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Quality Evaluation of Herbal Products : A Review

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ABSTRACT

The use of herbal medicine and formulation to diagnose or to treat is dates back too many centuries. The meaning of herbal formulation is a dosage form which constitutes one or more herbs in well processed form in different quantities. To get desired effect, to diagnose, to treat disease of human being. It is obtained by treating herbal substances many different processes like extraction, distillation, expression, fractionation, purification, concentration, drying, fermentation. In recent year many people around world about 80 percent of world population of turning to use herbal medicine for their healthcare. The Identification of pure herbal ingredient is important for quality of formulation therefore evaluation of the parameters based upon,physical,microbiological, therapeutic and toxicological studies are very important in the stability studies. evaluation of herbal formulation means confirmation and determination of quality and purity.This review seeks to enlighten people who are in herbal medicine on the need to establish quality evaluation parameters by using advanced analytical tools and well known standardization methods for ensuring quality and safety of herbal medicine.The process of evaluation of good quality assurance of herbal formulation using various methods were also attempted to discuss

Key words:Herbal medicine, Healthcare, Quality Control, Evaluation, Stability Studies, Safety

1.0 Introduction

The use of herbal medicinal formulations for the treatment of various diseases and health related problems and for the prevention from them has been practiced from very ancient period in India and worldwide.Approximately 25 percent of prescribed drugs have plant origin. In WHO's essential medicine list of 252 total drugs about 11 percent are exclusively derived from plants.80 percent rural population in India uses herbal drugs or formulation or indigenous system of medicine (1).

Complex extraction processes is reason behind why evaluation of quality of herbal drugs is difficult from other types of drugs. As in "General Guidelines for methodologies on Research and Evaluation of Traditional Medicine" (WHO, 2000). In some countries herbal medicine is still not recognised officially. The data about safety and quality with efficacy of herbal drugs is not near to sufficient to get support worldwide. The reason for this are health care policies with very least number of research methodology for evaluation of herbal medicine.The evaluation of herbal drugs are very crucial for production, quality control, regulations and safety surveillance of herbal formulations.

To get quality herbal drugs evaluation is essential based on concentration of their active ingredient, physical, chemical standardization and in-vivo in-vitro specifications (2).

The present review describe method of evaluation, stability testing and factor affecting the stability of drug, problem related to herbal products stability, analytical methods to determine stability of herbal products and methods to deal with herbal drugs instability.

2.0 Methods of QualityEvaluation of Herbal Products

Evaluation means verification of its identity and determination of quality and purity of the herbal medicine. Evaluation of crude medicine is necessary because of three main reasons:biochemical variations in the medicine, deterioration due to treatment and storehouse, negotiation and contamination as a result of negligence, ignorance or fraud or variability caused by differences in growth, geographical position, and time of harvesting. For the quality control of a traditional drug, the traditional styles are carried and studied, and documents and the traditional information about the identity and quality assessment are interpreted in terms of advanced assessment or monograph in herbal pharmacopoeia (3).The crude drug can be evaluated by following methods:

2.1 Organoleptic evaluation or morphological evaluation

It isapproach toevaluate drug via way means of the organs of sense like skin, eye, tongue, nostril and ear or macroscopic evaluation and it consists of assessment of medication via way of means of colour, scent, flavor, length, form and unique feature, like touch, texture etc. it's far the method of qualitative assessment primarily based totally at the examine of morphological and sensory profile of complete drugs. Eg. The fractured surfaces in cinchona, quillia and cascara barks and quassia timber are significantcharacteristics. Aromatic odour of umbelliferousfruits and candy flavor of liquorice are the examples of this kind of assessment wherein scent of drug relies upon the kind and high-satisfactory of odourous principles (unstable oils) present. Shape of drug can be cylindrical (sarsapilla), subcylindrical (podophyllum), conical (aconite) etc, size ofconstitute illustrated by length, breadth, thickness, diameter etc. colour method means outside colour which varies from white to brownish black are critical diagnostic characters. The widespread appearance (outside marking) of the weight of a crude drug frequently shows whether or not far probably to conform with prescribed manner like furrows(change despair or valleys), wrinkles (delicate furrows), annulations (transverse rings), fissures (splits), nodules (rounded outgrowth), scars (spot left after fall of leaves, stems or roots). Taste is particular kind of sensation felt via way of means of epithelial layer of tongue. It can be acidic (sour), saline (salt like), saccharic (sweetish), sour or tasteless (no flavor).

2.2 Microscopic evaluation

It includes precise analysis of the drug and it may be used to recognize the prepared drugs via way of means of their regarded histological characters. It is normally used for qualitative evaluation of prepared crude drugs in complete and powder form with using microscope.Using microscope identifying diverse cell tissues, trichomes, stomata, starch granules, calcium oxalate crystals and aleurone grains are a number of crucial parameters which play critical function in identity of particular crude drug. Crude drug also can be recognized microscopically through slicing the skinny TS (transverse section), LS (Longitudinal section) in particular in case of wood through staining them with right staining reagents e.g. starch and hemicelluloses is recognized through blue colour with iodine solution, all lignified tissue give pink stain with phloroglucinol and HCl and so forth. Mucilage is stained red with ruthenium red may be used to differentiate cell structure. Microscopic examination additionally consists of look at of ingredients withinside the powdered use of chemical reagents. Quantitative elements of microscopy consists of look at of stomatal number and index, palisade ratio, vein-islet range, size of starch grains, length of fibers and so forth which play critical function within the recognition of drug.

