



## A Review On Herbal medicines: Efficacy, safety, and regulations

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### ABSTRACT:

A medicine derived exclusively from a whole plant or parts of plants and manufactured in a crude form or as a purified pharmaceutical formulation. Herbal drug technology is a tool for converting botanical materials into therapeutically useful products and medicines. Herbal medicine is the use of plants to treatment of disease and enhance general health and well-being. Herbal medicines are popular they are extensively used in the developing world, where in many places they offer a more widely available and more affordable alternative to pharmaceutical drugs. Most research has focused on clinical and experimental medicine (safety, efficacy, and mechanism of action) and regulatory issues to the general neglect of public health dimensions. This article presents a systematic review of herbal medicine including historical background, safety, efficacy, quality control, clinical trials, and bioavailability.

### Introduction:

#### *Herbal medicine:*

Medicinal uses of plant seeds, barriers, roots, leaves, bark, or flowers are referred to as herbal medicine, botanical medicine, or phytomedicine. The use of herbs outside of medicine has a long history [1].

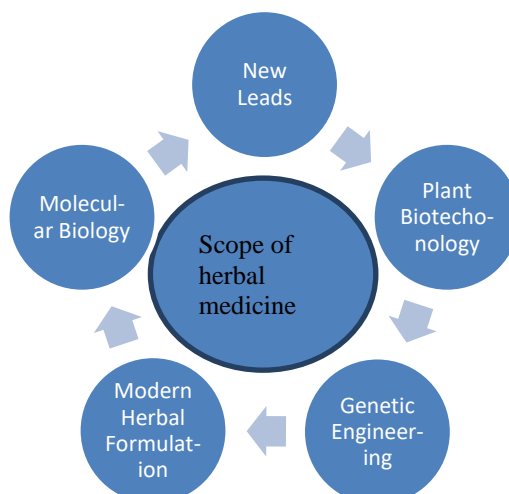
An example of herbal medicine is using a tincture made from ginger to relieve an upset stomach also called Herbalism, phytomedicine, or phytotherapy [2]. Herbal medicines, herbal preparations, and finished herbal products, that contain as active ingredients part of plants, or other plant materials, or a combination [3]. Using plants to cure illness and improve overall health and wellness is known as herbal medicine. Herbs should be used carefully because they may interact with other prescription drugs [4].

#### *Classification of herbal medicine:*

According to the usage, the herbs are classified into four parts:

1. Medicinal herbs
2. Culinary herbs
3. Aromatic herbs
4. Ornamental herbs [5].

#### *Prospects of herbal medicine/ industry [6]:*



**Benefits of Herbs:**

1. Strengthen the immune system.
2. Help reduce blood sugar levels and cholesterol.
3. Provide relief from toothache and bad breath.
4. Beneficial in treating arthritis and ulcerative colitis.
5. Reduce risk of cancer and Alzheimer's disease.
6. Help in maintaining healthy skin and hair [6].

**Advantages of herbal drugs:**

1. Strengthen immune response.
2. Better cultural acceptability.
3. Better compatibility with the human body.
4. Lower cost and no less side effect.
5. Natural and wide risk.
6. Prevents cancer risk.
7. Treats major diseases like Alzheimer's [7].

**Disadvantages of herbal drugs:**

1. Poison risk with wild herbs.
2. No proper regulations.
3. Lack of dosage instructions.
4. Herbs interact with modern medicines.
5. Inappropriate in many health conditions [8].

**Side effects of herbal medicine:**

1. Stomach upsets
2. Sleeplessness
3. Pains in your muscles or joints
4. Liver toxicity
5. Increased risk of bleeding
6. Allergic reaction [9].

**Drug development process of herbal medicine [10]:**

1. Identification and prioritizing the R and D needs
2. Literature survey
3. Hypothetical rational formulation
4. Drug development initiation (Quality control, Quality assurance)
5. Biological activity, stability studies, pre-clinical studies (with standard protocols)
6. Integrated protocols for clinical trials development (GCP and traditional methods)
7. Clinical trials of new drugs (with standard procedure and approval or regulatory authorities) [19].

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**Clinical trials of herbal medicine:**

After animal studies of drugs, herbal medicine is studied and tested on human beings as stated by good clinical guidelines.

