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### **Review Article**

#### **RECENT TRENDS IN HERBAL DRUGS: A REVIEW**

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#### **ABSTRACT**

Herbal medicines make up a significant constituent of the tendency toward alternative medicine. Herbal medicine is becoming ever more popular in today's world as people seek out natural remedies. Herbal medicines have been used since the dawn of civilization to maintain health and to treat various diseases. To compete with the growing pharmaceutical market, there is an importance to use and scientifically authenticate more medicinally useful herbal products. This article provides a general idea of herbal medicines and intended to explain the therapeutic effectiveness of various herbal medicines, adverse drug reactions, drug interactions, standardization and stability testing of herbal medicines, pharmacovigilance and regulatory status of herbal medicines.

**Keywords:** Herbal drugs, Standardization, Stability testing, Efficiency.

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#### **INTRODUCTION**

Herbal drugs referred as plants materials or herbalism, involves the use of whole plants or parts of plants, to treat injuries or illnesses<sup>1</sup>. Herbal drugs are use of therapeutic herbs to prevent and treat diseases and ailments or to support health and healing<sup>2</sup>. These are drugs or preparations made from a plant or plants and used for any of such purposes. Herbal drugs are the oldest form of health care known to mankind<sup>3</sup>. There are many herbal products offered that assert to treat the symptoms of a broad range of problems, from depression to cold and flu. World Health Organization<sup>4</sup> (WHO) has distinct herbal drugs as complete, labeled medicinal products that have vigorous ingredients, aerial or secretive parts of the plant or other plant material or combinations. World Health Organization has set

precise guidelines for the evaluation of the safety, efficacy, and quality of herbal medicines. WHO estimates that 80% of the world populations currently use herbal drugs for major healthcare. Exceptionally, in some countries herbal drugs may also enclose by tradition, natural organic or inorganic active constituents which are not of plant source. Herbal drug is a chief constituent in traditional medicine and a common constituent in ayurvedic, homeopathic, naturopathic and other medicine systems<sup>5</sup>. Herbs are usually considered as safe since they belong to natural sources<sup>6</sup>. The use of herbal drugs due to toxicity and side effects of allopathic medicines, has led to rapid increase in the number of herbal drug manufacturers. For the past few decades, herbal drugs have been more and more consumed by the people with no prescription.

Seeds, leaves, stems, bark, roots, flowers, and extracts of all of these have been used in herbal drugs over the millennia of their use. Herbal products have reached extensive adequacy as beneficial agents like antimicrobial, antidiabetic, antifertility, antiageing, antiarthritic, sedative, antidepressant, antianxiety, antispasmodic, analgesic, anti-inflammatory, anti-HIV, vasodilatory, hepatoprotective, treatment of cirrhosis, asthma, acne, impotence, menopause, migraine, gall stones, chronic fatigue, alzheimer's disease and memory enhancing activities<sup>7</sup>. Herbal drugs have been recognized for approximately 4000 years. These drugs have survived real world testing and thousands of years of human testing. Some drugs have been discontinued due to their toxicity, while others have been modified or combined with additional herbs to counterbalance side effects.

### **Advantages of Herbal Drugs**

- Low/Minimum cost
- potency and efficiency
- enhanced tolerance
- More protection
- fewer side-effects
- complete accessibility
- recyclable

### **Disadvantages of Herbal Drugs**

- Not able to cure rapid sickness and accidents
- Risk with self dosing
- Complexity in standardizations

### **Usage and Preparation of Herbal Drugs**

The use of herbal drugs in the correct way provides effectual and safe treatment for many ailments. The efficiency of the herbal drugs is typically subjective to the patient<sup>8</sup>. The strength of

the herbal drugs varies based on the genetic distinction, growing conditions, timing and method of harvesting, revelation of the herbs to air, light and dampness, and type of conservation of the herbs. Some of the plants that make up herbal drugs are cultured and processed in the country and others

are imported from around the world. Raw materials for herbal drugs may be derived from carefully cultivated plants or collected in the wild<sup>9</sup>. Herbal drugs are accessible in several forms and often require preparation before their use. They can be normally purchased in mass form as dried plants, plant parts or insecurely packed for herbal teas and decoctions. Decoctions are made by boiling the herb in water, then straining out of the plant material. More intense forms of herbal drugs are available in the form of hydro alcoholic tinctures and fluid extracts. Methods of preparation may differ because of the nature of the plants active chemical constituents<sup>10</sup>.

