

QUALITY CONTROL IN HERBAL MEDICINES: BRIDGING PHARMACOGNOSY AND PHARMACEUTICS

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Abstract

In order to guarantee the safety, effectiveness, and dependability of herbal medicines, quality control is an essential component that must be included. The purpose of this abstract is to investigate the inter-disciplinary connection that exists between pharmacognosy and pharmaceuticals, which serves as the foundation for efficient quality control procedures. The study of medicinal plants and the bioactive substances that they contain is known as pharmacognosy. This field of research establishes the basic information necessary for recognizing and authenticating herbal raw materials. The process include conducting in-depth analyses of various plant species, gaining a knowledge of the medicinal characteristics of those plants, and ensuring that the extracts are both pure and effective. Pharmaceuticals, which is concerned with the formulation and manufacture of medical goods, is a useful supplement to pharmacognosy since it applies scientific concepts to the process of producing herbal medicines that are standardized and of high quality. In addition to conforming to regulatory norms and Good Manufacturing Practices (GMP), it requires stringent testing to maintain consistency, ensure safety, and ensure effectiveness. Authentication of raw materials to avoid adulteration, standardization of extracts to ensure consistent therapeutic effects, safety evaluations to detect potential toxicities, and compliance with regulatory criteria are some of the important procedures that are included in quality control that are found in herbal medicines. Numerous techniques are available, ranging from the conventional microscopic examination to the more sophisticated chromatographic and spectroscopic approaches. Through the combination of pharmacognosy and pharmaceuticals, herbal medicines are guaranteed to fulfill stringent quality requirements, which in turn increases the level of customer confidence and improves the outcomes for public health. As the demand for natural and holistic health solutions continues to develop on a worldwide scale, this all-encompassing approach is becoming an increasingly significant means of response. It is possible to attain both efficacy and safety in the therapeutic use of herbal medicines through the quality control process. This is accomplished by combining classical botanical knowledge with contemporary pharmaceutical research.

keywords: Herbal Medicines, Pharmacognosy, Pharmaceuticals

Introduction

Due to the medicinal characteristics that herbal medicines provide, they have been utilized for ages across a variety of civilizations. Herbal medications are derived from plant sources. The resurgence of interest in these natural medicines, which is being driven by the inclination of consumers for holistic and alternative therapies, has brought to light the need of ensuring that they are of good quality, safe without compromising their

effectiveness. When it comes to herbal medications, quality control (QC) is an essential technique that successfully bridges the gap between the conventional understanding of pharmacognosy and the contemporary concepts of pharmaceuticals. Medicinal medications that are obtained from natural sources, most commonly plants, are the subject of the research known as pharmacognosy. In addition to the identification and confirmation of bioactive chemicals, it also includes the extraction of these compounds. Throughout the course of human history, pharmacognosy has been utilized as the foundation for the discovery of novel pharmaceuticals and the comprehension of the therapeutic characteristics of plants. This area of study comprises the application of a variety of methods in order to define the chemical components of plants, get an understanding of the biological activities of plants, and guarantee the correct identification and authenticity of herbal products. In contrast, the field of pharmaceuticals is concerned with the formulation, development, and production of medicines in order to guarantee the quality, efficacy, and safety of these therapeutic agents. It incorporates the science of dosage form design, which is one of the most important aspects of delivering the therapeutic advantages of pharmaceutical chemicals in a manner that is both safe and easily managed. Additionally, the practise of pharmaceuticals involves the regulatory requirements and quality assurance procedures that are required in order to manufacture pharmaceutical goods that are trustworthy and consistent. A complete quality control system for herbal medicines requires the combination of pharmacognosy and pharmaceuticals as two of its most important components. The use of this multidisciplinary method guarantees that the pharmaceutical compounds that are developed from plants are not only effective but also entirely risk-free for human use. Several essential phases are involved in the process of quality control in herbal medicines. The authentication of the raw materials: Making certain that the plant species are correctly identified and that there are no adulterants or pollutants present in the source material. The process of determining the quantity of active components and ensuring that different batches are consistent with one another is known as extract standardization. The evaluation of potential toxicity and interactions with other medications is included in the safety assessment. Maintaining compliance with national and international regulations regarding the manufacturing and distribution of herbal medicines is referred to as regulatory compliance. A wide range of techniques and processes are utilized in order to accomplish these goals. These techniques and methodology include the more conventional microscopic and macroscopic examination, as well as the more contemporary chromatographic and spectroscopic approaches. The process of quality control also includes the implementation of Good Manufacturing Practices (GMP) and the observance of pharmacopeial standards, both of which are essential components.

