Ayurveda system of medicine and standardization

Abstract- Asava-arishta, the 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 standardisation 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 standardisation of the dosage type as regards the procedure and the consistency and effectiveness of the finished product. In addition to the effort to include criteria of consistency and standardisation, the study includes 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.

Keys- Asava-Arishta, Ayurveda, Medicinal plant, Quality Control, Standardization.

Background-Ayurvedic medicine system is advantageous to humanity, but there is still a lack of appropriate standardisation techniques for determining its consistency, quantity and effectiveness. In order to standardise and admeasure the main biomarker molecules through nuclear drug and formulations from poly-herbal, chromatographic methods are precise, as per WHO guidelines. The oldest prevalent system for dealing with disease is utilise of therapeutic plants in treating diseases. In ancient civilised countries such as Africa, China, Egypt, India and 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 utilise of Ayurvedic plants products in the twentieth century. In recent years, thanks to thorough studies on pharmacological impact on human health care, herbal remedies have steadily acquired significant acceptance and renown. While much focus and study has been attempted in recent years, there is still inadequate knowledge on herbal medicine phytochemistry and metabolomics, which has developed a major challenge in standardisation 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 standardisation 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 highest quality evaluation of herbal ingredients, as described in the literature, relies on observational studies. Physicochemical, microscopic and macroscopic research[5]. For the authentication of herbal/polyherbalAyurvedic formulations, standardisation protocols using non-conventional analytical practises are therefore required. Preliminary analysis of biologically susceptible marker agent is currently getting much successful in herbal medication verification and thus helps to decrease adulteration[6,7].

Fig 1: WHO Guidelines for quality standardized herbal formulations

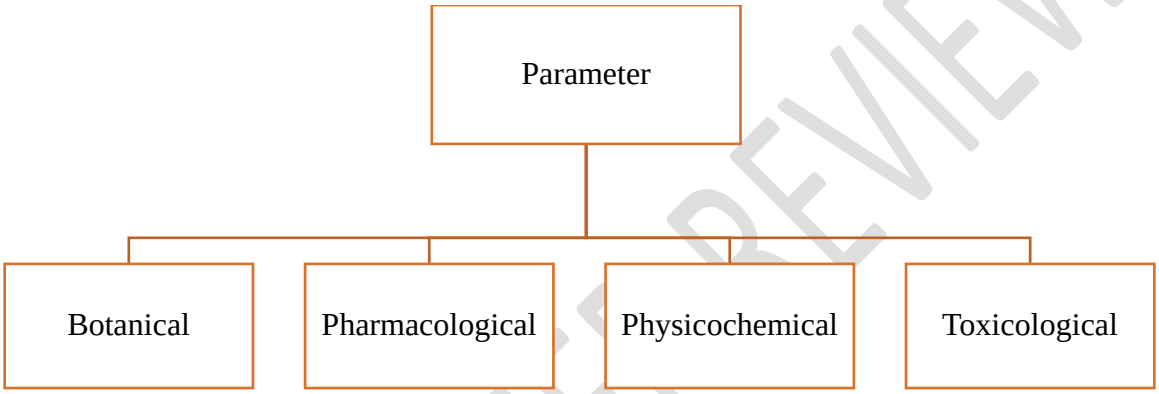
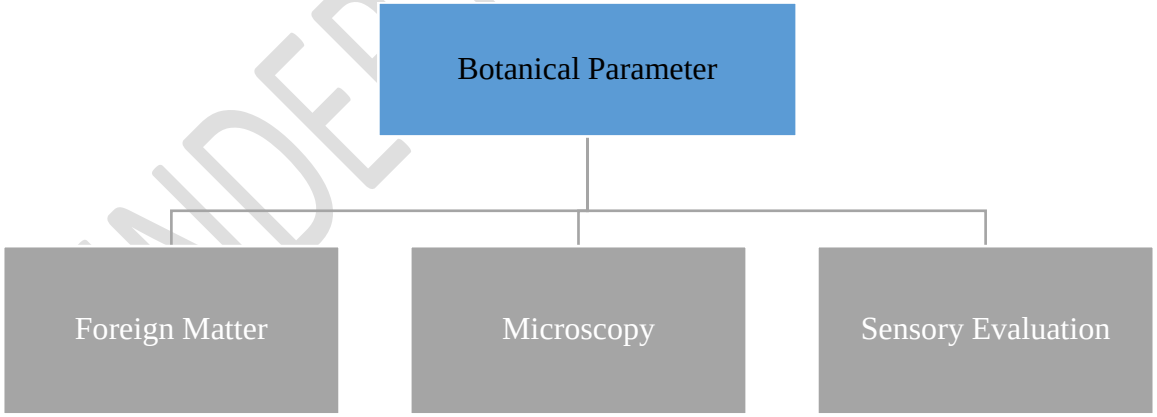


