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An Examination of the Present Situation Regarding the Standardization of Herbal Medicine

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Abstract: *The use of herbal remedies in modern medicine is becoming more widely recognized and accepted. While the majority of these uses are unconventional, it is a well-known fact that more than 80% of people worldwide rely on herbal products and treatments for good health. The increased usage of herbal goods has also led to a surge in product adulteration and misuse, which has disappointed producers and customers and, in some cases, had deadly results. The worldwide herbal business is dangerous due to the many and massive challenges. The purpose of this review is to inform those involved in the manufacture of herbal medicine about the need of establishing quality standards for the production, handling, processing, and collecting of herbal medicine. These standards will also be used to ensure the security of the worldwide herbal market. It was also covered how to standardize and ensure high-quality herbal items and medications.*

Keywords: Herbal medicine, standardization.

I. INTRODUCTION

Herbal therapy is the oldest kind of treatment and has been utilized in all civilizations (Barnes et al., 2007). Since early humans realized their dependency on nature for a healthy existence, they have relied on plant resources for food, clothing, shelter, and medicine to treat many maladies. Primitive people used non-food plants, animal parts, and minerals to heal disease based on instinct, taste, and experience. Trial and error taught primitive humans how to differentiate helpful plants from dangerous or inactive ones and which combinations or processing procedures yielded the best results. Even ancient tribes meticulously gathered plant data and created herbal pharmacopeias. A Neanderthal burial site excavated in a cave in northern Iraq in 1960 showed herbal treatments used sixty thousand years ago (Solecki, 1975). Even in the 20th century, tribal herbal wisdom influenced modern medicine's pharmacopeia. Plant-based drug knowledge emerged gradually and was handed on, creating the groundwork for many traditional medical systems worldwide. In certain cultures, herbal medicine is important to medicine.

Medical plants are found worldwide, but most abundantly in tropical countries. About 25% of current medications come from higher plants (WHO, 2005, 2002a,b, 1999a,b, 1998a,b, 1990, 1981, 1979; De Smet, 1995; Duke and Martinez, 1994; Majno, 1975; Ackerknecht, 1973). Several novel medications and non-drugs have been discovered using herbal medicine.

Herbal Medicine

Plants include medicinal, aromatic, and savory herbs. As biosynthetic chemical labs, plants produce chemicals. Herbal remedies have synergy. Herbal medicine treats using plants. Leaves, roots, bark seeds, and flowers are common plant parts. They are eaten, breathed, or applied. Many plant biochemicals make herbal remedies therapeutic. Medically active compounds are called “active ingredients” or “active principles” and vary by plant species, harvest season, soil type, herb preparation, etc.

Over the last decade, developing and industrialized nations have adopted natural medicines. Due to poverty and lack of modern treatment, 80% of the world's population, especially in developing nations, utilizes herbal medicine for basic care. These cultures value traditional medicine. Westerners appreciate herbal treatments because they promote health like our forefathers. Herbal remedies mild. Home remedy and OTC drug buyers spend billions on herbs. Their worldwide medicine market share is large.

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Consume the right dosage of herbs over time to benefit. Some herbal remedies are edible, although most physiologically active compounds are poisonous (Bisset, 1994).

Plant ingredient genetic, cultural, and environmental characteristics make herbal treatments harder to employ. Few, substandard raw materials, unknown active principles, and hard-to-manage and verify production batches are prevalent. Most countries market herbal remedies without safety or toxicity testing. Inefficient production and quality control equipment. Substandard herbal remedies bought without a prescription may not be obvious to consumers. A well-defined and stable drug composition is needed for good medication manufacture. The industry's survival and development rely on product quality since plant-based products are unpredictable and impacted by various variables (Bauer, 1998).

