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A REVIEW OF CLASSICAL AND MODERN STANDARDIZATION PARAMETERS OF *SANDHAN KALPANA*

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ABSTRACT

Ayurveda consists of different types of dosage forms such as *Swarasa*, *Kwatha*, *Grita*, *Taila*, *Sandhan Kalpana*, etc. Among these *Sandhan Kalpana* is one such pharmaceutical process where *Asavaarishta* are mentioned. *Asava-arishta* are fermented product as these are exposed to the fermentation by the addition of fermentative agent *Saccharomyces cerevisiae* obtained from *Dhataki pushpa*. *Asava-Arishta* is unique preparation of liquid dosage form in the field of Ayurveda because of easy palatability, effectiveness and longer shelf life. Standardization of medicine is not an easy task as numerous factors influence the bio efficacy and therapeutic effect. in these article attempt is made to describe the classical and modern standardization parameters of *Asava-arishta* these involve total solids, PH, specific gravity, refractive index, reducing sugar, non-reducing sugar, alcohol percentage, TLC. Further classical parameters matchstick test, additives sink the bottom, no effervescence sound, clear liquid without any froth.

KEYWORDS: *Sandhan Kalpana, Asava-Arishta, Dhataki pushpa, Standardization, Analytical methods.*

INTRODUCTION

Ayurveda is ancient medical system which means science of life. In *Ayurved Samhitas* lots of medicinal formulations where described like *Swarasa*, *Kwath*, *Vati*, *Choorna*, etc but all *Kalpana* have some limitation i.e. shelf life. *Asava Arishta* is unique formulation comes under the broad heading *Sandhan Kalpana*. Have better efficacy and longer shelf life. *Sandhan* the term literally means mixture combination or restoring. here medicines are combine together and are allowed to be in the same condition for specific time period.[1] *Sandhan* is process of fermentation where *Dravadravya* (*swarasa*, *kwatha*), *Madhur dravya*, *Prakshep dravya* and *Sandhan Dravya* are put together in inert vessel and sealed for specified time period to facilitate the process of fermentation. *Asava* & *arishta* are the two major product of this process.[2]

In fermentation process ethyl alcohol is produced by material used in pharmaceutical procedure is not added from outside. Further alcohol is formulated and extraction of active principle of herbal drug is done. Thus this formulation have longer shelf life, quick absorption & action and excellent therapeutic efficacy as compared to other *Ayurvedic* herbal medicine.[3]

Standardization is an essential measurement for insuring the quality control of the herbal drug.[4] in ancient *Ayurveda Samhitas* & modern science lots of standardization parameters are mentioned. But it is not easy task as there is lack of quality n herbal preparation due to geographical variation, adulteration and substitution and absence of proper standardization procedure for evaluation of raw drug and final products. Therefore there is urgent need to do the research regarding the standardization methods of herbomineral drugs like *Asava* and *Arishta kalpana*.[5] under the drug and the cosmetics act, the *Ayurvedic* pharmacopoeia of India (API) is the book of standard for single and compound drug included therein. Physiochemical properties like total solid content, specific gravity, PH, refractive index, alcohol percentage, reducing sugar, TLC, total phenolic content are commonly used parameters for standardization of *Asava-Arishta*.[6] The review highlights the role of various analytical technique, its application, importance and their methods in the analysis of *Asava* and *Arishta Kalpana*.

AIM

To review classical and modern Analytical parameters of *Sandhan Kalpana.*

OBJECTIVE

To understand classical and modern analytical parameters of *Sandhan Kalpana* and their importance and application.

MATERIAL AND METHOD

In the present study material related to Analytical standardization according to classical was collected from ancient *Ayurvedic* classics books such as *Sharangdhar Samhita*, *Charak samhita*, *Asava arishta vidyan* and modern parameters from pharmacopoeia 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.

