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Herbal Drug Preparation

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ABSTRACT

Herbal medicine has been used for thousands of years. It is estimated that 80% of world population rely on traditional herbal medicine for primary health care. In recent years, herbal remedies have been considered as dietary supplement for disease prevention and as alternative/complementary medicine. A wide variety of herbal medicines are readily available in the market all over the world. With the rising utilization of herbal products, safety and efficacy of herbal medicine have become a public health concern. Adverse health effects associated with herbal products could be attributed to both inherent toxic effects of herbal medicine and toxicities induced by adulterants/contaminants. Increasing evidence, regarding side effects of herbal medicine, has highlighted the demand and necessity of toxicological studies for herbal products. Toxicology constitutes an essential role in the development of herbal medicines. With the advancements of analytical techniques and molecular technology, coupling with the conventional test systems, the '-omics-' technology makes a significant contribution to the predictive and preclinical toxicology of herbal medicine. In this chapter, side effects related to herbal medicine and its adulterants/contaminants are summarized. The recent application of '-omics-' technology for toxicological evaluation of herbal products is also illustrated.

Keywords: Modern herbal medicines, Types of herbs, Methods of preparation, Evaluation of herbal drug products, Conclusion

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INTRODUCTION

Herbal derived drug preparations or herbal medicines have been used worldwide for centuries. Herbal medicines can contain single or multiple herbs in a single drug preparation. That is why herbal medicines could have a complex mixture of many herbs that contain many chemical compounds. According to the WHO guidelines herbal medicines are herbs, herbal materials, herbal preparations and finished herbal products. Herbs include crude materials that can derive from lichen, fungi, algae and parts of higher plant materials, which may be entire, fragmented or powdered, whilst herbal materials include fresh juices, gums, fixed oils, essential oils, resins and dry powders of herbs. These materials may be processed by steaming, roasting, backing with honey or alcoholic beverages. Herbal preparations may include comminuted or cut herbal materials, or extracts, tinctures and fatty oils of herbal materials. Finished herbal products and mixtures of herbal products may contain excipients in addition to the active ingredients i.e. herbal preparations made from one or more herbs or their extracts. If more than one herb is used, the term "mixture herbal product" was used. Products that contain chemically defined isolated constituents, or a mixture thereof, are not herbal medicine products. Botanicals can be available as two different products i.e. herbal medicinal products or as plant food supplements (PFS).Nowadays, herbal medicines in Indonesia are produced by many pharmaceutical companies, and according to the BPOM (Indonesian National Agency of Drug and Food (Control), 872 companies were registered in 2005; the growth Rate of these products in Indonesia was estimated at 20-30% annually. Due to the increasing application of herbal medicines, QC of the drug preparations derived from herbs is very important. This QC can be used to monitor their efficacy and toxicity [1].

Advantages:

Herbal medicines can treat minor conditions like scrapes, rashes and burns. They can also be used to treat migraines, arthritis and depression (University of New Hampshire) at a very low cost. The cost of herbal medicines are very low compared to pharmaceutical drugs because they can be found in local supermarkets or grown at home. According to Christopher Golden from Harvard University Center for the Environment, if people used herbal medicines in place of pharmaceuticals, they could save themselves 22-63% of what they spend on healthcare annually. Herbal medicine can also be found in everyday foods such as ginger, garlic and rhubarb.

Disadvantages:

Herbal Medicines may come with many advantages. But it also comes with a set of disadvantages as well. For one, herbal medicines take a longer time to work compared to

pharmaceutical drugs. If an individual decides to take the herbal alternative to pharmaceuticals, he or she must be very patient.

Herbal medicines are often self-administered. As a result, there is no dosage or warnings specified. When Herbal medicines are consumed with pharmaceutical drugs, the two can interact with each other resulting in injuries to health.

