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Standardization and evaluation of Ayurvedic Medicines - Needs

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ABSTRACT

Internationally there is an emerging interest to adopt and study the Ayurvedic medicines. To exploit its potentials to bring out the therapeutic approaches available in the oldest system of medicines and to put Ayurvedic products from our Natural heritage to National and international healthcare program with competence in the Global Healthcare market, there is extreme need of generating evidential data. The Ayurvedic products like pharmaceuticals products need to be standardized and evaluate with application of reliable evaluatory methods from Modern sciences. A complete literature review on the basis of systematic capture from diverse sources is extremely essential prior to designing pre-clinical and clinical studies. Authenticated and standardized raw materials need to be utilized to lead a quality product. Phytochemical standardization and development of qualitative parameters with the various analytical techniques is also essentials for assurance of quality of single or polyherbal formulations. In order to established reasonable safety of Ayurvedic therapeutics in clinical trials, toxicity studies are of important concerns. To explore effective dosages to be employed for clinical trials for the formulations under evaluations or to demonstrate new phramcological activities of already known medicinal plants or discovery of new natural prodcuts, it becomes obvious to conduct Phyto-phamacological evaluation in fairly reliable animals models. To survive in Global market, clinical research in compliance with internationally acceptable guidelines has to be conducted. All these above ideas are to develop a stable, viable, safe and efficacious Ayurvedic product to the application of Ayurvedic and modern research methodologies.

Key words: *Ayurveda, Standardisation, Ayurvedic drugs, Evaluation*

INTRODUCTION

In Vedic period, there were no controversies in identification of the drugs because in ancient times the system of study was by "*Gurukul Parampara*". The learning was in *Ashrams*, which were situated in forests. They could find many drugs and identify them, as taught by *Gurus*. The physician had liberty to modify the composition of any preparation according to prevailing local conditions and with a view to serving the needs of any individual patient. In course of time, though the name of formulation remained the same, variation in composition became an established practice. This resulted in the same preparation having different compositions as well as different therapeutic indications. This resulted in a sort of confusion in the minds of unwary physicians, who found themselves at loss to choose an appropriate remedy.

The increasing needs of the population and acute shortage of authentic raw materials have made it incumbent that some sort of uniformity in the

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manufacturing of Ayurvedic medicines should be brought about. The corollary of commercialization should be the endurance of quality using proper standardization techniques, to prevent adulterations and substitutions, spurious products and protect the manufacturer of ethical ayurvedic drugs, the prescribing physicians and the consumers.

Recently due to increased incidence of side effects of synthetic drugs there is an increased global awareness regarding the use of herbal drugs, which are not sometimes producing the desired effects, due to lacuna in quality control strategies.

There are many drugs mentioned in Ayurved with varied characters, their identification and study is a laborious process. The prime difficulty faced in Dravya-Guna is identification of drugs, which is possible when the monogram of each drug is legalised.

The therapeutic uniformity is secured and established by physical, morphological, biological and chemical assays of each drug. To conduct these experiments scientifically established and licensed laboratories are necessary.

It should be noted that herbal drug standardization is not new to Ayurveda. Acharya Charaka had mentioned about the same in his treaty Charaka Samhita in Vimana Sthana.[1] There are some additional parameters described in Ashtanga Sangraha Sutra Sthana,[2] regarding the examination of drug.

For the utilization of proper medication, Acharya Charaka had mentioned in Siddhisthana, as “The drug should be known as the proper medication which requires to be taken in small dosages, which is quick in action and is curative of even an excessive degree of morbidity, which is easy to take, easier to digest, palatable, pleasing, curative of the particular disease, not harmful even if complication arise, not very depressant and possess the most agreeable smell, odour, and taste.”[3]

For the use of appropriate drug, references are also mentioned in Ashtanga Hrudaya Sutrasthana[4] and Sushruta Sutrasthana.[5]

Present day justification for Ayurvedic Standardization[6]

