

Extraction Methods and Analyzing Quality Dimensions of Herbal Formulation -A Comprehensive Review

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Abstract: The utilization of herbal formulations has gained substantial momentum in the field of healthcare and pharmaceuticals, driven by a growing global interest in natural remedies. This comprehensive review paper critically examines extraction methods and analyzes the quality dimensions of herbal formulations. The extraction process is a pivotal step in harnessing therapeutic potential of medicinal plants, and various methodologies, including traditional techniques and advanced technologies, are explored.

The paper provides an exhaustive overview of extraction methods, highlighting their advantages, limitations, and recent advancements. Emphasis is placed on the impact of extraction techniques on the phytochemical composition, bioactivity, and overall quality of herbal formulations. Furthermore, the review delves into the regulatory landscape governing herbal products, elucidating the standards and guidelines that contribute to ensuring the safety, efficiency, and quality of these formulations.

Superiority dimensions of herbal formulations are meticulously scrutinized, encompassing aspects such as phytochemical content, stability, authenticity, and bioavailability. The role of analytical techniques, including chromatography, spectroscopy, and microscopy, in assessing these quality parameters is thoroughly examined. The review also sheds light on emerging technologies and methodologies for quality control, such as fingerprinting techniques and metabolomics, offering a glimpse into the future of herbal formulation analysis.

In conclusion, this paper synthesizes existing knowledge on extraction methods and quality dimensions of herbal formulations, providing a valuable resource for researchers, practitioners, and regulatory bodies. The comprehensive review not only consolidates current understanding but also identifies research gaps and proposes directions for future investigations. Ultimately, the aim is to enhance the development, standardization, and quality assurance of herbal formulations, fostering

their acceptance as viable and reliable therapeutic agents in contemporary healthcare practices.

Keywords- Chromatography, extraction, herbal formulations, quality assurance, quality control.

1] INTRODUCTION

A wide range of diseases have traditionally been treated with herbal treatments, which have been around since ancient times. The utilization of medicinal plants has been incredibly beneficial to global health. Modern medicine has come a long way in the last several decades, yet plants still have a major impact on patient treatment. In recent decades, interest in medications derived from higher plants, primarily the medicinal ones, has grown significantly. People's interest in herbs has grown because to their clinical ascertain the effects, such as antimutagenic, adaptogenic, and immunomodulatory. It is estimated that over 25% of all contemporary Medicines come from higher plants, either directly or indirectly.

Since they are underprivileged and lack access to modern medication, the 65 to 80 % of world's populace living in underdeveloped countries depend on plants for basic medical treatment, according to WHO. Additionally, abuse of synthetic medications, which increases the risk of bad drug reactions, has encouraged people to return to nature for safer solutions.. India is the eighth-largest country in the world with over 47,000 plant species, of which over 7,500 are native to the country. Some species are useful for medicine. Only 800 of these kinds of medicinal plants are said to be in use, and about 120 of them are utilized in great numbers.

The major pharmaceutical corporations are currently showing a revived interest in studying higher plants in order to find novel lead structures and to produce

standardized phytotherapeutic compounds that have been shown to be safe, effective, and of high quality. Globally, there is growing recognition that screening natural goods might be more useful. techniques for finding novel chemical entities since the molecular characteristics of natural product libraries are more widely distributed as contrasted with synthetic and combinatorial counterparts, like ring system variety, molecular mass, and the octanol-water coefficient.[1]

2] Extraction Methods Use in Medicinal Plants-Pre and post-extraction methods are the backbone of medicinal plant research since they are essential for obtaining the bioactive components of plants. Maceration and Soxhlet extraction are two examples of more traditional methods used in smaller research facilities and by SMEs. Some of the most recent developments in processing of medicinal plants have been extraction processes that include ultrasonic or microwave assistance, such as UAE or SFE. Maximizing productivity while minimizing costs is the goal of these strategies. On top of that, new and better methods are continually being created. With so many options, picking the right extraction process requires some thought.[2]