Quality Control and Standardization of Herbal Medicines – Concept and Scope

Both synthetic and plant-based medicines must be safe and effective (EMEA, 2005; WHO, 2002c, 1998c, 1996, 1991a,b, 1990, 1988). Simply collecting, drying, and storing plants or plant components produces phytopharmaceuticals, which are called “herbal drugs” (EMEA, 1998). They may vary. Growth, location, and harvesting time also affect variations.

Herbal medicine standardization involves prescribing intrinsic qualities, consistent parameters, decisive qualitative and quantitative values that ensure quality, effectiveness, safety, and repeatability. Technical standards are developed and agreed upon. Experimental and observational criteria are used to prescribe a herbal medicine's qualities. Thus, uniformity aids quality control.

Several problems not applicable to synthetic drugs often influence the quality of herbal drugs. For instance:

Herbal medications are often composed of many ingredients.

The active principle(s) are often unknown.

Commercially unavailable selective analytical procedures or reference chemicals.

Plant materials vary chemically and naturally.

Chemo-varieties and cultivars exist.

The source and quality of raw materials vary.

Herbal quality is further affected by harvesting, drying, storage, shipping, and processing There are no formal herbal preparation standards. Manufacturers testing their products have their own criteria, many of which are preliminary. The presence of all declared constituents in a formulation is difficult to determine. Thus, the first step is to evolve a parameter that can identify the presence of all ingredients. Chromatographic and spectrophotometric methods and physicochemical property evaluation can be used to evolve a pattern. These approaches may be used to quantify bioactive chemicals such alkaloids, flavonoids, and polyphenolic components or a specific molecule (Wani, 2007).

The need for standardization – Producers’ andconsumers’ perspective

Herbal medicine is growing globally as the risks and drawbacks of contemporary treatment become clearer. Drugs must be pure, safe, potent, and effective, according to regulations. Regulatory bodies use statutory good manufacturing practices to ensure raw material and product quality in pharmacopoeias, formularies, and manufacturing activities. Modern or ancient, these guidelines should apply to all pharmaceuticals.

Although herbal products are getting increasingly popular internationally, quality control is still an issue. The ingredients in herbal medicine impact its efficacy and safety. Modern analytical methods may help set quality control requirements for plant-based medicinal components, but their complexity and variety make it challenging. Some therapeutic benefits are unknown or partly documented. Traditional herbal mixes complicate this. One product frequently includes five botanicals. Without a reference standard for identification, batch-to-batch variation starts with raw material collection. Variations grow with storage and processing. Standardize herbal treatments and goods from medicinal plant cultivation to clinical application.

Plant materials and herbal therapies dominate the global market, thus quality assessment and control standards are essential.

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Standardization and quality control of herbal crude drugs – Processes and procedures

WHO (1996a and b, 1992) defines standardization and quality control of herbals as the physicochemical evaluation of crude drug aspects like selection and handling of crude material, safety, efficacy, and stability assessment of finished product, documentation of safety and risk based on experience, consumer information, and product promotion. These quality indicators are usually considered:

1. Macro and microscopic examination: Identifying diversity and detecting adulterants.
2. Foreign organic matter: Removes non-source plant materials for pure medication form.
3. Ash values: Assess crude drug identity and purity using the criteria of total ash, sulphated ash, water soluble ash, and acid insoluble ash.
4. Moisture content: Assessing moisture content may assist estimate medication material weight accurately. Product stability improves with low moisture.
5. Extractive values: Indicate the weights of chemical compounds extracted from crude drug in various solvents.
6. Crude fiber: Determines woody material component and helps assess purity.
7. Qualitative chemical evaluation: Identifies and characterizes crude drug phytochemical constituents. It detects and isolates active ingredients using various analytical methods. Phytochemical screening involves plant identification, solvent extraction, purification, and characterisation of pharmaceutically important active components.
8. Chromatographic examination: Identify crude drug using primary chemical ingredients as markers.
9. Quantitative chemical evaluation: Estimate key constituent amounts.
10. Toxicological investigations address pesticide residues, possible toxicity, animal safety, and microbe presence using LD50 and microbial assays.

