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STANDARDISATION OF AYURVEDIC FERMENTED PRODUCTS (ASAVARISHTAS) - AN UPHILL BATTLE

Divya S Balachandran

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ABSTRACT

Ayurveda was developed through daily life experiences with the mutual relationship between mankind and nature. Ayurveda comprises of various types of medicines including fermented forms, namely, *arishtas* and *asavas*. *Asavarishta* are unique liquid dosage form of Ayurveda that contains self-generated alcohol produced as a result of fermentation. Standardization of Ayurvedic formulations is an important step to ensure: a consistent biological activity, a consistent chemical profile, or simply a quality assurance program.For a standard end product, there should be quality assurance in each step beginning from the procurement of raw materials. The first measure to be taken is preparation of Standard Operating Procedure (SOP).In each of thesteps in SOP; certain Critical Control points (CCP) are to be taken into account. Standardization of Ayurvedic products is the need of the era. Standardization of *Asavarishtas*can be achieved to a great extent by strictly following the SOP and considering the CCP.

Key words: *Asavarishta*, Standardization, SOP, CCP

INTRODUCTION

The Indian subcontinent harbors many traditional health care systems. Ayurveda is one of the most ancient systems of medicine known today developed through experiences in daily life and relationship between mankind and nature[1]. The origin of this science is difficult to pinpoint, it have been placed by scholars of Ayurveda and ancient Indian literature at around 6000 BC.

This traditional system comprises of various types of medicines including fermented forms, namely, *arishtas* and *asavas*. Fermented dosage forms is highly palatable and stable[2].

Divya S Balachandran
(MD (Ay), Assistant production Manager, R&D, Oushadhi-The Pharmaceutical Corporation (IM) Kerala ltd, Kerala, India
E-mail: dsb_balu@yahoo.com

Fermentation technology is the oldest of all biotechnological processes. Fermentation is a process of chemical change caused by organisms or their products, usually causing effervescence and heat[3].The use of fermentation, particularly for beverages, has existed since the Neolithic and has been documented dating from 7000–6600 BCE in Jiahu, China, 5000 BCE in India[4]. In 1877, Pasteur published his famous paper on fermentation. He defined fermentation as "Life without air", but showed that specific types of microorganisms because specific types of fermentations and specific end-products.[5]

Even before the principles in fermentation technology was explored by scientists, the preceptors of Ayurveda were aware of it and they have explained the basic requirements of

fermentation, their quantity and quality checks[6]. *Asavarishta* is a very popular dosage form in Ayurvedic medicines. It is a unique liquid dosage form that contains self generated alcohol, process referred as *Sandhanakalpana*. This self generated alcohol is produced by method of fermentation. [7] Standardization is defined as the process of implementing and developing technical standards based on the consensus of different parties that include firms, users, interest groups, standards organizations and governments[8]. Standardization can help to maximize compatibility, interoperability, safety, repeatability, or quality. It can also facilitate commoditization of formerly custom processes. Standardization of Ayurvedic formulations is an important step for the establishment of a consistent biological activity, a consistent chemical profile, or simply a quality assurance program for production and manufacturing of herbal drugs. WHO specific guidelines for the assessment of the safety, efficacy and quality of herbal medicines as a prerequisite for global harmonization are of utmost importance.[9]Parameters for standardization of the final products are explained in The Ayurvedic Pharmacopoeia of India (API)published by the Government of India.

Standardization of *Asavarishtas*

As mentioned earlier, *Asavarishtas* are very potent medicine in Ayurveda with self-generated alcohol. Even before the advent of modern fermentation technology, the classics of Ayurveda had clearly defined the inputs and their ratio for effective fermentation. For fermentation the inputs are

1. A source of carbohydrate: in *asasavarishtas*, it may be sugar, jaggery or honey.
2. A fermentation initiator: in modern breweries, it is yeast. In *Asavarishtas*, the sources of yeast are many- Flower of Woodfordiafruticosa, honey, flowers of *Madhukaindica* etc. Among these the one appearing in the majority of formulations is Flower of Woodfordiafruticosa.
3. A medium for action: mostly decoction of the main ingredients or juices or boiled and cooled water.
4. Powder: the alcohol extractive of which gives the therapeutic action- said as *prakshepadravya.*

