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Approaches towards Development and Promotion of Herbal Drugs

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ABSTRACT
Herbal drugs have great growth potential in the global market. Natural product research continues to explore Indian Traditional Medicines to develop new novel drugs. In this paper we have focused on the strategies, significance, guidelines and the research methods to be followed in order to develop herbal medicines which will gain international acceptance. Chromatographic fingerprinting techniques are most significant methods which can be used for the routine herbal drug analysis and for quality assurance. The WHO guideline parameters are discussed and some *in vitro* models for antioxidant studies, cytotoxic studies , are given in flow chart form in order to provide simple and effective assessment of the biological screening of botanicals without animal models or extensive extraction and purification steps.
KEY WORDS- Herbal standardization, current status, *In vitro* MTT, SRB, Trypan blue, DPPH assays.

INTRODUCTION
Ayurveda is the most ancient health care system and is practiced widely in India, Srilanka and other countries (1). Atharveda (around 1200 BC), Charak Samhita and Sushrut Samhita (100 - 500 BC)(2) are the main classics that given detailed descriptions of over 700 herbs. Researches on pharmacognosy, chemistry, pharmacology and clinical therapeutics have been carried out on ayurvedic medicinal plants and many of the major pharmaceutical corporations have renewed their strategies in favour of natural products drug discovery. Numerous drugs have entered the international pharmacopoeia through the study of ethnopharmacology and traditional medicine (3). The R & D thrust in the pharmaceutical sector is focused on development of new innovative / indigenous plant- based drugs through investigation of leads from the traditional system of medicine(4).
The World Heath Organization has recognized the importance of traditional medicine and has created strategies, guidelines and standards for botanical medicines. Proven agro-industrial technologies need to be applied to the cultivation and processing of medicinal plants and the manufacture of herbal medicines(5). It is necessary to develop methods for rapid precise and accurate identification and estimation of active constituents in order to bring out consistency of important constituents in the formulations.

RECENT APPROACHES: RESEARCH AND DEVELOPMENT
There is a great demand for herbal medicines in the developed as well as developing countries because of their wide biological activities, higher safety margin than the synthetic drugs and lesser costs. Since herbal medicines are prepared from materials of plant origin they are prone to contamination, deterioration and variation in composition. This gives rise to inferior quality of herbal products with little or no therapeutic efficacy. Most often the desired biological response is due to not one but a mixture of bioactive constituents and the relative proportion of active constituents can vary from plant to plant of the same species and also in different plant parts. . For example- Gadre, A.Y. *et al*. had reported high variations in the marketed oil formulation of *Celastrus paniculates* by HPTLC technique(6). Hence before proceeding to clinical studies, scientists need a tool to authenticate plants and also to detect their potency.
Current estimates indicate that about 80% of people in developing countries still rely on traditional medicine - based largely on various species of plant and animals - for their primary healthcare. Thirty percent of the world- wide sales of drugs is based on natural products(7). Commercially these plant - derived medicines are worth about US $14 billion a year in the United States and US $40 billion worldwide. Advances in biotechnology, particularly methods for culturing plant cells and tissues, provides new means for chemicals that they produce(8-10). Opportunities for multidisciplinary research are immense the forces of natural products chemistry, molecular and cellular biology, synthetic and analytical chemistry, biochemistry, and pharmacology are combined to exploit the vast diversity of chemical structures and biological activities of natural products (11).
Another important area of drug development is to study the structural chemical databases with data bases on target genes and proteins and create new chemical entities through computational molecular modeling for pharmacological evaluation(12).
It is interesting to note that the value of animal testing to establish safety and toxicity is not so critical in botanicals if they are time tested and used widely in traditional forms and if they are recommended for oral administration by the Ayurvedic parishioners. On the contrary synthetic molecules drug developments requires about 12 – 15 years and for the drug to come into the market with an expense of US $ 900

