East and Central African Journal of Pharmaceutical Sciences
Vol. 8(2) 27 - 30

Quality Control of Herbal Medicines

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The use of traditional and herbal medicines is gaining recognition globally. To safeguard the patient, there are legitimate demands that all medicines be safe, efficacious and of good quality. The required parameters for their quality evaluation include assessment for inorganic matter (dust), absence of adulteration, microbial load, identification and profile of contents and where possible quantitation of the active compound or marker compounds. Also of importance are heavy metals, pesticides and product stability. The mixture of portions of herbs in traditional medicines complicates the quality control tests of these preparations. The content profile becomes difficult to replicate from batch to batch, while quantification of the active compound(s) in such multi-component products would require prior processing to isolate and identify the chemical compounds.

Key Words: Herbal medicines quality control

INTRODUCTION

Traditional medicine entails the use of plant (herbal) medicines, animal parts and minerals. Herbal medicines are the most widely used of the three. Herbal medicines are used throughout the developing and developed countries as home remedies, over the counter drug products and raw materials for the pharmaceutical industry. They represent a substantial proportion of the global drug market [1]. It is therefore important to establish internationally recognized guidelines for assessing their quality, as this has an influence on their safety.

To achieve this, it is necessary to consider a number of factors that ultimately impact on the quality control of herbs such as, how the herbs are grown, collected and prepared, the chemical groups found in various herbs and the practice of herbalists [2-3].

Cultivation of Herbs

Medicinal plants/herbs seldom grow in isolation, but as part of the flora. Herbs can be found growing naturally 'wild' or are cultivated. They may also be associates to cultivated crops. Modern farming uses fertilizers for maximum yields. Herbicides and pesticides are also extensively used to control unwanted plants and insects that would normally impinge on the quality and quantity of output. Harvested herbs may therefore contain residues of fertilizers, herbicides and pesticides. Good agricultural practices are encouraged to prevent inclusion of extraneous materials such as residues, soil, weeds and other unwanted plants [4-5].

Preparation of Products

Being of natural origin, plants are generally contaminated with bacteria and other organisms found in the locality of growth, some of which (for example *Clostridia* spp and *Escherichia coli)* are pathogenic to man.

Plants of medicinal value are prepared uniquely in different societies. Sometimes, various societies use different parts of a plant for the same sickness or another.

Pounding and/or boiling, then administering water infusions is a very common practice. Use of raw sap or latex also occurs. Such preparations would therefore demand that they be done under hygienic conditions. Microorganisms present, if not controlled, will degrade the preparation and those that are pathogenic may induce unintended disease in patients.

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Chemical Groups in Plants

Plants contain a variety of compounds such as alkaloids, sulfur compounds, cardiac glycosides, essential oils, flavonoids, hydroquinones, carbohydrates, saponins and tannins. These compounds occur in varying amounts in plants, sometimes in minute quantities. High levels of these compounds in plants may lead to undesirable side effects and toxicity when consumed. Plants also produce closely related compounds some of which might be responsible for the medicinal use of a plant.

Quality Control of Herbal Medicines

Medicinal plant materials are used either whole or in cut or powdered form. In a preparation, a plant may be used alone or in combination with others. The extraction of the plant material may involve soakage, percolation, decoction, reflux, steam-distillation and supercritical fluid extraction. It is also possible for a herbal preparation to contain animal and mineral source components, each source presenting unique problems dependent on endogenous materials. It is because of such a complex nature of preparation that the quality control of herbal medicines becomes complicated. To overcome this difficulty, the quality control tends to focus on the raw materials rather than on the preparation itself.

The quality control of herbal medicines starts with folklore on a medicinal plant. This can be from a renowned herbalist lineage. It can also be based on information collated from various herbalists. It helps to establish the identity of the plant, the part of plant used, the dosage form and procedures for preparation and posology.

Generally, when considering the quality control of herbal medicines, there is need to recognize that they exist in various levels of refinement such as the crude plant, powdered plant parts, whole or plant part extracts, the important fraction determined as active or any of the foregoing mixed with other excipients to facilitate handling.

Milestones in the Quality Control of Plant Medicines

The fourth international conference of drug regulatory authorities (ICDRA) meeting in Tokyo in 1986 requested the WHO to compile a list of medicinal plants and establish international specifications for the most widely used medicinal plants and preparations. This has led to two outcomes. First, the preparation by the WHO of guidelines for the assessment of herbal medicines and the adoption of these by the Sixth ICDRA meeting in Ottawa, Canada in 1991 [6] and second the publication of 28 monographs on selected medicinal plants by WHO in 1999 [3].

The tests for quality listed include the botanical identification of the plant, the description of the plant material of interest, dosage forms, medicinal uses, major chemical constituents, general identity tests, purity tests and chemical assays, pharmacology, contra-indication, warning(s), precaution(s), adverse reactions and posology. The last three are normally included in the pharmacopoeia where applicable.

Quality control methods for medicinal plant materials provide monographs for carrying out a series of quality defining parameters. However, analysis of such materials is not restricted to methods described in the monographs. Other techniques similar to those used for synthetic drugs can be applied.