### **Pharmacological Actions of Herbal Drugs**

#### *Anti-inflammatory activity*

The extracts of *Achillea millefolium*, *Artemisia vulgaris*, *Bauhinia tarapotensis*, *Curcuma longa*, *Forsythia suspense*, *Houttuynia cordata*, *Glycyrrhiza uralensis*, *Lonicera japonica*, *Ruta graveolens*, *Securidaca longipedunculata* and *Valeriana wallichii* have shown anti-inflammatory activity<sup>10</sup>.

#### *Antidiabetic activity*

From earliest period, peoples are using herbal plants as home remedies for the treatment of diabetes<sup>11</sup>. The a variety of herbal plants with antidiabetic activity are *Abroma augusta*, *Acacia melanoxylon*, *Acacia modesta*, *Acacia nilotica*, *Aconitum ferox*, *Adhatoda vasika*, *Adiantum capillus*, *Adiantum incisum*, *Agrimonia eupatoria*, *Allium sativum*, *Aloe barbadensis*, *Althaea officinalis*, *Apium graveolens*, *Arctium lappa*, *Commiphora abyssinca*, *Embilica officinalis*, *Eucalyptus globules*, *Ginseng panax*, *Gymnema sylvestre*, *Inula helenium*, *Juniperus communis*, *Medicago sativa*, *Nigella sativa*, *Orthosiphon stamineus*, *Panax quinquefolius*, *Polygala senega*, *Plantago ovata*, *Punica granatum*, *Salvia officinalis*, *Scoparia dulcis*, *Tanacetum vulgare*, *Taraxacum officinale*, *Tecoma stans*, *Trifolium alexandrinum*, *Trigonella foenum*, *Turnera diffusa*,

*Urtica, dioica, Xanthium strumarium, Zea mays* and *Zingiber officinale*<sup>12-15</sup>.

#### *Analgesic activity*

The extracts of *Bougainvillea spectabilis, Chelidonium majus, Ficus glomerata, Dalbergia lanceolaria, Glaucium grandiflorum, Glaucium paucilobum, Nepeta italic, Polyalthia longifolia, Sida acuta, Stylosanthes fruticosa, Toona ciliate, Zataria multiflora* and *Zingiber zerumbet* are used as analgesic agents<sup>16</sup>.

#### *Anticancer activity*

Medicinal plant products exhibiting anticancer activity continue to be the subject of extensive research aimed at the development of drugs for the treatment of different human tumors. The medicinal plants used for the treatment of cancer are, *Acalypha fruticosa, Alangium lamarki, Catharanthus roseus, Celastrus paniculatus, Embelia ribes, Ficus glomerata, Ficus racemosa, Ocimum basilicum, Plumbago zeylanica, Terminalia chebula, Tylophora indica, Wrightia tinctoria*. The extracts used for the treatment of breast cancer is *Buthus martensi, Colla cornu, Herba epimedii, Fructus lycii, Radix angelicae, Radix bupleuri, Rhizoma corydalis, Rhizoma curculiginis, Radix paeoniae, Radix glycyrrhizae, Scolopendra subspinipes, Squama manitis, Tuber curcumae*. The herbal drugs used for treatment of pancreatic cancer are *Embllica officinalis, Nigella sativa* and *Terminalia belleric*<sup>17-19</sup>.

#### *Antiageing activity*

Cell membranes are particularly susceptible to the hostility of free radicals. When the nucleus is injured, the cell loses its ability to replicate itself. The impaired cell replication results in the destabilized immune system, skin ageing and many age related disorders. Various antioxidants neutralize the free radicals and prevent oxidation on a cellular level. The most effectual antioxidants include pine bark extract, grape seed extract, and blue berries were effectual against the hostility of free radicals. Some commonly used herbs as antiageing agents are *Allium sativum, Arnica*

*montana, Cucumis sativum, Curcuma longa, Ficus bengalensis, Lycium barbarum, Ocimum sanctum, Panax ginseng, Prunus amygdalus, Santalum album, Rosa damascene* and *Withania somnifera*<sup>20, 21</sup>.