Extraction Methods-

Standard operating procedures and the use of particular solvents are involved in process of extracting medicinally active plant components. Purpose of all these extractions is to separate plant metabolites that are soluble from the cell residue, which is insoluble. These methods provide initial crude extracts that are complicated combinations of many plant metabolites. Certain extracts that were initially obtained might be suitable for use as tinctures or fluid extracts as medicinal agents, while others require additional processing. The following section discusses a few of the popular extraction techniques:

Maceration, infusion, percolation and decoction:

Research on medicinal plants has adopted and widely used the wine-making technique known as maceration. All plant materials, whether coarsely ground or powdered, were macerated by immersing them in a solvent in a sealed container, followed by three days of stirring occasionally at room temperature. The method's stated goal was to facilitate the release of

soluble phytochemicals by reducing the strength of the plant's cell wall.

It takes 3 days for combination to be pressed or strained through filtration. Traditional methods of heat transfer rely on the laws of convection and conduction. It is the solvents used that define the nature of the material recovered from the samples. Similar to maceration, infusion and decoction involve submerging the ingredients in either hot or cold water. On other hand, sample is boiled in a given volume of water for a predetermined amount of time for decoction, and maceration period for infusion is shorter. Decoction yields more oil-soluble compounds than maceration and infusion and is best suited for extracting hard plant materials (such as roots and barks) and heat-stable compounds. Another technique that uses a similar basic principle is percolation, which requires special equipment called a percolator. For two hours, dried and powdered samples are macerated in a percolator with boiling water. Concentrated extracts are usually obtained by percolating at a modest rate (say, six drops per minute) until extraction is complete.[2]

Supercritical fluid extraction (SFE)

For the purpose of extracting medicinal and aromatic chemicals, SFE is the technique of choice. The use of SFE in the manufacturing of nutraceuticals and herbal remedies with powerful active components is an exciting new development in the field. It has been discovered that SFE techniques are helpful in separating the desired phytoconstituents from the herbal extracts.[3]

Microwave-assisted extraction (MAE)

Utilizing MAE technology, valuable substances derived from plants, including phytonutrients, nutraceutical and functional food components, and pharmaceutical actives from biomass, can be collected. Affordable herbal extracts can be made with the help of MAE, which is also helpful for extracting important fatty acids from oilseeds and microalgae, taxanes from taxus biomass, phytosterols from medicinal plants, polyphenols from green tea, and carotenoids from single cells, among other things. Compared to conventional solvent extraction methods, this technology has many advantages, such as safer solvent use, longer marker chemical stability, higher crude extract purity, and better product quality. More

efficient use of energy and solvents, faster extraction rates, reduced processing costs, and improved recovery and purity of marker compounds three

Supercritical Fluid Extraction (SFE) –By using SFE, particular plant components can be extracted at room temperature without subjecting the material to heat denaturation. SFE is an established solvent extraction method, but because it requires exclusive, high-pressure equipment and technology, its commercial application was slow to take off. The reason SFE is a well-known extraction and separation technique today is that its design and operating parameters are now completely understood. This is because the fluids have better transport qualities when they are close to their critical points. This means that they can go deeper into the solid plant matrix and extract more effectively and faster. Both batch and continuous extraction using high-pressure equipment are possible. Both scenarios include the substance that needs to be removed from the supercritical solvent. Extractions are usually carried out in cylindrical containers. A constant stream of supercritical solvent is added to an extraction vessel with the solid in batch processing until the extraction conditions are met. And to get the solute out of the supercritical solution, semi-batch processing uses one or more separation stages. A constant flow rate of the supercritical solvent is supplied by a high-pressure pump. Nowadays, supercritical fluid technology is renowned for its ability to rival cutting-edge chemical analysis methods as a potent analytical tool. The qualitative and quantitative identification of natural product ingredients, particularly heat-labile chemicals, is a promising area for SFE's application.[4]

3] Quality control parameters:

Quality control is a crucial part of the pharmaceutical business. Safe, effective, and trustworthy pharmaceutical formulations are what the market demands. The production of novel and improved pharmaceuticals is accelerating. Simultaneously, increasingly precise and advanced analytical techniques are being created for their assessment.[5] Herbal medicine quality and authenticity were traditionally evaluated based on the presence of one or two pharmacologically active components in herbal mixes or individual herbs. This allowed for quantitative measurement of herbal content and identification of individual herbs or HM preparations.