million(13, 14). But the knowledge and experimental data base of Ayurvedic medicine can provide new functional leads to reduce time, money and toxicity - the three main hurdles in drug development. These medicines are effectively tested for thousand of years on people[15]. It is rightly said that 'laboratories to clinics' becomes 'clinics to laboratories' - a true reverse pharmacology approach[16]. The biological assay is now replaced by easy, reproduceable and highly reliable *in vitro* methods using reagents which give a sharp end point or colour change. This change is then measured spectrophotometrically and the qualitative and quantitative assays can be done by plotting a caliberation graph of concentration v/s absorption in the particular wavelength. For example the xanthine oxidase assay, Mclord assay, DPPH assay methods for the screening of free radical scavenging activities screening for anti-oxidant activity. Some *in vitro* cytotoxicity assay methods such as sulphorhodamine B, (SRB) and microculture tetrazolium (MTT) assays**.** The trypan blue viability test is another simple method for the cytotoxic assay.

India has about 45,000 plant species; medicinal properties have been assigned to several thousands. Currently, with over 400,0000 registered ayurvedic practitioners, the Government of India has formal structures to regulate quality, safety, efficacy and practice of herbal medicine (National policy on Indian systems of Medicine and Homeopathy - 2002.). The turnover of herbal medicines in India as over - the counter products, ethical and classical formulations and have remedies of Ayurveda, Unani and Siddha systems of medicine is about $1 billion with a meagre export of $ 80 million. Even though India is the gold mine of herbal medicine. 80% of its exports to the developed countries are of crude drugs and not finished formulations leading to low revenue for the country. *Allium salivum*, *Aloe barbadensis* and Panax species are three of the 10 most widely selling herbal medicines in developed countries which are imported fromportIndia is alsothe largest grower of Psyllium (*Plantago ovata*), Senna (*Cassia Senna*) and Castor (*Ricinus communis*) plant. Herbal preparation are being marketed as nutraceuticals or health foods and many pharma and biotech companies market pure compounds of natural origin like lovastatin [a lipid lowering agent from red rice yeast), docisahexaenoic acid (a cardiovascular stimulant from algae), stevols, curcumin (from plants), etc. which do not involve regulatory clearances. These are being marketed as health foods without following even the minimum standards laid down by WHO.

HERBAL DRUG STANDARDIZATION

Herbal medicine is still the mainstay of about 75-80% of the world population, mainly in the developing countries, for primary health care because of better cultural acceptability, better compatibility with the human body and lesser side effects. There has been a major increase in their use in the last few years in the developed countries like Germany, France, European unions and U.S.A(17). In Indian, the herbal drug market is about $ one billion and the export of plant-based crude drugs in around $ 80 million(18). But, unlike China, India has not been able to capitalize on this herbal wealth by promoting its use in the developed world despite their renewed interest in herbal medicines. Strategically, India should enter through those plant- based medicines which are already well accepted in Europe, USA and Japan based on diseases for which no medicine or only palliative therapy is available.

India is sitting on a gold mine of well-recorded and well-practiced knowledge of tradition herbal medicine. The basic requirements for gaining entry into developed countries include well - documented traditional use, Single- plant medicines, Medicinal plants free from pesticides, heavy metals, etc., Standardization based on chemical and activity profile and Safety and stability(17).

HERBAL MEDICINE SCENARIO IN INDIA

The turnover of herbal medicines in India as over - the counter products, ethical and classical formulations and have remedies of Ayurveda, Unani and Siddha systems of medicine is about $1 billion with a meagre export of $ 80 million. 80% of the exports to developed countries are of crude drugs and not finished formulations leading to low revenue for the country. The list of medicinal plants exported from India are *Aconitum* species (root*), Acorus calamus* (rhizome), *Adatoda vasica* (whole plant), *Berberis aristata* (root), *Cassia augustifolia* (leaf and pod), *Colchicum luteum* (rhizome and seed), *Hedychium spicatum* (rhizome), *Heradeum candicans* (rhizome), *Inula racemose* (rhizome), *Juglans regia* (husk), *Juniperus communis* (fruit), *Juniperus macropoda* (fruit), *Picrorhiza kurrooa* (root), *Plantago ovata* (seed and husk), *Podophyllum emodi* (rhizome), *Pinica granatum* (flower, root and bark), *Rauwolfia serpentina* (root), *Rheum emodi* (rhizome), *Saussurea lappa* (rhizome), *Swertia shirayita* (whole plant), *Valeriana jatamansi* (rhizome), *Zingiber officinale* (rhizome). Five of these, *i.e Glycerriza glabra, Commiphora mukul*, *Plantago ovata*, *Aloe barbadensis* and *Azardica indica* are used in modern medicine. Others are used in 52 to 141 herbal formulations and Triphala (*Terminalia chebula, Terminalia belerica* and *Embelica officinalis*) along is used in 219 formulation (18).

