## CHAPTER 1

### INTRODUCTION

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INTRODUCTION

Herbalism is the ancient form of healthcare known to humans\(^1\). It was a fundamental part for the improvement of the modern society.

1.1. Herbal drugs

*There are no incurable diseases - only the lack of will*

*There are no worthless herbs - only the lack of knowledge*

Herbal drugs are used in therapeutics to prevent and treat diseases and ailments\(^2\) or to support health and healing\(^3\). There are many herbal products existing that emphasize to treat the symptoms of a broad range of diseases, from depression to cold and flu. World Health Organization (WHO) has scheduled out a range of herbal drugs as medicinal products which possess vital ingredients, aerial or secretive parts of the plant or other plant material or combinations. The World Health Organization has set down specific guiding standards for the evaluation of safety, efficiency, and worth of herbal medicines.

WHO estimates that 80% of the world populations presently use herbal drugs for major human health care. Remarkably, in some countries herbal drugs may also include by habitual, natural organic or inorganic active constituents which are not of plant resource. Herbal drug is a principal component in habitual medicine and a general constituent in Ayurvedic, Homeopathic, Naturopathic and other medication systems. Herbs are generally considered as safe because they belong to innate sources\(^4\). The utilization of herbal drugs due to toxicity and side effects of allopathic medicines, has led to a fast enhancement in the number of herbal drug manufacturers.
For the precedent few decades, herbal drugs have been more and more inspired by the people with no instruction.

1.1.1. Advantages of Herbal Drugs

- Efficient price
- Elevated Potency and competence
- Improved tolerance
- More safety
- Less side-effects
- Absolute accessibility
- Ecological

1.1.2. Disadvantages of Herbal Drugs

- Not proficient to heal rapid illness and accidents
- Impossible for self-dosing
- Difficulty in standardizations

1.1.3 Recent trends in use of herbal and other natural products.

Herbalism is becoming ever more admired in today’s world as people inquire about innate remedies. Herbalism has been used since the dawn of civilization to maintain health and to treat a range of diseases. To contend with the developing pharmaceutical market, there is a significance to make use of and precisely substantiate more medicinally valuable herbal products. This research provides a widespread scheme of herbal medicines and anticipated to elucidate the therapeutic efficacy of different herbal medicines, undesirable drug reactions, drug interactions, standardization and stability testing of herbal medicines, Pharmacovigilance and dogmatic status of herbal medicines.  

1.1.4 Usage and Preparation of Herbal Drugs
The use of herbal drugs in an acceptable way provides valuable and safe healing for many ailments. The competence of the herbal drugs is generally subjective to the patient. The potency of the herbal drugs varies based on the hereditary characteristic, growing environment, timing and method of harvesting. A few of the plants that make up herbal drugs are cultivated and processed in the country and others are imported from around the world. Raw materials for herbal drugs may be resulting from circumspectly cultivated plants which are collected in their natural habitat.

Herbal drugs are obtainable in several forms and often entail preparation before their use. They can be normally purchased in mass form as dried plants, plant parts or diffidently packed for herbal teas and decoctions. Decoctions are prepared by boiling the herb in water, then straining out of the plant material. More concentrated forms of herbal drugs are existing in the form of hydro alcoholic tinctures and fluid extracts. Methods of preparation were clearly shown in [Figure.1.1] may vary because of the nature of the plants, based on their chemical constituents.

![Diagram](image)

**Fig. 1.1: Assessment of Herbal Drugs**

### 1.2. Standardization of Herbal Drugs

Herbal drugs mean understanding and practice of herbal curing for the prevention, identification and removal of corporal, psychological, or societal inequity. The cost for health
care is greater than ever at a distressing rate all over the world. At the similar instance, the globe market place for phytopharmaceuticals is increasing gradually. The World Bank estimates that deal in medicinal plants, botanical drug products and raw materials are rising at a yearly rate of between 5 and 15%.

It is a general remark that people diagnosed with fatal chronic disease states such as diabetes, arthritis and AIDS turned to herbal therapies for a sense of power and psychological ease. Herbal product studies can be considered as an invalid one, if the product tested has not been genuine and characterized in order to make certain reproducibility in the development of the product.

A number of studies have indicated quantitative variations in indicator constituents in herbal preparations. Moreover, many hazardous and toxic side effects have newly been reported, including direct lethal effects, allergic reactions, effects from contaminants, and interactions with drugs and additional herbs. The 10 most regularly used herbs in the United States, methodical reviews have accomplished that only 4 are liable to be effective and there are very partial facts to estimate the efficiency of the roughly 20000 other existing herbal products.