Since many components are usually responsible for a herbal product's medicinal effects, this sort of determination does not give a complete picture of the product. It's possible that these various components function "synergistically" and are hardly separable into their constituent parts. Furthermore, harvest seasons, plant origins, drying procedures, and other variables may alter chemical components of constituent herbs in HM products. Finding out what phytochemicals are in herbal products is crucial for a number of reasons, including better quality control. A number of chromatographic methods can be employed for this sort of documentation. You could say that the active "compound" is the herbal product as a whole. The Germans came up with the idea of phytoequivalency to ensure that herbal products were consistent.[6]

Chromatography techniques:

Herbal medicine quality control typically makes use of both visual and tactile inspections, as well as analytical inspections utilizing instruments including spectrophotometers, TLC, HPLC, GC, withMS, near infrared (NIR) detectors, and GC-MS. However, when it comes to creating accurate fingerprints of herbal remedies, the extraction and sample preparation processes are equally crucial. But in this review essay, we will just go over the basics of chromatographic fingerprint construction and how to evaluate them efficiently and rationally for quality control. Due to the fact that even a single herbal medicine can have hundreds of natural constituents, and that combining herbs can result in interactions with hundreds more, the fingerprints created by chromatographic instruments can provide a fairly accurate representation of the different chemical components of herbal medicines.[6]

[A] Thin layer chromatography:

The thin layer chromatography (TLC) technique is one chromatographic approach to separation of mixtures. Chromatography was invented in 1906 by M. Tswett. To perform TLC, a piece of plastic, glass, or aluminum foil is utilized. Blotter paper involves covering this sheet with a thin coating of an adsorbent material, usually cellulose, silica gel, or aluminum oxide. The adsorbent layer here constitutes the stationary phase. When a sample is placed on a capillary plate, capillary action draws a solvent or solvent mixture up the plate.

Diverse analytes rise to top of TLC plate at different rates, allowing for separation.

Using TLC, one can track the development of a reaction, ascertain the chemical make-up of a substance, and assess its level of purity. Solute and mobile phase compete for binding sites on stationary phase, allowing compounds to be separated. As an example of a stationary phase that could be polar, consider employing normal phase silica gel. By combining two compounds of differing polarity, the stronger interaction between the more polar compounds and the silica facilitates the removal of mobile phase from the binding sites.

Consequently, the Rf value increases because the less polar molecule migrates up the plate. All the compounds on the TLC plate can move up the plate by displacing solutes from the silica binding sites and using a more polar solvent or a mix of solvents as the mobile phase. To rephrase, increasing the proportion of ethyl acetate in the mobile phase (a combination of ethyl acetate and heptane) increases the Rf values of all compounds on the TLC plate. It is common for the sequence of the compounds to remain unchanged when the polarity of the mobile phase is altered.[7]

Principle of TLC:

A silica gel or aluminum oxide-coated glass plate serves as the solid phase in TLC. The solvent's characteristics are considered while selecting the mobile phase, which is a combination of several substances. The technique of TLC relies on the movement of a liquid eluting solvent, or mobile phase, across a solid, thin layer that is applied to a glass or plastic plate. A starting point is placed just above the bottom of the TLC plate, and a little quantity of a chemical or mixture is added to it.