Scientific studies encompass physical, chemical, and biological examination using different analytical techniques and equipment. The methods used to ensure herbal quality vary as do the goals.

Physical evaluation

Each book provides botanical, macroscopic, and microscopic descriptions of each plant's physical properties to verify authenticity and purity. Each description includes extensive pictures and photographs to verify material identification.

Microscopic evaluation

Plant material must be physically examined to be fully characterized. Microscopic plant studies are essential for identifying the material and screening for contaminants.

Chemical evaluation

This includes chemical component screening, isolation, identification, and purification. Chemical examination of the medicine determines vegetable material's active principle potency. Chemical screening or testing may involve color reaction tests to identify drug substances and probable adulteration.

Biological evaluation

Pharmacological activity has been used to assess and standardize medications. Assays on live animals and their intact or isolated organs may show medication or preparation strength. Bioassays are biological assays.

Analytical methods

Analytical procedures for identification, purity, and potency are essential to monograph compliance. Many analytical approaches exist. It might be hard to choose the right analytical instrument for monograph standardization, but chromatography is essential.

Chromatography

Chromatography separates molecules by structure and content. Chromatography moves a "test preparation" across a stationary support to separate components. Similar molecules in the test preparation will separate due to differing interactions with the stationary support. Tighter support contacts delay test molecules compared to weaker interactions. Different molecules may be segregated as they pass across the support material. Chromatographic separations can be done on immobilized silica on glass plates (thin layer chromatography), very sensitive High Performance Thin Layer Chromatography (HPTLC), volatile gases, paper, and liquids with hydrophilic, insoluble molecules. HPTLC is used for assessing botanical material quality. It efficiently and cheaply analyzes many chemicals. Analytical time may be greatly

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reduced by running many samples in one assay. HPTLC allows the same study to be examined in multiple wavelengths, offering a more comprehensive plant profile than other methods.

Quantitative analysis

The best quantitative analytical approach using chromatograms is preferred. The approaches aim to measure chemicals most connected with pharmacological action or qualitative indicators using approved methodologies (Wani, 2007).

Control of starting material

Controlling beginning materials ensures repeatable herbal medicine quality (De Smet, 2004; Gaedcke and Steinhoff, 2003; WHO, 2002b; Phillipson, 1993). Starting material control should consider the following:

Authentication and reproducibility of herbalingredients

Unregulated herbal goods demonstrate the public health risks of improperly verified herbal substances. Macroscopic and microscopic comparison with real herbs or reliable descriptions of authentic plants must identify herbal constituents (Houghton, 1998). Herbal ingredients must be referred to by their binomial Latin genus and species names using only allowed synonyms. Even when verified, samples of the same herbal component may vary in quality owing to variables like:

Inter- or intra-species variance is mostly genetic and may be influenced by the place of origin.

2. Environmental factors: Climate, altitude, and cultivation circumstances might impact the quality of herbal ingredients.

When harvesting herbs, it is important to specify the optimal period since ingredient concentrations might fluctuate during the growth cycle or even within a day.

4. Plant component used: Herbal ingredients may include unusual plant sections with varying active elements. 'Exhausted' plant material is also utilized as adulterants to raise the weight of a herbal component batch.

5. Post-harvesting factors: Storage and processing may significantly impact herbal component quality. Drying and improper storage after harvesting might cause microbial contamination and loss of thermo-labile active components.

Adulteration/substitution

Herbal treatments have been contaminated with other plants and drugs. Reports of herbal treatments without active ingredients emphasize the necessity for quality control.

Identity and purity

It is important to confirm the botanical identification and batch-to-batch repeatability of herbal ingredients to assure the quality of approved herbal medications. In addition to macroscopic and microscopic examination, identification tests are needed. Simple chemical tests like color or precipitation and chromatographic testing are examples. Gas–liquid chromatography may identify volatile-oil-containing herbal compounds, however thin-layer chromatography is usually utilized. Such tests may confirm the existence of active principles, but the nature of the active principle is often unknown. Chemical and chromatographic testing assist give batch-to-batch comparability, and the chromatogram may be used as a 'fingerprint' for the herbal component by showing flavonoids, alkaloids, and terpenes.

