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RESEARCH ERA OF HERBAL PLANTS IN AYURVEDA WITH SPECIAL REFERENCE TO BASIC PRINCIPLES

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ABSTRACT:

Natural products of botanical, animal or mineral origin have initiated the scientific quest of drugs, since antiquity. Even now more than fifty percent of the current drugs can be traced to natural products use globally. Several ayurvedic plants / drugs were & are being globally used. While doing research on Herbal, Herbo – mineral compounds mentioned in Ayurvedic Texts for various diseases the emphasis should also be given on application of the Basic principles of Ayurveda. Ayurveda designed wide range of pharmaceuticals preparations specific for different disease conditions by giving due consideration to the fundamentals like palatability, adoptability, stability etc. These basic fundamentals can be applied on various herbs used traditionally by Indians in various forms. The siddhantas mentioned in "Ashtang Ayurveda" should be adhered while doing research with the help of modern available techniques of research such as animal experimentations various analytical methods etc. The Ayurvedic pharmaceuticals (Bhaisajya Kalpana) embrace within its fold. The drug of plant, animal & mineral origin; both single drug & compounded formulations. The vital aspects such as manufacturing of drugs / formulations for research purpose; their package, dosage, distribution, standardization & quality control, planning & designing of pre-clinical and clinical studies etc. are detailed in classical literature in basic form, and may be comparable to various contemporary approaches. Bhaisajya Kalpana (Ayurvedic Pharmaceutics) forms a branch of Ayurveda which mainly deals with collection & selection of drugs, purification study of their nature & combination as well as preparation, preservation, besides mode of administration and dosage specification. Dravyagunavigyana includes identification (pharmacognosy – Namarupa vigyana), preparation (pharmacy – kalpa vigyana) and administration (clinical pharmacology – Yoga vigyana). The later deals with the effects of drugs on various systems (pharmacodynamics – Gunakarma vigyana) and their application in different diseases (therapeutic – Prayoga vigyana)

***Key words**: Ashtang Ayurved, Basic principles, Bhasaijya Kalpana, Dravyagunavigyana, Herbal.*

INTRODUCTION

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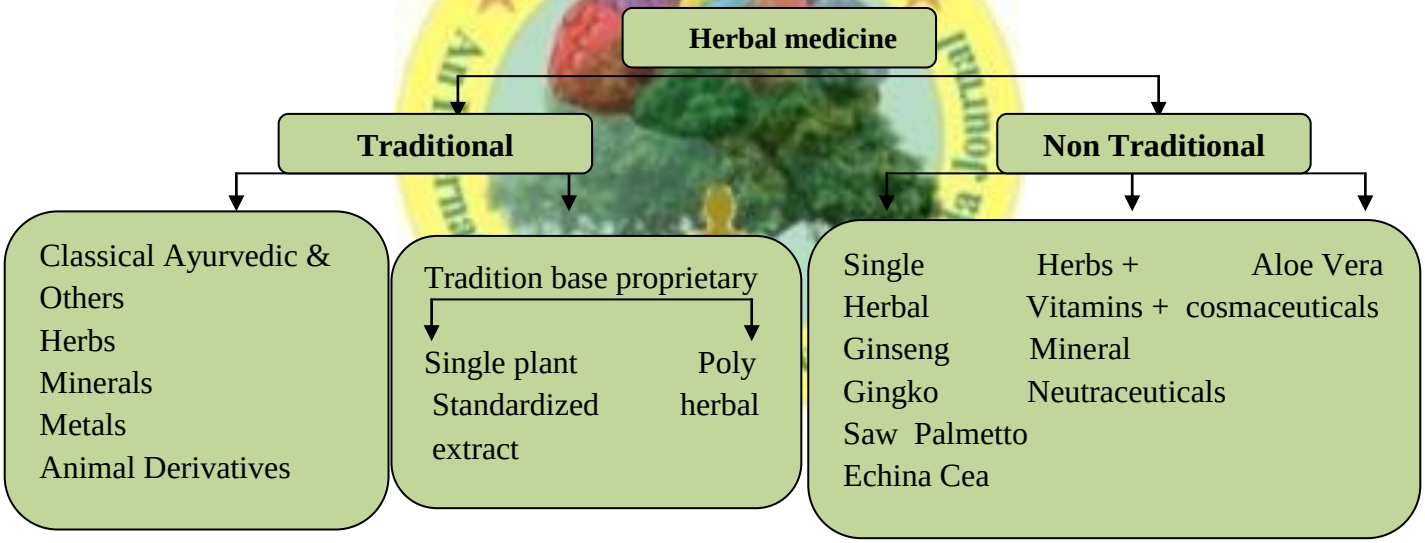
Research means search for knowledge. Research is a scientific and systematic search for pertinent information on a specific topic. The WHO estimates that approx 80% of the world population use herbal medicine for some aspect of primary health care. During the last decade, use of traditional herbal medicine has expanded globally and has gained popularity. Traditional herbal medicine has not only been continuously in use for primary health care by the poor in developing countries but has also been used in countries where conventional medicine is predominant in the national health care system. With the tremendous expansion in the use of traditional medicine worldwide, safety and efficacy as well as quality control of herbal and traditional medicines have become important concerns for both health authorities and the public insufficient evidences of safety are not justifiable because such products carry serious health hazards.[1]