1. Socio economic changes in Ayurvedic practice.

Modern day awareness of the needs for Ayurvedic Standardization and Evaluation has been aptly summarized in the words of the Former Drugs Controller of India Mr. Ashwini Kumar: "In earlier days, the activity of herb procurement, preparation and dispensing remained mainly the responsibility of practitioners and was on a one to one relationship between physician and his patients. It was a matter of sacred trust. However, the socio-economic changes in modern times, the technological advances, commercial factors, consumer preferences, changing lifestyles, etc. has influenced the way Herbal drugs are being 'manufactured' and distributed in the country. A Vaidya/Physician as well as the patient now seek assurance from the manufacturer about quality, safety and efficacy of a readymade Herbal/Ayurvedic Medicine"

2. Changes in Physical constitution, social habits and environmental stressors.

It may be safely assumed that in earlier days with the pollution-free environment and closer to nature lifestyle, the average Indian was healthier than the present day citizen. There has been a remarkable change in the average patient’s physical constitution and his natural immunity towards the disease state, the nature and severity of diseases and the dietary and social conditions within which the Physician has to treat the patient.

3. Evolutionary phenotypic and agronomic changes in plant species.

The herbs and their properties as described thousands of years ago have undergone changes along with that of the phytochemical profile due to evolution and changed environmental and growing conditions. The pharmacological actions of these plants as mentioned in the literature need to be revalidated in today’s times.

4. Substitution of drugs due to non-availability or scarcity.

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Achrya Bhava Mishra and Acharaya Sharangdhar have mentioned the substitution of herbs that were not found easily or scarce in certain regions. In some cases the substitutes have acquired the status of the original herb and are sometimes wrongly attributed with all the properties of the original herb.

5. Proliferation of Proprietory Formulas over Traditional Generic Formulas.

The market for branded Ayurvedic products in India and abroad is fast outgrowing than that of the traditional preparations. The efficacy and safety of traditional formulas has been confirmed by informal system of trials down the ages but the branded preparations are not prepared as per Ayurvedic texts hence their final efficacy is open to question. Thus the need to confirm their efficacy.

6. Translating Ayurveda with the help of contemporary methods.

There are several lines of Ayurvedic treatment like *Rasayana*, *Panchakarma* and *Vajikarana*, which have no parallel in modern medicine. Evaluations based on contemporary and internationally accepted parameters of such medications would help in rediscovering these hidden gems for present day use by the masses.

7. Revalidating Ayurvedic principles as per present day needs.

Several guidelines in Ayurvedic treatment are either difficult to adhere to in present 21st century lifestyle or are not taken seriously by the patients. Re-establishing the importance the guidelines of anupan, pathya-apathya, dosages, etc. by modern techniques can go a long way in improving patient compliance and achieving better results to therapies.

8. Change in the prescribing pattern of traditional products.

Chyavanprasha was originally prescribed only to old age people to increase longevity but now it is prescribed even to children. It must be established with trials if indeed *Chyavanprasha* is beneficial for children and young adults or if some other preparation is more recommended.

9. Modernisation of manufacturing process.

Historically preparation of ayurvedic formulations used to involve traditional methods mentioned in scriptures. Modernisation of manufacturing processes at the large scale with the use of sophisticated equipments raised the doubt about stability of these preparations. To combat these GMP norms should be followed and the shelf life has to be evaluated.

10. Proliferation of OTC / Personal Care products.

In the last half century there OTC herbal products have grown more than any other segment in the Ayurvedic Industry. There is now an Herbal variant of all OTC, food, cosmetic, personal care products on the store shelves. In the name of Ayurveda, there has been mass proliferation of pseudo-herbal products. In the interest of the unwary consumer and in the overall long-term interest of the Science and Industry itself, it is imperative to stop these unscrupulous practices.

11. Protection of Intellectual property

Whatever “biopiracy” is taking place it is not without the cooperation of the source country. If our biodiversity and our traditional knowledge (in healthcare, agriculture and forestry) is not properly studied and codified then it is open to plunder by technology pirates and patent-hunters. Standardization and complete screening of our flora and fauna is the only way to protect and retain ownership of our traditional knowledge.