2.3 Chemical evaluation

Most of medicines have exact chemical components to which their biotic or pharmacological action is associated. To identify certain drug or to test their purity qualitative chemical test are used. The isolation, purification, identity of active elements is primarily based on chemical strategies of evaluation.Qualitative chemical test similar as acid value, saponification value etc. Some of these are useful in evaluation of resins (acid value, sulphated ash), balsams (acid value, saponification value and bester values), volatile oils (acetyl and ester values) and gums (methoxydetermination and volatile acidity). Primary phytochemical screening is a part of chemical evaluation. These qualitative chemical tests are useful in identification of chemical ingredients and detection of contamination.

2.4 Physical evaluation

To evaluate particular drugs physical constants are sometimes taken into consideration. Such physical constants include moisturecontent, melting point, specific gravity, optical rotation, refractive index, viscosity and solubility in different solvents.Every physical propertyis useful in detection and identification of constituentspresent in plant.

2.5 Biological evaluation

Specific biological and pharmacological activities of some drugs are used for their evaluation. In the plant extract there are specific type of constituents present, due to these constituents specific biological activity is found. On both intact and isolated organs of living animals experiments were carried out for evaluation.In preparation the strength of drug with the help of bioassay can be evaluated.Some of the biological evaluations are as follow:

2.5.1 Antibiotic activity

To determine the degree of anticeptic activity some bacteria are used such as Staphylococcus aureus, E. coli and Salmonella typhi. By using Micrococcusflavus, Klebsiella pneumonia, Sarciraluteaantibiotic activity also determined. To evaluate certain vitamins living bacteria, mold and yeast are used. In evaluation turbidimetric method and Microbiological assays by cylinder plate method are used.

2.5.2 Antifertility activity

Contraceptives and abortificientsare included as antifertility drugs. To prevent pregnancy contraceptive drugs are used and to terminate pregnancy abortificientsused. For antifertility of herbal drugs female rats are used I.e. antiovulation and anti-implantation (to measure the pregnancy rate) and for antispermatogenic activity (inhibition of spermatogenesis)and spermicidal activity (sperm motility) of herbal drugs male rats are used.

2.5.3 Hypoglycemic activity

To test hypoglycemic activity of plant extract rabbits, rats or mice are used. For measurement of insulin levels Radio-immunoassay (RIA) orEnzyme linked immunosorbate assay (ELISA) are done.

2.5.4 Neuropharmacological activity

Testing effects of the herbal drugs on central and autonomic nervous system. Using rodents CNS acting drugs such as morphine (Papaver somniferum), cannabinol (Cannabis sativa),cocaine (Erythroxylum coca) are tested. Guinea pig ileum is used for testing herbal drugs for antispasmodic activity on theirANS, for adrenergic activity rabbit jejunum is used, for muscle relaxant activity rat phrenic nerve-diaphragm, for skeletal muscles activity frog rectus is used.

3.0 AnalyticalMethodsFor Evaluation of Stability of HerbalProducts

Generally macroscopic and microscopic examinations are the methods which are used for quality control of herbal drugs and it also involves sensory inspection.With these techniques analytical methods for quality control are appliedusing instrumental techniques such as High-performance liquid chromatography (HPLC), thin layer chromatography (TLC), GC–MS, LC–MS, near infrared (NIR), and spectrophotometer, etc. (4). As analytical methods for evaluation of herbal drugs are importantthe methods of extraction and sample preparation are also very crucial for production of good herbal medicine. For the purpose of quality control of herbal drugs our attention is to fairly construct chromatographic fingerprints with there logical and efficient evaluation. Many natural constituents may be present in single herbal medicine and during the preparation of extracts composition of some herbs may give to interaction with hundreds of natural constituents,the fingerprints produced by the chromatographic instruments may present are comparativelygreat integral representation of different chemical components of herbal medicines, are predominantly discussed.

3.1 Thin layer chromatography

Prior to instrumental chromatography methods like GC and HPLC were accepted TLC was the general method of choice for herbal analysis. For evaluation of herbal drugsTLC is still much often used. Subsequently several pharmacopoeias like American Herbal Pharmacopoeia (AHP)(Upton, Santa Cruz, US, 2002), Pharmacopoeia of the People's Republic of China (Chemical Industry Press, Beijing, 1997), Chinese drug monographs and analysis (Wagner, Kotzting/Bayer, Wald, ¨Germany, 1997), etc. still use TLC to provide first characteristic fingerprints of herbal drugs.successively with other chromatographic techniques TLC is used as an easier method ofinitial screening with a semi-quantitative evaluation. As there are comparatively small changes in the simple TLC separation of herbal medicines than that with the instrumental techniques for chromatography, only a short summary is given here, for more knowledge and specifications about TLC readers could go through references.In analyzing herbal medicines TLC has the advantages of many-fold possibilities of detection.Also TLC can be employed for multiple drug sample analysis and it is simple technique for analysis of herbal drugs. In one time more than 30 spots of samples canbe studied simultaneously, for each plate. for this reasons TLC for use to analyse herbal drugs is still prevalent. It is possible to get useful qualitative and quantitative information from the developed TLC plate with the help of the CAMAG video store system (CAMAG, Switerland) and TLCQA-UV methods.

With the help of digitized technique developed in computer science and image analysis, it is also possible to evaluate similarities between different samples. In constructing the fingerprints of herbal medicines, the advantages of using TLC are its simplicity, specific sensitivity, versatility, simple sample preparation and high velocity. Thus for determining the possible adulteration and the quality of herbal medicine TLC is very convenient advantageous and appropriate method. The presented review give a very honest and proper review on this respect (5). It established and proved the importance of the different techniques like over pressured-layer chromatography (OPLC), rotation planar chromatography (RPC) and electroplanar chromatography (EPC) and summaries the progress in forced-flow planar chromatography (FFPC). Incomplex and potent preparative forced-flow technique was also reputed. To increase mobile-phase velocity hydrostatic pressure is used in this technique. For the analysis of very complex formats Parallel and serially-coupled layers develop new ways for the analysis of a large number of samples such as up to 216.