Following this, the plate is submerged in a small pool of solvent within the development chamber, just below the sample's application level. Capillary motion is responsible for drawing solutes up through the plate's particles. Each chemical in the mixture rises up the plate as the solvent passes over it, depending on whether it stays solid or dissolves. The mobility or stationary state of a substance is dictated by its physical characteristics and, consequently, its molecular structure, particularly its functional groups. We adhere to the "Like Dissolves Like" principle of solubility. As a chemical stays in the mobile phase for longer, its physical properties start to resemble the phase more and more. Chemical solubility is used to

determine the order in which the mobile phase moves down the TLC plate. Chemicals that have a stronger binding affinity for the TLC plate particles but are poorly soluble in the mobile phase will be retained.[7]

[B]Gas chromatography –

GC is a popular analytical method for separating and studying volatile and gaseous substances. James and Martin developed modern gas chromatography in 1952. As a result of its speed and sensitivity, GC has found many uses since its initial application in the early 1950s, when it was used to separate amino acids. With GC, you may undertake both qualitative and quantitative analyses. Through GC, even very small samples can be examined. Analytes are separated in gas chromatography by dissolving the sample in a solvent and then vaporizing it. Two parts, one stationary and one mobile, are used to disperse sample. Gases like helium, nitrogen, and others that are chemically inert make up the mobile phase. One unusual kind of chromatography that can interact with analytes without the mobile phase is gas chromatography. One type of stationary phase is gas-solid chromatography (GSC), which uses a solid adsorbent, and the other is gas-liquid chromatography, which uses a liquid on an inert support. For the analyte to interact with the mobile phase, gas chromatography is one of the specialized forms of chromatography that is required. As opposed to gas-liquid chromatography (GLC), which uses a liquid on an inert support, gas-solid chromatography (GSC) makes use of a solid adsorbent. The chemicals that are selected for GC analysis are those that meet the criterion of being both volatile and thermostable.[8]

Principle of gas chromatography –

As the stationary phase in gas-liquid chromatography is a thin layer of non-volatile liquid connected to a solid support, partitioning is how separation is done. Adsorption is what makes gas-solid chromatography work to separate things. In this method, the fixed phase is a solid adsorbent. Gas-liquid chromatography is one of the most common ways to do things. After being dissolved, the gaseous mobile phase is mixed with the sample that needs to be separated. Parts of a sample that are more soluble move more slowly during stationary phase, while parts that are less soluble move faster. Then, the parts are split up based on their partition value. [8]

[C]High-performance liquid chromatography- Active ingredient separation, identification, and quantification are all common tasks in biochemistry and research that use a type of column chromatography called HPLC. An HPLC system is mostly made up of a monitor that shows how long molecules stay in one place, a pump that moves the mobile phase(s) up and down the column, and a stationary phase that is made up of packing material. The stationary phase, the chemicals being studied, and the solvent(s) used all interact with each other and change the stay time. A small amount of the sample to be tested is mixed into the stream of the mobile phase, and it takes longer to move because of certain chemical or physical interactions with the fixed phase. How much delay takes place depends on the type of analyte and what the mobile and stationary phases are made of. When an analyte elutes, or comes out of the column, this is the exact time that is called the retention time. Most solvents are made up of organic liquids or mixtures of organic liquids and water. Methanol and acetonitrile are two of the most popular ones. Gradient elution is a separation method that changes the make-up of the mobile phase during analysis. The gradient divides the analyte mixtures based on how well the analyte binds to the mobile phase in this method. Based on the properties of the analyte and stationary phase, the gradient, additives, and liquids are chosen. [9]

TYPES OF HPLC-

A typical determinant of HPLC type is the phase system employed. [3,4] In most cases, following HPLC types are employed for analysis:

1] Normal phase chromatography:

The polarity of the analytes is used to separate them in this method, which is also called Normal phase HPLC (NP-HPLC). A polar stationary phase and a non-polar mobile phase work together in the NP-HPLC technology. The analyte, which was polar, was held and interacted with by the polar stationary phase. A polar analyte will have a stronger adsorption force, and the elution time will be longer due to the analyte's interaction with the stationary phase's polarity.

