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REVIEW ARTICLE

Overview on Standardization herbal drugs

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ABSTRACT

Through this review work overview on the standardization on the various herbal drugs with general guidelines and intervention of DNA fingerprinting in drug quality assessment for showing the various parameters for standardizing the herbal products.

Key words: *Standardization, Parameters, DNA Fingerprinting*

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INTRODUCTION

Products made from plants are now more widely used. They are increasingly in demand as medications. In addition to prescription medications from non-allopathic physicians, health food shops and pharmacies also carry nutraceuticals and cosmetics for self-medication. Natural treatments are frequently used in healthcare systems [1, 2]. Both developed and developing nations face significant challenges. Plants are present in very few chemical combinations. They are less effective since they take longer to be absorbed. once ingested [3] Around the world, more than 80% of people still use herbal cures and other traditional treatments, according to a World Health Organization (WHO) estimate. For their demands in terms of fundamental healthcare, herbal formulas have developed to a high level of sophistication [4]. medications for diabetes, liver illness, cough, arthritis, and other conditions as treatments of acceptance Adoptogens, medications, and memory boosters. As stated by There are three categories of herbal medicines, according to the WHO: medicinal plants, processed plants, and raw plants. Herbal medicines are packaged, labeled finished commodities that contain active substances like plant aerial or underground parts, other plant material, or a combination of them, whether in their natural condition or as plant preparations, whether in their native state or a mixture. In keeping with the widespread trend of people going back to natural therapies, the usage of herbal medications has considerably increased [6]. As dietary supplements, people use herbal medicine products to improve their health. Tablets, capsules, powders, teas, extracts, and fresh or dried plants are among the shapes these products take [7]. Herbs are often seen to have more health benefits than drugs, and more individuals are utilizing them without a prescription. safe. However, some of them may interfere with other medications, while others may be useless and some may be dangerous to your health. For the purpose of evaluating the quality of herbal formulations, standardization is crucial. Based on how concentrated their active ingredients are, medications are categorized [8]. The industry and other organizations that deal with ayurveda and herbal products have come to rely heavily on the quality evaluation of herbal medicines. the expanding usage of botanicals, which are products like medications and other stuff made from plants. Action is being forced by public pressure to evaluate the health claims made by these agents and to set production and quality requirements. It is obvious that the herbal industry needs strict regulations and such restrictions. Herbal

medicine is governed by laws. According to a report [9], medicines are lawful in India, and information is also supplied regarding the legality of herbal medicine in the USA, China, Australia, Brazil, Canada, and Germany.A herbal product must undergo safety standardization in accordance with WHO criteria before going on sale.

HERBAL DRUG DEVELOPMENT

The process of turning botanical materials into medications is known as herbal drug technology, and it requires applying standardization and quality control while properly integrating both modern scientific methods and conventional wisdom [10–11]. Several regulatory authorities are pushing for the standardization of herbal formulations in response to an increase in reports of negative side effects. This is because the composition and quality of herbal medicinal treatments can vary from those of conventional pharmaceutical medicines. Proper identification and quality control are required for herbal medicine in order to assure reproducible quality, which supports its safety and efficacy [12]. The numerous methods utilized in the extraction, characterisation, and standardization of herbal, polyherbal, and nanoherbal medications are covered in this review article.

Standardization of herbal drugs

The process of turning botanical materials into medications is known as herbal drug technology, and it requires applying standardization and quality control while properly integrating both modern scientific methods and conventional wisdom [10–11]. Several regulatory authorities are pushing for the standardization of herbal formulations in response to an increase in reports of negative side effects. This is because the composition and quality of herbal medicinal treatments can vary from those of conventional pharmaceutical medicines. Proper identification and quality control are required for herbal medicine in order to assure reproducible quality, which supports its safety and efficacy [12]. The numerous methods utilized in the extraction, characterisation, and standardization of herbal, polyherbal, and nanoherbal medications are covered in this review article. Examples of application in manufacturing include drugs that establish a consistent biological activity, a consistent chemical profile, or even merely a quality assurance program [13]. For pharmaceutical firms, the general public, and to guarantee reproducible quality of herbal medicine, it is essential to recognize adulterants made from real medicinal plants and authenticate herbal remedies. Integration of natural remedies A procedure known as standardization[12] ensures that each dose's constituents have a specific degree of amount, quality, and therapeutic impact. If the medication tested has not been documented and confirmed to assure consistency in the production process, herbal treatments cannot be used. In addition, there are numerous harmful side effects. Effects that are directly dangerous, newly documented allergic responses, pollutants' effects, and combinations are only a few examples of interactions between herbal remedies. [6] Medicinal A herbal preparation's phytochemical composition is important. constituents. The creation of trustworthy analytical techniques to properly profile the phytochemical composition, including quantitative marker evaluations, bioactive chemicals, and other essential elements, is one of the largest difficulties facing scientists today. Standardization is a crucial step in the establishment process in light of the aforementioned. for the development and manufacturing of a natural medication, of a routine biological activity, routine chemical profile, or just a quality control method. [13]. Herbal drug identification and authenticity It is crucial to use real medical herbs free of adulterants for the benefit of pharmaceutical businesses, the general public, and to ensure that herbal medicine has a reproducible quality.

