1. INTRODUCTION:

Since time immemorial, man’s quest for medicinal agents, that alleviate his sufferings has remained unquenched. The instinctive behaviour of primitive man helped him to realise the beneficial action of plants in the treatment of various ailments. From about 11th to 18th centuries, a dogma known as the “doctrine of signatures” was almost the sole means by which man attributed medicinal value to certain plants. This dogma held that the colour, shape, habitat or other physical characteristics of a plant were indicative of its medicinal value. Thus, the worm shaped embryo of chenopodium (worm seed) suggested it to be of value as an anthelmintic, the yellow colour of Saffron served to point out its value in liver disorders, the serpentine roots (snake root) indicated that they should be useful in treating snake bite, due to soap forming property of quillaia bark it was used as detergent and so on. However, as man experimented, he found by trial and error, certain plants useful for the treatment of some of his myriad illnesses. Later through conscious rational action he gained better understanding about the medicinal properties of the plants.1

Our ancient literature like Rigveda (4500-1500 B.C.), Yajurveda, Atharvaveda (1200 B.C.), Charak Samhita (900 B.C.) and Sushruta Samhita (600 B.C.) also described the medicinal values of number of medicinal plants2. Besides Ayurveda, the records of therapeutic values of the plants was found to be systematically incorporated in other systems of medicines like Siddha, Chinese medicine, Greco, Arab or Unani, Egyptian and Tibb. These Indigenous systems of medicine till date derive more than 80% therapeutic agents from plants. Till the advent of synthetic chemistry, the allopathic system of medicine was also dependent on plant based products. Even today phytopharmaceuticals like morphine, digitalis glycosides, vincristine, vinblastine are still used as drugs of choice by allopathic physicians. For synthesis of steroidal drugs, particularly steroidal sex hormones like progesterone, testosterone, dihydroandrosterone, cortisone etc. scientists are totally found to be dependent on plants containing diosgenin. About two-third of the drugs of the modern system of medicine have been developed from natural resources, mainly from plants. Thus the medicinal plants belong to the oldest known health care products that have been used by mankind all over the world in the form of folklore medicine, traditional medicines or ethnic medicines3,7.

Therapeutic uses of medicinal plants have gained considerable momentum in the world during the past decade. The Western or modern system of medicine which was all along proud of its armory of mostly synthetic drugs, the chemo-therapeutic agents and later the antibiotics, slowly realised their power of devastation of several human systems by their side effects and toxicity and an inestimable damage to the intestinal flora. The Western world slowly started realising the value of the herbal medicines especially because of their minimum side effects4,5. Resurgence of interest in herbal drugs in the Western and European countries is evident from the fact that two volumes of British Herbal Pharmacopoeia have been published and $ 33 million worth literature on herbal product was sold in the USA in 1990. Moreover it has started preparing monographs on herbals. The ‘green wave’ in the utilisation of medicinal plants has resulted in higher consumption of the herbs. Research workers and industrialists engaged in the field of medicinal plants have increased many folds6.
Today we understand that plants represent an immense repository of biochemicals including pharmaceuticals, flavours and novel bioactive substances, which often serve as chemical models of templates for the design and synthesis of new drug entities. Medicinal plants play an important role in the health care of developing countries. Correctly, nearly 80% of the world population use herbal medicine and World Health Organisation (WHO) also encourages, recommends and promotes the inclusion of herbal drugs in national health care programmes because such drugs are easily available at a price within the reach of common man and as such are time tested and thus considered to be safer than modern synthetic drugs.

1.1. SCENARIO OF HERBAL DRUGS IN VARIOUS COUNTRIES:

1.1.1. CHINA AND JAPAN:

China has done a far better job than India in maintaining and making the traditional system of medicine, more relevant to its health care need. More than 40% share of the medicine market in China belongs to traditional medicine and in rural areas 90% of the people rely and treat themselves through traditional health care.

Forty five percent of all patents on herbs or herbal based or related medicines are with China, closely followed by Japan with 28% share.

1.1.2. U.S.A.:

Recently herbs have been gaining renewed interest in America. More and more health care consumers are turning to herbs for disease prevention and for relief of ailments, especially those not helped by conventional medicine. Indeed, it is noticed that one out of three Americans uses alternative health care; Federal laws do not permit the sale of herbs as drugs, that is with claims of efficacy appearing on their labels. For efficacy proof, one has to spend about $100 million per drug and since no one is willing to spend this much amount of money, herbs are sold with their names and available literature explaining the medicinal uses of them, primarily from ‘health food’ stores.

The current market for the health care natural products in USA is approximately around $15 billion.

1.1.3. GERMANY, FRANCE AND OTHER EUROPEAN COUNTRIES:

In Germany and France, many herbs and herbal extracts are sold as prescription drugs and are covered by national health insurance. Herbal remedies always rank among the top 10 in drugs sales in Germany. 80% of all German physicians regularly prescribe herbal medications. Herbal drugs sale in European Union in 1991 was $6 billion. Most of the research done in Germany on herbas is conducted by German herbal medicine producers or sponsored by them in German University laboratories. Of the 10 top selling herbs in health-food stores in U.S. in 1995, six have been popularised largely on the basis of European research.