Asavas and *Aristas* are alcoholic preparations, prepared either by soaking the powdered drugs or the decoction of a drug, in a solution of jaggery along with a fermenter for a specified period of time and produce alcohol by fermentation. These self-generated alcohols facilitate the extraction of active principles present in the drug and also serve as a preservative.[7]

METHOD

Preparation of *Kwath* or *Swarasa* and then add *Prakshep Dravya* in *Choorn* form then add *Madhur Dravya* sugar, Jaggery, honey and *Sandhan Dravya Dhataki Pushpa* and mix it properly and put in ceramic or earthen vessel. Keep the mouth properly close with a cloth. Keep watching the fermentation process in between. After completing fermentation filter through clean cloth in good vessel and stored.[8]

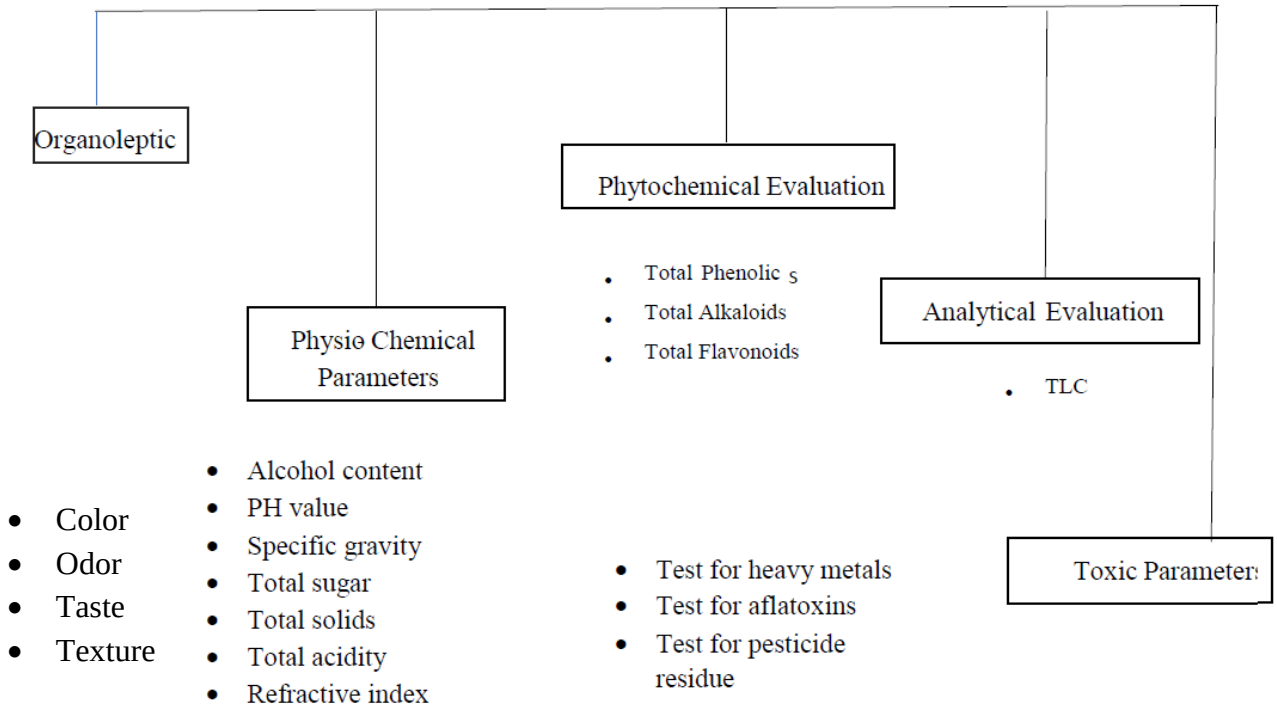
Siddhi Lakshana (Analytical parameters) according to Classics

Matchstick test, no effervescence sound, clear liquid without any froth, additives sink to the bottom.[9]

Analytical Parameters according to Modern

Organoleptic parameters, PH, specific gravity, total solids, reducing sugar, non-reducing sugar, alcohol content, total phenolic content, TLC, heavy metal test, test for aflatoxin, and biological.

