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Review on Standardization of Ayurvedic Medicine

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Authors' contributions

This work was carried out in collaboration between both authors. Both authors read and approved the final manuscript.

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Review Article

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ABSTRACT

Standardization in Ayurvedic formulations ensures the establishment of standards for the quality and purity of raw materials, quality control during the drug manufacturing process, production of a good quality finished product, storage and distribution to maintain the quality of the final product. It is an essential tool for establishing quality control methods for Ayurvedic drugs. In Ayurveda, standardization has been well defined and documented in the classical and contemporary texts. Still, these have been written with an individualistic intent and not for industrial or commercial purposes. Careful contemplation of the classical literature of Ayurveda was done, the current guidelines of WHO on standardization of herbal drugs, latest researches on the same via the internet were explored and examined in the purview of the newest standardization procedures. In this article, an attempt has been made to bring to light the classical references related to standardization, the milestones in this on-going pursuit have been exhibited, with the use of the latest scientific methods being incorporated for a standardized Ayurvedic drug. It can be concluded from the review that standardization in Ayurveda is an on-going process where one needs to be strictly vigilant about the new scientific methods to study the fine chemical procedures and the intermediate compounds formed, but at the same time be aware of the classical. Ayurvedic methods concepts of the procedure. Asava-arista's medicinal characteristics of Ayurvedic classical dosage forms, liquid dosage forms based on self-generated alcohol with faster absorption, long shelf life, and increased market conformity have led to a continuous rise in demand. New fermentation methods and packaging innovations tend to have been embraced by many Ayurvedic processing units. The importance of standardization of such goods is underlined by these advances in manufacturing, distribution and storage. Therefore, it is of concern to examine the latest manufacturing situation and the standardization of the dosage type regarding the procedure and

the consistency and effectiveness of the finished product. In addition to the effort to include criteria of consistency and standardization, the study consists of an overview and deliberates on the importance of improvements made to the conventional preparation processes, ingredients and material used in the process and the potential impact on its efficacy.

Keywords: Asava-Arishta; ayurveda; medicinal plant; quality control; standardization.

1. BACKGROUND

Ayurvedic medicine system is advantageous to humanity, but there is still a lack of appropriate standardization techniques for determining its consistency, quantity and effectiveness. As per WHO guidelines, chromatographic methods are precise to standardize and admeasure the main biomarker molecules through nuclear drugs and formulations from poly-herbal. The oldest prevalent system for dealing with the disease is utilizing medicinal plants to treat diseases. In ancient civilized countries such as Africa, China, Egypt, India, South America, etc., 80% of the community relies on herbal treatment to treat countless fatal Illnesses such as AIDS, cancer, malaria, etc. A variety of local programmes announce the presence of about 800 medicinal plants, such as Ayurveda, Siddha, &Unani medicines [1]. Production of conventional drugs has contributed to a reduction in ayurvedic plant products in the twentieth century. In recent years, thanks to thorough studies on the pharmacological impact on human health care, herbal remedies have steadily acquired significant acceptance and renown. While much research has been attempted in recent years, there is still inadequate knowledge on herbal medicine phytochemistry and metabolomics, which has developed a major challenge in standardization methods [2]. The proper protection and effectiveness standards for human quality of life should be practised by herbal remedies or phytomedicine [3]. Therefore, the quality management and standardization protocols of herbal drugs have required a system.

There are two types of Ayurveda formulations: developed only from 1 herb and poly-herbal formulations processed from the mixture of several herbs [4]. The literature describes the highest quality evaluation of herbal ingredients relies on observational studies (i.e. physicochemical, microscopic and macroscopic research) [5]. Therefore, for the authentication of herbal/polyherbal Ayurvedic formulations, standardization protocols using non-conventional analytical practices are required. Preliminary analysis of biologically susceptible marker agents is currently getting much successful in herbal medication verification and thus helps to decrease adulteration [6,7].

2. DETERMINATION OF FOREIGN MATTER

Drugs, such as mud, sand, stone, and foreign matter, must be mould-free and insect-free. Often foreign matter consists of sections of plant organs other than that provided by the WHO standards for the substance by itself or above the cap. The number of foreign substances should not be greater than the recommended limit. It is important to weigh 100-500g of the drug content or use the amount recommended by the WHO guidelines. Foreign matter can be observed by unassisted eye examination or using a 6X power lens. Segregate the external matter and measure the current proportion [9].