3.2 Gas chromatography and volatile components inherbal medicines

It's well- known that numerous pharmacologically active constituents in herbal medicaments are volatile chemical composites. Therefore, the analysis of volatile composites by gas chromatography is veritably important in the analysis of herbal drugs. The GC analysis of the volatileoils can be used to identify theplant.The composition and relative attention of the organic composites in the volatile oils are characteristic of the particular factory and the presence of contaminations in the volatile oils can be readily detected. Secondly, the birth of the volatile oils is fairly straightforward and can be formalized and the factors can be readily linked using GC – MS analysis. The relative amounts of the factors can be used to cover or assess certain characteristics of the herbal drugs. Changes in composition of the volatile oils may also be used as pointers of oxidation, enzymatic changes or microbial turmoil. The advantages of GC easily lie in its high perceptivity of discovery for nearly all the volatile chemical composites. This is especially true for the usual FID discovery and GC –MS. Likewise, the

high selectivity of capillary columns enables separation of numerous unpredictable composites contemporaneously within comparatively short times. Therefore, over the once decades, GC is a popular and useful logical tool in the exploration field of herbal drugs[18]. Especially, with the use of hyphenated GC – MS instrument, dependable information on the identity of the composites is available as well (see coming section for further detail). Still, the most serious disadvantage of GC is that it isn't accessible for its analysis of the samples of polar andnon-volatile composites. For this, it's necessary to use tedious sample work-up which may include derivatization. Thus, the liquid chromatography becomes an another necessary tool for us to apply the comprehensive analysis of the herbal medications.

3.3 High-performance liquid chromatography

HPLC is a widespread approach for the evaluation of herbal drugs as it is simple to examine and use and isn't restricted through the volatility or stability of the sample compound. In general, HPLC may be used to research nearly all of the compounds withinside the natural drugs. Thus, over the last decades, HPLC has acquired the maximum enormous utility withinside the evaluation of natural drugs. Reversed-phase (RP) columns can be the almost common columns used withinside the analytical separation of herbal drugs. It is important to observe that the most desirable separation circumstance for the HPLC includes many factors, consisting of the differentcompositions of the cell phases, their pH adjustment, pump pressures, etc. Thus, a great experimental layout for the most desirable separation appears in preferred important. In order to achieve higher separation, a few new strategies had been currently evolved in studies subject of liquid chromatography. These are micellar electrokinetic capillary chromatography (MECC), high-speed counter-contemporary chromatography (HSCCC), low-pressure size-exclusion chromatography (SEC), reversed-phase ion-pairing HPLC (RP-IPC-HPLC) and strong anion-exchange HPLC (SAX-HPLC). They will offer new possibilities for accurate separation for a few particular extracts of a few natural drugs. On the alternative hand, the benefits of HPLC lie in its versatility for the evaluation of the chemical substances in natural drugs, However, the normally used detector in HPLC, say single wavelength UV detector, appears to be not able to meet the task, due to the fact plenty of chemical substances in natural drugs are non-chromophoric compounds. Consequently, a marked growth withinside the use of HPLC evaluation coupled with evaporative mild scattering detection (ELSD) in a latest decade proven that ELSD is an wonderful detection approach for the evaluation of non-chromophoric compounds. This new detector affords a opportunity for the direct HPLC evaluation of many pharmacologically energetic additives in natural drugs, because the reaction of ELSD relies upon best at the size, shape, and variety of eluate debris in preference to the evaluation shape and/or chromophore of analytes as UV detector does. Especially, this method is pretty appropriate for the development of the fingerprints of the herbal drugs. Moreover, the qualitative evaluation or shape elucidation of the chemical additives in HM via way of means of easy HPLC isn't possible, as they rely upon the software of strategies the use of hyphenated HPLC, consisting of HPLC–MS, HPLC-NMR, for the evaluation ofherbal drugs. This subject matter might be in addition mentioned later on.

3.4 Electrophoretic methods

Capillary electrophoresis become established in early Eighties as a effective analytical and separation technique (6) and has seeing that been evolved nearly explosively. It permits an effective manner to record the purity/complexity of a pattern and may deal with clearly each sort of charged pattern additives starting from easy inorganic ions to DNA. Thus, there has been an apparent growth of electrophoretic methods, mainly capillary electrophoresis, used withinside the evaluation of herbal drug treatments in final decades. The greater or much less explosive improvement of capillary electrophoresis seeing that itsintroduction has to a excellent volume paralleled that of liquid chromatography. Most of the used strategies are capillary area electrophoresis (CZE), capillary gel electrophoresis (CGE) and capillary isoelectric focusing (cIEF). CE is promising for the separation and evaluation of active components in herbal drug treatments, because it wishes most effective small quantities of requirements and may examine samples hastily with a superb separation ability. Also, it is a great device for generating the chemical fingerprints of the herbal drug treatments, because it has comparable technical traits of liquid chromatography. Recently, numerous research handling natural drug treatments, were suggested and sorts of medicinal compounds, i.e. alkaloids and flavonoids were studied extensively.In general, CE is a flexible and effective separation device with a excessive separation performance and selectivity while evaluating compounds of low-molecular-mass additives.However, as Shibabi and Hinsdale talked about that the quick improvement in capillary electrophoresis has up to now been centered at the development of decision and throughput instead of reproducibility and absolute precision. One a success method to enhance the reproducibility of each mobility and crucial information has been primarily based totally on inner standards. Many papers have been posted at the challenge over the past years however unluckily they frequently most effective provide a constrained photograph at the actual opportunities of CE withinside the area of fingerprinting herbal drug treatments. On the stony way to to regular results, now no longer only the complexity, heterogeneity and polydispersity of herbal drug treatments can also additionally restrict trustworthy conclusions, however additionally many artifacts can end result from the selected separation buffer chemistry with hidden instrumental constraints. However, we trust that CE and capillary electrochromatography strategies might make a contribution to a best knowledge of the answer conduct of herbal drug treatments, specifically while moreover combined (offline or online) with the effective spectrometric detectors.