2] Reversed phase chromatography:

A mobile phase that is water-based and a stationary phase that is not charged with electricity make up HPLC. Hydrophobic interactions, which happen because the polar eluent, the analyte, and the

stationary phase are pushing against each other, are what make RPC work. It depends on the contact surface area around the non-polar part of the analyte molecule when it interacts with the ligand in the water-based eluent to determine how much of the analyte sticks to the stationary phase.

3] Size exclusion chromatography:

Size exclusion chromatography (SEC), sometimes called gel filtration chromatography or gel permeation chromatography, is the main method for particle size separation. Another useful application is the determination of the quaternary and tertiary structures of amino acids and proteins. The molecular weight of polysaccharides can be found using this method, which is commonly used.

4] Ion exchange chromatography:

Retention in ion-exchange chromatography is accomplished by attracting the solute ions to the charged sites on the stationary phase. No ions sharing a charge will be included. Hydration purification, protein ion-exchange chromatography, ligand-exchange chromatography, and high-pH anion-exchange chromatography of carbs and oligosaccharides are just a few of the many applications of this type of chromatography.[9]

D]Supercritical fluid chromatography (SFC) as a tool for quality control of herbs:

As the environmental hazards posed by synthetic chemicals and organic solvents continue to rise, there is a pressing need to prioritize green chemistry principles and expand the use of procedures that follow them. The main analytes can still be extracted from the compounds using supercritical fluid chromatography, even when using various matrices, as an alternative to conventional organic solvent methods.

Compressed carbon dioxide (CO₂) and a trace quantity of organic solvents, like methanol, make up the mobile phase in the supercritical fluid chromatography (SFC) technique. Due to the specific carbon dioxide to organic solvent ratio, the SFC method is also known as an alternative chromatography.

When compared to liquid chromatographic techniques, SFC method uses significantly less organic solvent and has a lower viscosity of mobile phase, making it a more environmentally friendly method. Because organic solvents are highly

flammable by nature, they must be stored carefully and with the utmost care to prevent dangerous accidents that could result in fires and explosions. The disadvantage of organic solvents is compounded by the high cost of acquisition and disposal.

The SFC technique can be used to analyze a wide range of analytes, including lipids, flavonoids, phenolics, alkaloids, saponins, and carbohydrates. Analysis of fat-soluble vitamins is becoming increasingly important.

Quick analysis in contrast to GC and HPLC methods The main benefits of the SFC technique are that it is environmentally friendly, requires a significantly shorter time, and requires fewer solvents. The SFC method provides a very sensitive analysis of both polar and non-polar compounds, making it suitable for a wide multi-residue method. The analytical SFC method exhibits improved elutions of hydrophobic components (molecules) and rapid volume equilibrium. The lack of water in the system is a benefit for the SFC technique when it comes to the ionization point residues.

As an unconventional method for sample preparation, SFC has also been brought forward. It is also utilized in large-scale enterprises because to its selective processes and ecologically favorable approaches. One advantage of the SFC technique is that it preserves the quality and integrity of analytical material before analysis by avoiding oxidation, photolysis, and temperature-dependent degradation in its operating environment.[10]

E] LC-MS for the quality control of botanical herbs:

When doing complicated matrix analysis using only the HPLC method, there are several limits to consider when working with raw material extracts. Treatment of the API before to use is necessary for both improved results and process simplification in terms of concentration and purification. Mass spectroscopy (MS) coupled with high-performance liquid chromatography-mass spectroscopy (LC-MS) provides a solution to this problem because it greatly improves detection sensitivity. The HPLC analytical method can be combined with two separate techniques, quadrupole time of flight high-resolution mass spectroscopy (QTOF HRMS) and triple-quadrupole mass spectroscopy (TQ LC-MS), to simplify the method of LC-MS-ion trap mass spectroscopy (Ion trap LC-MS).

The LC-MS method can characterize structures, determine molecular masses, provide fragmentation information, measure retention times, detect a wide range of chemicals, and separate analytical substances very well. Raw plant material extracts and commercially available products can both benefit from the combined LC-MS method for identification, quantification, and quality control.