1.1.4. INDIA:

Nature has endowed India with a unique gift of as many as 15,000 plant varieties. India accounts for two-thirds of the flowering plants of the world of which about 2500 are reported to possess medicinal and curative qualities. In India, there are about 6,780
pharmacies in the Indian system of medicine and the annual herbal drug production has been estimated to be around Rs. 4000 crores. The top most research institutions in India have been showing much interest in the scientific research on herbal drugs. For example, the Indian Council for Medical Research (ICMR) has evolved a new strategy for research on plant based drugs since 1986 onwards. The council has identified six diseases termed as "refractory", that is not amenable to satisfactory treatment by the available modern allopathic system of medicine, as thrust areas for indepth research. The diseases selected based on the current urgent need for new drugs for India, were anal fistula, bronchial asthma, urolithiasis, filariasis, diabetes and viral hepatitis. The council has devoted good amount of time, efforts and funds in these areas for pharmacologically and clinically evaluating the time tested herbs and herbal formulations against each of the diseases. This strategy has already paid dividends in the form of success achieved in two thrust areas, one of them is 'kshaarsootra' (Ayurvedic medicated thread), which has shown clinical efficacy comparable to surgery (fistulectomy), in the management of anal fistula and also has lower rate of recurrence. The other area in which partial success has been achieved relates to plants useful as hepatoprotective agents, where three plants Picrorrhiza kurroa, Andrographis paniculata and Phyllanthus species have been found to possess significant hepatoprotective properties. Inspite of the tremendous advancement made in the modern system of medicine for the management of hepatitis, till date, an ideal or a suitable drug has not been yet investigated.

1.2. QUALITY OF INDIAN HERBAL DRUGS:
Some of the major factors affecting the quality of the Indian herbs are discussed below:

1. Majority of the Indian herbal drugs are collected from the plants growing in wild state. These drugs are inevitably inconsistent because they are influenced by several factors such as origin, age, harvesting period, method of drying, ontogenic, ecotypic and genotypic variations. Hence the plant collectors are required to be trained for consideration of all these factors for the procurement of the best quality of the drug. The best solution for this would be to collect the plant material from the cultivated plants under proper supervision.

2. Different plants are used under one common name in different geographical areas of India. This adds to the confusion and has resulted in controversial identity of many plants e.g. under the common name of Rasna three different drugs (Pluche lanceolata, Vanda roxburgii and Alpinia galangal) are used.

3. The botanical identity of many known drugs and even those which are included in Ayurvedic Formulary of India is not correct e.g. the botanical name of Ajamoda is wrongly mentioned as Trachyspermum roxburhianum (the correct one is Sisili indicum) and that of Tamalaki as Phyllanthus niruri (the correct one is P. amarus).

4. Substituted drugs which are mentioned in place of genuine one, sometimes differ to such an extent that it causes much damage to the quality of the product. e.g. 'Tabakshir'- the starchy product prepared from Curcuma angustifolia forms a substitute for a silicious material (Vanskapur) obtained from Bambusa bambos.
5. The use of one part of the plant (aerial) in place of the other one (root part) is found to be the common practice in Ayurveda. For example, Ayurvedic Formulary clearly mentions the incorporation of 10 roots of different species of plants in ‘Dashmula formulation’ but due to scarcity of the root drugs, stem part is always used in place of the roots. Similarly in ‘Vasa formulations’ instead of roots of *A. Vasica*, leaves are used.

6. Adulteration of the crude drugs is found to be a common practice and many methods have been used and are still in use for this. There is about 70% adulteration in herbal drugs in India. Some of the drugs commonly used in Ayurveda are never found to be genuine e.g. Aloe, Honey, Guggul, Benzoin, Myrrh, Vanshlochan, Shilajit, Galo satwa, Vidarikand, Atiwish etc. The remark passed for adulteration by one of the scientists Dr. Albert Leung is worth to record here. He writes “Over a 15 years period he found 10% of the herbal products on the market contain wrongly identified herbs and at least another 20% or more contain adulterated herb and herbal extracts.”

1.3 QUALITY OF THE INDIAN HERBAL FORMULATIONS:

Use of inferior substandard drugs, substitutes, adulterants etc. are bound to lower the quality of the herbal formulations to a great extent but the major difficulty which one faces is their detection in the Ayurvedic formulation. Some aspects of these have been discussed below:

As a rule, Ayurvedic formulations are generally made up of mixture of many herbs. The detection of these herbs usually becomes a difficult task because of the presence of their small quantity in polyherbal formulations. Some basic parameters for detecting the quality of single drug have been prescribed for 80 drugs in Ayurvedic Pharmacopoeia of India vol.-I. These parameters, in fact, are not sufficient to judge the quality of the herb itself, so no question of their detection arises in the formulations. The benefits of this poor situation are fully enjoyed by the India Herbal Drug Industries by which use of inferior drugs, adulterants or omission of certain costly or endangered drugs in the polyherbal formulations has become their common practice.

World Health Organisation has strongly emphasized the need for the quality control of herbs and herbal formulations by using modern techniques. Internationally, several pharmacopoeias have provided monographs stating quality parameters and standards of many herbs and herbal products. Government of India is also trying to develop some parameters for detection of herbal drugs by using modern techniques like TLC, GLC, HPTLC, HPLC etc. but it will take many more years to come into action. Other Indian organisations like IDMA are also coming forth to develop some standards for certain herbal drugs e.g. Indian Herbal Pharmacopoeia vol.-I gives monographs for 20 herbs, focusing on their microscopical identity, marker compound analysis, physicochemical parameters, therapeutic category, pharmacology, safety and dosage, adulterants, substitutes etc. Without such full data, the quality and purity of Indian herbal drugs and their polyherbal formulations is not possible to judge. No doubt use of sophisticated tools for standardisation of herbal material would be a tedious and costly affair especially for small Ayurvedic manufacturing units but if the Government organising research units are
erected where all sophisticated facilities for testing the quality of the herbs and their formulations are installed, they can make use of these facilities. To gain the international reputation, Indian herbal formulations should be of quality tested products and not the commercial one as they are existing today.