Fig 2: Botanical Parameter

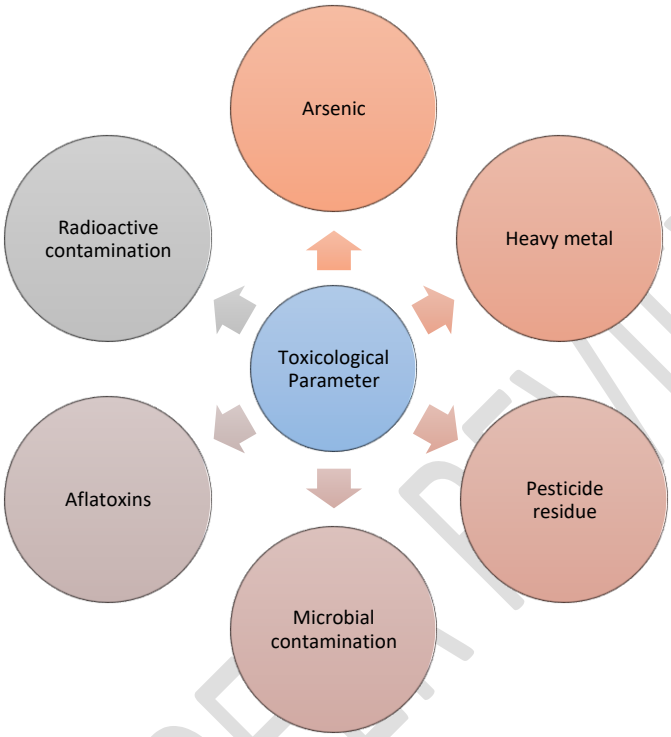


Determination of Foreign Matter

Drugs, such as mud, sand, stone, and foreign matter must be mould-free and insects free. Often foreign matter often consists of sections of the plant organ other than those provided by the WHO standards for the substance by itself or above the cap. The quantity of foreign substance should not greater than the recommended limit. It is important to weigh 100-500g

of the drug content, or to use the amount recommended by the WHO guidelines. Foreign matter can be observed by unassisted eye examination or by using a 6X power lens. Segregate the external matter and measure the current proportion[8].

Fig 3: Toxicological Parameter



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 those of a normal stain.

APPROACHES TO STANDARDIZATION

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

Over a period of several years different approaches to standardiseasava-arishta have been undertaken. These quality control approaches can be broadly divided into 3 categories -

- Approachrelatedtorawmaterialandequipment
- Approachrelatedtostandardisationofmanufacturingprocess
- Approachrelatedtostandardisationofpropertiesandqualityoftheendproduct

2.1. Approach related to raw material and equipment

The quality of raw material, herbs and other ingredients used for these preparations have a strong bearing on 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 are envisaged as these will have impact on the main fermentation process and certain impurities may get retained through the process. It is desirable that the right storage conditions are followed for these raw material before being taken up for main production process. [33] The type of equipment used, material used for fermentation and storage vessels, treatment mooted to the vessels, temperature and storage conditions factors that will impact the process.