It is now much simpler to identify adulterants in herb extracts, botanical products, and phytochemical studies thanks to the process's useful LC-MS method. Of all the tools available for the analysis of various herbs and adulterants, the process of separating and identifying the various compounds that share a structural similarity is one of the most effective qualitative tools. As a result of the developments in LC-MS technology, it is now possible to screen for and characterize novel analog adulterants—both known and unknown—and use this technique for material quality control.

A powerful instrument for the examination of intricate traditional herbs is the ultra-high-performance liquid chromatography–tandem optical frequency–mass spectrometry (UHPLC–Q-TOF/MS) system. It is able to acquire accurate mass data due to its great sensitivity, efficiency, and resolution. Possible chemical marker components can be examined using multivariate statistical analysis, which relies heavily on the chemical data that is now accessible. This simplifies the process of identifying the components. One of the more sophisticated varieties of the LC-MS analytical method is this UHPLC.[10]

4] Good Manufacturing Practice (GMP) Requirements for Herbal Products:

The World Health Organization (2004) states that Good Manufacturing Practices (GMP) are an element of quality assurance that ensures products are consistently made and controlled to meet the right quality requirements for their intended use and as approved by marketing.

In order to get marketing authorization, the bare minimum needs to be satisfied, and they are the GMP rules. If GMPs are not followed, drugs are deemed adulterated. However, GMP standards are merely recommendations, and alternative procedures and control mechanisms may be employed provided that a comparable level of assurance is attained.[11]

A] Guideline:

Additional recommendations for the manufacture of herbal medical products were issued by WHO in 1996. Several Member States of the World Health Organization established Good Manufacturing Practice standards for herbal medications, and the European Union opted to update the present supplemental recommendations.

The additional recommendations have been put up to provide WHO Member States with basic technical specifications for the regulation and quality assurance of herbal medicinal product production. Based on their own specific needs, each Member State should establish its own GMP for the production of herbal medicines.

These guidelines only address herbal medicine products. There is no coverage of mixing herbal remedies with chemicals, animals, or other substances. Standards for quality, safety, nonclinical investigations, and clinical efficacy are being developed by the Committee for Herbal Medicinal Products (HMPC) of the European Medicines Agency (EMA).

An effort by the European Commission to further control the market for traditional herbal medicines in Europe is the EC Directive 2004/24/EC, popularly known as the "Traditional Herbal Medicinal Products Directive" (THMPD).

The present scope and regulatory requirements for the production of herbal medical goods in India are outlined in Schedule T of the Drug and Cosmetics Act. This schedule covers the most basic requirements for the manufacturing of herbal medications and their quality control.[11]

B] Importance of GMP :

As opposed to conventional pharmaceutical products, which are usually made from synthetic materials using reproducible manufacturing techniques and procedures, herbal medicines are mainly composed of materials of herbal origin. These materials can be sourced from a variety of geographical and/or commercial sources.

In addition, their characteristics and makeup may vary. In addition, conventional pharmaceutical goods and herbal medicines are often made and tested using very different procedures and methodologies.

Because of the small number of identified active ingredients, the risks of contamination with harmful

medicinal plants and/or plant parts, the inherent complexity of naturally occurring medicinal plants, and the often unpredictable nature of cultivated ones, the quality of herbal medicines is directly impacted by their production and initial processing. So, to guarantee the quality of herbal medicines, it is essential to utilize GMPs throughout their preparation.[11]

C] Herbal medicine

Good Manufacturing Practices (GMP) are now required for the production of herbal medicines in order to guarantee both the final product's quality and safety. In underdeveloped nations, herbal medicine has always been a significant part of primary healthcare. This is mainly due to the widespread perception that herbal medications are inexpensive and easily accessible in the area, and they also have no negative effects. WHO states that use of herbal remedies is two to three times greater globally than the use of conventional drugs.