Identity and purity address the most crucial question: Is the herb right? Many quality factors are thoroughly explored to answer this. Purity and chemical composition matter. Type of preparation, sensory qualities, physical constants, adulteration, pollutants, moisture, ash content, and solvent residues must be tested for identity and purity. Macro- and microscopical exams reveal identity. Reference voucher specimens are trustworthy. Plant diseases may affect their appearance and lead to misidentification (De Smet, 1999). Labelling botanical quality incorrectly may be a concern. A South American beverage called “Paraguay Tea” caused anticholinergic toxicity in New York in the 1990s. Chemical investigation showed a class of components distinct from Paraguay tea's source metabolites.

Another way to verify product identification and purity is to assay herbal components with recognized active principles. To determine the minimum acceptable active substance percentage, an assay should be developed. When feasible, such tests should be selective to particular chemicals, using high-pressure liquid and gas–liquid chromatography. When such tests are not available, non-specific classical techniques like titration or colorimetric assays may be employed to assess the overall content of a collection of closely similar substances.

Values, contaminants (e.g., other herbs), and heavy metals affect medicine purity and safety. Modern purity assessment encompasses microbiological contaminants, aflatoxins, radioactivity, and pesticide residues, owing to enhanced analytical technologies. Photometric analysis, TLC, HPLC, and GC may be used to determine herbal preparation

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composition. Different ideas like "normalization versus standardization" must be utilized to develop uniformity standards depending on whether the active principles of the preparation are known or unknown.

Content assay is the hardest quality control task since most herbal medications have unknown active ingredients. Markers are sometimes used. In all other circumstances, when no active ingredient or marker can be established for the herbal medication, pharmacopeias may utilize the percentage extractable materials using a solvent as an assay. The extraction solvent relies on the chemicals and may be inferred from previous applications. When making tea from a herbal medication, the hot water extractable matter, given as milligrams per gram of air-dried material, may be employed. Steam distillation of essential oils is a unique assay. When active constituents (like sennosides in Senna) or markers (like alky amides in Echinacea) are known, a wide range of modern chemical analytical methods can be used (Watson, 1999).

Good agricultural/Manufacturing practices

Herbal medicine quality control and standardization also include raw material source and quality, cultivation, and production. These approaches affect herbal preparation quality and stability (WHO, 2004, 2003, 2000, 1992, 1988b; EMEA, 2002; Blumenthal et al., 1998; Roberts and Tyler, 1997). GAP can regulate growth conditions that impact plant product quality. This involves seed choice, growth conditions, fertilizer, harvesting, drying, and storage. GAP procedures are crucial to quality.

Use of fresh plants, age and portion of plant obtained, period, time, and manner of collecting, processing temperature, light exposure, water, nutrients, drying, packaging, shipping, and storage may considerably impact herbal medicine quality and therapeutic value. Herbal drug quality, safety, and efficacy may also be affected by extraction technique, microbial, heavy metal, and pesticide contamination. Instead of wild plants, controlled ones may alleviate most of these concerns (Eskinazi et al., 1999; Blumenthal, 1998; Bauer, 1998). Enzymic actions from collection to marketing may degrade active principles, affecting composition. Thus, herbal compositions and raw ingredients must be standardized and quality monitored.