#### *Antifertility activity*

Plant drugs have involved in the concentration of many scientists as a primary source of naturally occurring fertility regulating agents because of their little or no side effects. The plants that have been reported to have antifertility activity are *Amaranthus retroflexus, Artabotrys odoratissimus, Barberis vulgaris, Carica papaya, Dieffenbachia seguine, Evodia rutacapra, Fatsia horrid, Ferula assafoetida, Hibiscus rosasinensis, Lonicera ciliosa, Magnolia virginiana, Mardenia cundurango, Pisum sativum, Podophyllum peltatum, Punica granatum, Raphanus sativus, Rehmannia glutinosa, Semecarpus anacardium, Sesbania sesban, Stemona japonica, Thuja occidentalis, Taxus baccata* and *Verbena officinalis*<sup>22</sup>.

#### *Antipsoriasis activity*

A variety of natural proprietary formulas and preparations containing plant materials have been used to provide symptomatic relief in psoriasis. The different herbal remedies for psoriasis are, turmeric, curcumin, shark cartilage extract, oregano oil, milk thistle. Various antimicrobial agents *Azadirachta indica, Calendula officinalis, Cassia tora, Wrightia tinctoria* have been used in the management of psoriasis<sup>23, 24</sup>.

#### *Antidepressive activity*

A number of nutritional and herbal supplements have shown promise as alternative treatments for depression. A large number of plants have potential functions to treat depression which are described as, *Bacopa monniera, Panax quinquefolius, Piper methysticum, Rhodiola rosea, Valeriana officinalis* and *Hypericum perforatum*<sup>25</sup>.

#### *Antivitaligo Activity*

Antivitaligo oil is a herbal remedy manufactured with potent herbs and is produced with traditional methods and is also a complete traditional herbal formulation. The plants which can be used in the treatment of vitiligo are *Acorus calamus*, *Adiantum capillus*, *Boswellia serrata*, *Cassia angustifolia*, *Cassia tora*, *Cinnamomum cassia*, *Fumaria officinalis*, *Glycyhizza glabra*, *Lavandula stoechas*, *Psoralea cordyfolia*, *Pterocarpus santalinus*, *Rosa damascene*, *Sphaeranthus indicus*, *Tephrosia purpuria*, *Vitis vinifera*, *Zingiber officinale* and *Zizyphus sativa*<sup>26</sup>.

#### **Treatment of dental diseases**

The plants having the dental care properties are *Acacia catechu*, *Acacia arabica*, *Althea officinalis*, *Anacyclus pyrethrum*, *Azadirachta indica*, *Barleria prionitis*, *Cinnamomum camphora*, *Cuminum cyminum*, *Eucalyptus globules*, *gardenia gummifera*, *Holarrhenia antidysenterica*, *Jasminum grandiflorum*, *Juglans regia*, *Mimusops elengi*, *Myrica sapida*, *Myroxylon balsamum*, *Ochrocarpus longifolius*, *Ocimum sanctum*, *Origanum vulgare*, *Piper longum*, *Piper nigrum*, *Pistacia lentiscus*, *Pterocarpus marsupium*, *Punica granatum*, *Salvadora persica*, *Salvia officinalis*, *Solanum xanthocarpum*, *Symplocos racemosa*, *Syzygium aromaticum*,

*Thalictrum foliolosum* and *Zanthoxylum alatum*. All these regimens play an important role in suppressing the dental problems<sup>27, 28</sup>.

#### **Adverse Drug Reactions**

Herbal drugs are not completely free of adverse drug reactions. Some adverse drug reactions of typically used herbs are, impulsive bleeding by *Gingo biloba*, gastrointestinal disturbances, allergic reactions, fatigue, dizziness, photosensitivity, confusion *Hypericum perforatum*, hypertension, cardiac arrhythmias, myocardial infarction, anxiety by ephedrine, headache by Paprika, diarrhea by Chast tree fruit and liver toxicity by *Piper methysticum*<sup>29, 30</sup>.

#### **Herbal Drug Interactions**

Patients enchanting drugs with a narrow therapeutic index like cyclosporine, digoxin, phenytoin, procainamide, theophylline, warfarin etc. should be dispirited from using herbal products. All drugs with narrow therapeutic index may either have increased adverse effects or be less effective when used in combination with herbal drugs. Ginko is used for Alzheimer's disease and causes increased bleeding with aspirin. Ginseng has multiple uses and causing synergism with monoamine oxidase inhibitors. Kava is used as anxiolytic and shows synergism with benzodiazepines. St. Use of heavy metals is permitted in traditional medicines but in specific concentrations, which were mentioned by ancient physicians. There are now many examples of the toxicity caused by the use of heavy metals in the preparations of traditional drugs. Lead, copper, mercury, arsenic, silver and gold that are commonly added to these preparations, have caused toxicity on many occasions. Patients should not use herbal drugs arbitrarily with modern medicines, as there are potential of drug interactions and increased risk of adverse drug reactions<sup>31-34</sup>.