It is also important to know that plants used as an herbal medicine may poison rather than cure someone. It may be the case where a certain part of a plant may be edible and another part may be poisonous. Take rhubarb for example. The roots of rhubarb is used as a laxative and the stem is edible. However, its leaves are poisonous. An individual may not be able to identify a poisonous plant. This would put the individual at the risk of poisoning themselves or others.

Modern herbal medicine:

The World Health Organization (WHO) estimates that 80 percent of the population of some Asian and African countries presently use herbal medicine for some aspect of primary health care. Some prescription drugs have a basis as herbal remedies, including artemisinin, aspirin, digitalis, and quinine.[2]

Types of herbs:

- Tinctures
- Herbal capsule
- Herbal ointment
- Herbal balms
- Herbal creams
- Herbal oils
- Herbal soaps

Tinctures

Tinctures are normally alcohol and water extracts of plant materials. Many plant constituents dissolve more easily in a mixture of alcohol and. Water than in pure water. The preparation of tinctures by maceration of herbal parts in water-ethanol solutions results in the extraction of many structurally diverse compounds with varying polarities. An alcohol content of 25 %v/v is recommended for water-soluble constituents like tannins, mucilage and certain flavonoids and some Saponins, while an alcohol concentration of 45-60 %v/v is required for alkaloids, essential oils, some glycosides and most Saponins Jun, and 90 % v/v alcohol for resins and oleoresins. The use of the right ethanol concentration is important in maximizing the quality of the herbal preparations. When kept properly, most tinctures have a shelf life of around five years.

Herbal capsule

Capsules are solid dosage forms containing drug and usually, appropriate filler (s) enclosed in a gelatin container. Capsules may be available in hard gelatin for dry powdered herbal ingredients or granules, or soft gelatin shells for herbal oils and for herbal ingredients that are dissolved or suspended in oil. The gelatin shell readily ruptures and dissolves following oral administration. Drugs are normally more readily released from capsules compared to tablets[3].

Figure 1: Herbal capsules

Herbal capsules normally consist of hard shelled gelatin capsules with the plant material finely milled and sifted and filled into shell or extracts of the herbal material(s) with appropriate excipients such as fillers. The stability of herbal capsule preparations is relatively better when compared to aqueous preparations such as decoctions and infusions. Stability and shelf life of capsule preparations should be determined to provide appropriate instructions for storage of the product.

Herbal ointment

Ointments are semi-solid, greasy preparations for application to the skin, rectum or nasal mucosa. The base is usually anhydrous (hydrophobic) and immiscible with skin secretions. Ointments may be used as emollients or to apply suspended or dissolved medicaments to the skin. Herbal ointments normally have the plant material(s) either in finely sifted or extracted form incorporated into the base. Herbal Ointments should not be used for deep wounds.

Figure 2: Herbal ointment

Ointments are relatively stable when compared with other liquid dosage forms. However, the presence of herbal materials in an herbal ointment may lead to quick deterioration of the product. The stability of herbal ointments is necessary to provide appropriate labelling instructions for storage and shelf-life. The chemical stability of an ointment containing herbal tinctures of calendula and arnica for the treatment of hemorrhoids was determined using a stability-indicating thin-layer chromatography technique. The shelf-life was determined to be one month and two months at 25 °C±2 °C/60% RH and 5 °C±3 °C, when protected from light, respectively [4].

Herbal balms

These may be classified as ointments meant for massage into the skin for relief of body aches and pains. They normally contain herbal materials which provide a rubefacient effect on the skin and by so doing cause relief of pain. The stability of herbal balms may be compared to that of herbal ointments since the bases for preparation are similar. The difference arises in the type of herbal material being used to exert a particular effect.

Figure 3: Herbal balms

Herbal Creams

Herbal creams are semi-solid emulsions that are mixtures of oil and water (hydrophilic). Herbal creams normally contain the herbal material in either finely sifted form or incorporated as an extract. Creams normally contain antimicrobial preservatives due to the Presence of water in the base and may have a relatively shorter shelf life compared to ointments. Some herbalists tend to confuse creams and ointments. Herbal creams are those which have a hydrophilic base. If the base is purely hydrophobic, then the preparation must be qualified as an ointment[5] .