Classification of herbal medicines



HISTORICAL ASPECT

The drugs are the most potent ones when they are endowed with strong potency due to excellence of place, time properties & containers

Place is of three types- arid, marshy & medium. Of them the arid zone is mostly vacant. As regards plants, there are dense fruits of *Kadara, Khadira, Sallanki, Sala, Somvalka, badari, tinduka, asvatha, vata* and *amalaki*, predominance of *sami, kakubha* & *simsapa*, young (immature) plants firm, dry & shaken with severe winds as if dancing, the land is abounding in mirage is thin, coarse, rough & having plenty of sand & gravels; the region is traversed by the birds like common quail, partridge, *chakore*, the place abounds in *vata* & *pitta* & is inhabited mostly by firm & hard people

Marshy place has dense forests of hintala,tamala,coconuts & banana plants, borders on coasts of sea & rivers, abounds in cold breeze; the land is intercepted by water streams having *vanjula* & *vanira* (willow) plants on banks, adorned with hills & bowers, abounds in trees attended by mild breeze; the region is full of the rows of flowered plants in abundance, embraced with amorous branches of trees resounding with coos of swan, *cakravaka*, *cranes*, *nandimukha*, *pundarika*, *kadamba*, *madgu*, *bringaraja*, *sataparna* & intoxicated *koyal*, inhabited by delicate people & having predominance of *vata* & *kapha*

The place is the medium one which has the combined characters of the above two in respect of plants, birds & animals & is inhabited by people firm, delicate, endowed with strength, complexion &compactness & other medium qualities.[2]

Medicinal plants grown in medium or arid zones, nourished timely with cold, sun(heat), air & water, even clean with facilities of water, except cremation ground, sacred place, temple meeting place, ditch, orchard, ant-hill & barren land, covered with *Kusa* & *rohisa* plants, having unctuous black, sweet or golden sweet soil, soft, unplugged, unaffected by other stronger plants are commended

Of Them those which are grow in time (proper season), mature with taste potency & smell, have smell, colour, taste, touch & efficacy unaffected by time, sun, fire, water, air & organisms are fresh & situated in northern direction (should be collected). Their branches & leaves should be collected in rainy & spring season, roots in summer or late winter. When the leaves have fallen down or are fully matured, bark, tubers and latex in autumn, heartwood in early winter & flowers & fruits according to their seasons. These should be collected by one with auspicious behavior, benevolent conduct, worshipping, observing fast & facing towards east or north

After collection they should be kept in suitable & good containers and stored in rooms facing eastward or northward, devoid of wind but well ventilated (with exhaust fans in a portion) & daily ritualized with offering of flower & other things, holing them up in a swing of rope well- covered & making them unapproachable for fire, water, humidity, smoke, dust, rats &quadrupeds.[3]

Good Collection practices of raw drugs and proper Identification

- Place / soil
- Seasons for collection
- Parts used

On this background, the method of collection storage and transport in addition to the time and place of collection were specified in the good collection practices of raw drugs and proper identification of a plant which is evolved by *Ayurvedic* practioner by certain methods of collection and identification of raw drugs which included identification by synonyms, morphological description ex. shape of flower, leaf, fruit, roots etc. and classified them in a systematic way so as to be recognized by a physician. In the current scenario various phytochemical markers and pharmacognostic parameters have been evolved to identify the correct desired raw drugs eg. *Dronapushpi* - flower shape is like a *droni*, *Chaturangul* (*Aragvadha*) - size of the leaf is measuring 4 angulas (Fingers) ; *Saptaparna* – compound leaf contains 7 leafets ; *Sankhapushpi* - flower shape resembles *sankha*.[4]

Place / Soil : *Acharya* have mentioned certain restrictions regarding place while

collecting the drugs. Drugs should be collected after performing holy rituals and with pleasant mind and clean body. Herbs should be collected from a clean place with good soil e.g.