The commonly used analytical methods like chromatography have narrow scope in the analysis of heterogeneous botanical extracts. Most often a desired biological response is due to not one, but a mixture of bioactive plant components and the relative proportions of single bioactive compound can vary from batch to batch, while the bioactivity still remains within tolerable limits. New trends are emerging in the standardization of herbal raw materials whereby it is carried out to reflect the total content of phytoconstituents like polyphenols which can be correlated with biological activity like antioxidant activity which many times has a direct or indirect correlation to the pathophysiological disorders like diabetes, cancer, inflammatory and age related disorders (19).

Allium sativum, Aloe barbadensis and Panax species are three of the 10 most widely selling herbal medicines in developed countries which are imported from India. India is also the largest grower of Psyllium (*Plantago ovata*) , Senna (*Cassia Senna*) and Castor (*Ricinus communis*) plant. Accordingly many multinationals and academic institutions have created joint research programmes for plant medicine research, for

example, Virginia Polytechnic Insitute, Bedriif Genees Middelen Voorziening Suriname Conservation, International-Suriname and Bristol -Myers Squibb Pharmaceutical Research Institute. Indian Pharmacetuical companies like Dabur, Zandu, Arya Vaidya, Nicholas Piramal, Lupin and Ranbaxy have also launched new projects. The major traditional sector Pharmas, namely Himalaya, Zandu, Dabur, Haindard, Maharishi, etc and modern sector Pharmas, namely Ranbaxy, Lupin, Allembic, etc are standardizing their herbal formulations by chromatography techiniques like TLC/ HPLC finger printing , etc. There are about 7000 firms in the small-scale sector manufacturing traditional medicines with or without standardization and with no confirmation of herbal drugs in experimental animal models(20).

Some of the prominent commercial plant-derived medicinal compounds include : colchium, colchicine, bettulinic acid, camptothecin, topotecan (Hycamlin), CPT-II(irinotecan,Camptosar), 9-aminocaptothecin, delta-9-tetrahydrocanabinol (dronabinol, Marino), beta lapachone, lapachol, podophyllotoxin, etoposide, podophyllinic acid, omblastine (Vellam), viscristine, (leurocristine, Oncovin), vindesine(Velbam), Vincoristine(Leurocristine, Oncovin), vindesine (Eldisine, Filfesin), Vinorelbine (Navelbine), docetaxel (Taxotere), paclitaxel (Taxol), tubocurarine, pilocarpine, scopolamine(21-22).

WHO GUIDELINES FOR ASSESSMENT OF HERBAL MEDICINES

Every herbal formulation must be standardized as per WHO guidelines. WHO collaborates and assists health ministries in establishing mechanisms for the introduction of traditional plant medicines into primary healthcare programmes, in assessing safety and efficacy and in ensuring adequate supplies and the quality control of raw and processed materials. According to WHO guidelines less stringent selection procedures could be applied for the screening, chemical analyses, clinical trials and regulatory measures but the procedure for pure phytochemicals for quality control should be identical to that for synthetic drugs according to WHO guidelines(25).

The World Health Organization (WHO) has recently defined traditional medicine as comprising therapeutic practices that have been in existence, often for hundreds of years, before the development and spread of modern medicine and are still in use today. The traditional preparations comprise medicinal plants, minerals, organic matter, etc.

Some of the important parameters are stability testing, safety assessment, specific therapeutic activity analysis and estimation of the active constituents in plant raw material and finished products. The objective of WHO guidelines is to define basic criteria for the evaluation of quality, safety and efficacy of herbal medicines and therefore to assist national regulatory authorities, scientific organizations, and manufacturers to undertake an assessment of the documentation / submission / dossiers in respect of such products(23, 24).