Figure 4: Herbal creams

Herbal oils

These preparations are normally meant for external or topical use as liniments. In a few cases, however, some of these preparations may be meant for oral use. Herbal materials such as leaves with essential oils may normally be found incorporated in these oils. The stability and shelf life of a herbal oil depends largely on the type of oil being used in the extraction process since the stability of various essential oils differs[6].

Herbal soaps

A soap is a salt of a fatty acid usually made by saponification of a fatty acid with caustic soda or a suitable base. Herbal soaps have the herbal materials incorporated in the detergent base. These herbal materials normally have an antifungal and antibacterial effect on the skin and helps in cleansing of the skin. Herbal soaps are normally meant for microbial skin conditions such as dandruff, ringworm and boils. Soaps have a relatively longer shelf-life when preservatives or antioxidants are added.

Figure 5: Herbal soaps

Herbal paste

Herbal pastes may contain the herbal ingredient dissolved or dispersed in a base (fatty base if it is meant for topical use or a more aqueous stiff base if it is meant for oral use as is done in herbal

toothpaste). The Stability of an herbal paste depends on the type of base used as well as the nature of the herbal material incorporated[7].

Herbal teas

These are preparations meant for infusion or preparation to be taken as tea. Prepared infusions should be taken immediately after preparation since they do not store well due to the use of water in the extraction process. They normally come as tea bags for hot infusion or as powdered herbal materials (normally pulverized leaves) for boiling in hot water for a few minutes before straining and drinking as tea. The stability of the powdered plant material used in the preparation depends on the type and nature of the herbal material as well the moisture content of the powder in the bags and packaging[8].

Figure 6: Herbal teas

Herbal powders

These are preparations that come as powdered herbal materials meant for direct use or by incorporation into foods, beverages for drinking, insufflation, and wounds. They may be finely sifted herbal materials from various parts of plants meant for a particular therapeutic effect. Like the herbal teas, the stability of the powder depends on the type and nature of the herbal material as well as the moisture content of the powder in the bags and packaging. The dried herb and extract of the root of Nucleal latifolia S. M., an antimalarial plant found growing in Africa, was found to be stable under tropical room temperature conditions for over one year in sealed glass containers[9].

METHOD OF PREPARATION:

Internal preparation

Tincture

Herbal tinctures are prepared from raw, dry powder or cut (coarse cut 4 mm, medium cut 2.8 mm fine cut 2 mm) herbal materials and soaked in alcohol to extract the active properties from herbs that will not dissolve in water or in the presence of heat. When working with dried plants, use 2

oz of plant material (cut or powder) for every 8 oz (1 cup) of liquid in the ratio 1:4 or the ratio be 1:5 (200 g or 7 oz dry herb per 1 L or 2.2 pints vodka); measure the amount of cut herb by weight and not volume since many cut herbs can be bulky. Put the herb (powder or cut) in a container containing 40% alcohol (ethanol, 80 US proof vodka, rum, etc.) and leave for 2–6 weeks, strain and use. In the Amazon, a sugar-cane alcohol resembling rum and called aguardiente (alcoholic beverages) is often used to prepare plant tinctures and it is 40–50% alcohol (or 80–100 US proofs). A standard 4:1 tincture usually means 1 part herb to 4 parts liquid (1 oz herb to 4 oz of liquid). To prepare approximately 1 cup of tincture place 2 oz of the herb (powder or cut) into your clean glass container. Pour ½ cup (4 oz) of distilled water and ½ cup (4 oz) of 180 proof alcohols into the container (or 1 cup of 80proof vodka without water). Seal the container and keep at room temperature away from direct sunlight for at least 2 weeks to soak (larger woody cut pieces need 4 weeks) and shake the container (bottle/jar) periodically, at least once daily. At the end of 2 or 4 weeks, strain the tincture through a muslin cloth or fine mesh strainer. Squeeze out the excess liquid from the herb matter. Discard the plant matter and bottle the tincture in a dark glass bottle and seal[10].