#### **Standardization of Herbal Drugs**

Herbal drugs imply knowledge and practice of herbal healing for the prevention, diagnosis, and elimination of physical, mental, or social imbalance<sup>35</sup>. The costs for health care are rising at an alarming rate throughout the world. At the same time, the world market for phytopharmaceuticals is growing progressively. The World Bank estimates that trade in medicinal plants, botanical drug products, and raw materials are growing at an annual rate of between 5 and 15 %<sup>36, 37</sup>. It is a common observation that people diagnosed with incurable chronic disease states such as diabetes, arthritis, and AIDS turned to herbal therapies for a sense of control and mental comfort from taking action<sup>38</sup>. Herbal product studies cannot be considered scientifically valid if the product tested has not been authenticated and characterized in order to ensure reproducibility in the manufacturing of the product in question. Several studies have indicated quantitative variations in marker

constituents in herbal preparations. Moreover, many dangerous and lethal side effects have recently been reported, including direct toxic effects, allergic reactions, effects from contaminants, and interactions with drugs and other herbs. The 10 most commonly used herbs in the United States, systematic reviews have concluded that only 4 are likely to be effective and there is very limited evidence to evaluate the efficacy of the approximately 20000 other available herbal products<sup>39</sup>. Standardized herbal products of consistent quality and containing well-defined constituents are required for reliable clinical trials and to provide consistent beneficial therapeutic effects. Pharmacological properties of an herbal formulation depend on phytochemical constituents present therein. Development of authentic analytical methods which can reliably profile the phytochemical composition, including quantitative analyses of marker/bioactive compounds and other major constituents, is a major challenge to scientists. Without consistent quality of a phytochemical mixture, a consistent pharmacological effect is not expected. Resurgence of interest and the growing market of herbal medicinal products necessitate strong commitment by the stakeholders to safeguard the consumer and the industry. Standardization is the first step for the establishment of a consistent biological activity, a consistent chemical profile, or simply a quality assurance program for production and manufacturing. Therefore, the EU has defined three categories of herbal products:

- Those containing constituents (single compounds or families of compounds) with known and experienced therapeutic activity that are deemed solely responsible for clinical efficacy.
- Those containing chemically defined constituents possessing relevant pharmacological properties which are likely to contribute to the clinical efficacy.

- Those in which no constituents have been identified as being responsible for the therapeutic activity.

Standardization as defined in the text for guidance on the quality of herbal medicinal products means adjusting the herbal drug preparation to a defined content of a constituent or group of substances with known therapeutic activity. The European Medicines Agency (EMA) makes the distinction between constituents with known therapeutic activity which can be used to standardize a biological effect and marker compounds which allow standardization on a set amount of the chosen compound. The EMA defines marker compounds as chemically defined constituents of a herbal drug which are of interest for control purposes, independent of whether they have any therapeutic activity or not. Examples of markers are the valerianic acids in *Valeriana officinalis* L., ginkgolides and flavonoids in *Ginkgo biloba* L. and hypericin and hyperforin in *Hypericum perforatum* L.<sup>40, 41</sup>

### **Stability testing of Herbal Drugs**

Stability testing of herbal drugs is a challenging risk, because the entire herb or herbal product is regarded as the active matter, regardless of whether constituents with defined therapeutic activity are known<sup>42</sup>. The purpose of a stability testing is to provide proof on how the quality of the herbal products varies with the time under the influence of environmental factors such as temperature, light, oxygen, moisture, other ingredient or excipients in the dosage form, particle size of drug, microbial contamination, trace metal contamination, leaching from the container and to establish a recommended storage condition and shelf-life. Stability testing is necessary to ensure that the product is of satisfactory quality throughout its entire storage period. Stability studies should be performed on at least three production batches of the herbal products for the proposed shelf-life, which is normally denoted as long term stability and is performed under natural atmospheric conditions. Stability data can also be generated under

accelerated atmospheric conditions of temperature, humidity and light, which is referred to as short term stability and the data so obtained is used for predicting shelf-life of the product. Stability testing should be conducted on the dosage form packaged in the container closure system proposed for marketing. With the help of modern analytical techniques like spectrophotometry, HPLC, HPTLC and by employing proper guidelines it is possible to generate a sound stability data of herbal products and predict their shelf-life, which will help in improving global acceptability of herbal products<sup>43</sup>.