3.5 Hyphenation procedures

In the lastdecades,combining a chromatographic separation techniques on line with a spectroscopic detector to be able to acquire structural statistics at the analytes found in a method has come to be the maximum crucial method for the identity and/or aproval of the identification of goal and unknown chemical compounds. For maximum (trace-level) analytical troubles withinside the studies discipline of herbal drug treatments, the mixture of column liquid chromatography or capillary fueloline chromatography with a UV–vis or a mass spectrometer (HPLC–DAD, CE-DAD, GC–MS and LC–MS, respectively) turns into the favored technique for the evaluation of herbal drugs. It additionally actual that extra and/or complementary statistics is, in quite some of cases, urgently required. This may be supplied by, for example, atomic emission, Fourier-remodel infrared (FTIR), fluorescence emission (FE), or nuclear magnetic resonance (NMR) spectrometry. It is validated that, from a realistic factor of view, worthwhile outcomes may be acquired, in view that we want a good deal greater statistics to cope with the maximum complicated analytical structures together with the ones samples from natural drug treatments. Furthermore, the information acquired from such hyphenated units are the so-referred to as -manner information, say one manner for chromatogram and the opposite manner for spectrum, that could offer a good deal greater statistics than the conventional one-manner chromatography. With the assist of chemometrics, a alternatively new area evolved each in chemistry and facts withinside the later a part of the 1970s, we can absolutely get greater chance to cope with the tough troubles withinside the evaluation of natural drug treatments and additionally the troubles in excellent manage of natural drug treatments, so one can be mentioned in a few element on this review.

3.5.1 GC–MS and herbal medicines

Mass spectrometry is the maximum perceptive and selective technique for molecular evaluation and may yield facts at the molecular weight in addition to the shape of the molecule. Combining chromatography with mass spectrometry offers the benefit of each chromatography as a separation technique and mass spectrometry as an identity technique. In mass spectrometry, there may be quite number techniques to ionize compounds after which separate the ions. Common techniques of ionization used along with fueloline chromatography are electron impact (EI) and electron capture ionization (ECI). EI is mainly configured to pick effective ions, while ECI is normally configured for terrible ions (ECNI). EI is especially beneficial for routine evaluation and offers reproducible mass spectra with structural facts which permits library searching. GC–MS become the primary a hit on-line mixture of chromatography with mass spectrometry, and is broadly used withinside the evaluation of vital oil in natural medicines. With the GC–MS, human beings should produce now no longer handiest a chromatographic fingerprint of the vital oil of the natural medication however additionally the facts associated with its maximum qualitative and relative quantitative composition. Used withinside the evaluation of the natural medicines, there are at the least vast benefits for GC–MS, that is: 1) with the capillary column, GC–MS has in wellknown excellent separation ability, that can produce a chemical fingerprint of excessive quality; 2) with the coupled mass spectroscopy and the corresponding mass spectral database, the qualitative and comparatively quantitative composition facts of the herb investigated will be supplied with the aid of using GC–MS, in order to be extraordinarily beneficial for the in addition studies for elucidating the connection among chemical materials in natural medication and its pharmacology in similarly studies. Thus, in our opinion, GC–MS need to be the maximum premier tool for the evaluation of the unstable chemical substances in natural medicines.

3.5.2 HPLC–DAD, HPLC–MS and Others

HPLC-DAD has now become a standard technique in most analytical laboratories around the world. With additional information about UV spectroscopy, qualitative analysis of complex patterns in herbal medicines is becoming much easier than in the past. For example, check the purity of the peaks and compare the existing standard spectrum of a known compound with the spectrum of the sample under study. In particular, with the advent of electrode mass spectrometry, the combination of liquid chromatography and mass spectrometry paved the way for wide and widespread application in the analysis of medicinal plants. Becomes possible.Several valuable papers on LC-MS and its application in the analysis of plant extracts have been published. Over the past decades, the increasing use of LC-MS and HPLC-DAD in the analysis of herbal medicines is quite evident. In which the most widely used technique is HPLC, specifically the hyphenated HPLC technique. In addition, the combined HPLC-DAD – MS technique utilizes chromatography as a separation method and both DAD and MS method of identification. DAD and MS can provide UV and MS information online for each individual peak in the chromatogram. With the help of this hyphen, chromatographic peaks can in most cases be determined directly online by comparison with literature data or with standard compounds, which has makes LC-DAD-MS a powerful approach for the rapid identification of children in plant extracts, and it can be used to avoid tedious isolation of all the compounds to be determined. Recently, the hyphen between HPLC and NMR has also appeared, which can become an important and attractive analytical tool for drug analysis in biological fluids and herbal medicine analysis.In fact, trend hyphenate or polyhyphenate chromatography with four commonly used spectroscopic detectors, such as UV, Fourier, MS and NMR transform infrared spectroscopy, to elucidate the structures of compounds chemistry, is in progress. A recent paper gave a good review on this topic. A “total analytical device” was recently demonstrated in the HPLC-UV (DAD) online analysis case -FT-IR-RMN-MS. Is also underway. Since electrochemical detection has been described to be superior to fluorescence and UV-vis spectroscopy for the determination

of certain chemical compounds, such as trace polyphenols, a very Sensitivity was obtained using a multichannel electrochemical detector. Two-dimensional chromatograms are obtained, since the detector has 12 (or more) electrodes in series that are gradually adjusted to different potentials. Therefore, as well as for UV-vis spectroscopy, the kinetic potential can be used to verify peak purity and identify peaks.