Percolation

Methods of preparation, quantitative presence of the active drug constituents in the preparation as well as its mode of use are important for a desired therapeutic effect from an herbal preparation. Fresh materials are considered to be the best, but can be dried to ensure a constant supply throughout the year. In case of dry material, half of the quantity of fresh material may serve the purpose. Methods of preparation of herbal remedies depend on the part of the plant, the active ingredient or the mode of administration. In traditional herbal medicine systems, herbal remedies are prepared in several ways. Some of the methods are described below.

External preparation

Herbal capsule

To take herbs as capsules, you must first buy empty verge-caps, and fill them with the herb. To do this, cover a plate with the powdered herb and take the halves of the capsule apart. Move the halves of the capsule toward each other through the herb powder, filling them in the process. Push the halves of the capsules together to close. Generally speaking, 4 caps need to be taken together to equal 1 teaspoon of herb matter[11].

Herbal ointment

Herbal ointment was prepared by mixing accurately weighed Neem and Turmeric extract to the ointment base by levigating method to prepare a smooth paste with 2 or 3 times its weight of

base, gradually incorporating baser until to form homogeneous ointment, finally transferred in a suitable container.

EVALUTION OF HERBAL DRUG PRODUCTS:

Biological parameter (bioassay): It is well established that the biological potency of the herbal constituents is due to not one but a mixture of bioactive plant constituents and the relative properties of a single bioactive compound can vary from batch to batch while the biological activity remains within the desirable limits. Some of the examples are:

Apoptogenic activity profiles of herbal preparation: Adaptogens help the body to come up with stress and enhance general health and performance. AVM is an herbal formulation. Composition- Emelia officinalis, Wataniya Somniferous, Asparagus Racemizes, Onium Sanctum, Tribulus Terrestre's and Piper linguae shows significant anti stress, Immunomodulatory and anabolic activities in different animal models thereby proving a promising adaptogen[12].

Evaluation of antioxidant activity of herbal products: A new test method for measuring the antioxidant power of herbal products, based on solid phase spectrophotometry using tetanoid, f, j, n, l, 5, 9, 13- tetraazacyl-clohexadecin- Cu (II) complex immobilized on silica gel is proposed. the method represents an alternative to the mostly used scavenging capacity assays. The method was approved in the analysis of the most popular herbal beverages and drugs Echinacea determined spectrophotometrically[13].

Evaluation of microbial contamination reduction on plants through a technological process of decoction and spray dry: The technological process of raw material has many stages, generally, adverse to microbial growth, but its complete elimination depends on the initial and work condition utilized. The aim of this work was to verify the microbial contamination, such as extracting solution (SE) and spray dried extract (PSA) with the purpose of evaluating the decrease of contamination after the decoction and the spray dry. The microbiological analysis of the products was performed by total plate count and MPN coliform[14].

Evaluation of nitric oxide scavenging activity of selected medicinal plants used in inflammatory diseases: Four traditional medicinal plants, namely Ventil ago madras Atana Garten., Rubia cordifolia Linn., Lantana camara Linn. and Marinda centifolia Linn. were selected for a study on the inhibition of nitric oxide (NO), a key mediator in the phenomenon of inflammation, signifying the presence of effective anti-inflammatory constituents therein. Plant samples were extracted with different solvents for evaluation of their inhibitory activity on NO produced in vitro from sodium nitroprusside, and in LPS- activated murine peritoneal macrophages, ex-vivo[15].

CONCLUSION:

Herbal products have gained wide acceptance in both developing and advanced countries and are being produced in commercial quantities. The stability of these herbal products is of paramount importance to assure product quality, safety and efficacy. It is expected that herbal product manufacturers will apply the necessary protocols and techniques to achieve and maintain the stability of their products during manufacture, storage, transportation and usage. This will contribute to patient safety, product efficacy and enhance patient confidence in herbal products and improve compliance.

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