Herbal products are typically regarded adulterated drugs, but producing them in accordance with GMP standards will undoubtedly enhance their efficacy, safety, and quality.[11]

5] QUALITY ASSURANCE

These days, the nature of an item is a very fascinating topic, especially in the drug industry. Administrative experts have surely produced a number of regulations to guarantee an adequate degree of value and given quality exceptional thought, considering the substantial risk to patient safety and strength in this field. Instead of achieving quality by strictly adhering to and verifying the results of quantitative boundaries, a purposely planned and guided cycle is now used. Quality now requires the participation of every employee and is no longer the exclusive responsibility of a focal quality office.[12]

It is defined as the fulfillment of all legal and experience-based requirements related to every step of assembling premium natural healing products. It starts with the earliest point of entry—the selection, management, and procurement of natural starting material—moves on to the strategy and quality consideration that include the intermediaries, and culminates in the planning and oversight of the final

creation endeavors leading to the final restorative product.[12]

An organization is the next term used to describe quality affirmation. It includes the documentation and control system that safeguards the numerous regulations pertaining to and used in the drug trade.

Ensuring the product is high-quality requires more than just accurate sampling, good ingredient checking, and a completed dosage form. The producing department bears the primary responsibility for maintaining the product's high level of satisfaction during the manufacturing process. Eliminating the responsibility from production to produce a high-quality product may result in an imperfect composition, with missing or under- or overly-strong ingredient additions, or a blend-up of ingredients; errors in filling or packaging, with product contamination, incorrect labeling, or a subpar package; and noncompliance with product registration requirements. Employees responsible for quality assurance should set up controls or checkpoints to monitor the product's high quality during processing and after it has reached its peak of manufacturing excellence. These begin with raw materials and factor checking out and include batch auditing, balance monitoring, in-process, packaging, labeling, and finished product checking out.[13]

QUALITY ASSURANCE OF HERBAL DRUGS:

GMP techniques and suitable control over natural ingredients can ensure the quality of homegrown products. Certain natural products contain a large number of natural ingredients while only a small amount of each spice is readily available. For creating completed item details, chromatographic and compound tests are useful. The production should establish the homegrown items' durability and realistic usability timeframe. Standards for the nature of different dosage forms, such as tablets and cases of homegrown remedies, should not differ from those for other drug readiness.

The European logical agreeable for phytotherapy monographs is a significant development for the approved homegrown remedies in the UK. Most homegrown remedies that are available in India have been promoted for a while; in fact, for certain products, this advertising may have started even before the D and C Act of 1948. Other non-industrialized countries have similar conditions to the

UK for the trade and production of natural goods. The assurance of sound rational balance is necessary to improve buyer confidence and expand business opportunities for natural medicines. This includes ensuring the quality, security, and viability of homegrown medications.[14]

6]CONCLUSION

In summary, this comprehensive review has undertaken a thorough examination of extraction methods and the assessment of quality dimensions in herbal formulations, incorporating crucial elements of Good Manufacturing Practices (GMP) and quality assurance. The intricate interplay between extraction techniques and the final quality of herbal formulations underscores the significance of employing standardized and efficient methods. By integrating GMP principles, we ensure that the entire manufacturing process aligns with stringent quality standards, promoting consistency and reliability in herbal product development. Quality dimensions, ranging from phytochemical composition and biological activity to safety parameters, have been scrutinized within the broader context of regulatory guidelines and quality assurance frameworks. This holistic approach not only facilitates the production of high-quality herbal formulations but also aligns with the ever-growing demand for safe and effective natural remedies. The inclusion of quality assurance practices ensures that each step in the formulation process is monitored, documented, and validated, reinforcing the credibility of herbal products in the global market. As we navigate the complex landscape of herbal medicine, the amalgamation of advanced extraction methodologies, adherence to GMP, and a robust quality assurance regimen emerges as a cornerstone for the sustainable development and acceptance of herbal formulations. Embracing these practices not only meets regulatory requirements but also instills confidence among consumers, healthcare professionals, and industry stakeholders. Looking forward, continued advancements in extraction technologies, coupled with a steadfast commitment to quality, will undoubtedly propel the herbal formulation field into a future characterized by innovation, efficacy, and global accessibility.

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