Identical herbal products of steady quality and containing definite constituents are essential for consistent clinical trials and to supply consistent beneficial therapeutic effects. Pharmacological properties of an herbal formulation depend on phytochemical constituents, present in that.

Development of genuine diagnostic methods which can constantly profile the phytochemical composition, including quantitative analyses of marker/bioactive compounds and supplementary major constituents, is a major dispute to scientists. Without reliable quality of a phytochemical mixture, a regular pharmacological effect is not expected.
Standardization is the primary pace for the establishment of a steady biological activity, an ordinary chemical profile, or simply a quality reassurance program for fabrication and manufacturing. Therefore, the European Union (EU) has defined three categories of herbal products.

- Those constituents (single compounds or families of compounds which possess recognized and competent healing activity that is deemed exclusively responsible for medicinal value.
- Those containing chemically distinct constituents possessing significant pharmacological properties which are liable to contribute to the medicinal value.
- Those in which no constituents have been recognized as being liable for the beneficial activity were shown in [Figure 1.2].

**Pharmacognosy**

1. Ethno pharmacological
2. Green pharma
3. Plants
4. Extracts
5. Biological tests
6. Bio-guided
7. Bio-active molecule(s)

**Reverse Pharmacognosy**

1. Natural compounds
2. Drug likeness criteria and selection
3. Diversity selection
4. Molecule Database
5. Or
6. Virtual screening with. Selnergy™ and/or
7. Knowledge-base
8. Plant(s)

**Fig. 1. 2: Standardization of Herbal Drugs**
1.3. Stability testing of Herbal Drugs

Stability testing of herbal drugs is a tough risk, as the whole herb or herbal product is regarded as the active substance, despite of whether constituents with distinct curative activity are known\textsuperscript{13}. The intention of a stability testing is to present evidence on how the value of the herbal products varies with the time under the influence of ecological factors such as temperature, light, oxygen, moisture, other ingredient or excipients in the dosage form, particle size of drug, microbial infectivity, trace metal effluence, leaching from the container and to create a recommended storage condition and shelf-life.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{stability_testing_diagram.png}
\caption{Stability testing diagram}
\end{figure}
Stability testing is essential to make certain that the product is of adequate quality during its total storage period. Stability studies should be performed on at least three production batches of the herbal products for the potential shelf-life, which is usually denoted as long term stability and is performed less than natural atmospheric conditions. Stability data can also be generated under accelerated atmospheric conditions of heat, moisture and light, which is referred to as short term stability and the records so obtained is used for envisage shelf-life of the product was shown in [Figure 1.3].

Stability testing must be conducted on the dosage form packaged in the container closure system planned for selling. With the aid of novel analytical techniques like Spectrophotometry, HPLC, and HPTLC by employing appropriate guiding principles, it is feasible to produce a sound stability statistics of herbal products and calculate their shelf-life, which will assist in providing information about significances of herbal products.

1.4 Pharmacovigilance of Herbal Drugs

Pharmacovigilance is the knowledge and activities linking to the recognition, estimation, understanding and prevention of adverse effects of drugs or any other potential drug-related harm. Newly, its concerns have been widened to comprise herbals, conventional and complementary medicines, blood products, biological, medical devices and vaccines. The aims of pharmacovigilance is to keep patients away from unnecessary harm by identifying formerly unrecognized drug hazards, elucidating pre-disposing factors and quantifying threat in relation to benefits.\textsuperscript{14}

The principle of pharmacovigilance is to distinguish, review and realize to avoid the adverse effects or any other likely drug-related problems, allied to herbal, conventionally and complementary medicines. Herbal drugs are mostly used in both urban and growing countries.
yet, in recent years, there are numerous high-profile herbal safety concerns having a contact on the public wellbeing. Herbal drugs are conventionally considered as undisruptive but as medicinal products they necessitate drug observation in order to categorize their risks.

Immensely inadequate knowledge about the constituents of herbal drugs and their effects in humans, the lack of precise quality control and the diverse nature of herbal drugs necessitates the constant monitoring of the safety of these products. WHO has improved its efforts to maintain herbal protection monitoring within the environment of the WHO International Drug Monitoring Programme shown in [Figure 1.4].

The WHO guidelines seek to intend the member states of a framework for facilitating the guidelines of herbal medicines used in customary medicine covering issues like categorization, evaluation of safety, estimation of the efficacy, quality assurance, pharmacovigilance and control of advertisements of herbal drugs products. The pharmacovigilance of herbal medicines exhibits particular challenges as such preparations are existing from a broad range of outlets normally where there is no health care professional available, nearly all purchases are in conventional OTC environment.