**Stages of clinical trials:**

- I. Phase studies: Phase 1 trial for herbal medicine is not necessary because these drugs convey reasonable confidence that they can be safely administered.
- II. Phase studies: In this phase evaluation of range of dosage in individuals with disease (100-300) is studied.
- III. Phase studies: In this phase, the trial is done after establishing dose-ranging phase 2 data and involves expended trials of safety and efficacy [11, 12].

*List of herbal medicines:*

1. Turmeric



2. Garlic



3. Echinacea



4. Ginger



5. Ginkgo



6. Neem



7. Shatavari



8. Aloe vera



## 9. Tulsi



## 10. Moringa




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### Safety of herbal medicine:

Natural substances derived from plant components are used to make herbal remedies or supplements. The leaves, barks, roots, seeds, or flowers of the plant are used by manufacturers to extract active substances. There are numerous ways to consume herbal supplements, including tablets, teas, powders, and extracts. They are used to treat a variety of chronic illnesses, such as decreased libido, insomnia, and anxiety. The FDA has not approved herbal supplements, and certain natural items might be harmful. If a person is also on prescription medication they should speak with a doctor before using herbal supplements as they may result in negative drug reactions [14]. Herbal remedies were the primary means of treating human ailments approximately a century ago. Aspirin, ephedrine, and paclitaxel are just a few examples of plants that were previously utilized to make an estimated 25% of current medication [15]. Nevertheless, the safety and effectiveness of the majority of herbal products are not well supported by scientific research [16].

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### Efficacy of herbal medicine:

**Efficacy:** The probability of benefit to individuals in a defined population from a medical technology applied for a given medical problem under ideal conditions of use [17].

Herbal medicine has gained popularity as a kind of healthcare; however, even though herbal and conventional pharmaceutical treatments differ in several ways, herbal medicine still needs to be evaluated for efficacy using the conventional trial methodology, even though some particular herbal extracts are effective [18].

### *Efficacy and Effectiveness of a Traditional Herbal Remedy:*

To assess the safety, efficacy, and effectiveness of traditional herbal therapy, the following fundamental questions must be addressed:

1. Which course of action ought to be investigated?
2. Is it possible to research it using the methods of contemporary science?
3. Is it appropriate from a scientific standpoint to directly transfer a treatment to another nation?
4. Is a safe and effective conventional treatment already in place?
5. It is morally right to research such kind of treatment?

The result of any traditional treatment, whether in experimental or clinical settings, depends on several factors, knowledge, and practical skill of the provider, as well as the patient's positive or negative preconceptions about the therapy provider, cultural variations in the treatment's acceptability and adherence, and the patient-doctor relationship [19].

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### Regulation of herbal medicine:

In India, herbal pharmaceuticals are governed under the Drug and Cosmetic Act (D and C) 1940 and Rule 1945, which have explicit regulations for Ayurvedic, Unani, and Siddha treatment. The department of AYUSH is in charge of regulation and requires that any production or sale of herbal medications only occurs once a manufacturing license has been obtained, if necessary. Control over licensing, formulation composition, manufacture, labeling, packing, quality, and export are expanded under the D and C Acts. The act's Schedule "T" outlines the good manufacturing practice (GMP) guidelines that must be adhered to when producing herbal medications. The allowed texts stated in the first schedule of the D and C Act must be adhered to to provide a license for any herbal product falling under either of the two categories:

1. ASU medications
2. Exclusive or patented medications [19].

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### Conclusion:

A search of the literature shows that over the last 15 years, great growth and worldwide interest in herbal medicines has taken place, both in developed and developing countries. The growth of the botanical market has attracted much interest on the part of pharmaceutical companies, which has in turn stimulated the appearance of pre-clinical pharmacological studies and well-controlled and randomized clinical trials to prove their safety and efficacy. The most important scientific journals have dedicated significant efforts to publishing both basic and clinical scientific studies on herbal medicine, and thus certainly will create the scientific basis for the physician's prescription of herbal drugs. Despite this, so far insufficient data exist to provide an accurate assessment of the quality, efficacy, and safety of most herbal medicines. There is a belief that herbs, as natural products, are inherently safe without side effects and that efficacy can be obtained over a wide range of doses. Plants, herbs, and ethnobotanicals have been used since the early days of humankind and are still used throughout the world for health promotion and treatment of disease. Plants and natural sources form the basis of today's modern medicine and contribute largely to the commercial drug preparation manufactured today. About 25% of drugs prescribed worldwide are derived from plants.

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