As per the classical texts, these are mixed together in the given ratio and tied in earthen pot with airtight sealing, and buried in the ground. The action taking place here is probably – the sugar medium serves as a substrate for the growth of yeast. The yeast multiplies and respires in the sugar medium, producing alcohol and carbon dioxide. As the alcohol is generated, the alcoholic extractive of the powder starts dissolving in the medium. At the stage of saturation, the self generated alcohol suppresses the multiplication of yeast. After one month, the pot is taken out and opened, filtered and stored for usage.

With the advent of modern fermentation techniques which aided easy bulk manufacturing, earthen pots were replaced by fermenters. Inspite of burying in the ground to attain temperature control, it was effectively achieved by water jacketed fermenters connected to temperature controllable chilling system. The fermenters are equipped with stirrers, sampling outlets, carbon dioxide vent, outlet for waste removal, provision for washing and steam sterilization.

For a standard end product, there should be quality assurance in each step beginning from the procurement of raw materials. The first measure to be taken is preparation of Standard Operating Procedure (SOP). A set of written instructions that document a routine or repetitive activity.

It should consider the following points

1. Procurement of Raw material(RM) – place, season, part used
2. RM Quality Control (QC)-varies with each group of raw material – herbs, minerals, sugars etc…
3. Semi-Processing of RM –Cleaning washing etc.
4. Pre processing – size reduction, size separation
5. *Kashaya* (decoction)/ *swarasa* (juice)/ boiled &cooled water

6. Addition of substrate (the source of carbohydrate which serves as the growth medium for yeast)
7. Cooling- in chilling chamber
8. Addition of honey- in honey mixer
9. Main process- fermentation
10. Transferring to fermentors
11. Addition of *Dhataki* (Woodfordiafruticosa)
12. Addition of *prakshepa*
13. In process Quality Control (QC)

Parameters to be checked

a. *Kashayam:* Total soluble solids(TS), pH, Specific Gravity to ensure optimum concentration, batch to batch standard
b. *Kashayam* + substrate: TS, pH, Specific Gr, Acidity
c. While entering into fermentor : temperature
d. During fermentation: Organoleptic, Temp. of circulating water, Total Soluble solids, pH, Specific Gravity, Acidity, Reducing Sugar,Non-reducing sugar, Alcohol %, Microbial contamination.
e. Sampling at 5 days interval : to ensure proper fermentation & other features, and to take corrective actions wherever necessary

14. Finished Goods(FG) QC: The analytical standards for *Asavarishta*, laid down by The Ayurvedic PharmacopoeiaofIndia are

a. Organoleptic : Taste, colour, odour
b. Physicochemical: Total solids, pH, Specific gravity, Reducing sugar, Non- reducing sugar, Alcohol content, Total phenolics
c. Microbiological : Total bacterial count, Total yeast and mould
d. Others: Aflatoxins, Pesticide residue, TLC

In each of these steps in SOP, certain Critical Control points (CCP) are to be taken into account. Step or procedure at which controls can be applied and a Quality variation can be prevented, eliminated or reduced to acceptable (critical) levels. For *asavarishta* preparation, CCP's are:

1. Herbal raw materials: should be in the dried state. Decoction of fresh drugs may contain more mucilage and the specific gravity may be increased which causes delay in the initiation of fermentation. All raw materials should be free of any contaminations as presence of microbes adversely affects fermentation. Woodfordia flower should be clean, dry and free of extraneous matters like leaves, soil, etc. For size reduction of *kashayachoorna*, shredding is advisable. If more size reduction is done, there is increase in total solids and specific gravity which causes difficulty in initiation offermentation/delayed fermentation. Size reduction of powdered drugs- powdered drugs should not be finer than 60-80#. More fineness lead to poor sedimentation, decrease in output volume, variation in consistency, secondary fermentation
2. Quality of Jaggery: Jaggery should be of uniform colour in all lots as it directly affects the colour of the end product. Total sugar should be around 90% which is optimum for fermentation. Extraneous matter should not be more than 2% as more extraneous matter causes decrease in total sugar which affects the final output and fermentation process. Considerable presence of hydrose affects the rate of fermentation which results in Delayed fermentation, low alcohol content causing sour taste.
3. Quality of water: should be tested for pH, TS, Specific gravity and microbial load. If pH is low it causes more acidity. More dissolved solids leads to increase in specific gravity which leads to sour taste& difficult to initiate fermentation
4. Preparation of decoction: Fix the value of total dissolved solids for each *kashaya*- To get uniform concentration of *kashaya* for every batch. Sometimes the quality of raw drug and its state may alter TS, it affects specific gravity &taste may vary batch to batch. More extraction causes delayed fermentation due to increase in specific gravity
5. Jaggery mixing: If added by boiling immediate cooling is to be done to avoid more exposure time- Less exposure reduce chance of contamination. Temperature of the substrate should be checked and make sure that it is cooled to ambient temperature before feeding

to the fermenter, if it is not cooled to ambient temperature then there is delay in the fermentation initiation.

6. Filling into fermenter: Thorough mixing should be done. Make sure Woodfordia flower do not float on top, the yeast activity occurs only when the flower comes in contact with sugar solution. If this is not taken care, it causes delayed fermentation & fungal growth. Proper head space should be given- The oxygen present in the head space is essential for yeast multiplication in the first stage- which favors initiation of fermentation. Occasional stirring should be done to disturb the equilibrium which in turn speeds up fermentation.
7. Temperature control: Ensure that the temp. inside the fermenter is optimum. (water jacketed vessel or the environment temperature is maintained by artificial method)-During the time of fermentation temperature increases rapidly. If it exceeds the optimum level then the rate of fermentation decreases causing low alcohol content, sour taste, secondary fermentation
8. Filtration: It is done only after ensuring that all the parameters satisfy the desired value. Make sure that the fermentation is also completed- If the alcohol content is not enough then there is chance of contamination in the final product leading to secondary fermentation , fungal and bacterial toxins, non-agreeable taste and odour
9. Sedimentation: Proper sedimentation should be ensured and the product should be clear. Use of a centrifuge is advisable- If sediments are more than the quality and stability of *arishta* is compromised. By the removal of sediments the micro organisms are also removed to a great extent. Or else it causes secondary fermentation affecting quality and stability.
10. Packaging and sealing, hygeinity etc., are other points to be critically controlled.

Only if the SOP is followed and CCP are considered will the final product be up to the required standard.

Bottle necks

1. Standardization of raw materials: The quality of the final products depends directly on the quality of the input raw materials. But the standards of some of the herbal raw materials may vary according to season, place and time of collection. Many of these factors are beyond the scope of standardization.
2. Cleanliness and purity of all the raw materials including Woodfordia flower: many of the raw materials may be collected and stored in non-hygienic conditions which cause contamination and adversely affect fermentation. Mere washing or drying may not be enough many a times.
3. Control over fermentation: for perfect fermentation to be achieved there should be pin point control over all the factors discussed above.
4. Standardization of the final product: in spite of strictly following all the factors, the final product may sometimes show slight variation from batch to batch which cannot be corrected at the final stage. Even though they are of least concern while considering therapeutic efficacy yet, it may affect the customer satisfaction.
5. Once alcoholic fermentation is diverted to acidic fermentation, in case of *asavarishtas*, it is very difficult or rather impossible to revert it by natural means.

CONCLUSION

Standardization of *Asavarishtas* can be achieved to a great extent by strictly following the SOP and considering the CCP. Standardization of Ayurvedic products is the need of the era. Even though Ayurveda is India's own oldest health care system, lack of standardization and scientific evaluation is the one reason why it is downgraded to the position of an alternative or complimentary medicine. For a science, which can cope with contemporary sciences and be sustained for thousands of years, the authenticity is explicit. Yet for the modern scientific community to get convinced, the scientific validation of any data is indispensable.

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