Objective

1. To In order to prevent the use of erroneous species, eliminate adulteration and contamination, and properly identify and authenticate herbal raw materials, proper identification and authentication are required.
2. To It is essential to develop and maintain uniformity in the concentration of active components throughout all batches of herbal medicines in order to guarantee that the therapeutic efficacy is consistent over time.
3. To The implementation of stringent quality control methods is essential to establishing and sustaining customer confidence in the effectiveness and safety of herbal medicines.

Overview of herbal medication products

According to Liu et al. (2013), herbal medication products, which are sometimes referred to as herbal medicines or phytotherapeutic goods, are defined as medical products that are generated from plants or a variety of plant components. In order to improve health and treat or prevent illnesses, these products make use of the medicinal characteristics of a variety of plant species, such as the leaves, flowers, roots, stems, or extracts of those plant species (Sinha et al., 2015). The pharmacological effects of herbal medication products are significantly influenced by the presence of a variety of active chemicals, including alkaloids, flavonoids, terpenes, and phenolic compounds, which are frequently found in herbal medication products. Products that contain herbal medicines can be categorized according to a variety of specifications. We provide a summary of the categorization rules of traditional Chinese herbal medicine (Figure 1), which are based on several classification techniques. Traditional Chinese medicine (TCM) and Ayurvedic herbal pharmaceutical products both have a comprehensive system of healthcare and healing that has been practiced for over 2,000 years in China and other areas of East Asia (Balachandran and Govindarajan, 2005; Joshi et al., 2017; Prasad et al., 2021). Both of these systems have been combined to provide a holistic approach to healthcare and healing. In order to restore balance and cure a variety of health issues, Traditional Chinese Medicine (TCM) makes use of a wide variety of medicinal herbs, minerals, and animal products (Wang et al., 2022). Since ancient times, people have been making use of these natural chemicals due to the medicinal capabilities and health advantages that they possess (Dina et al., 2022). According to Zhu et al. (2019), herbal formulae are frequently recommended to patients based on the specific pattern of disharmony unique to each individual. The chemical components that are found in diverse herbs are distinct, and these chemicals have a variety of impacts on the body. According to Karsch-Volk et al. (2014) and Sharifi-Rad et al. (2018), for instance, echinacea is being used to strengthen the immune system, ginger is being utilized to treat digestive disorders, and ginkgo biloba is being utilized to improve cognitive performance. Because of the medicinal benefits that they provide, some minerals and substances that are rich in minerals are utilized in traditional medicine. For example, calcium, magnesium, iron, sulphur, and zinc were provided for the purpose of maintaining bone health and muscular function, treating anemia and increasing hemoglobin levels, treating skin disorders such as acne and eczema, bolstering the immune system, and facilitating the healing of wounds (Song et al., 2021; Xiao et al., 2022). According to Cheng et al. (2022), traditional medical practices, particularly those that are prevalent in East Asia, have traditionally made use of animal products for their therapeutic characteristics. While bear bile is used in certain traditional Chinese remedies, the usage of bear bile is controversial owing to concerns about animal cruelty (Wu et al., 2013; Yu et al., 2017). certain examples include deer antler velvet, which is said to strengthen the body, enhance energy, and promote joint health. Bear bile is also used in some traditional Chinese treatments. Cordyceps is a type of fungus that is utilized for a variety of health advantages, including the support of the respiratory system and the augmentation of energy (Chen et al., 2017; Lou et al., 2019; Ashraf et al., 2020; Yang et al., 2020). Cordyceps is a beneficial organism that parasitizes insects. (Yuan et al., 2016) It is vital to note that although traditional medicine systems have been employing these substances for decades, the safety and efficacy of medicinal herbs, minerals, and animal products are not necessarily backed by current scientific data. This is something that should be taken into consideration. According to Saini et al. (2022), some of these drugs may have the potential to interact with pharmaceuticals or have possible adverse effects. Therefore, it is of the utmost importance to consult with certified healthcare experts, such as herbalists or practitioners of traditional medicine, who are knowledgeable and experienced in the use of these natural medicines in a safe manner. There is a growing interest in the study of traditional medicinal practices and the evaluation of the therapeutic potential of these natural compounds via rigorous scientific research (Schwabl and Vennos, 2015; Jaiswal et al., 2016). This interest is on the rise in current times. The quality control of the herbal medicine business is very vital for the efficiency and safety of herbal medication