Contaminants of herbal ingredients

High-quality herbs should be insect-, animal-, and excreta-free. Specifications should minimize pollutants because they cannot be eliminated:

1. Ash values: Incinerating herbal ingredients creates inorganic ash. Acid-insoluble ash, mostly silica, may be used to evaluate soil content after hydrochloric acid treatment. Ash and acid-insoluble ash of herbs may be limited.
2. Foreign organic matter: Herbal ingredients need modest quantities of related plant parts or other plants. Standardize such plant pollutants to reduce their proportion.
3. Aerobic bacteria and fungus are common in plant material, but might increase due to improper growth, harvesting, storage, or processing. Herbal compounds with high starch concentration may promote microbial development. Pathogens such Enterobacter, Enterococcus, Clostridium, Pseudomonas, Shigella, and Streptococcus infect herbal components. Microbial contamination limitations are critical, and the European Pharmacopoeia currently provides non-mandatory recommendations (Barnes et al., 2007).
4. Pesticides: Herbal ingredients, especially cultivated crops, may be contaminated by DDT, chlorinated hydrocarbons, organophosphates, carbamates, or polychlorinated biphenyls. Limit tests are necessary to determine acceptable pesticide levels. The European Pharmacopoeia specifies test procedures and limits for 34 pesticide residues (Barnes et al., 2007).
5. Fumigants such as ethylene oxide, methyl bromide, and phosphine are used to combat pests that taint herbal components. Europe bans herbal medicinal fumigants containing ethylene oxide (Barnes et al., 2007).
6. Toxic metals: Herbal components may include lead, cadmium, mercury, thallium, and arsenic. Herbal components must pass harmful metal limit testing.
7. Radioactive contamination: Ionization radiation, including radionuclides, in the environment has several origins. Thus, some exposure is inevitable. (AOAC, 2005; WHO, 2000; De Smet, 1992).
8. Other contaminants: To assure high-quality herbal components for medical reasons, endotoxins and mycotoxins may be tested when standards rise (Barnes et al., 2007).

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Standardization of herbal medicines

The herbal medication preparation is adjusted to a specific content of a component or group of compounds with recognized therapeutic action by adding excipients or combining herbal pharmaceuticals. Direct botanical extracts from crude plant material vary in content, quality, and medicinal benefits. Standardized extracts are high-quality, consistent-compound extracts that are rigorously tested throughout cultivation, harvesting, and processing. There is no regulatory definition for supplement standardization. Thus, "standardization" has numerous meanings. Some firms misinterpret standardization to mean consistent production techniques, although following a formula does not make a product standardized. The term "standardized" on a supplement label does not always reflect product quality.

For analysis and standardization, marker compounds should be created when active principles are unknown. Marker compounds are chemically identified herbal medication ingredients that affect product quality. The chemical markers should be the same molecules that have pharmacological effects. Two forms of standardization exist. A certain phytochemical or combination of components has action in "true" standardization. Ginkgo, with 26% flavones and 6% terpenes, is typical. Now called phytopharmaceuticals, these concentrated compounds no longer reflect the complete plant. These are often far more effective than the entire plant. However, the technique may reduce effectiveness and increase bad effects and herb–drug interactions. Another sort of standardization is based on producers' guarantees of a particular proportion of marker chemicals that are not indications of herb quality or medicinal effectiveness.

The cultivation and basic processing of medicinal plants and herbal drugs affects the quality of their active pharmacological components. An effective quality assurance system is needed since naturally grown medicinal plants are complicated and easy analytical methods to detect and describe active ingredients by chemical or biological means are few. This assurance is needed throughout cultivation, harvesting, primary processing, handling, storage, packaging, and distribution. At any step, adulteration and microbiological contamination might occur. Good farming, harvesting, and manufacturing techniques for herbal starting materials are crucial to reducing these issues. Producers, processors, and merchants of therapeutic plants and herbal medications have a responsibility. Herbal product producers and suppliers should follow quality control and excellent manufacturing procedures. Very few firms follow thorough quality control and excellent production techniques, including microscopic, physical, chemical, and biological investigation. NAFDAC and Health Canada conduct premarket assessments of all pharmaceuticals before they are sold to protect Nigerian and Canadian health. Regular analysis of market items ensures they are safe and contain the contents listed on the labels.