2.2. Approach related to standardization of manufacturing processes

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

2.2.1. Effect of temperature

2.2.2. Fermentation time

2.2.3. Use of various vessels and fermentation conditions

OUTCOME OF THE STANDARDIZATION EFFORTS

Table- 1 Outcome of Standardization: Summary Chart

Parameter	Outcome/ Impact	Explanation/Remarks
	1 (a)Rawmaterial standardisation	
Rawmaterial	Authenticationandstorage	AsperPharmacopoeiaandGMPguidelines
	1(b)Manufacturingprocesses	
Temperature	Hotdecoction:LowerpH&higher(titrable)acidity thancold decoction	OptimumTemperature forFermentationprocessisinbetween20-35˚C
	Hotdecoction:Yeastcellsaredestroyedbecauseof higher temperature;Notfavorableforfermentation	
	Cold decoction:Yeastcellsarenotdestroyed hencefavorable forfermentation.	
Fermentationtime	Enhanceinalcoholcontentwithenhanceintimeforfermentation.	Fermentation timedependson geographiclocation andseason& ingredientsused(Liquidingredients)
Earthenpot	Thereismoreevaporation ofwater,limitssolubilityof compound,alters pHmediumandaffectsperformanceofmicro organisms	Requiresdelicatehandling,tendencyofbreakage&leakage

Aluminium	Tracesofaluminium andferrousionsfoundinfinalproduct	Inappropriateforproduction
Wooden vessel	FinalProduct:Denserinconsistency	Absorptionofliquidbywood
Stainlesssteel	Nosignificantvariationsinphysicochemicalparameters	Canbeusedforlargescaleproduction
Glassvessels	Finalproductinglasscontainerismore acidicthaninearthen pot	Notconvenientforlargescaleproduction
Tinnedcopper	Abetterchoiceforfermentation	Canbeusedforlargescaleproduction
1(c)Endproduct standardisation		
pH	Affected bytemperatureandfermentation Time	Affectthesolubility,stabilityand qualityoftheproductEssentialiftheproductismore acidicoralkaline
	Utilisationofabuffertocontrolpotentialchangesin thesolution pH	
Specific gravity	Temperature	Affecttheflowproperty
Totalsolidcontent	Totalsolidcontent:FermentationTime	Solidcontentsareconvertedtofermentationproduct
Reducingsugarpercentage(RSP)	RSPreduceswith fermentation time	Whenthepercentageremains stable,Thefinalisationof the fermentation reaction is anindicator fordetermining
Non-reducing sugarpercentage(NRSP)	NRSPvarieswithtemperatureandwithfermentationtime(Duetopresenceofmicroorganism)	Itisanindicatorforassessingtheendofthefermentationreactionwhetherthepercentagestaysconstant.
Totalsugarpercent	Totalpercentageofsugaratfermentationtime	Alsodepends ontypeofsweeteningagent added, Convertedtoalcohol
	Islessinfinishedproductandvarieswithtypeof vesselsused.	
Ashvalue	Morein marketsamplethanlab method	Indicativeofadulteration
Alcoholpercentage	Enhanced withreferencetotimedurationforFermentation	Important with respect totherapeuticactivityandstability
	Whenpreparedinglassvessel	Productmaybecomeacidic
Thinlayerchromatography	Identification of Phytoconstituents: as aStandard tocompare	QualitativeStandardisationtechnique
High performanceliquid chromatography	Comparisonwithmarkercompound, isolationoffunctionalgroupusedasstandardparameter	QuantitativeStandardisationtechnique

NOTE:

The study highlights the efficacy of "Ayurveda" which is an ancient tradition, used in some parts of India. This ancient concept should be carefully evaluated in the light of modern medical science and can be utilized partially if found suitable.

COMPETING INTERESTS DISCLAIMER:

Authors have declared that no competing interests exist. The products used for this research are commonly and predominantly use products in our area of research and country. There is absolutely 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 any litigation but for the advancement of knowledge. Also, the research was not funded by the producing company rather it was funded by personal efforts of the authors.

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