Classification of modern analytical parameter



RESULTS

Table No. 1: shows Classical Parameters of *Sandhana Kalpana.*

Sr. no.	Name of parameter	Inference & significance
1.	Matchstick test	In fermentation vessel matchstick burn continuously in the presence of O2.but during fermentation process due to anaerobic conversion of glucose into ethanol and CO2 act as fire suppressor. It is use to confirm whether fermentation was complete are not.
2.	No effervescence sound	Effervescence is the escape of gases from an aqueous solution. During fermentation due to anaerobic conversion of glucose gases are evolved and sound can be here. It is use to confirm whether fermentation was complete are not.
3.	Clear liquid without any froth	During fermentation process anaerobic conversion of glucose into ethanol and CO2 causes bubble formation. It is use to confirm whether fermentation was complete are not.
4.	Additives sink to the bottom	After completion of fermentation solid particles in liquid are pulled down due to gravitational force. Density of solid raw material higher than the surrounding liquid media.

Modern parameters

Table No 2: Shows organoleptic parameters of *Sandhana Kalpana.*[10]

Sr. no	Name of parameter	Significance
1.	Odor	Fermentation influence the formation of aromatic compounds like phenols, ethanol.
2.	Color	During or after fermentation chemical reaction in between insource materials gave specific color to product.
3.	Taste	It is used to confirm whether fermentation product ready or not because after completion of process it gives specific taste to specific *Asava-arishta*.

Table No. 3: Shows physico-chemical parameters.[11]

Sr. No.	Name of parameter	Definition	Significance and inference
1.	PH	Quantitative measure of the acidity or basicity of aqueous or other liquid solution. Or Power of H+ or OH-	- Affect the solubility, stability and quality of the product. - Essential if the product is more acidic/alkaline. But all *Asava-arishta* are acidic in nature. - Essential for storage and packaging.
2.	Specific gravity	Weight of a given volume of that substance at the status temperature as compared with the weight of an equal volume of water at the same temperature.	- It affects the flowing property - Important for packaging of product - To analyze quality and purity of drug.
3.	Total solid content	Total solid is measure of the suspended and dissolved solids in sample.	- Solid content affects the fermentation time. - Solid content are converted to fermentation product. - To examine the quality of drug.
4.	Total sugar		- To know how much sweetening agents (glucose) converted to ethanol.
6.	Non-reducing sugar	Sugars that is not oxidized by a weak oxidizing agent in basic aqueous solution.	- It varies with temperature and fermentation time. - When percentage remains stable it is a marker to determine completion of fermentation
7.	Alcohol content	The ethanol content of liquid is expressed as the number of volume of ethanol contain in 100 ml volume of liquid.	- It is increases with fermentation time. - Important with respect to therapeutic activity and stability. - Product may become acidic.
8.	TLC	Thin layer chromatography is technique that identifies and separate components from the mixture in different color.	- Identification of phyto constituents as a standard to compare. - Qualitative standardization technique.

			- Determination of adulterants and purity of sample.
9.	Total phenolic content	The total phenolic content of the extract was determine by folin ciocalteu reagent in an alkaline atmosphere. Principle of this method is the formation of complex blue compound that can be measured at a wavelength of 765nm.	- Presence of phenolic content indicates sample have antioxidant property. It is a health protecting factor.
10.	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 examine the quality and purity of drug. - Measuring the amount of heavy metals as toxicity.
11.	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 aflatoxins 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 sample.
12.	Biological test	Quantitative determination microbes as total bacteria at aerobic condition and number of bacterial colony forming units per g of the sample.	- To evaluation of bacterial and fungal contamination and hygienic conditions for handling and storage conditions.

Table No. 4: shows Comparative Analytical Analysis of different *Asava/ Arishta*.[7]

Sr. no.	Name of parameter	*Abhayarishta*	*Arvindasava*	*Khadirarishta*	*Jirkadyarishta*	*Dashmularishta*
1.	PH	3.6 to 4.2	3 to 4.5	3.50 to 4.2	3.5 to 4.5	3.6 to 3.7
2.	Specific gravity	1.01 to 1.12	1.0 to 1.1	1.01 to 1.15	1.08 to 1.20	1.09 to 1.1 g/ml
3.	Total solid	Not less than 17.5% w/v	10 to 20% w/v	Not less than 11.50% w/v	22.0% w/v	24 to 54% w/v
4.	Reducing sugar	Not less than 9.50% w/v	3.5 to 4.5% w/v	Not less than 6.5 % w/v	14.00% w/v	14 to 24% w/v
5.	Non reducing sugar	Not more than 0.40% w/v	Not more than 1.0% w/v	Not more than 0.50% w/v	1.00% w/v	Not more than 1% w/v
6.	Alcohol content	6.5 to 10 % v/v	5 to 10 % v/v	5 to 10% v/v	5 to 10% v/v	5 to 7% v/v
7.	Total phenolic content	0.2 to 3% w/v equivalent to tannic acid.	Not less than 0.05% w/v equivalent to tannic acid	0.070 to 0.091 % w/v equivalent to tannic acid.	0.154 to 0.189% w/v	0.2% w/v equivalent to tannic acid.