The manufacturing procedure and formula including the amount of excipients should be described in detail. A method of identification, and where possible quantification of the plant material in the finished product should be defined. If the identification of an active principle is not possible, it should be sufficient to identify a characteristic substance or mixture of substances (e.g., “chromatographic fingerprint") to ensure consistent quality of the product (26). According to WHO, "Herbal Medicines" should be regarded as, "Finished, labeled medicinal products that contain as active ingredients aerial or underground parts of plants, or other plant material, or combinations thereof, whether in the crude state or as plant preparations. Plant material includes juices, gums, fatty oils, essential oils, and any other substance of this nature. Herbal medicines may contain excipients in addition to the active ingredients. Medicines containing plant material combined with chemically defined active substances, including chemically defined, isolated constituents of plants are not considered to be herbal medicines. Exceptionally, in some countries herbal medicines may also contain, by tradition, natural organic or inorganic active ingredients which are not of plant origin (27).

Multi-component botanical formulations can be standardized with newer techniques such as DNA fingerprinting, high pressure thin layer chromatography (HPTLC), liquid chromatography, mass spectroscopy. The value of animal testing to establish safety and toxicity is not so critical if the botanicals are used in traditional forms. Nevertheless, all the critical pharmacopoeial tests such as dissolution time, microbial, pesticide and heavy metals contamination etc. must be in accordance with global standards and all the Ayurvedic medicine manufacture must be in accordance with current good manufacturing procedures for herbs (28-30).

ANALYSIS OF RAW MATERIALS FROM PLANTS

Raw material can be defined as starting material or any intermediate which will be utilized for further processing. Before finished pharmaceutical dosage forms are produced, the identity, purity and quality of raw materials as per specifications for impurities and other related substances present must be established with use of suitable test methods. Pharmacopoeias and formularies of various countries provide standardized test methods for the most common and widely used materials in their monographs (31).

Stored drug samples are prone to attack by harmful mycotoxin producing fungi. Detection of mycotoxins (aflatoxin B, acliratoxin, citrinin and zearalenone) is certainly a matter of great concern in stored drugs of important medicinal plants, e.g. fruits of *Emblica officinalis* (1.51 μg/g); *Terminalia chebula* (1.19 μg/g)(32-35). S. Sapna *et al.*, have developed a HPTLC method for the detection of aflatoxins B_1, B_2, G_1 and G-2 from herbal raw materials and estimated the production of aflatoxins in caffeinated and decaffeinated tea samples. Studies revealed that caffeine acts as a good inhibitor for the growth of aflatoxins in stored drugs(36).

QUALITY CONTROL TECHNIQUES

A lot of analytical techniques have been developed for renewed for quality control of drugs from plant origin One quality control mode is done by selecting a known active constituent or a marker compound as the qualitative and quantitative target to assess ins authenticity and inherent quality. But many traditional medicines are claimed to exert their effects because each type of chemical compound

present many have a different activity and then seem of all of these may modify the action of the major "active" component(37).

Chromatographic fingerprinting emphasizes an integral formulation of pharmacologically active and phytopharmaceutically characteristic components of samples with similar or different attributions. This technique can be used for the assessment of quality consistency and stability of herbal extracts or products by visible observation and comparison of the standardized fingerprint pattern(38). Fingerprinting of the herbals are done by HPLC (High performance liquid chromatography), HPTLC (High performance Thin Layer Chromatography), MS, LC - MS, H^1NMR, etc. Apart from this there are some methods to evaluate the fingerprint quality of herbal materials or pharmaceutical products, such as correlative chromatography, comparative analysis, wavelet analysis and artificial neural networks (ANN). Either taking advantage of spectral correlation and chromatographic features or using chemometric methods and pattern recognition techniques such as K-nearest neighbors (KNN) and soft independent modeling of class analogy (SIMCA), these techniques distinguish which are of good quality and which not within chromatographic fingerprint sets.