3.5.3 Hyphenation of CE

The situation of CE analysis in the development of hyphen is somewhat similar to that of HPLC analysis. Hyphenated EC devices, such as CEDAD, CEMS and CENMR, have all emerged in recent decades. The inline combination of capillary electrophoresis with mass spectrometry and other spectrometric measurements enables efficient CE separation and specific and sensitive detection. In addition, the artifacts that occur in CE measurement can be overcome with the help of certain information processing techniques, such as some methods developed in chemical measurement, since the spectra can be used in conjunction with additional information to correct for artifacts of the selected split buffer. Or hidden instrument constraints (see below for more details).In summary, as hyphenation techniques in chromatography and electrophoresis devices develop, the ability to analyze herbal medicines, both qualitatively and quantitatively, as well as the ability to monitor the quality of medicinal products. Herbs will get stronger and stronger. We are quite sure that we will have a very bright future for herbal medicine quality control.

4.0 Problems Relatedto TheQuality of HerbalProducts

Most herbal product labels are often unable to fully disclose what is in the container. Studies show that consumers are less than 50% likely to actually get what is on the label and there is a difference in bottled products, so there is no guarantee that word “Standardization” on product labels is a guarantee. Of outstanding product quality, as there is no legal definition of the word “standardized” (7). Consumers often face the burden of deciding what is safe and effective for them, and the lack of consistent branding across herbal products drives consumer frustration. It is good practice for herbal product manufacturers to provide information such as “product has been manufactured to approved standards,” Listing the active ingredients, amounts, strengths, and frequencies. Dose on the label.Standardization of medicinal herbs is the process of specifying a set of standards or inherent characteristics, constant parameters, qualitative and quantitative values that ultimately guarantee quality, efficacy, safety and quality. Reproducibility. It is the process of developing and unifying technical standards. Specific standards are developed through experimentation and observation, which will lead to the process of prescribing a particular set of herbal drug properties (8). Therefore, standardization is a tool in the quality management process. Quality control and standardization of medicinal herbs include several stages. Obviously, plant source, raw material quality, processing and storage are of great importance to ensure the quality and stability of herbal preparations. Light, water source, nutrients, harvest time and duration, method of collection, drying, packaging, storage and transportation of raw materials, age and part of the harvested plant, etc., have can greatly affect the quality and thus the therapeutic value of herbal medicines. Some plant components are not heat stable and the plants containing them must be dried at low temperatures. In addition, other active ingredients are destroyed by enzymatic processes that continue long after the plant is harvested. This explains why the composition of herbal medicines is often quite variable. For these reasons, pharmaceutical companies prefer to use plants grown from the wild, because they have a lower variability in composition. In addition, and certainly more importantly, when medicinal plants are produced by cultivation, major secondary metabolites can be monitored and this helps to determine the best period of harvest.

Recent advances in the purification, isolation and structural elucidation of natural substances have helped to establish appropriate strategies for the analysis and standardization of the quality of herbal preparations. In order to maintain as much aspossiblethe homogeneity of the plant extract. Among other methods, thin layer chromatography, gas chromatography, high performance liquid chromatography, mass spectrometry, infrared spectroscopy, ultraviolet/visible spectroscopy, etc., used alone or in combination, play a major role. It plays an important role in standardization and quality control of both raw materials and finished herbal medicinal products. The process of ensuring materials of reasonable consistency includes the production and careful selection of the materials and processes used in the manufacture of the product. These checks, together with sections on testing and testing, documents and profiles, product types and their developments, which can be found in the white paper, will help companies reflect on their requirements of GMP (good manufacturing practice) for plants.

Despite advances in the standardization of herbal formulations, various challenges have been identified in the quality control of herbal products and ingredients. First of all, the problem of adulteration of herbal products and ingredients has been highlighted in several studies. It involves the mixing or replacement of the original medicinal plant material with other unnecessary, defective, defective, damaged, or other unnecessary artificial parts of the same plant or harmful substances or unsatisfactory drugs. Official standards. This can happen because herbal medicines are usually a mixture of many ingredients and the active ingredients are in most cases not known. Adultery can result from direct or intentional adultery and can also result from indirect or unintentional adultery. For example, one study found that when nutmeg was blended with linden and processed to the required shape and size, colored paraffin wax was used instead of beeswax (9). Instead of Ailanthus leaves, papaya seeds to dope Piper nigrum. In some cases, there has been adulteration with toxic or fictitious substances, e.g. shards of amber glass in turpentine, limestone in asafoetida, lead splash in opium, white oil in coconut oil, cocoa butter with stearin or

paraffin.In addition, many studies have also documented a blend of licorice powder or gentian powder mixed with olive seed powder, under the name cinchona. Raw materials and the variation of raw materials. This is largely due to chemically and naturally modified plant materials as well as to the availability of chemoresistant varieties and cultivars. To geographic location. Sometimes the quality of an herbal ingredient can be affected by environmental factors such as climate, altitude and other conditions in which it is grown. In some cases, optimal harvest time should be observed as it is well known that the concentrations of plant constituents can vary during the growing cycle or even over the course of a day. In addition, the more active ingredients often vary between plant parts and it is not uncommon for herbal ingredients to be adulterated with parts of the plant that are not normally used. Depletion" is sometimes used as an adulterant to increase the weight of a batch of botanical ingredients. Does not remove associated structures e.The stem is harvested along with the leaves, flowers, and fruits. Do not remove unwanted parts or structures e. Cork must not be removed from ginger rhizomes Appropriate drying conditions must be followed Improper drying may lead to unintentional adulteration e.If digitalis leaves are dried above 65 °C, glycosides are degraded by enzymatic hydrolysis. Harvesting, drying, storage, transportation and processing methods (e.g. extraction methods, component instability, etc.) also affect the quality of medicinal herbs.