products (Kankanamalage et al., 2014). This is exactly because of the diversity of Chinese herbal medicines, which in turn makes the quality control of the herbal medicine industry so significant. Therefore, integrative medicine methods aim to deliver complete and individualized healthcare solutions by combining the most effective techniques from both traditional medicine and modern medicine.

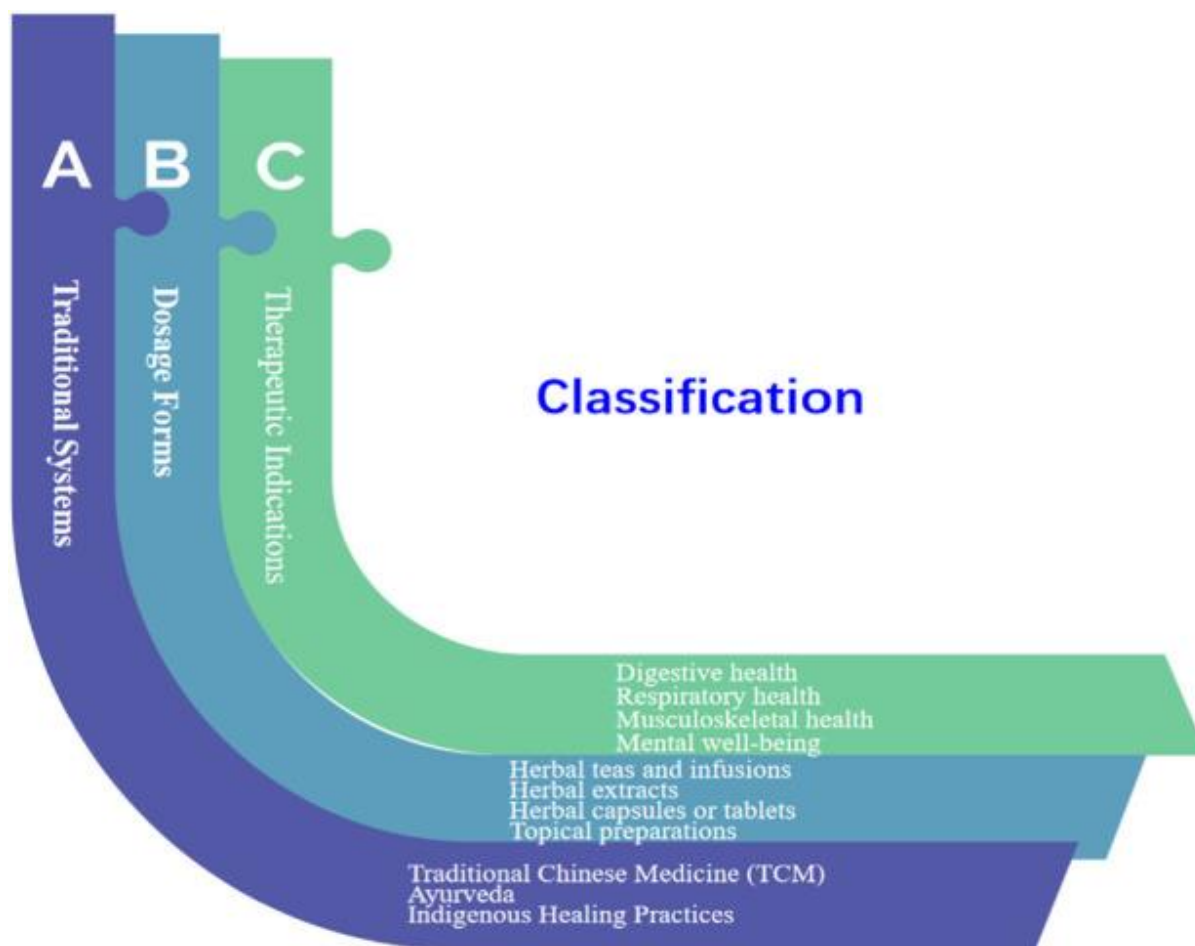


Figure 1 A categorization of goods that are used for herbal medicine.

Quality control for herbal medication products

In order to ensure that the quality of herbal products is maintained throughout the whole production process, quality control is a methodical strategy that involves monitoring and managing many areas of the product creation, manufacturing, and distribution processes. It is necessary for every company or organization to implement quality control measures since these measures play a key part in ensuring that the goods or services comply with the standards and specifications that are expected of them. Evaluating procedures and locating areas that might use improvement are both essential components of effective quality control systems. It is possible for companies to improve their productivity and reach better production levels while using fewer resources if they streamline their processes, eliminate bottlenecks, and remove inefficiencies.

Standardization and identification of herbs

The initial stage is to establish a standard for the identification and standardization of herbs in order to implement efficient quality control methods. Establishing regular and dependable quantities of active

components or indicators in herbal medicinal items is a necessary step in the process of standardizing and identifying herbs. In addition to ensuring that every product satisfies defined quality standards, it seeks to reduce the amount of variation that occurs from batch to batch. Discover the primary active chemicals or markers that are present in the plant and contribute to the medicinal characteristics that it possesses. The