Due to lack of regulation, herbal product strength and quality may be unknown. It is apparent that plant growing circumstances affect the quality of a plant product. Thus, the good agricultural practice (GAP) system for cultivated plants requires seed selection, growth conditions, fertilizer usage, harvest time optimization, harvesting, and drying to meet certain standards. GAP methods may soon be part of quality control.

Critical Factors Affecting the Quality Control of Herbal Drugs

Microscopic evaluation

Herbal medication quality control has always been focused on appearance, but microscopic examination is now essential for recognizing plants, minute pieces of crude or powdered herbs, foreign materials, and adulterants. Visual inspection, usually with a magnifying lens, helps verify that the plant is the proper species and that the right section is being utilized. Sometimes microscopic investigation is required to identify the species or the proper section of it. In flowers, pollen morphology may identify the species, while leaf stomata can identify the plant component. This may sound apparent, but it's crucial when using various plant sections for different treatments. The aerial portions of stinging nettle (Urtica urens) heal rheumatism, whereas the roots treat benign prostatic hyperplasia (AOAC, 2005).

Foreign matter

Herbal medications should only include the indicated plant portion. Molds, insects, excreta, visible contaminants like sand and stones, dangerous foreign materials, and chemical residues should be absent. Herbal medications may potentially include insects and "invisible" microbiological pollutants that create poisons (WHO, 2004, 2003; EMEA, 2002). Macroscopic inspection may readily detect foreign materials, although microscopy is necessary in certain circumstances (such as starch used to "dilute" plant material). For example, TLC is essential to identify chemical residues (AOAC, 2005; WHO, 1999a, 1998a).

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Ash content

Burning plant material yields total and acid-insoluble ash. The total quantity of material remaining after burning comprises plant ash and acid-insoluble ash. The latter is the residue after boiling complete ash with dilute hydrochloric acid and burning insoluble particles. The second method quantifies silica, notably sand and siliceous soil (AOAC, 2005).

Heavy metals

Accidental or purposeful hazardous metal contamination. Herbal remedies contaminated with heavy metals like mercury, lead, copper, cadmium, and arsenic can pose clinically relevant health risks to users and should be limited due to many factors, including environmental pollution. From the product's amount of dangerous metal and suggested or anticipated dose, the potential ingestion may be determined. Comparing this potential exposure to FAO-WHO's Provisional Tolerable Weekly Intake values (PTWI) for toxic metals puts it in a toxicological context. Many pharmacopoeias use color reactions with specific reagents like thioacetamide or diethyldithiocarbamate to estimate heavy metal amounts and compare them to standards. Instrumental analyses are needed for trace, admixture, or quantitative metal studies. Most approaches employ atomic absorption spectrophotometry (AAS), inductively coupled plasma (ICP), and neutron activation analysis (NAA) (Watson, 1999).

Microbial contaminants and aflatoxins

Bacteria, fungus, and viruses may contaminate medicinal plants. Naturally, this microbial background relies on environmental circumstances and affects herbal product and preparation quality. Thus, contemporary Hazard Analysis and Critical Control Point (HACCP) methods need risk evaluation of medicinal plant microbial loads.

Herbal medications include soil-derived microbes and molds. While a large range of bacteria and fungi are from naturally occurring microflora, aerobic spore-forming bacteria often predominate. Poor harvesting, cleaning, drying, handling, and storage may also cause contamination. Microbial contamination laboratory protocols are outlined in well-known pharmacopeias and WHO recommendations (WHO, 2000, 1998a). Limit values are included in the sources. The total aerobic microbial count, fungal count, Entero-bacteriaceae count, and Escherichia coli, Staphylococcus aureus, Shigella, Pseudomonas aeruginosa, and Salmonella spp. counts are usually measured. The European Pharmacopoeia prohibits E. coli and Salmonella spp. in herbal products.