Currently, there are no official standards for herbal preparations. Selective analytical methods or reference compounds may not be commercially available. These manufacturers, currently testing their formulations, have their own parameters, many of which are very preliminary in nature. Currently, it is difficult to determine the presence of all the ingredients listed in a formulation. The situation is even more difficult for finished herbal products as it cannot be concluded that all the plants or raw materials have been included in the mix. Products.Therefore, the first important task is to develop a parameter such that the presence of the entire composition can be determined, the various chromatographic and spectroscopic methods and the evaluation of the chemical properties can be obtained. Theory can be tried to develop models to determine the presence of different components. If possible, these methods can be applied to quantitatively estimate the bioactive group of compounds such as alkaloids, flavonoids, polyphenols, or estimate a specific compound. The deterioration mainly occurs during storage, resulting in loss of active substance, generation of inactive metabolites and, in severe cases, production of toxic metabolites. Post-harvest factors:

Storage and processing conditions can greatly affect the quality of medicinal herbs.Improper storage after harvest can lead to microbial contamination and processes such as drying can lead to loss of heat stable active ingredients.

5.0 CHALLENGES IN SAFETY OF HERBAL PRODUCTS:-

Herbal medicines are considered by the public to be more effective in certain health conditions, with relatively low risks, and in safety than Western medicines. However, numerous reports indicate an increase in the number of patients experiencing negative health consequences from the use of herbal medicines in recent years. Many cases of poisoning have been reported in the literature resulting in abdominal pain, vomiting, severe anemia, peripheral neuropathy, and psychosis (10). These adverse events may be the result of a number of factors including, but not limited to the following: Use of herbal products, undeclared drugs, misidentification of the plant species, Overdose, abuse of herbal products from plants by herbalists, consumers and concurrent consumption with drugs for allergic diseases. Consumption of herbal products contaminated with foreign substances such as infectious bacteria and toxic substances such as heavy metals and pesticides is a matter of particular concern and should be controlled.Therefore, it is important to note that the safety of herbal products cannot be guaranteed as most of the products are commonly used as self-medicating drugs, endangering the lives of people. Consumption due to inappropriate use. Despite these fluctuations, the distribution and use of these products is endemic in Uganda. Given the weak regulatory infrastructure and lack of common quality standards for herbal products, the quality and safety of these products are rarely covered in low-income countries such as Uganda. Therefore, the risk of consuming toxic herbal products is high in low resource settings.

Associated with these agents has shown promising potential for the efficacy of a good number of well-established herbal products, many of these have not been tested. And their use is either poorly monitored or not at all.The majority of adverse events reported associated with the use of herbal products are due to poor product quality. It is also understood that the safety of most herbal products is still affected by lack of appropriate quality control measures, inadequate labeling and lack of appropriate patient information. Most herbal products are considered safe due to their long history of use in the prevention, treatment and control of various diseases. In such cases, the use of toxic botanical ingredients has been widely used. Toxicity and rejection reports can largely be attributed to misidentification and overdose of certain ingredients. However, when there is no documented long-term history of herbal medicine, or when its safety is in doubt, additional toxicity studies should be performed.Phytotoxicity can result from the inherent toxicity of plant ingredients and ingredients as well as from negligence and contamination. The absence of reporting or recording of side effects is not an absolute guarantee of the safety of herbal medicines. Conduct adequate toxicity studies to examine effects that are difficult or impossible to detect clinically. Some of these tests include genotoxicity, immunotoxicity, carcinogenic toxicity, and reproductive toxicity.Testing can be done in vitro to reduce the number of in vivo tests. Common techniques used to study the safety of herbal medicines are cell flow techniques, DNA microchips, and standardized

techniques to model toxicity satisfactorily. All tests must be conducted ethically in accordance with WHO research. Guidelines for evaluating the safety and effectiveness of male medicinal products. Several studies have been done to uncover the toxic effects of herbal compounds in the body. However, several shortcomings have been identified in the safety assessment of these herbal products.First of all, herbs contain a large number of complex and chemically abundant compounds that are not easily isolated as a single compound. This is further aggravated by the fact that plant phytochemicals are affected by a number of factors including geographical area, edema factor, plant genotype, parts used for harvesting. , processing and storage conditions. Another important challenge in assessing the safety of herbal products is that most herbal experimental drugs must be tested for batch homogeneity of the active ingredients. In clinical trials, it was difficult to have active and control groups that had identical color, smell and taste of herbal medicine, which could not be imitated under placebo manufacturing. Reactions to drugs and other medical substances, including herbs, traditional or alternative medicines. Currently, there is no effective pharmacovigilance system for herbal medicines in Uganda.

Mixing problems and deviations from conventional pharmacological approaches remain a major problem, as are the consequences of using the wrong plant or parent ingredient, and varying concentrations of active ingredients. Change and the treatment window is narrow with herbal medicines. Toxic metals, bacteria, viruses or pesticides may also occur.