Finger-printing of Ayurvedic Drugs-

Herbal medicines are prepared from materials of plant origin which are prone to contamination, deterioration and variation in composition. Therefore, quality control of herbal medicines offers a host of problems. A marker can be defined as a chemical entity, in the plant material which may or may not be chemically defined and serves as a characteristic fingerprint for that plant. In other ways through various analytical techniques like TLC, HPLC and HPTLC we can visualize the presence of this compound in the plant and also quantify it to ascertain the limits. A biomarker on the other hand are a group of chemical compounds which are in addition to being unique for that plant material also correlate with biological efficacy(39). Batch to batch variations start from the collection of raw material itself in the absence of any reference standards for proper identification, and multiply during storage and further processing. So the need arises to lay standards by which the right material is selected and incorporated into the formulation. So here arises the concept of multiple markers and biomarkers to define the right material.

Chemical marker for herbal standardization-

Fingerprinting in essence which means establishing a characteristic chemical pattern for the plant material or its cut or fraction or extract. It is important to understand that a plant extract consists of established classes of chemical compounds. These include the primary metabolites, secondary metabolites and inorganic salts and metals. Primary metabolites are compounds like carbohydrates, proteins, lipids which are essential for the plant physiology. Secondary metabolites are compounds which are not essential for the plant physiology as such but are formed as byproducts in the biochemical pathways. These include very interesting and useful classes of compounds like alkaloids, flavonoids, coumarins, terpenoids, anthocyanins, etc, and we can utilize these secondary metabolites for the identification of plant material as our knowledge of chemistry has advanced sufficiently and through sophisticated analytical techniques we can measure these compounds qualitatively and quantitatively.

Liquid chromatography like HPLC which is useful only when a marker compound is known and can be used as reference compound; and finally planar chromatography like TLC and more advanced version like HPTLC which accounts for all the variations found in TLC. The extracts obtained similarly from each batch are loaded onto a TLC plate and are developed in suitable solvent system. We may use different solvent systems to develop a better TLC pattern. This developed plated is then studied under different conditions in the scanner which utilizes a laser beam and detects and quantifies distinct spots due to different compounds on the plate. The different conditions which can be used for detecting spots on plate include UV at different wavelength, derivitisation of plate to obtain distinct colored spots which are then detected by the software program and a characteristic graph obtained. There is a very distinct graphic pattern for each plant material and the extracts from different batches usually give overlapping graphic patterns. So basically we can optimize this pattern to give a distinct HPTLC profile for each fractionated plant part(40).

CONCLUSION

A golden triangle consisting of Ayurveda, modern medicine and science will converge to form a real discovery engine that can result in newer, safer, cheaper and effective therapies (15). Globally there is a positive trend towards holistic health, integrative sciences, systems biology approaches in drug discovery and therapeutics which is the unique feature of Ayurveda. Ayurveda and modern medicine techniques must be coupled in order to bring out high quality herbal products with rapid onset of action and good bioavailability.

Herbal drug development is possible only through the development of standardized herbal products with reference to their active phytoconstituents present for commercialization, correct identification and supply of raw material and to avoid adulteration. Since some botanicals have undergone changes in their physical characteristics, the concept of active markers needs a flexible approach in favour of the complex nature of these material (41).The ultimate goal of ethnopharmacology must be to identity drugs to eliminate human illness by a thorough analysis of plants through out the world.

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Novel approach of delivering herbal drugs will increase the efficacy and safety of herbal medicines along with the increased stability of the drug product. These techniques provide improved patient compliance, sustained release and targeted action of plant actives and extracts.Â In recent years, scientists are extensively. involved in the research and development of. novel approach of delivering herbal drugs [1]. Natural products isolated from the plants are. known as â€˜herbal drugsâ€™ and are the core of. traditional medicinal systems that are being.Â approaches of delivering herbal products, several. researchers are working towards the. development of novel drug delivery systems like. mouth dissolving tablets, sustained and extended. release formulations, muco-adhesive systems Approaches Towards Development and Promotion of Herbal Drugs. Pharmacognosy Review, 1 (1): 180-184. 17. Borris, J., 1996.Â Asian Herbal Products: The Basis for Development of High Quality Dietary Supplements and New Medicines. 23. Ariga, T. and T. Seki, 2005. Funtional Foods from Garlic and Onion, pp: 433-489.