identification of active compounds, quantitative analysis, and reference standards are some of the most important parts of them. These can be accomplished by scientific research, traditional knowledge, or the information that is already available in the literature (Zhao et al., 2022). In order to arrive at quantitative measurements of the amounts of active chemicals or markers, it is necessary to develop methodologies (An et al., 2022). This may entail the use of chromatography (high-performance liquid chromatography, gas chromatography), spectroscopy (UV-Vis, infrared), or certain chemical tests (Pan et al., 2018). It is recommended that reference standards or reference materials be established in order to accurately reflect the amounts of active chemicals or markers that are sought (Xiong et al., 2022). According to Jin et al. (2018), these standards serve as benchmarks for comparison during quality control testing and contribute to the maintenance of consistency across batches during the testing process. It is possible for medical experts to prescribe treatments with complete assurance when they have the ability to monitor and regulate the quality and effectiveness of herbal medicinal items, which is made possible by standardization.

Authenticity testing methods are essential in quality control for herbal medication products. These methods ensure the accurate identification and verification of the herbs that are being used. This is done to ensure that the correct herb is being used, as different species or plant parts may have different therapeutic properties and safety profiles (Zhang et al., 2022). According to Lo and Shaw (2019), the process of precisely identifying the botanical species or plant material that serves as the basis for herbal medicinal items is referred to as herb identification. The macroscopic inspection, the microscopic examination, thin-layer chromatography, high-performance liquid chromatography, DNA barcoding, and chemical profiling are some of the procedures that are frequently used for authenticity testing (Figure 2).

