty acids are normally formed during decomposition of oil glycerides.	Measurement the amount of fatty acids liberated by hydrolysis from the glycerides due to action of moisture, temper temperature and lipolytic enzyme lipase. Tool for standardization of sample.
8	Peroxide value	The number expresses in milliequivalents of active oxygen quantity of perioxide contained in 1000gms of substance.	As indicative tool for the degree of oxidation in fat or oil which directly impart the quality and stability. It is useful for assessing the extent to which spoilage has advanced.
9	Thin layer chromatography	It is a chromatography analytical technique that identifies and separates components from mix in	Determination of batch-to-batch variation in batch manufacturing process, and determination of

		different color spots/bands	chemicals/salts as adulterants in *ayurvedi*c herbal formulations. Act as a precursor for method /protocol development to quantify the phytochemical by HPTLC
10	High profile thin layer chromatography	Utilizes a column that holds chromatographic packing material, a pump that moves the mobile phases through column and a detector.	It shows the retention times of the molecules. Retention time varies depends upon the interactions between the stationary phase, the molecules being analyzed and solvent used. It is a criterion to judge the quality, identity, purity of sample drug.
11	Test for heavy metals	Heavy metal analysis are a group of tests that measures the quantity of specific potentially toxic metals in ayurvedic formulation. These metals are lead, cadmium, mercury and arsenic.	To judge the quality and purity of drug. Measuring the amount of heavy metals as toxicity.
12	Test for Aflatoxins	It is based on the chromatographic technique. Aflatoxins can easily separate and visualize by thin layer chromatographic system with detection at UV wavelength at 254 and 366nm.	Determination of af;atoxins residue in raw material and finish products ensures the quality evaluation of toxic substances that can cause several complications to human. Evaluation of toxicity in the sample.
13	Biological test	Quantitative determination microbes as total bacteria at aerobic condition and number of bacterial colonies forming units per g of the sample.	To evaluation of bacterial and fungal contamination and hygienic conditions for handling and storage conditions.

Table no. 3: Shows comparative Analytical Analysis of different *Tail.*

Sr no	Name of parameter	*Yashtimadhu Tail* [11]	*Gunja Tail* [12]	*Durvadi Tail* [12]	*Sahacharadi Tail* [13]	*Shrungatakadi Tail* [14]
1	Refractive index	1.473m/sec	1.47m/sec	1.4525m/sec	1.4715m/sec	1.471m/sec
2	Acid value	2.91mgkoh/g	1.03mgkoh/g	1.45mgkoh/g	5.521mgkoh/g	0.54mgkoh/g
3	Rancidity	Absent	Absent	Absent	Absent	Absent
4	Peroxide value	4.73meq/kg	6.63meq/kg	1.43meq/kg	38.805meq/kg	5.73meq/kg
5	Iodine value	9.152mgl2/g	113.71mgl2/g	11.67mgl2/g	129.050mgl2/g	55.58mgl2/g
6	Saponification value	212.69mgkoh/g	197.98mgkoh/g	263.77mgkoh/g	179.13mgkoh/g	86.50mgkoh/g
7	Viscosity	93.875/cm2	3778cps	3180cps	_	_

DISCUSSION AND CONCLUSION

An attempt has been made to review and understand the standardization of *Sneha Kalpana* by classical and modern method. Classical and modern parameters of standardization divided in three steps raw material standardization, in process standardization and finished product standardization.

Raw material standardization – in classical for raw material standardization *grahya agrahyatva lakshana* are mention in API. And in modern organoleptic and microscopic evaluation describe.

In process standardization – in Ayurveda classics confirmatory tests are describe such as "***vartivat snehakalka angulya vimardita, shabdahino Agni nikshipta, fenoudgam Taila fenashanti sarpi, Gandhavarnarasadinam sampatao."***

Finished product standardization- in case of finished product standardization the central council for research in Ayurveda and Sidhha and Pharmacopoeial laboratory for Indian medicine have notified standard protocol for quality control of Sneha Kalpana.