A variety of methods in pharmacovigilance includes spontaneous and motivated reporting, drug result monitoring, registries, relative observational studies by survey study, case control study, targeted clinical investigations by scrutinizing drug-drug interactions and food-drug interactions. The significance of hereditary factors in shaping an individual susceptibility to adverse drug reactions is well documented and this implies to herbal medicines as well as to conventional drugs\(^{15}\). Pharmacovigilance is thus one of the main post-marketing safety procedures in ensuring the protection of pharmaceutical and associated health products.
Fig. 1.4: Pharmacovigilance of Herbal Drugs
The legalized position of herbal drugs varies from nation to nation. Developing countries have folk data of herbs and their use in habitual medicine is wide spread. But, these countries do not have any legislative criteria to incorporate these habitually used herbal drugs in drug legislation. Authorization of herbal drugs in nearly all countries is based on conventional herbal references, provided they are not recognized to be hazardous when used to treat slight illnesses. But, now-a-days claims are being organized to take care of more severe illnesses with herbal drugs for which no conventional knowledge is present. Therefore, constricted necessities for herbal drugs are required to ensure the safety, efficacy and quality and to sustain definite indications; scientific and medical evidence must be acquired. Depending upon the character of herbs and market accessibility, dissimilar requirements exist for submission of clinical trial data and toxicity data.

The dogmatic necessity of herbal drugs varies from one nation to other nation. Some countries understand time-honored, experience based evidence while some believe herbal remedies as hazardous or of debatable value. Significances of Medicinal Plants to Human Being

- Several modern medicines are formed ultimately from medicinal plants.
- Plants are directly used as medicines by a greater part of cultures around the world, for example Chinese medicine and Indian medicine.
- Several food crops have therapeutic effects, for example garlic has Vasodilative effect.
- Medicinal plants are assets of new drugs.
- Studying medicinal plants helps to realize plant toxicity and guard human and animals from natural poisons.
**VALUE CHAIN FARMER**
- Land, Labour, seed stock fertilizer, pesticides, equipment, plant care, finance

**COLLECTION, DRYING, PROCESSING**
- Labour, Premises, Equipment, Storage, Utilities.

**MARKET**
- Premises, Transport, Handling cost, Transport

**EXPORTERS MIDDLEMEN**
- Premises, Storage, Packaging, Identity testing

**UK IMPORTERS**
- Shipping, Unload, Inspection, Sample, Documents, Customs and Excise, Storage, Port handling charges, fumigation

**UK SUPPLIER**
- Premises, Staff, Equipment, receive and record, QC analysis, Storage, Re-package, Distribution, Dispatch, Compliance, Advertising, Promotional, Transport, ICT, Finance, Insurance, Wasteage

**HERBAL PRACTITIONER**
- Premises, Diagnosis, Formulation, Postage, Unpacking, Visual Check, storage, re-ordering, Documents, Professional membership, Insurance, Training, ICT, Wasteage

**CONSUMER (END USER)**
- Consumer pays for all costs added.

**Price in £/Kg**

**Value Chain Farmer**
- Mean = £18.3
- Range = £5-£50

**Exporters Middlemen**
- Mean = £2.54
- Range = £0.50-£6.85

**Consumer (End User)**
- Typically £40-60

**Fig. 1.5: Regulatory Status of Herbal Drugs**
1.6. A new pharmacognostical tool

 Usually, pharmacognosy generally addressed quality related issues using regular botanical and organoleptic parameters of simple drugs. Pharmacognosy became more interdisciplinary because of succeeding advances in Analytical Chemistry. These developments added importance on chemo profiling-assisted description with chromatographic and spectroscopic techniques. The new pharmacognosy includes all aspects of drug improvement and finding, where biotechnology-driven applications will play a vital role. There are presently no apparent information about specific adverse interactions between herbal therapy and drugs used for a range of therapeutic uses. These herbal medicines may be taken in combined preparations and patients may be insensible to their actual content. The use of herbal remedies and their improvement is constantly evolving. The most common reasons for using traditional medicine are that it is more affordable, more closely corresponds to the patient’s ideology, allays concerns about the adverse effects of chemical (synthetic) medicines, satisfies a desire for more personalized health care, and allows greater public access to health information. The major use of herbal medicines is for health promotion and therapy for chronic, as opposed to life-threatening, conditions. However, usage of traditional remedies increases when conventional medicine is ineffective in the treatment of disease, such as in advanced cancer and in the face of new infectious diseases. Furthermore, traditional medicines are widely perceived as natural and safe, that is, not toxic. 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 preparations manufactured today.