The advantages and disadvantages of herbal drugs biology essay

Science, Biology

In 2735 B. C., the Chinese emperor Shen Nong wrote an authoritative treatise on herbs that is still in use today. Shen Nong recommended the use of Ma Huang (known as ephedra in the western world), for example, against respiratory distress. Ephedrine, extracted from ephedra, is widely used as a decongestant. The records of King Hammurabi of Babylon (1800 B. C.) include instructions for using medicinal plants. Hammurabi prescribed the use of mint for digestive disorders. Modern research has confirmed that peppermint does indeed relieve nausea and vomiting by mildly anaesthetizing the lining of the stomach. The first U. S. Pharmacopeia was published in 1820. This volume included an authoritative listing of herbal drugs, with descriptions of their properties, uses, dosages, and tests of purity. It was periodically revised and became the legal standard for medical compounds in 1906. But as western medicine evolved from an art science in the nineteenth century, information that had at one time been widely available became the domain of comparatively few. Once scientific methods were developed to extract and synthesize the active ingredients in plants, pharmaceutical laboratories took over from providers of medicinal herbs as the producers of drugs.

Herbal drug

There are no incurable diseases - only the lack of willThere are no worthless herbs - only the lack of knowledgeHerbal drugs referred as plant materials or Herbalism, involves the use of whole plants or parts of plants, to treat injuries or illnesses1. Herbal drugs are used in therapeutics to prevent and treat diseases and ailments or to support health and healing2. 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 mankind3. 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 (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. The 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 health care. Exceptionally, in some countries herbal drugs may also enclose by traditional, 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. Herbs are usually considered as safe since they belong to natural sources4. The use of herbal drugs due to toxicity and side effects of allopathic medicines, has led to a 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.

Advantages of Herbal Drugs

Cost effectiveHigh Potency and efficiencyEnhanced toleranceMore protectionFewer side-effectsComplete accessibilityRecyclable

Disadvantages of Herbal Drugs

Not able to cure rapid sickness and accidentsRisk with self-dosingComplexity in standardizations

1. 1. 3 Recent trends in use of herbal and other natural products.

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 research 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 medicines5.

1. 1. 4 Usage and Preparation of Herbal Drugs

The use of herbal drugs in the correct way provides effective and safe treatment for many ailments. The efficiency of the herbal drugs is usually subjective to the patient. The strength of the herbal drugs varies based on the genetic distinction, growing conditions, timing and method of harvesting. 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 are collected in the wild6. Herbal drugs are available 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 were clearly shown in [Figure. 1. 1] may differ because of the nature of the plants active their chemical constituents7.

Fig. 1. 1: Assessment of Herbal Drugs

1. 2. Standardization of Herbal Drugs

Herbal drugs imply knowledge and practice of herbal healing for the prevention, diagnosis and removal of physical, mental, or social imbalance8. 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 % 9, 10. 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 action11. 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. 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. 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. 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 manufacturing12. Therefore, the European Union (EU) has defined three categories of herbal products. Those containing constituents (single compounds or families of compounds) with known and experienced therapeutic activity that is 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 were shown in [Figure 1. 2].

Vegetal realm

Vegetal realmPharmacognosy

Natural compounds

Vegetal realm Reverse Pharmacognosy

Ethno pharmacological& botanical selectionDrug likeness criteria and selectionSelectionMolecule DatabaseOrMolecule LibraryPlantsGreen pharmaCriteria selectionDiversity selectionBio-guidedIdentificationBiological testsBio-active molecule(s)ExtractsVirtual screening with. Selnergy TMand/orBiological testsKnowledge-baseIdentificationPlant(s)

Fig. 1. 2: Standardization of Herbal Drugs

1. 3. Stability testing of Herbal Drugs

Collection of Raw materialBotanical IdentificationStabilisation (Drying/Freezing)Grinding/PowderingExtraction ProcessQualitative Analysis (Chromatographic Techniques)Isolation of active compoundsPurificationFractionation and Toxicity EvaluationStability 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 known13. 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.

Fig. 1. 3: Stability testing of Herbal Drugs

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 predict shelf-life of the product was shown in [Figure 1. 3]. 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, and HPTLC 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.

1. 4 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. 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 benefits14. 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. 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 accurate 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 support herbal safety monitoring within the background of the WHO International Drug Monitoring Programme shown in [Figure 1. 4]. 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 inactive 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. 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 drugs15. Pharmacovigilance is therefore one of the important post-marketing safety tools in ensuring the safety of pharmaceutical and related health products. Manpower-Clinicians, pharmacologists, Clinical pharmacists, Toxicologists, EpidemiologistsFunds and Govt. SupportAccommodation, TechnologyPhone, FAX, Computer, Internet, Photocopier,. PharmacovigilanceCentreFree availability of Case Report Forms (CRFs) to healthcare workersMandatory reporting of adverse drug reactions by pharmaceuticalHealth care workers furnish reports of adverse drug reactions and events in CRFs or by e-mailsAdverse drug reactions reported by patientsData collection, Classification andStorageSignal generated relevant? YesPooled data subjected to data mining, analysis, hypothesizing, signalDISSEMINATION, INFORMATION, EDUCATION, COMMUNICATION

Fig. 1. 4: Pharmacovigilance of Herbal Drugs

1. 5. 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 legislation16. 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. 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 value17.