The pharmacopoeia standards for compound formulations does help in achieving uniformity and consistency in preparation of A*yurvedic* drugs.

In P*anchakarma* procedures these preparations are most commonly used. *Murchanna* procedures was discovered in nineteenth century for enhancing therapeutic potential of medicated fatty preparations.

Murchana is the pharmaceutical refining of oils aimed at attaining various objectives such as removal of *Aam*, impartment of color and odor, longer stability of oils and increased therapeutic efficacy. Hence this work was planned to establish the pharmaceutical standardization of various *Taila*. The proportion of Sneha Kalpana preprations recorded in *Ayurvedic* classical text is 1part of all herbal drugs together 4 parts of oil ghee, 16 parts of water.

According to *sharangdhar samhita* the preparations of oils should not be completed within a day. Longer the duration of preparation more the absorption of fat soluble constituents of the ingredients takes places. Thus the potency of Tail*/ghrita* is expected to been enhanced.

According to Analytical findings,

- Rancidity was absent in all samples.
- Refractive index of *Yashtimadhu Taila* was found slightly more than that of other oils. Increased value of R.I.in same was found to be more which may be due to coloration and additional phyto-constituents.

- Iodine value indicates the degree of unsaturation of oil. Greater the degree of unsaturation greater will be the possibility of oil becoming rancid due to atmospheric oxidation. Iodine value of *Sahacharadi* (129mgl2/g) was more than that of other *Yashtimadhu Tail*(9.152mgl2/g), Gunja Tail(113.71mgl2/g), *Durvadi Tail(*11.67 mgl2/g),
- *Shrungatakadi Tail*(55.58mgl2/g) which shows the degree of unsaturation. Hence lesser iodine value shows increased shelf life of oil.
- Saponification value gives an idea about the weight of fats/oils. The saponification number and molecular weight of oil are inversely proportional to each other, this high saponification values indicates that fat is made up of low molecular weight fatty acids and vice versa. Increased saponification value increases the stability of oil.
- Acid value indicates the amount of free fatty acids present in oils and fats. A high acid value in oil may lead to early Rancidity of the oil. In Shrungatakadi Tail(0.54 mgKOH/g) lesser acid value than that in other Tail.
- Peroxide value in *Durvadi Tail* (1.43meq/kg) are less than that of others which may shows that the increasing the chemical stability of oil due to antioxidant property of Durvadi Tail.
- Crackling sound and froath was observed when *kalka* was added to the hot oil initially, which is probably due to the moisture content in the *kalka*. Continuous stirring is required or else the *kalka* may stick to the bottom of the vessel thus resulting over charring of kalka. After 5-10min. Cracking sound and froath got reduced this indicates loss of moisture.
- For preparing Tail and *kashay mandagni* was maintained in order to reduce the loss of active principles due to overheating. Some chemical constituents present in the preparations may change their properties due to effect of thermodynamics.
- Test for heavy metals- heavy metals are toxic elements and hazardous for health in herbal medicines and changed in form in *rasa and bhasma* medicines beneficial for health permissible limit of heavy metals are mercury- 1 ppm, cadmium- 0.3 ppm, lead- 10 ppm, arsenic- 3 ppm. (ppm- parts per million)[15]

  Test for aflatoxins- aflatoxins are very dangerous to the human body. Accurate analysis is required to determine residuals or lower leval detection of aflatoxins. Level of toxicity B1> G1>B2>G2. Permissible limit of aflatoxins are B1- 0.5 ppm, G1- 0.5 ppm, B2- 0.1 ppm, G2- 0.1 ppm.15

- Biological test- according to API and WHO guidelines, bacterial and fungal contamination are very dangerous to the human body. Fungus or bacterial colonies can be easily quantified based on their growth at selected media and calculated using dilution factor. Permissible limits –

  Staphylococcus aureus / g – absent

  Salmonella sp. /g – absent

  p. areuginosa / g- absent

  E.coli – absent

  Total microbial plate count- 105 /g*

  Total yeast and mould- 103/g*.
- (For topical use the limit shall be 107/g).15

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