6.0 Factors Affecting The Quality of Herbal Products:-

From the growing process of medicinal herbs to the final herbal product, there are many factors that affect the quality of herbal medicines

6.1 Contamination

Contaminants are more likely to be found in plant materials or Herbal products include, but are not limited to, heavy metals, pesticides, bacteria, and mycotoxins.

6.2 Heavy metals

Heavy metals have been found in herbal medicines with some frequency. The three most commonly detected toxic metals are mercury, arsenic and lead; others include cadmium, copper and thallium (11). These heavy metals are commonly found in Asian herbal medicines, especially Chinese Patent Medicines (CPM) and Indian Ayurvedic Medicines. (AMI). Several herbal products from Africa, Europe, and South America have also been reported to contain high levels of these toxic metals. Several recent analytical investigations have confirmed the toxic metal contamination of herbal medicines in different regions. 1) accumulation of heavy metals in the environment (eg.from contaminated soil or atmosphere); (2) accidental pollution during production; (3) or intentionally added. Minerals, including toxic metals, are commonly used in some traditional medicine systems for specific medicinal purposes (Traditional Chinese Medicine or Ayurvedic Indian Medicine). For example, Zhusha (Cinnabaris) and Xionghuang (Realgar), which contain mercury and arsenic, are used in some preparations and topical medications. Of the 572 Chinese prescriptions listed in the Chinese Pharmacopoeia, 53 include Zhusha or Xionghuang.[40] It is incorrect to use the term “pollution” for such intentional heavy metal addition

The idea that heavy metals have positive health effects is based on old notions that are not feasible. Examination according to modern science. Put in herbal medicines. Unless there is convincing evidence that their benefits outweigh the risks. For example, the benefit of Realgar for leukemia has been confirmed, and the functional mechanism has gradually been elucidated. (1) different herbal medicines in different countries are contaminated with different frequencies; (2) Chinese herbal medicines and patented drugs exported to other countries are less susceptible to heavy metal contamination than those used domestically. This may be due to higher quality standards in developed countries.

6.3 Pesticides

Pesticides include insecticides, fungicides, and herbicides. To some extent, pesticide residues, including their metabolites and/or degradation products, will remain in plants, animals or soil. These residues have become a significant source of contamination for medicinal plants. WHO and other organizations have established requirements to limit pesticide residues in plant materials. Organochlorine pesticides (OCPs) are commonly detected in herbal medicines. , including benzene hexachloride (BHC), dichlorodiphenyltrichloroethane (DDT), and pentachloronitrobenzene (PCNB).OCPs have been banned in many countries for about 30 years due to adverse health effects; however, due to their slow breakdown, they can persist in the environment (soil) and accumulate in the food chain.4 Other pesticides, such as organophosphates and carbamates, are less commonly detected in products drugs of plant origin, as they break down more easily. At present, high potency, low residue pyrethroid insecticides are commonly used; Residues of these modern compounds, such as fenvalerate or deltamethrin, are also found in some medicinal plants.Many Chinese studies have addressed the problem of pesticide residues in medicinal plants. These residues have been detected in both domestic and imported medicinal plants, such as Panaxnotoginseng root, Panaxquinquefolium root and Panax ginseng root. Two recent studies examined pesticide residues in 155 medicinal samples (25 species) collected from 11 cultivation facilities in Guizhou province. Five pyrethroid insecticides were detected and 14.8% of all samples exceeded the permissible limit. The aboveground parts are more severely affected than the roots. OCPs (including 9 types) were detected and 7.09%

of samples exceeded the legal limit. Roots are more severely affected than aerial parts. Soil contaminated by OCPs still affects the environment today. High doses or too close to the time of harvest also lead to residue contamination.SO2) against insects or mold are other pollution factors.

6.4 Microbes and mycotoxins

Contamination by bacteria is a common problem in herbal medicines. Pathogenic organisms, including Enterobacteriaceae, Enterococci, Shigella and Streptococci, have been shown to grow on plant material. Mycotoxins include fusarium toxin, aflatoxin, ochratoxin, citreoviridin, penicilic acid, etc. Conventional and highly toxic. A study of herbal medicines collected from a Brazilian market showed that more than 50% of these samples exceeded the microbiological limit set by the United States Pharmacopoeia. Period set. Other studies have also detected fungal and mycotoxin contamination in herbal medicines from India, South Africa, Malaysia, Indonesia and China. Herbal medicines are contaminated with microorganisms. It can occur at any stage of production and marketing Storage and processing conditions are important in determining the quality of the final herbal products. Problems are more common in the tropics and subtropics, as high temperatures and humidity favor fungal growth and toxin production.foreign bodies Other foreign bodies, including ash, excipients or organic solvents, can also lead to external contamination of herbal medicines. To ensure good quality of the end product, it is necessary to minimize this problem.

