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Standardization of Herbal Ayurvedic Formulation

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ABSTRACT
Standardization in Ayurvedic formulation is distributed with the acceptance of standards for the quality and purity of raw materials, quality control at the flow of the drug manufacturing process, production of a good quality complete product, storage, and distribution to keep the quality of the end product. Numerous pharmaceutical companies be manufacturing and marketing different Ayurvedic formulations, developed as per the classical texts and the regulatory standards It is a main tool for establishing quality control methods for Ayurvedic drugs. Ayurveda is known for theutilization of poly-herbal formulations and multi-component therapeutics for the treatment of health and diseases.

Keywords: Ayurvedic, formulation, quality, herbal, drugs, medicine, manufacturing.

I. INTRODUCTION

Standardizationis major important to establish a system of standardization for every plant medicine in the market.Because the scope for variation in different batches of medicine is enormous. Ayurvedic care is not so highly effectiveStandardization is aprincipal factor forpolyherbal formulation in order to analyze the quality of the drugs and turn on the concentration of their active principle. The proper mode of action, pharmacology, pharmacokinetics, and pharmacovigilance of many important Ayurvedic drugs are still not fully explored.[1]In India, around 15,000 medicinal plants have been registered, which only used is7,000-7,500 plants for curing different diseases.In Ayurveda, single or multiple herbs (polyherbal) are used for the treatment. In Ayurveda, single or multiple herbs (polyherbal) work for the treatment.In India, around 15,000 medicinal plants have been registered, which the only used are 7,000-7,500 plants for curing different diseases.[2]

Herbs count crude plant material, such as leaves, flowers, fruit, seeds, stems, wood, bark, roots, rhizomes, or other plant parts, which may be entire, fragmented, or powdered.Herbal medicines containherbs, herbal materials, herbal preparations, and finished herbal products. In some countries, herbal medicinesmay include, by tradition, natural organic or inorganic active ingredients that are not of plant origin (e.g., animal and mineral materials).[3]In this article, an attempt has been made to bring to light the classical references related to standardization, the milestones in this ongoing pursuit have been exhibited, with the use of the latest scientific methods being incorporated for a standardized Ayurvedic drug.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.It is arequired tool for establishing quality control methods for Ayurvedic drugs. Careful contemplation of the classical literature of Ayurveda was done, and thepresent guidelines of WHO on the standardization of herbal drugs, the latest research on the same via the internet were explored and examined in the purview of the newest standardization procedures.[4]In Ayurveda, standardization has been well-defined and documented in classical and contemporary texts. Still, these have been written with an individualistic intent and not for industrial or commercial purposes.[5] It can be concluded from the review that standardization in Ayurveda is an ongoing 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

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of the classical. Ayurvedic procedure concepts of the procedure. [6]

Role of standardization on the herbal ayurvedic formulation

In order to getquality-oriented herbal products care should be taken right from the proper Empathy of plants, season, area of collection, their extraction and purification,andrationalizing the combination in the case of polyherbal drugs.The Modern system of medicine is based on sound experimental data, toxicity studies, and human clinical studies. But, Pharmacopoeia standards on raw materialsand finished products are not available. cGMP for the herbal industry is not well defined nor the barest minimum standards of medicinal plant productsare maintained or regulated.Standardization of herbal drugs is not an easy task as numerous factors influence the bioefficacy and reproducible therapeutic effect. The lack of quality standards has resulted in mild to seriousadverse effects ranging from hepatic toxicity to death. Hence, herbal ingredients require tools for determining identity, purity and quality, and tools have to be technically sufficient, rapid and cost- effective with GMP requirements. World health organization has set specific guidelines for the assessment of the safety, efficacy, and quality of herbal medicines.[7]