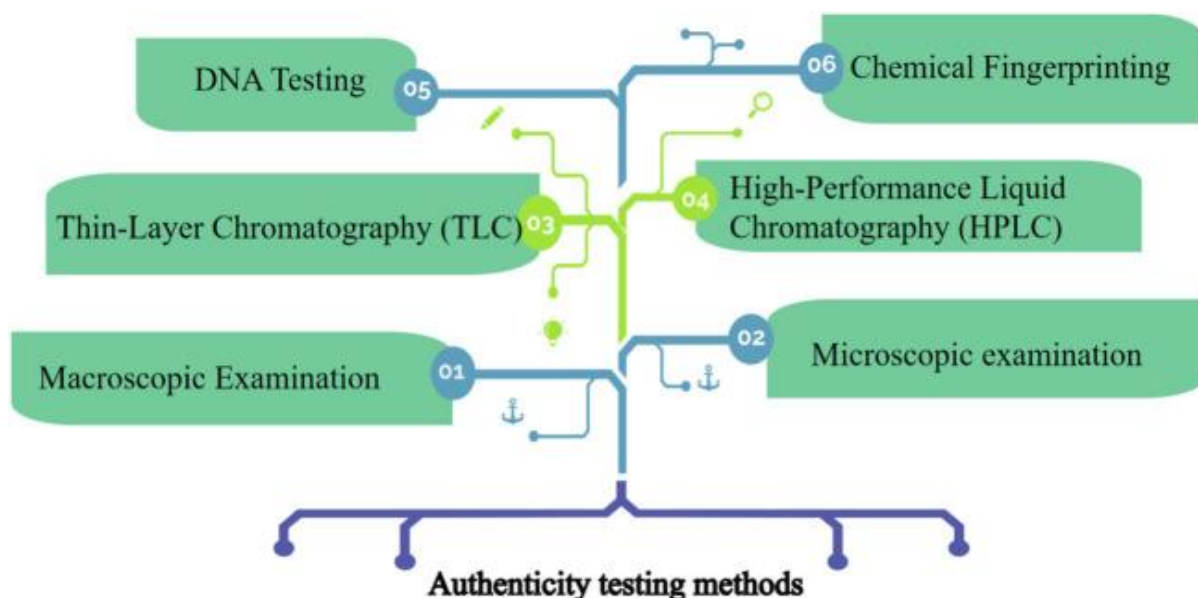


Figure 2 Accurately identifying and verifying the herbs using quality control procedures.

Visual inspection and analysis of the herb's physical qualities, such as its color, shape, size, and texture, as well as any distinctive traits, are included in the macroscopic examination (K et al., 2021). Through the use

of macroscopic inspection, the herb may be identified and differentiated from other plants that appear to be quite similar to it. When doing a microscopic study, one must make use of a microscope in order to investigate the cellular structures and distinguishing characteristics of the plant. Through the use of this technology, certain plant components, such as leaves, stems, or roots, may be identified and their authenticity can be verified. TLC is a method that is utilized for the purpose of separating and analyzing the chemical components that make up a plant. The process entails depositing a very thin layer of the herb extract onto a solid substrate, which is then developed with the help of an appropriate solvent solution. By comparing the chromatogram that was produced to reference standards, it is possible to identify the herb and identify any adulterants or impurities that may have been present. High-performance liquid chromatography (HPLC) is a very effective analytical method that can isolate and quantify the chemical components that are present in a plant. For the purpose of assuring the consistency and quality of herbal pharmaceutical items, it may be utilized to identify the presence of specified marker compounds or active components, as well as their concentration. Authenticating and identifying herbal species may be accomplished by the use of DNA testing, more particularly DNA barcoding, which is a molecular approach. Sequencing a particular portion of the DNA of the plant, such as the barcode region, which is peculiar to each species, is required for this type of analysis. It is possible to determine the genetic identity of the herb by comparing the DNA sequence that was acquired with a reference database. This allows for the identification of any potential adulteration or replacement, as well as the guarantee that the herb is of the proper species. DNA testing is a technology that is quite reliable for identifying herbs, and it is especially helpful in situations when the herbs are in powdered or processed forms. The next step in the process is called chemical fingerprinting, and it entails evaluating the chemical components of herbs through the use of analytical methods such as high-performance liquid chromatography (HPLC), gas chromatography-mass spectrometry (GC-MS), or nuclear magnetic resonance (NMR). It is possible for manufacturers to validate the authenticity, consistency, and quality of the herbs by comparing the chemical profiles acquired from a sample of the herb with chemical profiles that have been created as reference profiles. The use of chemical fingerprinting allows for the identification of certain marker compounds or active components, which helps to guarantee that herbal pharmaceutical products have the appropriate level of therapeutic efficacy and potency. For the purpose of quality control in herbal pharmaceutical items, chemical fingerprinting and DNA testing give data that is both objective and statistically sound. It is possible for manufacturers to establish robust standards, maintain consistency, meet regulatory requirements, verify the authenticity of herbal ingredients, detect any adulterations or contaminants, and ensure the consistency and safety of herbal medication products simply by incorporating these techniques into their quality control processes. Both macroscopic and microscopic examinations should be supplemented with other testing methods, such as thin-layer chromatography (TLC), high-performance liquid chromatography (HPLC), DNA barcoding, or chemical profiling, in order to provide a comprehensive quality control approach for herbal medication products. It is important to note that these various testing methods should be used in conjunction with one another. These techniques of authenticity testing serve to assure the proper identification and quality control of herbs that are used in herbal pharmaceutical goods, which might potentially undermine the products' safety and effectiveness.