6.5 Adulteration

Acknowledgment is always fraud and means “to make impure by adding extraneous, inappropriate, or substandard ingredients”. Examples of herbal medicines being counterfeited with orthodox medicines and botanical ingredients have been documented many times. Changes can be classified into three categories: herbal medicine, substitution (using fake or substandard botanical ingredients), and addition of foreign material (herbal parts informal, sand, metal). Several medicinal products have been found in medicinal plants and adulteration rates of commercially available herbal preparations have been reported to be 7% in California, 5.5% in New Zealand and 1.23% in Singapore. In recent years, sildenafil has been commonly found in some herbal products marked as tonic. The addition of foreign substitutes and ingredients Herbal medicines are often aimed at maximizing profits by fraudulently increasing the weight or amount of plant material. This usually happens from the second to fifth steps of the manufacturing process.In China, many compound drugs containing both pharmaceutical and synthetic drugs are allowed for sale (eg, antipyretic analgesics in cold medicines, hydrochlorothiazide in antihypertensive drugs). As defined by WHO, these drugs are not considered herbal. The legal addition of synthetic drugs to herbal medicines is not considered “adulterated”. Herbal remedies, including unpublished orthodox drugs, are illegal. A lack of regulation or control can lead to inappropriate labeling and adulteration of herbal medicines. Contamination is a potentially serious problem that needs to be addressed through strong regulatory measures.Misidentification Unlike adulteration/substitution (intentional behavior), misidentification occurs by accident. Misidentification can occur when an importer or retailer confuses one plant with another, due to incorrect labeling and similar-looking herbal ingredients. Misleading nomenclature can be one of the reasons.A plant may be known by several names: one or more common, Latin, local, and brand names. Several different herbal medicines from different plant species with different ingredients may have similar names. For example, the herb names ‘’ Mutong ‘’, ‘’ Chuanmutong ‘’ and ‘’ Guan mutong ‘’, can be used in Chinese prescriptions with the same common name ‘’ Mutong ‘’. Likewise, “Fangji”, “Feng fangji” and “Guangfangji” can be used as “Fangji”. Thus, the names of “Mutong” and “Fangji” refer to several different species of plants from different unrelated plant families.The misidentification of ‘’Mutong’’ (Caulis Akebiae was replaced by Caulis AristolochiaeManshuriensis) and ‘’ Fangji’’ (Stephaniatetrandra was replaced by Aristolochiafangch) has resulted in the serious problem of ‘’acid nephropathy. Aristolochic ‘’. Similar occurrences, confusion regarding historical records and local usage may also contribute to misidentification of herbs. The matter is made even more complicated by confusing terms and the use of different languages in different countries. The common names of herbs generally do not reflect differences in scientific classification; and the description and microscopic identification of the plant cannot determine its constituents.Therefore, the study of ancient documents and the use of modern analytical techniques are often necessary to authenticate plant material accurately. WHO and other organizations are working on harmonization and specification of botanical nomenclature.

6.6 Internal challenges

Any health effects of herbal medicines are caused by pharmacologically active phytochemicals contained in thesemedicines. External quality issues are complex, internalones, however, can be even more challenging.Complex phytochemicalsPlants can synthesize a bewildering variety of phytochemicals, such as fatty acids, sterols, alkaloids, flavonoids,glycosides, saponins, tannins, terpenes and phenolics.Even a single plant extract may contain hundreds of organicchemicals. For instance, more than 28 ginsenosides havebeen extracted from P. ginseng, and each might be associated with different therapeutic actions.In mixtures ofmore than one herbs, the chemical compositions is evenmore complex. In many instance, it may be difficult todetermine which ingredient is responsible for any given therapeutic effect.

6.7 Nonuniform ingredients

Depending on the growing conditions and geographic region,the composition of herbal medicines varies. A host ofenvironmental factors, including soil, altitude, seasonalvariation in temperature, atmospheric humidity, length ofdaylight, rainfall pattern, etc, may affect the concentrationof components in any given batch. Other factors, includinggenetic make-up, seeding time, use of pesticides and fertilizers, planting density, etc, also play important roles.The processing of raw materials may involve heating orboiling, which can further alter the pharmacological activity of the organic constituents. A recent analysis of 25ginseng products found a 15—200-fold variation in the concentration of the two ingredients believed to have biologicalactivity: ginsenosides and eleutherosides.(12).In addition,combining multi-ingredient herbal medicines with prescription medicines can lead to herb—herb and/or herb—druginteractions.

All the health effects of medicinal plants are caused by the phytochemicals present in these drugs. External quality issues are complex, but internal problems can be even more difficult. Complex phytochemicals Plants can synthesize a wide range of phytochemicals, such as fatty acids, sterols, alkaloids, flavonoids, glycosides, saponins, tannins, terpenes, and phenolic compounds.Even a single plant extract may also contain hundreds of organic chemicals. For example, more than 28 ginsenosides have been extracted from P.ginseng, and each can have different medicinal effects. In the mixtures of some herbs, the chemical composition is even more complex. In many cases, it can be difficult to determine which ingredient is responsible for a certain therapeutic effect.

Conclusion

Herbal medicine and plant materials are used in developed and developing countries as remedies at home, in more than over-the-counter pharmaceuticals they are used as raw materials for the pharmaceutical industry, and they make up a significant part of them on the global drug market. The quality of herbal medicine is the sum of all factors contribute directly or indirectly to the safety, efficacy, and acceptability of a product. Today, the field of herbal medicine and formulations Is developing very rapidly and there is still much to be discovered in terms of their evaluation. Therefore,While developing herbal formulation it is essential to have all the knowledge regarding this drug, namely covering all its organoleptic characteristics to the phytocons composition for pharmacological activity to evaluateit.Inadhere to different parameters through different techniques quality assurance issues of herbal medicine Have been solved to a large extent using DNA fingerprint analysis chromatography.

More advanced techniquesfor evaluating herbal medicines are needed. The quality control of herbal products not only needs to establish reasonable analytical methods to analyze the active ingredients in herbal medicines, but also has to affect various factors such as protective drug residues. Vegetation, toxin content, heavy metal pollution, good agricultural practice (GAP), good manufacturing practice (GMP), etc. There is a need to develop techniques that include both traditional standardization and assessment methods. These improve the quality of herbal medicine and inspire practitioners to participate in the standardization process and assessment methods.Like all medicines, herbal products need to be adequately controlled for evaluation and pharmaceutical quality, to prevent contamination, substitution or adulteration of plant materials and to determine theconcentrations of ingredients potentially toxic part. An adequate pharmacovigilance system should be in place to improve the proper use of herbs and minimize potential health risks.

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