Standardization of herbal ayurvedic formulation

Inaddition, the study of various parameters such as pharmacodynamics, pharmacokinetics, dosage, stability, self-life, toxicity evaluation, and chemical profiling of the herbal formulations is considered essential. Heavy metals contaminations, Good Agricultural Practices (GAP) in herbal drug standardization are equally important.It can be concluded from the review that standardization in Ayurveda is an ongoing 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 herbal formulation, in general, can be standardized as to formulate the medicament using raw material collected from different localities and a comparative chemical efficacy of different batches of the formulation are to be observed.As usual, allherbal ayurvedic formulations even if they are synthetic or of plant origin, should fulfill the basic requirement of being safe and effective. The term herbal drug denotes plants or plant parts that have been converted into phytopharmaceuticals by means of simple processes involving harvesting, storage, and drying therefore they are capable of variation. This variability is also caused by differences in growth, geographical locations and time of harvesting.The preparations with better clinical efficacy are to be selected.[8] All the routine physical, chemical, and pharmacological parameters are checked for all the batches in order to select the final finished product and validate the whole manufacturing process. Standardization is an important aspect for maintaining and assessing the quality and safety of the polyherbal formulation as these are combinations of more than one herb to attain the desired therapeutic effect. Standardization minimizes batch- to- batch variation; assures the safety, efficacy, quality, and acceptability of the polyherbal formulations. of herbal formulation requires the implementation of Good Manufacturing Practices. 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.[9] The main standardization of such goods is underlined by these advances in manufacturing, distribution, and storage. Hence, 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 task and the potential impact on its efficacy.[10] shown in fig no (1)

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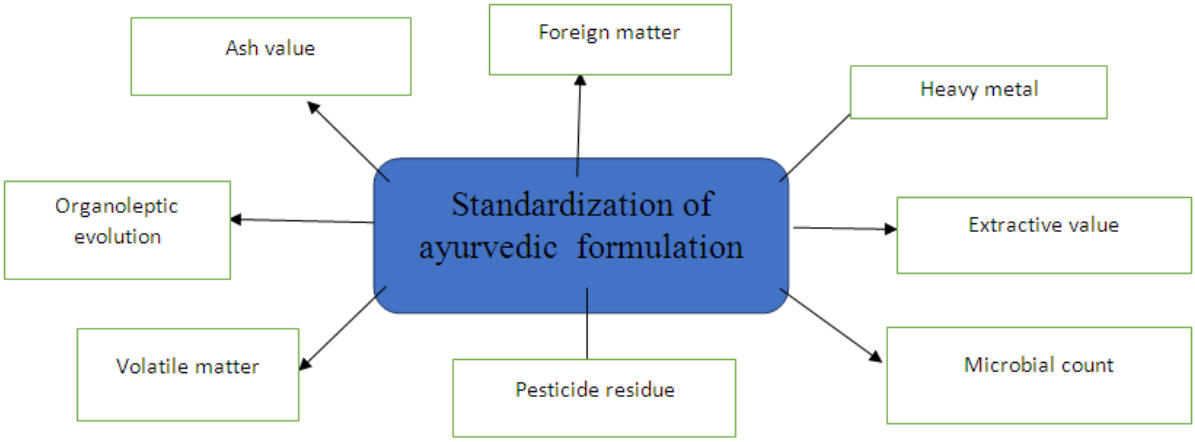

Fig no. (1)

WHO GUIDELINES FOR QUALITYSTANDARDIZED HERBAL FORMULATIONS

- Quality control of crude drug material, plant preparations, and finished productsAssessment of efficacy by ethnomedical information and biological activity evaluations. The bioactive extract should be standardized on the basisof active principles or major compounds along with the chromatographic fingerprints (TLC, HPTLC, HPLC, and GC).
- Safety assessment; documentation of safety based on experience or toxicological studies.
- Stability assessment and shelf life. [11]

Quality Control of Herbal Drugs

Quality control is a term that refers to actively involved in maintaining the quality and validity of a manufactured product.Quality control for the efficacy and safety of herbal productsis of paramount importance. Quality can be defined as thestatus of a drug that is determined by identity, purity,content, and another chemical, physical, or biological properties, or by the manufacturing processes.[12] This variability is also caused by d ingrowth, geographical location, and time of harvesting. A practical addition to the definition is also to include othercrude products derived from plants, which no longer showany organic structure, such as essential oils, fatty oils,resins, and gums.The term “herbal drugs” denotes plants or plant parts that have been converted into phytopharmaceuticals by means of simple processes involving harvesting, drying, and storage. Hence, they are capable of variation.[13]