Analysis of herbal remedies using chromatography and chemical fingerprinting

As a general rule, the procedures for quality control of herbal medicines include both sensory inspection (both macroscopic and microscopic exams) and analytical inspection utilizing instrumental techniques such as thin layer chromatography, high-performance liquid chromatography, gas chromatography–mass spectrometry,

liquid chromatography–mass spectrometry, near infrared (NIR), and spectrophotometer, amongst others. In contrast, the procedures for extracting the herbal medicine and preparing the samples are also of major significance when it comes to the development of accurate fingerprints of herbal medicines. However, in this review article, we will only concentrate on how to generate chromatographic fingerprints in an acceptable manner, as well as how to evaluate them in a reasonable and efficient manner for the goal of quality control. Because a single herbal medicine may contain a large number of natural constituents, and because the preparation of extracts from a combination of several herbs may result in interactions with hundreds of natural constituents, the fingerprints that are produced by chromatographic instruments are the primary focus of this review. These fingerprints have the potential to provide a relatively good integral representation of the various chemical components that are found in herbal medicines.

Thin layer chromatography

Before instrumental chromatography techniques such as gas chromatography and high-performance liquid chromatography were developed, TLC was the method of choice for herbal analysis. Even in modern times, thin-layer chromatography (TLC) is still widely utilized for the purpose of analyzing herbal medicines. This is due to the fact that numerous pharmacopoeias, including the American Herbal Pharmacopoeia (AHP), Chinese drug monographs, and the analysis Pharmacopoeia of the People's Republic of China, among others, continue to utilize TLC in order to provide unique fingerprints of herbs. In its place, thin-layer chromatography (TLC) is utilized as a more straightforward approach to initial screening, while also using additional chromatographic techniques for semi quantitative evaluation. For the purpose of providing readers with further information on TLC, a brief synopsis is provided here. This is due to the fact that the simple TLC separation of herbal medicines occurs with a comparatively less amount of change compared to the separation achieved using instrumental chromatography.

When it comes to the analysis of herbal remedies, TLC has the added benefit of having a multitude of detection options. In addition, TLC is a relatively straightforward technique that may be utilized for the study of many samples. There is the potential to study more than thirty locations of samples simultaneously in a single instance for each plate. Because of this, the utilization of TLC for the analysis of herbal medications is still widely used. It is possible to obtain valuable qualitative and quantitative information from the TLC plate that has been generated with the assistance of the CAMAG video storage system (CAMAG, Switzerland) and the TLCQA-UV procedures. It is possible to make the observation that, with regard to the four samples of *Cordyceps sinensis* that were obtained through the collaboration between China and Japan, the medicinal effects of these samples are more beneficial than those of other samples since they included the most effective component, cordycepin. In addition, the evaluation of the degree of resemblance between various samples is also feasible with the assistance of image analysis and the digitizing approach that was established in the field of computer science. For the purpose of constructing the fingerprints of natural medications, the use of TLC is advantageous because to its simplicity, adaptability, high velocity, particular sensitivity, and straightforward sample preparation. Consequently, TLC is a practical approach for verifying the quality of herbal goods and identifying any instances of probable adulteration. It should be brought to your attention that the TLC technique is also undergoing ongoing updates at the moment. Regarding this particular aspect, a recent study provided a very good overview. It provided a concise summary of the advancements that have been made in forced-flow planar chromatography (FFPC) and illustrated the significance of various techniques such as rotation planar chromatography (RPC), over pressured-layer chromatography (OPLC), and electroplanar chromatography (EPC). A preparative forced-flow approach that is not only straightforward but

also very effective was also described; in this technique, hydrostatic pressure is utilized to increase the velocity of the mobile medium. When it comes to high throughput screening and the analysis of highly complex matrices, parallel and serially connected layers open up new avenues of possibility. These layers allow for the examination of a large number of samples (up to 216). In order to illustrate the adaptability of the various FFPC procedures, a few applications were presented. These applications related to diverse types of chemicals.