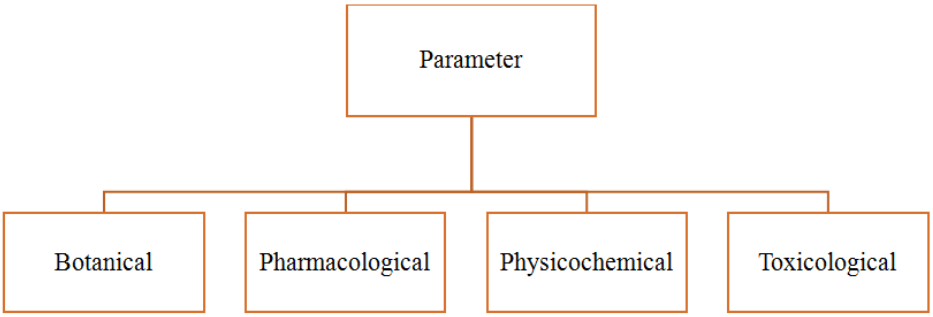

Fig. 1. WHO Guidelines for quality standardized herbal formulations [3]

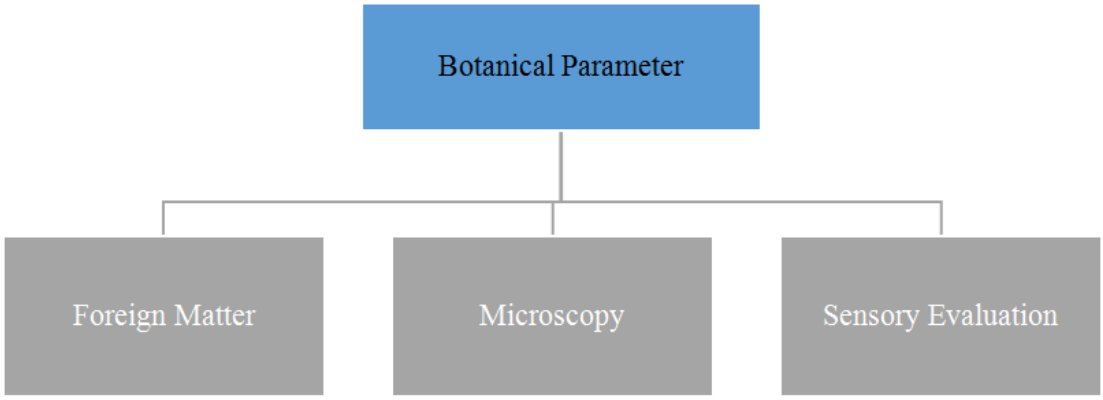

Fig. 2. Botanical parameter [8]

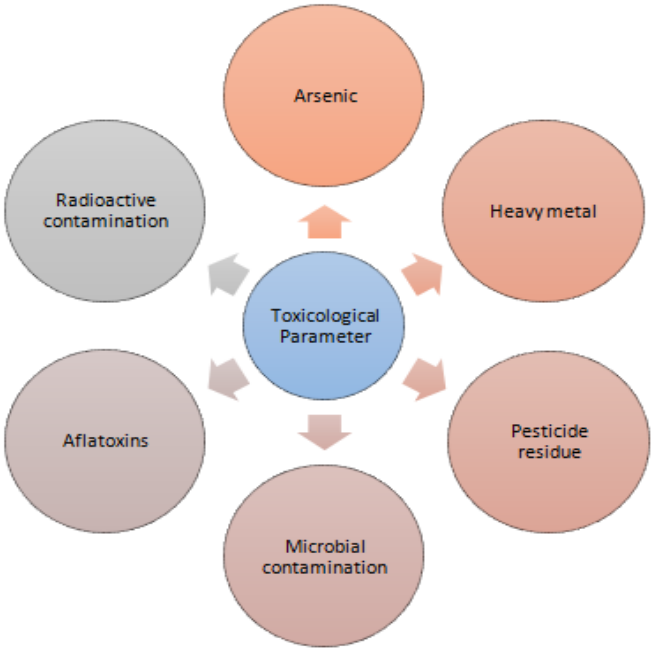

Fig. 3. Toxicological parameter [8]

3. DETERMINATION OF ARSENIC AND HEAVY METALS

Many effects can be ascribed to the toxicity of herbal plant products with arsenic and heavy metals, along with environmental air quality and pesticide residues. The quantity of arsenic in the therapeutic organic matter is calculated by pairing the colour with a normal stain.

4. APPROACHES TO STANDARDIZATION

Standardization of Ayurvedic products is an area of scientific and industrial interest. Large scale production needs changes in preparations of classical Ayurvedic products. Satisfying the needs of the large-scale output while adhering to the principles of Ayurveda requires careful considerations before adapting to new methods. Different parameters have been applied to standardize this self-generated alcohol-based liquid classical dosage form.