- Identity
- Purity
- Strength and potency dose
- Uniformity of dosage form
- Bioavailability
- Stability

Advantages of Herbal ayurvedic: -

- They have a long history of use and better patient tolerance as well as acceptance.
- Medicinal plants have a renewable source, which is the only hope for sustainable supplies of cheaper medicines for the worlds growing population.
- Accessibility of medicinal plants is not a problem, especially in developing countries like India having rich agro-climatic, cultural, and ethnic biodiversity.
- Extend and apparently uneventful use of herbal medicines may offer testimony of their safety and efficacy.
- All over the world, herbal medicine has provided many of the most potent medicines to the vast arsenal of drugs available to modern medicinal science, both in crude form and as a pure chemical upon which modern medicines are structured.[14]

Disadvantages of herbal ayurvedic: -

- Produce negative effects.
- Headaches
- Dizziness
- Agitation
- Dry mouth
- Seizures[15]

Application of ayurvedic:

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Due to this stringency in the regulations, the quality of the synthetically manufactured pharmaceuticals is maintained up to the mark whichassures both safety and efficacy of the pharmaceutical products. As there is a growing demand for herbal pharmaceuticals, there is a need to assure their quality. Almost about 80% of the population is depending on the herbs for the treatment, cure, and prevention.They have to undergo various series the tests and quality control checks before being marketed and consumed by patients and consumers.[16]There must be guidelines and norms framed for carrying out the quality control testing of the herbs which are almost or equally strict as that of the synthetic pharmaceuticals. As there is a growing demand for herbal pharmaceuticals, there is a need to assure their quality. Almost about 80% of the population is depending on herbs for treatment, cure, and prevention.[17]So, different tools and techniques must be implied to verify and ensure the required quality to be incorporated into herbal material and products. This will help to maintain the quality standards of the herbal pharmaceutical which is the challenging task and need of the hour in pharmaceutical research and quality assurance.Quality is of prime concern to human beings in all aspects of life.When it comes to the quality of the pharmaceuticals which humans consume, it is of utmost importance as they are used for the well-being of the humankind. There are stringent guidelines and regulations for the quality control of synthetically synthesized chemical pharmaceuticals. [18]

Thermal analysis for the characterization of herbs and herbal products

In the thermal examination, time and temperature purpose are used as definingparameters. The temperature ranges from 25 to 1000 °C are used in thethermal analytical procedures. Mass Signals are obtained during the heating processes of the analysis which reveal the mass loss (mass lost in the thermal degradation process) in different defining steps (endothermic and exothermic).[19]

The drugs are to be disposed of after the thermal degradation is grasped place, so prior to this disposal process, studies are conducted where on the behavioral patterns of the drug after and during the degradation process are studies so that the level of toxicity nature of the drugs and drug product can be analyzed which can help in accessing the process to be selected for disposing of such degraded drugs and drug product as the preventive measure to reduce the potential hazard source by the disposed degraded substances to the environment.[20]

II. CONCLUSION

The plant environment and genetic factors made it significantly affect the biochemical components of the plant extract, in which plants are still the most abundant and cost-effective resource for drug innovation**.** In the case of herbal products which are part of the traditional medicine system, the novel formulations developed are required to be standardized for safety, efficacy, and potency. It is requiredthat various techniques are used for the quality control examination of the herbs, which can be regulated to gain the required quality products by setting proper norms. And this in turn will provide the safer use and effective treatment and required potency of the products which will benefit mankind and society by providing means of well-being. Standardization guarantees the content of one or more active constituents and marker compounds.

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CONFLICT OF INTEREST

We have no Conflict of interest.

AUTHORS CONTRIBUTION STATEMENT

Prof. Vikhe Sunayana and miss. Dighe pooja had given her contributed to directing articles and helps to find out adifferent article based on the standardization of herbal ayurvedic formulation. Mr. Dighe Jaideep had given his contributedin collecting data from a different journal articles and making manuscripts.

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