The cardinal principle of quality control demands that when a drug is given to a patient, it is precisely the one needed and in an appropriate form so that it may elicit the desired response. A drug is, therefore, expected to conform to the specifications of identity, purity, strength, content uniformity, physiological availability and other criteria as may be deemed necessary.

Quality Control Procedures

The quality control of herbal medicines requires a variety of tests the choice of which is dictated by the type of preparation.

GENERAL TESTS

Organoleptic, Macroscopical and Microscopical Methods

This is the examination of the plant or a preparation by means of sight, smell, taste or touch in order to identify the plant. Macroscopical

characteristics of herbal drugs include shape, size, color, surface characteristics, texture, fracture and characteristics of the cut surface. Microscopical characteristics include histological features observable under a microscope with or without the aid of chemical reagents. It is important to compare these characters with those of the sample under examination as the first step in establishing identity and purity. Authentic specimens of the drug of pharmacopoeia quality should be used wherever possible as a reference.

Foreign Matter

Foreign matter is generally defined as material that is extraneous to the medicinal plant. This includes other plant parts, organisms and mineral admixture (stones, sand and dust). Its determination is achievable through macroscopic and microscopic examination of the plant material.

Water and Volatile Contents

Water and other volatile content are determined by thermal gravimetric methods. In finely powdered materials, Karl Fischer titration can be used to determine the content of water. This test is very important for materials that are stored in a dried state as a high water content will normally give a conducive environment for microbial growth that can lead to degradation of the material.

Loss on ignition

This test is done on materials containing large amounts of tightly bound water.

Ash values

Ash value represents content of inorganic residue remaining after incineration. It represents salts occurring in materials and/or extraneous contamination and therefore this test is useful for examining powdered plant materials to, ensure absence of undue extraneous mineral matter, and of other plants as in cardamon fruit, to detect adulterations with materials containing stone cells and to detect adulteration with exhausted drug as in ginger.

There are four types of ashes each having unique significance. Total ash is valuable in substances where little or no calcium oxalate is present such as ginger. Material that contains oxalate gives variable results if only total ash is used. Acid-insoluble ash is useful in detecting excess soil in plant materials. Water-soluble ash is specified for ginger while sulfated ash is used to control the extent of contamination by non-volatile inorganic impurities in plant parts. This test can also be used to control traces of alkali metals.

Herbicides and Residues

Residues of pesticides and herbicides accumulate from agricultural practices such as spraying, treatment of soils during cultivation and administration of fumigants during storage. Residues of concern are those of organochlorides, organophosphates, carbamates and derivatives, and pesticides of plant origin (such as pyrethrum extracts) whose levels must not exceed allowed limits. These residues should be determined using recommended methods including gas liquid chromatography.

Haemolytic Activity

It is necessary to carry out this test especially for those plants that contain saponins. This is more so for those plants derived from the families Dioscoreaceae, Araliaceae, Cryophyllaceae, Sapindacea and Primulaceae.

Foaming Index

For plants containing saponins, it is necessary to determine the foaming index of the aqueous decoctions of the plant materials as well as their extracts. Preparation of decoctions and accurate dosing are difficult to achieve in the presence of foaming.

Heavy metals

Environmental pollution can lead to contamination of plant materials with arsenic, lead and other heavy metals. High levels of lead are often found in materials harvested at roadsides or down wind of factories using fossil fuels to which lead has been added. Limit tests for these metals in plant materials or products are necessary [8].

These should be estimated against standards and set requirements.

Microbial Load

In addition to observing hygiene in the harvest and preparation of plant materials, it is necessary to test for absence of pathogenic bacteria in herbal preparations using methods similar to those in conventional drugs. Absence of common fungi is also important to minimize spoilage.

Quantification of Active Component

The most challenging part of quality control of a herbal medicines is the quantification of the active component(s). Mostly, it is based on chemical group(s) found in the plants used or on the level of biological activity. The approaches to determining activity will therefore be dependent on the type of preparation. Some preparations have known active compounds; others are semi-purified while some contain only known active fraction(s). In some instances, the preparations are admixtures of various plants or their extracts or simply the crude plant.

A plant (herb) normally produces closely related substances of which one or several could be responsible for an observed activity. It also produces other useful compounds that are of no medicinal value. Where herbal medicines contain chemicals known to be active, then their quality control in terms of quantification is based on the main component(s). Where the main active compound is not easy to obtain, it would require a marker compound, easy to isolate and quantify, on which to base evaluation of assumed content and hence batch reproducibility.

Identification therefore requires separation methods such as thin layer chromatography. Likewise, a marker compound can be quantified as an indication of the quantities of the active ingredients by use of conventional methods such as liquid chromatograph and gas chromatography.
In the case of a herbal medicine where more than two plants are mixed, the picture gets more complex and quality control more difficult. Nonetheless, developments in herbal medicine have advanced enough to obtain standardized preparations and in Europe, China and other parts of the world, these preparations are currently available in the market.

CONCLUSION

In conclusion, comprehensive quality control of all herbal medicines will take some time to achieve. This will be gradually attained by applying emerging knowledge from research activities concerned with identifying and isolating compounds responsible for activity. The final result will be that accurate dosages are given with the attendant increased recognition of the contribution of herbal medicine towards global health.

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