Compared to synthetic medications, vegetable-based products have greater microbial contamination levels, and the European Pharmacopoeia allows higher amounts in herbal therapies. Drug processing may also affect contamination levels. Using hot water to prepare herbs allows increased contamination levels. Several common fungus generate poisons, including aflatoxins, thus they should be carefully examined. Even trace levels of herbal medication aflatoxins may be harmful (WHO, 2000). Aflatoxin-producing fungi may accumulate during storage (De Smet, 1992). WHO (2000) publishes aflatoxin detection procedures for natural medications. A thorough clean-up is followed by TLC validation. In addition to bacterial and viral contamination, herbal treatments may include microbial toxins, which may cause bacterial endotoxins and mycotoxins. Some therapeutic plants from other nations may include toxic fungus (Aspergillus, Fusarium). Contaminating microorganisms may chemically change plant components. Withering increases enzymatic activity, converting certain plant components into new metabolites. These newly generated constituents and molds like Penicillium nigricans and P. jensi may cause harm (De Smet, 1992).

Pesticide residues

Even if pesticides and fumigants have not been linked to major toxicity, herbs and herbal products should be free of them or managed for hazardous amounts (De Smet, 1992). Herbal medications may include pesticide residues from spraying, soil treatment, and fumigant storage. However, testing herbal medications for broad groups rather than pesticides may be better. Total organic chlorine analysis may assess chlorine in several pesticide molecules. Measurements of total organic phosphorus may also identify phosphate-containing pesticides.

A standard process extracts herbal samples, partitions and/or adsorbs contaminants, and measures pesticides by GC, MS, or GC-MS. WHO published easy techniques and European Pharmacopoeia established limits for pesticide residues in medicine (WHO, 1996a, 1998a, 2000; De Smet, 1999; AOAC, 2005).

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Radioactive contamination

However, nuclear accidents may cause dangerous pollution. The WHO, along with numerous other international organizations, has created recommendations for widespread radioactive contamination after catastrophic nuclear accidents. These publications emphasize that radioactive contamination from naturally occurring radio nuclides does not pose a health risk, but those from major nuclear accidents like Chernobyl and Fukushima may be serious, depending on the radionuclide, level of contamination, and amount consumed. Considering how much herbal medication a person consumes, is unlikely to be harmful. Thus, radioactive pollution has no current limitations (AOAC, 2005; WHO, 2000; De Smet, 1992).

Analytical methods

There are various pharmacopeia monographs for herbal medication quality control, which is the most practical method. When pharmacopoeia monographs are unavailable, manufacturers must create and validate analytical processes. The optimum approach is to follow pharmacopoeia definitions of identification, purity, and content or test. Pharmacopeias and WHO guidelines are useful sources for generic analytical methods. General scientific literature provides further information, notably on chromatographic and spectroscopic procedures. Biological approaches may assess pharmacological activity, potency, and toxicity of the plant or extract.

A simple chromatographic method like TLC may help identify plant material. This is particularly relevant for species with varied active components. Metabolites and product breakdown may be assessed qualitatively and quantitatively (AOAC, 2005). TLC fingerprinting is crucial for herbal medications consisting of complicated combinations of essential oils, resins, and gums that no longer have organic structure. Macroscopy and microscopy may fail to differentiate chemical classes, yet it is strong and fast. Chromatograms of essential oils, reported in scientific literature, may aid identification. UV-Visible instruments are simple to use, and validation methods are exact. Measurements are fast, however sample preparation takes time and works best for simpler samples and UV-visible chemicals. HPLC is best for quantitative examination of complicated mixtures. HPLC may separate volatile components like essential and fatty oils, although GC or GC-MS is better. Analytical instrumentation has simplified component quantification. Recent developments in the isolation, purification, and structural elucidation of naturally occurring metabolites have enabled adequate quality assessment and standardization of herbal products. Chemotaxonomy classifies plants and creatures by chemical composition.