Gas chromatography and volatile components in herbal medicines

It is well known that a significant number of the pharmacologically active components found in herbal remedies are chemical compounds that are volatile. As a result, the utilization of gas chromatography for the identification of volatile chemicals is of utmost significance in the field of herbal medicine inspection. There are a lot of benefits that come from doing a GC analysis on volatile oils. First and foremost, the gas chromatography analysis of the volatile oil provides a convincing "fingerprint" that may be utilized to identify the plant. Not only is it possible to easily identify the presence of contaminants in volatile oil, but the composition of the volatile oil as well as the relative concentration of the organic compounds that are present in the volatile oil are also distinctive of the specific plant. Second, the extraction of the volatile oil is not overly complicated and can be standardized. Additionally, the components can be easily recognized through the use of GC–MS analysis due to its comparatively easy nature. In order to monitor or evaluate particular aspects of herbal remedies, it is possible to make use of the relative proportions of the components. Alterations in the volatile oil's composition can also serve as indications of oxidation, enzymatic alterations, or microbial fermentation. These might be utilized in conjunction with one another. The remarkable sensitivity of the gas chromatograph (GC) to identify virtually all volatile chemical substances is unquestionably one of its most significant benefits. In particular, this holds true for the conventional FID detection as well as the GC–MS. Additionally, the great selectivity of capillary columns makes it possible to separate a large number of volatile molecules concurrently within a very short amount of time that is quite quick. The use of GC as an analytical method in the field of herbal medicine research has been more common and beneficial over the course of the last several decades [53–62]. In particular, the utilization of hyphenated GC–MS instruments makes it possible to be in possession of trustworthy information on the identity of the compounds (for further details, please refer to the next section). But the most significant drawback of gas chromatography is that it is not a convenient method for analyzing samples of polar and non-volatile chemicals. This is the most significant disadvantage of GC. It is important to perform laborious sample work-up, which may involve derivatization, in order to accomplish this thing. It is for this reason that liquid chromatography has become an additional instrument that is essential for us to utilize in order to carry out the full examination of herbal medicines.

Conclusion

Ensuring the safety, effectiveness, and consistency of herbal medicines is a vital procedure that involves quality control. In order to overcome the specific obstacles presented by natural goods, a holistic strategy for quality control might be developed by combining the fields of pharmacognosy and pharmaceuticals. With the use of pharmacognosy, herbal materials may be positively identified and authenticated, guaranteeing that only the most authentic and pure plant species are utilized. In order to create successful herbal medications, this area also helps us comprehend the intricate chemical makeups and medicinal characteristics of plants. To ensure that herbal medicines are manufactured under strict quality standards, pharmaceuticals incorporate this

botanical expertise into the formulation and manufacturing procedures. As part of this process, we conduct thorough safety evaluations, standardize extracts to ensure consistent amounts of active ingredients, and adhere to all applicable national and international regulations. Herbal remedies that have been both researched and approved by the FDA can be more easily created when these fields work together. To precisely monitor and verify the integrity of herbal products, quality control systems include a number of analytical techniques, including contemporary chromatography and spectroscopy as well as conventional microscopy. The significance of strong quality control procedures in herbal medicine is paramount, given the ever-increasing worldwide fascination in alternative and natural treatment. Not only does this safeguard customer health, but it also increases the legitimacy and acceptability of herbal remedies in conventional medicine by guaranteeing that these products are safe, effective, and of good quality. The integration of pharmacognosy and pharmaceuticals will allow herbal medicine to go further, providing people with trustworthy and evidence-based treatment choices.

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