Significances of Medicinal Plants to Human Being

Many of the modern medicines are produced indirectly from medicinal plants. Plants are directly used as medicines by a majority of cultures around the world, for example Chinese medicine and Indian medicine. Many food crops have medicinal effects, for example garlic has Vasodilative effect. Medicinal plants are resources of new drugs. It is estimated there are more than 2, 50, 000 flower plant species. Studying medicinal plants helps to understand plant toxicity and protect human and animals from natural poisons.

COLLECTION, DRYING, PROCESSING

Land, Labour, seed stock fertilizer, pesticides equipment, plant care, finance

VALUE CHAIN FARMER

Labour, Premises, Equipment, Storage, Utilities.

Premises, Transport, Handling cost Transport

MARKET

EXPORTERS MIDDLEMEN

UK IMPORTERS

Premises, Storage Packaging, Identity testing

Shipping, Unload, Inspectinon, Sample, Documents, Customs and excise, Storage, Port handling charges fumigation

UK SUPPLIER

HERBAL PRACTITIONER

CONSUMER (END USER)

Premises, Staff, Equipment, receive and record, QC analysis, Storage, Re-package, Distrubution, Dispatch Complience, Advertising, Promotional, Transport, ICT, Finance, Insurance, Wastage

Premises, Diagnosis, Formulaiton Postage Unpacking, Visual Check, storage, re-ordering, Documents, Professional membership, Insurance, Training, ICT, Wastage.

Consumer pays for all costs added.

Price in £/Kg

Mean = £ 18. 3

Range = £5-£50

SD = £11. 4

Mean = £2. 54

Range = £0. 50-£6. 85

SD = £11. 4

Typically £40-60

Fig. 1. 5: Regulatory Status of Herbal Drugs

1. 6. DNA markers as new pharmacognostical tool

Traditionally, pharmacognosy mainly addressed quality related issues using routine botanical and organoleptic parameters of crude drugs. Pharmacognosy became more interdisciplinary because of subsequent advances in Analytical Chemistry. These developments added emphasis on chemo profiling-assisted characterization with chromatographic and spectroscopic techniques. The new pharmacognosy includes all aspects of drug development and discovery, where biotechnology-driven applications will play an important role. Extensive research on DNA-based molecular markers is in progress in many research institutes all over the world18. This technique remains important in plant genome examine with its applications in pharmacognostic identification and analysis. Chinese researchers have applied DNA markers extensively for characterization of botanicals from the Chinese Materia Medica. These markers have shown remarkable utility in

quality control of commercially important botanicals like Ginseng, Echinacea, Atractylodes. In India several agricultural Universities and Research Institutes are actively involved in exploring DNA-based techniques in genotyping of medicinal plants19. Although considerable progress has been made in DNA marker technology, applications of these techniques for characterizing semi-processed and processed botanical formulations to ensure the desirable quality remain inefficiently. Although DNA analysis is currently considered to be cutting-edge technology, it has certain limitations due to which its use has been limited to academia. Another important issue is that DNA fingerprint will remain the same irrespective of the plant part used, while the phytochemical content will vary with the plant part used, physiology and environment20. DNA fingerprinting ensures presence of the correct genotype but does not reveal the contents of the active principle or chemical constituents. Hence DNA analysis and pharmacognostic techniques for chemo profiling such as TLC – Thin Layer Chromatography, HPTLC – High Performance Thin Layer Chromatography, etc. will have to be used hand in hand rather than in isolation. Several attempts have been made in recent years, to correlate DNA markers with qualitative and quantitative variations in phytochemical composition among closely related species21. Proper integration of molecular techniques and analytical tools will lead to the development of a comprehensive system of botanical characterization that can be conveniently applied at the industry level for quality control of botanicals. Ayurvedic classification of medicinal plant is based on basic principles and therapeutic characters that may have a genetic basis. We have undertaken an exploratory study on the use of molecular markers for

quick identification of botanical materials in crude, semi-processed and processed herbal formulations. Our strategy involves identification of species-specific marker after screening a number of species and varieties of the medicinal plant using random oligonucleotide primers, followed by cloning and subsequently converting it to SCAR - Sequence Characterized Amplified Region markers for better specificity and reproducibility. Also, application of RAPD – Randomly Amplified Polymorphic DNA markers has been explored for standardization of botanical formulations containing ayurvedic medicines like Emblica officinalis and Tinospora cordifolia22.