Traditional approaches of standardizing herbal formulation

The standardization of herbal raw medicines includes botanical authentication, microscopic and molecular investigation, identification of chemical composition using various chromatographic techniques, and biological activity of the entire plant.[5]

Several researches [15–17] have reported on the macroscopic and microscopic evaluation as well as the chemical profile of the herbal materials for quality control and standardization. As opposed to microscopy, which contrasts microscopic analyses of powdered herbal medicines, macroscopic evaluation criteria such as shape, size, color, texture, aroma, and taste are used to identify medicinal plant components. By using light and scanning electron microscopes (SEM) to identify herbal raw materials, developments in microscope technology have also increased the accuracy and capabilities of microscopy. drug uniformization [18]. Additionally, a wide range of cutting-edge techniques are presently used to standardize herbal medications [5,17,18-22], including electrophoresis, polarography, chromatography, spectrophotometry, and combinations of these techniques. The origins of key historical occurrences like governmental regulations, quality assurance, and the standardization of herbal treatments are difficult for scientists to comprehend. For the reasons listed above, standardization is a crucial step in the process of generating a regular biological activity, regular chemical profile, or simply a system for quality assurance

for the development and production of a natural medicine[13]. Herbal drug identification and authenticity Utilizing pure, genuine therapeutic herbs is essential. To guarantee that herbal remedies have a beneficial effect on Consistent quality in pharmaceutical and public health organizations.

Standardization of mixtures of herbs

Standardization is crucial for maintaining and evaluating the efficacy and security of polyherbal formulations, which combine several plants to produce the desired therapeutic effect[23]. Based on its organoleptic, physical, and physico-chemical properties, the polyherbal treatment for hyperlipdemia has been standardized[24]. A US patent [25] has been issued for the development and standardization of a polyherbal mixture containing four botanicals and designed for the treatment of arthritis. With the use of reliable markers and cutting-edge scientific tools, this effort was completed.

Standardization of several commercially available herbal and polyherbal formulations, such as Madhumehari Churna (Baidynath), which combines eight herbal antidiabetic drugs, including Momordica charantia (seeds), Syzigium cumini (seeds), Trigonella foenum (seeds), Azadirachta indica (leaves), and Emblica officinalis (fruits), , Gymnema (rhizomes and heartwood of Pterocarpus marsupium)]There have been reports of Gokshuradi Churna, Megni, Jawarish-e-Darchini, [26], Pancasama Churna, which is known to be beneficial in gastrointestinal illnesses, [27], Dashamularishta, a conventional formulation, utilized in the normalization of physiological processes after childbirth, and [28-30]. However, many polyherbal mixes are now primarily used for ethanobotanical purposes, necessitating standardization. Through standardization, which also reduces batch-to-batch variable, polyherbal formulations' acceptability, safety, efficacy, and quality are guaranteed[31].

As a safe alternative to synthetic methionine in chicken diets and as a supplement in people's primary diets, Methiorep Premix, a blend of herbs including Cicer arientinum, Phaseolus mungo, Mucuna pruriens, Triticum sativum, and allium cepa, has been suggested. utilize frequently [32]. To determine the origin, identity, and , and efficacy of TLC and HPTLC fingerprint profiles were utilized to develop standards for both the polyherbal and ayurvedic formulations [33].

DNA Analysis

DNA analysis is a method that has been proven to be effective. herbal remedies harmonized. This strategy works well. to distinguish between real medicines and fake or contaminated meds that have the same phytochemical components. According to a paper, the phytochemical content will vary depending on the physiology, habitat, and the plant part utilized, but the DNA fingerprint genome will remain constant regardless of the plant part used. The presence of intact genomic DNA specificity in commercial herbal remedies, which aids in the detection of adulterants even in processed samples, is the second useful application of DNA fingerprinting [34].

The relationship between DNA markers and the phytochemical makeup of closely related species has been the subject of numerous investigations in recent years [35]. using random amplified polymorphic random varying fragment length Interspecies variation in numerous taxa, such as Glycerrhiza, Echinacea, Curcuma, and Arabidopsis, has been identified using DNA markers [36]. Through the successful union of molecular approaches and analytical instruments, a thorough methodology of botanical characterisation was developed that can be utilized at the industry level to provide botanical quality control. DNA markers can be utilized to create healthy, functional proteins in place of sick ones, making them useful for identifying cells, persons, or species. These indications also assist in identifying genuine herbs from imitation medicines, which is beneficial in the management of numerous ailments [36].

Inter-simple sequence repeat, or ISSR

Phylogenetic analysis, genomic instability identification, gene tagging, clonal variation detection, and hybridization assessment are all part of the well-known and distinctive ISSR, a PCR-based application [37]. ISSR markers have been used to differentiate Cannabis sativa and Arabidopsis thaliana L. Heyne from the erroneous species from which they are hybrids. Herbs can be distinguished from adulterants using effective and reliable molecular characterization using Sequence-Charged Amplified Region (SCAR) markers.Additionally, SCAR markers can be used to discriminate across plant species with similar morphologies[37].

Differentiating between them required the application of DNA-based molecular techniques. Accessions of the plants Taxus wallichiana, Azarchdichta indica, Juniperus communis L., Codonopsis pilosula, Allium schoenoprasum L., and Andrographis paniculata were collected from various geographical locations. The importance of markers has been proven. [38]

Norms for the standardized use of herbal medicines

The following are the behaviors that the WHO suggests: quantitative measurements, histological and histochemical data, evaluation of foreign organic compounds, and microscopic analysis; b) chemical and physical properties, fingerprint chromatography, extractive values, ash values, tests for volatile oils and alkaloids, quantitative moisture content estimate techniques; c) estimation of biological activity using measurements of astringency, bitterness, and hemolytic index variables (swelling, foaming index); d) specific pest. [39]

CONCLUSION

Through this research work it was concluded that there are different techniques, tools used for the identifying various constituents of drug substances on various parameters for qualitative and quantitative analysis of substances.

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