DISCUSSION AND CONCLUSION

It is an attempt to review and understand the standardization of *Asava-Arishta* 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 effervescence sound, clear liquid without any froth, matchsticks test.

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 *Asava-Arishta*. The pharmacopoeia standards for compound formulations does help in retaining uniformity and consistency in preparation of *Ayurvedic* drugs.

1. PH- the PH value of sample is direct function of the hydrogen ions presents. PH may be defined as a measure of free acidity. it is essential for stability and physiological stability for shelf life determination of pharmaceutical products. *Asava-arishta* used in this study is found to be in the range of 3 to 4.5 which is clearly indicated that the preparation is acidic. Ex., PH of *Drakshasava* 3.82 and PH of *Draksharishta* 4.40.[12]

2. Viscosity- it is liquid property that's measures its frictional resistance. Viscosity parameter is essential to conclude the consistency and stability of pharmaceutical product. Ex., viscosity of *Drakshasava* 0.07515 and viscosity of *Draksharishta* 0.02135.[12]
3. Specific gravity- specific gravity of liquid is based on the density of material which directly reflects pharmacokinetic profile of drug i.e., absorption, metabolism, excretion etc. site of action and compatibility with body fluids are also affected by specific gravity of drug. The range of Specific gravity in above mentioned *Asava-Arishta* is found in between 1.0 to 1.15g/ml. specific gravity of *asava-arishta* varies according to different *asava-arishta*. Ex., specific gravity of *Drakshasava* 5.4 and *Draksharishta* 5.5 to 5.6.[12]
4. Viscosity and specific gravity are two different things viscosity is a characteristic property of liquid, it determines the stickiness of the fluid. And specific gravity means how much an object dense or heavy will occupy that much space.
5. Sugar content- sugar is a relevant ingredient in many food and drugs for better palatability and taste. But in *asava-arishta* used for long time stabilization of product and act as preservative. Its range varies depending on the amount of sugar addition in *asava-arishta*. Ex., reducing in *Drakshasava* 31.57% and non-reducing sugar is 3.315 and in *Draksharishta* reducing sugar 41.18%, non-reducing sugar 3.165.[12]
6. Alcohol content- *Asava-arishta* are very important dosage forms of Ayurveda and they contain naturally generated alcohol. This alcohol acts as the medium for active ingredients of the herbs to dissolve in it. In above *asava-arishta* it is found to be in the range of 5 to 10% v/v. alcohol content of drug also depends on amount of sweetening agent added for example alcohol content in *Drakshasava* 5.32 % and that of *Draksharishta* 8.56 %.[12]
7. Total solids- a high concentration of total solids makes *Asava-arishta* unpalatable and might have adverse effects on people. Level of total solid that are too high or too low can also reduce the efficiency. Means it is directly proportional to the efficacy of the drug. *Asava-arishta* are polyherbal formulations so, in above *asava-arishta* range of total solid may varies. Ex., total solid of *Drakshava* 8.8861% to 11.6619% and that of *Draksharishta* 7.11% to 29.5601%.[12]
8. Total phenolic content- it is a special class of secondary metabolites that indicates mostly antioxidant, antimicrobial, anticancer etc. like therapeutic activity. It should be maximum or not less than in sample material for better efficacy.in the above asava-arishta its range found in between 0.07% to 3.0% w/v.
9. 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)[13]
10. Test for Aflatoxins- Aflatoxins are very dangerous to the human body. Accurate analysis is required to determine residuals or lower level 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.[13]
11. 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- 10^5 /g*
Total yeast and mould- 10^3 /g*.
(For topical use the limit shall be 10^7/g).[13]

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