1. Herbs grown in dirty places, marshy land and in places near burial ground should not be taken and those infected with worms and affected by fire / snow should also be avoided. This facilitates to avoid contamination / pollution and heavy metal content.

2. Herbs should be collected according to the need e.g. Heat producing herbs can be taken from Vindhya mountains in summer, like wise herbs for cooling purpose can be collected in winter from Himalays.

Season : The best season mentioned for the collection of herbs for all preparations in general is *Sharad Ritus* i.e. during October and November months. During this time of collection, the active phytochemical ingredients will be optimum in concentration. It has also been mentioned that.

1. Leaves and branches should be collected in rainy and spring (early summer) seasons as the leaves and branches are at their fresh and healthy state and contain an optimum of the products of the plant metabolism and one can obtain most desirable therapeutic action.

2.Particular part of the plant in a particular season will possess more active principles.

3.Acharyas explained about collection of different parts of plants in different seasons.

4.Root should be collected in summer or in the late winter. Flowers and fruits were considered to be auspicious in spring season and they may be collected accordingly.

5.The bark, stem and latex were said to be the best in early winter (Sharad Ritu) The heartwood is high in its quality when it is collected in the winter.[5]

Useful Part : The parts to be used are also specified by *Acharyas*. They clearly mentioned that the entire root has to be taken in case of tender ones in case of big trees, the root bark should be taken, and the whole plant should be taken where no specification is mentioned. The physician should always discard fruits, which are unripe and immature excepting *bilva* (in which latter is more useful when it is unripe and immature.) Fruits of *draksha*, *bilva*, *siva* etc. are more useful when these are dry.

Acharyas have mentioned different *prayojyaangas* for different medicinal plants due to presence of maximum active ingredients such as –

Table No. 1 - *Prayojyaangas*

1.	Abrus precatorius Linn (*Gunja*)	Leaf, root, seed
2.	Achyranthes aspera Linn. (*Apamarga*)	Entire plant
3.	Aloe barbadensis Mill. (*Kumari*)	Leaf, Pulp
4.	Terminalia arjuna (*Arjuna*)	Bark
5.	Terminalia chebula Retz. (*Haritaki*)	Fruit, Bark
6.	Uraria picta (*Prishni* parni)	Complet plant.[6]

Action of drug

The drug have been mentioned to be collected according to their action and constituents with regards to the five basic elements viz. for performing Therapeutic Emesis (*Vamana*), drugs should be collected in *Vasant Ritu* and they should be of *Agni* and *Akash* predominance, for Therapeutic Purgation (*Virechana Dravyas*), *Vasant Ritu* and *Prithvi* and *Jala* predominance were suggested.

The action of the drug also depends upon various factors like age status of the patient, severity of the disease, constitution of individual, geographical distribution, time of intake of drug etc. This reveals the pharmacodynamics and pharmacokinetics principles of drug action.

Asper the general principles said by the *Acharyas* were based on a scientific method method of approach and reveals should knowledge of understanding pharmaceuticals / therapeutic besides drug designing.

Identification and analytical specification and pharmacopoeial standard formulation.

Table No. 2 – Tests comparison of classical trends

1	Description	*Darshana pareeksha*
2	Colour	*Darshana Pareeksha*
3	Odour	*Ghrana Pareeksha*
4	Taste	*Rasana Pareekasha*
5	Loss on drying at 11^0c Total Ash Acid Insoluable ash Total Solid pH, volatise oils	*Bahya / rasayanika pareeksha*
6	Practical size Bulk density Tap density	*Darshana* and *sparshana pareeksha*
7	Heavy / Toxic metal analysis Lead Cadmium Mercury Test for Arsenic	*Bahyal / rasayanika parikasha*
8	Microbial analysis Total viable aerobic count Total entero bacteriaeceae Total fungal count	*Krimi / desha pariksha*
9	Test for specific pathogen E coli Salmonella sp. S. aureus Pseudomonas aeruginosa	*Krimi / desha pareeksha*
10	Pesticide residue analysis Organo chlorine pesticide Organoposphorous Pesticide Synthetic pyre thyroids	*Desha pareeksha*
11	Test for Aflotoxins	*prabhava karakas* (B1 + B2 + G1 + G2)
12	TLC / HPLC / HPTLC – Profile with marker	*Darshana pareeksha*
13	Tablets / Capsules	*Mana Pariksha* uniformity of weight