### **Pharmacovigilance of Herbal Drugs**

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects of drugs or any other possible drug-related problems. Recently, its concerns have been widened to include: herbals, traditional and complementary medicines, blood products, biological, medical devices and vaccines<sup>44</sup>. The aims of pharmacovigilance is to protect patients from unnecessary harm by identifying previously unrecognized drug hazards, elucidating pre-disposing factors and quantifying risk in relation to benefits<sup>45</sup>. The purpose of pharmacovigilance is to detect, assess and understand to prevent the adverse effects or any other possible drug-related problems, related to herbal, traditionally and complementary medicines<sup>46</sup>. Herbal drugs are broadly used in both developed and developing countries however, in current years, there are several high-profile herbal safety concerns having an impact on the public health. Herbal drugs are traditionally considered as harmless but as medicinal products they require drug observation in order to identify their risks. Published data shows that the risk is due either to a contaminant or to an added drug. Tremendously limited knowledge about the constituents of herbal drugs and their effects in humans, the lack of rigorous quality control and the heterogeneous nature of herbal drugs necessitates the continuous monitoring of the safety of these products. WHO has increased its efforts to promote herbal safety

monitoring within the background of the WHO International Drug Monitoring Programme. The WHO guidelines aim to propose the member states of a frame work for facilitating the regulation of herbal medicines used in traditional medicine covering issues like classification, assessment of safety, assessment of the efficacy, quality assurance, pharmacovigilance and control of advertisements of herbal drugs products. The pharmacovigilance of herbal medicines exhibits particular challenges because such preparations are available from a wide range of outlets typically where there is no health care professional available, most purchases are in conventional OTC environment. Various methods in pharmacovigilance are passive observation includes impulsive reporting and stimulated reporting, active surveillance by sentinel sites, drug event monitoring, registries, comparative observational studies by survey study, case control study, targeted clinical investigations by investigate drug-drug interactions and food-drug interactions<sup>47</sup>. The importance of genetic factors in determining an individual vulnerability to adverse drug reactions is well documented and this implies to herbal medicines as well as to conventional drugs. Pharmacovigilance is therefore one of the important post-marketing safety tools in ensuring the safety of pharmaceutical and related health products<sup>48</sup>.

### **Regulatory Status of Herbal Drugs**

The lawful situation of herbal drugs varies from country to country. Developing countries have folk knowledge of herbs and their use in traditional medicine is wide spread. But, these countries do not have any lawmaking criteria to include these traditionally used herbal drugs in drug legislation<sup>49</sup>. Endorsement of herbal drugs in most countries is based on traditional herbal references, provided they are not known to be unsafe when used to treat slight illnesses. But, now-a-days claims are being made to treat more serious illnesses with herbal drugs for which no traditional knowledge is present<sup>50</sup>. Therefore, narrow requirements for herbal drugs are necessary to ensure the safety,

efficacy and quality and to support specific indications; scientific and clinical evidence must be acquired. Depending upon the nature of herbs and market availability, different requirements exist for submission of clinical trial data and toxicity data. The regulatory requirements of herbal drugs is varies from one country to other country. Some countries accept traditional, experience based evidence while some consider herbal remedies as dangerous or of questionable value<sup>51</sup>.

## CONCLUSION

Medicinal herbs as potential source of therapeutics aids has attained a significant role in health care system all over the world for human beings not only in the diseased condition but also as potential material for maintaining proper health<sup>52</sup>. It is clear that the herbal industry can make great strides in the world. With the increased use of herbal products, the future worldwide labeling practice should adequately address quality aspects. Standardization of methods and quality control data on safety and efficacy are required for understanding of the use of herbal drugs. A major factor impeding the development of the medicinal plant based industries in developing countries has been the lack of information on the social and economic benefits that could be derived from the industrial utilization of medicinal plants. Further research is required to exploit the compounds responsible for the observed biological activity<sup>53</sup>.

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