For several years different approaches to standardization of Asava-arista have been undertaken. These quality control approaches can be broadly divided into 3 categories:

- Approach related to raw material and equipment

- Approach related to standardization of manufacturing process
- Approach related to standardization of properties and quality of the end product

4.1 Approach Related to Raw Material and Equipment

The quality of raw material, herbs, and other ingredients used for these preparations strongly bear the process and the finished product. Raw material for these preparations must be authenticated and examined for required quality. Testing of limits of heavy metals, microbial load, and residual pesticides is envisaged as these will impact the main fermentation process, and certain impurities may get retained through the process. The right storage conditions should be followed for this raw material before taking up the main production process. The type of equipment used, material used for fermentation and storage vessels, treatment mooted to the vessels, temperature and storage conditions factors will impact the process.

4.2 Approach Related to Standardization of Manufacturing Processes

The 3 most relevant parameters for the standardization of *asava- arista* are -

1. Effect of temperature
2. Fermentation time
3. Use of various vessels and fermentation conditions

OUTCOME OF THE STANDARDIZA-TION EFFORTS

Table 1. Outcome of Standardization: Summary Chart [10 11]

Parameter	Outcome/ Impact	Explanation/Remarks
1 (a)Rawmaterialstandardisation		
Raw material	Authentication and storage	As per Pharmacopoeia and GMP guidelines
1(b)Manufacturing processes		
Temperature	Hot decoction: Lower pH &higher acidic tythan cold decoction Hot decoction: Yeast cells are destroyed because of higher temperature;Notfavorableforfermentation Cold decoction: Yeast cells are not destroyed; hence favourable for fermentation.	The optimum temperature for the fermentation process is between 20-35°C
Fermentation time	Enhance in alcohol content with enhance in time for fermentation.	Fermentation time depends on the geographic location and season, and ingredients used (Liquid ingredients)
Earthen pot	There is more evaporation of water, limits the solubility of the compound, alters pH medium and affects the performance of micro-organisms	Requires delicate handling, the tendency of breakage & leakage
Aluminium	Traces of aluminium and ferrous ions found in the final product	Inappropriate for production
Wooden vessel	Final Product: Denser inconsistency	Absorption of liquid by wood
Stainless steel	No significant variations in physicochemical parameters	It can be used for large scale production
Glass vessels	The final product in a glass container is more acidic than in an earthen pot	Not convenient for large scale production
Tinned copper	A better choice for fermentation	It can be used for large scale production

Parameter	Outcome/ Impact	Explanation/Remarks
1(c)Endproductstandardisation		
pH	Affected by temperature and fermentation time	Affect the solubility, stability and quality of the product, essential if the product is more acidic or alkaline
	The utilization of a buffer to control potential changes in the solution pH	
Specific gravity	Temperature	Affect the flow property
Total solid content	Total solid content: Fermentation Time	Solid contents are converted to a fermentation product
Reducing sugar percentage (RSP)	RSP reduces with fermentation time	When the percentage remains stable, The finalization of the fermentation reaction is an indicator for determining
Non-reducing sugar percentage(NRSP)	⁄aries with temperature and with fermentation time. (Due to the presence of micro-organisms)	It is an indicator for assessing whether the percentage stays constant for the end of the fermentation reaction.
Total sugar percent	Total percentage of sugar at fermentation time	It also depends on the type of sweetening agent added,
	It is a less unfinished product and varies with the vessels used.	Convertedtoalcohol
Ash value	More in markets ample than lab method	Indicativeofadulteration
Alcohol percentage	Enhanced with reference to the time duration for fermentation	Important with respect to therapeutic activity and stability
	When prepared in a glass vessel	Product may become acidic
Thin-layer chromatography	Identification of Phytoconstituents: as a standard to compare	Qualitative standardization technique
High-performance liquid chromatography	Comparison with marker compound, isolation of functional group used as a standard parameter	Quantitative standardization technique

6. CONCLUSION

The study consists of an overview and deliberates on the importance of improvements made to the conventional preparation processes, ingredients and material used in the process and the potential impact on its efficacy.

DISCLAIMER

The products used for this research are commonly and predominantly used in our area of study and country. There is no conflict of interest between the authors and producers of the products because we do not intend to use these products as an avenue for litigation but for the advancement of knowledge. Also, the research was not funded by the producing company; rather, it was financed by the personal efforts of the authors.

CONSENT

It is not applicable.

ETHICAL APPROVAL

It is not applicable.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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