		/ content
14	Disitegration time	*Darshana pareeksha*
15	Friability CIF tablet	*Darshana pareeksha*
16	Hardness	*Darshana pareeksha*
17	Lethal dosa	*Vishakta matra*
18	Optimum effective dose	*prabhava sheela matra*
19	Shelf life	*saviryata avadhi*
20	Preservative	*prakshipta Dravyas*
21	Active compound	*Virya*
22	Binders	*Sandhana Karakas*. *Panchgyanendriya pareeksha* - Examination of sensory organs.[7]

Pre-clinical formalities – *Vishakta pareeksha* (safety & Toxicity Evaluation)

Ayurveda is well versed with the preclinical testing. The *Vishanna / virudhana pareeksha* conducted on animals is the key for the preclinical tests conducted on animals. Safety of the drug and dosage should be observed through animal experiments before involving Human beings. *Acharya's* have mentioned the animal experiments like testing the food / drug by giving it to the animals like birds (pigeon, peacock), animals (rabbit, monkey) in order to establish the safety and toxicity. The effect of medicine on prisoners to determine the toxic effects of drug. This method of testing the drug on the human system and the study of a particular effective drug for its long term toxicity is certainly more scientific than the present day pharmacological testing of drugs on lower animals only. The basic of preclinical and clinical toxicology are dealt in principle in classical literature, may be comparable to contemporary methods as follows.[8]

Pre – clinical stage:

The drug discovery period is also called pre clinical. It is in this period that the chemical synthesis resulting in a new compound occurs, and laboratory and animals tests are performed. Pre clinical studies are necessary to ensure that the potential new drug is effective and safe prior to putting the drug into clinical research and development. The term clinical, in this context applies to search conducted in human beings. Therefore the preclinical period refers to testing prior to the introduction of the drug into human subjects.

Drug developments period

Phase I, II, III, and IV

There are 4 phases of clinical studies conducted in the drug development period: Phase I, Phase II, Phase III, and Phase IV.[9]

Phase I :- Is the first introduction of the drug into human beings. It usually employs 20 to 100 healthy volunteers who do not have the targeted indication for the new drug. At this point, researchers use healthy subjects because the objective in phase I is to develop a safety profile and dosage range for the product Occasionally searchers use patients with the targeted indication because it is clear that the product of treatment involves a health risk in itself. Information typically gathered in a phase I study.

Pharmacodynamics :

The effect the drug has on the body. Looks at bodily responses to pharmacological, biochemical, physiological and therapeutic effect. (e. g. based on *prakriti* etc.)

Pharmacokinetics :

The effect the body has on the drug. ADME (absorption distribution, metabolism and excretion)

Bio – availability

Rate and extent to which a drug is absorbed or is otherwise available to the treatment site in the body.

Bio – equivalence

scientific basis on which generic and brand name drugs are compared. To be considered bio-equivalent, the bio – availability of two products must not differ significantly when the two products are given in studies at the same dosage under similar conditions. e. g. a proprietary formulation of *Ashwagandha* extract may be compared with standardized extract of the same using biological markers.[10]

Phase II : assesses both the safety and efficacy of the product in approximately 200 to 300 subjects who have the targeted indication. The study is usually double blinded i.e. neither the investigation nor the subject knows whether the subject is taking the drug under investigation or a control, i.e. another active agent or a placebo, The objectives of Phase II studies are to describe existing data and to outline the remainder of the development plan.[11]

Phase III : The Phase III is the part of the development process that gathers data to support the package insert and labeling of the new drug. It usually employs 1,000 to 3,000 human subjects and lasts several years. The objectives are further to verify the products effectiveness and to monitor its safety profile .Phase III also completes the long term toxicological studies on the product and initiates planning for phase IV - drug studies conducted after the product has gone on market. It is at this point in the investigation that sponsors apply for the FDA's approval of the product, on what is called a new drug application. (NDA)

Modified research guidelines and methodologies for drug development in *Ayurveda* and *Siddhaa*.