TLC, HPLC, GC, QTLC, and HPTLC may assess plant extract homogeneity. Over-pressured layer chromatography (OPLC), infrared and UV-Visible spectrometry, MS, GC, liquid chromatography (LC) used alone or in combinations like GC-MS and LC-MS, nuclear magnetic resonance (NMR), and electrophoretic techniques, especially hyphenated chromatographic techniques, are powerful tools for standardization and quality control. These advanced methods produce a chemical fingerprint of plant or extract compounds or contaminants (WHO, 2002c). Photo equivalence allows herbal medication chromatographic fingerprints to be utilized for quality control. Information theory, similarity estimation, chemical pattern recognition, spectral correlative chromatograms (SCC), multivariate resolution, chromatographic fingerprints, and chemometric fingerprint evaluation are powerful herbal product quality control methods.

Validation

Herbal product validation is a serious public health issue in developed and developing nations, where illicit herbal medication sales are frequent. Despite rules in certain nations and WHO standards, government bodies have little control over this. Drug control administrators must validate and monitor herbal products sold as therapeutic agents, regardless of whether they cure or reduce disease severity. Scientific validation might limit the manufacture of contaminated herbal items and assure their sensible usage. This might potentially lead to industry regulation so only certified doctors can prescribe the drug.

Herbal medication monographs are in many major pharmacopoeias. Standardization and validation of analytical methods are the main benefits of a pharmacopoeia monograph. Validation is time-consuming, thus this is crucial.

Validation proves an analytical technique is suitable for pharmaceutical use. Validations are guided by USPC (USPC, 1994–2001), ICH, and FDA guidelines. Whether the analytical technique is qualitative or quantitative, validation

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studies must include specificity, linearity, accuracy, precision, range, detection, and quantitative limitations (De Smet et al., 1997). Also crucial is standard availability. In general, macroscopic and microscopic methods need accurate plant reference samples. This challenge is usually solved by a botanical source like voucher specimens. Chromatographic standards are harder to get. Commercially accessible active or marker plant components are rare. Sometimes LC-MS is called a characterisation method. Further, elucidating the structure of such a molecule after isolation would be difficult. As a standard, retention values and durations are calculated for widely accessible substances that perform similarly in the specified chromatographic systems. Qualitative chemical analysis finds and isolates active chemicals. Most analytical methods involve TLC and HPLC. Plant extract quality may be determined by a "fingerprint" chromatogram when active components are unknown or complicated (De Smet et al., 1997).

Labelling of herbal products

Quality customer information is as crucial as the herbal product. Warnings on packets and labels minimize improper usage and unpleasant responses (De Smet et al., 1997). The label is the main source of herbal product information. There is no institution or government agency that verifies herb or supplement labeling. Herbal medicine labels can lie about what's inside. Consumers have less than a 50% chance of obtaining what is specified on the label, and published examinations of herbal supplements have identified considerable variations between the label and the bottle. The term "standardized" on a product label does not guarantee improved quality since it has no legal meaning. Consumers are typically left to judge what is safe and effective, and herbal product labeling may be frustrating. Labels must include "the product has been manufactured according to Pharmacopoeia standards," active components and quantities, serving quantity (dosage), and medication intake frequency.

II. CONCLUSION

Plant materials make up a large part of the worldwide medication business, employed as home cures, over-the-counter drugs, and pharmaceutical raw materials. Therefore, globally recognized quality standards are needed. While certain plants have grown popular, the public, doctors, and media still don't comprehend safe and effective herbal medicine usage. A growing body of research warns against indiscriminate herb usage. The reality is usually veiled by media hype, poorly understood science, or overblown claims. Standardizing herbals is crucial given their widespread recognition as treatments for many illnesses and disorders.

For successful herbal product quality control, advanced analytical equipment are essential for assessing quality criteria. The quality of a herbal medication from collection to packaging must be monitored to ensure safety and effectiveness. Government agencies should implement WHO standards and create monographs using the quality characteristics above to standardize herbal quality. This will improve regulation and reduce quality issues.

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