Phase of drug

Objectives

Approximate Development

Period

1.Prevalence Survey

Survey on prevalent diseases / conditions – 3 months in desired area to conduct clinical study.

2.Formulation of drug / collection of appropriate basis through – 3 months combination for targeted literary survey, assessment of previous indication / activity. Clinical data of ingredients / any other data of claims / classical evidences.

3.Cultivation / Collection of cultivation and collection considering – 3 months raw drugs. Current good agricultural practices, good field collection practices and Ayurveda / siddha textual methods.

4.Botanical identification, based on currently available technology pharmacognosits studies and classical methods of ingredients.

5. Formulation of SOPs and considering with classical methods – 9 months standardization, stability and currently available physical / chemical, studies for quality assured biological parameters for standardization drugs. Modified research guidelines and methodologies for drug development in Ayurveda and Siddha.

Phase of drug

Objectives

Approximate Development period

6. Pre – clinical safety studies Acute / Sub Acute / Chronic studies as – 12 months.

Pre the clinical use of the drug with appropriate animal ethical clearance, WHO guidelines / Ayush guidelines.

7. Animal studies for specific targeted / general activities for biological activity / clinical correlation targeted activity.

8. Design of study and considering current GCP / WHO – 6 months formulation of clinical guidelines and adopting of classical plan protocols, method.

9.Execution of the clinical Ethical clearance, trial conduct – 2.5 years. Trial Direct phase II trial, trial monitoring, trial co-ordination, data analysis, publication. Total period for drug development approx 5 to 6 years.[12]

Phase IV/V : Once a drug has received approval, the drug enters the market phase IV starts.[13]

DISSCUSSION

Ayurveda – Ancient science of life is believed to be prevalent for last 5000 years in India. It is most noted system of medicine in the world. *Ayurveda* is based on the hypothesis that everything in the universe is composed of five basic elements viz. space, air, energy, liquid and solid. They exist in the human body in combined forms like *Vata*, *Pitta* and *Kapha.* Herbal Drug research is an important link between Pharmacology and Medicinal chemistry. As a result of rapid development of phytochemistry and pharmacological testing methods in recent years new plant drugs are finding their way into medicines as purified photochemical, rather than in the form of traditional preparations.

In the modern pharmacognosy the crude drug is classified according to their alphabetical status, the taxonomy of plants, their morphology, chemical nature of their active constituents, pharmacological actions and therapeutic application, where as *Ayurveda* has given emphasis of *Desha*, *Kala*, *Mahabhuta* predominance etc. which should be taken into consideration while doing drug research. As geographical source or habitat gives us information regarding the original of drug, cassia *angustifolia* (Indian Senna) is grown in and around Tamil Nadu, so from other region it will show some difference in chemical constituents.

The cultivation technology for a crude drug has to be studied systematically with reference to the selection of proper strains of seeds, types of soil systems, optimum climatic or ecological factors like light, temperature, rainfall, attitude and other factors which affect the richness of crud drugs in their active constituent content. So the '*Desha'*, '*Kala' siddhanta* is very essential to be considered while doing Herbal drug research. One of the major problems faced by industry is non – availability of rigid quality control profiles for herbal raw materials and their formulations. Owing to the medicinal properties attributed to a crude drug, it is necessary to maintain its quality and purity in commercial market .The chemistry of plants is as divergent as the great variety of forms in which plants occur. Therefore while doing research on herbal drugs the Basic *Ayurvedic* Principal of Classification of drugs according to *Panch Mahabhut Siddhanta* will be very useful.

CONCLUSION

While doing the quality control of herbal crude drugs the Time of collection, soil, season, Part to be used these different criteria's as told in *Ayurvedic* Text should be followed before applying the Modern Methods of standardization so that it will be more easy in justifying their acceptability in modern system of medicine. The crude drugs can be identified on the basis of their morphological, histological, chemical, physical and biological studies. In the initial phase of drugs search these different studies are essential. Pharmacokinetic studies of *Ayurvedic*, Herbal formulations should be carried out with the consideration of basics like *Prakriti*, *Saara*, *Sanhanan*, *Agni* etc. related with the human body. Also the *Anupana*, *Sahapana* and time of administration does have an effect on the fate of drug, so without considering these basics from *Ayurvedic* concepts will be only unidirectional and will lead to misinterpretation of *Ayurvedic* basics.

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