12. Effective overseas marketing

The international market for Ayurvedic products has the potential to grow larger than our own domestic market. However the overseas markets demand well-standardized product and documented evidence of efficacy and safety from most products they buy for healthcare - herbal or synthetic. Hence it is in the interest of manufacturers and exporters and in also in the larger interest of the government to have the will, the skills and the systems in place for Quality Control

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of Ayurvedic Medicines and Supplements for exports. Only a concerted industry and public sector program will help India promote its vast wealth of Ayurveda effectively before it is too late.

Types of Standardization

Standardization of raw material, common ayurvedic practices and the finished preparations would be considered as separate areas of research for the Ayurvedic Pharmacist / Clinician. Some research projects such as those involving basic issue of herb standards clearly need to be taken up in the public sector and academia. Research on finished product has always been a daunting task particularly from the point of view of chemical standardization. Standardization of branded products ofcourse remains the responsibility of the brand-owners but FDA legislation and implementation should be changed to ensure that manufacturers take this responsibility seriously now.

Types of Raw Material Standardization[7-9]

1. Pharmacognostical and Phytochemical profiling.

Complete Monograph preparation of 500 commonly traded drugs of commerce. Comparative studies with common substitutes and adulterants. In this area, some progress has been made by way of the Indian Herbal Pharmacopoeia and Ayurvedic Pharmacopoeia being published. However, standardization of herbs and compound preparations will come a long way if a concerted effort is made for isolation of biologically active compounds for use as HPLC and HPTLC markers.

2. Pharmacological (Animal) Screening for established and novel activities in popular drugs of commerce.

The west is publishing every day some novel activity of common Indian herbs and then utilizing such know-how commercially whereas India is not able to even revalidate known pharmacological activities of common Indian plants. Hence this should be one of the key areas of public and private sector research in India. Revalidation of the Categorization of herbs as per Tridosha can also be undertaken.

3. Clinical evaluation of herbs for modern pathologies, using allopathic drugs of choice as control.

The translation of Ayurvedic practice into a language that can be understood by modern physicians will be possible only when this activity is taken up on a large scale.

4. Dose determination and Safety studies.

Due to changes over years in patient population, environmental conditions, disease patterns, plant phenotypes, etc. a fresh evaluation of therapeutic and toxic doses should be carried out.

5. Pharmacokinetics and Pharmacotherapeutics.

Finally the effect of several such Ayurvedic recommendations may be revalidated using organized clinical techniques.

Finished Product Standardization and Evaluation[10,11]

Even as we have made some progress on analytical methods for the raw materials, the finished product quality control in the Indian Ayurvedic industry is squarely absent. Industry is right now using the excuse that product quality control is a costly process and there are neither inhouse skills nor equipments nor outside labs that can take up this type of work. Which is true to some extent? Hence if some simple and cheap universal methods can be devised in the public domain for common polyherbal combinations then there may be more incentive for manufacturers to test their finished product batches.

1. Analytical Method Development of large-selling popular generic products like Chyavanprash, Triphala churna and others.

Present parameters for standardization of traditional medicines are largely organoleptic and subjective in nature. Modern analytical techniques even for simple two to three herb preparations like Gulkand and Triphala are mostly lacking. There are a large number of manufacturers making these common products however; no private initiative has been taken by any of these parties for quality control of their products from which they earn substantial revenues. It is

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probably in their short-term vested interest to maintain this status quo. Hence either publicly funded research or privately funded academic research may be initiated for this important area of Ayurvedic Standardization.

Evaluation of self life using accelerated stability studies to insure physical, microbial and chemical stability of the product.

2. Clinical evaluation of Common Ayurvedic products.

Finally, having attained standardized product quality and batch to batch uniformity, the most important area of Ayurvedic evaluation would be organized clinical research of common generic products.

Needs of the Hour[12]

1. Government Funding and Support

Government should speed up Ayurvedic Pharmacopoeial work that has been started; support UG and PG level work in Pharmacognosy and Dravyagun and provide funding to private companies that wish to undertake such work that may benefit the industry at large. A Reference compound library containing purified actives for chromatography is badly needed. These should be authentic and cheaply available. Analytical method development in some of the areas described earlier and Extension activity (education of industry and trade) for disseminating knowledge of drug quality control is called for.

2. Drug Testing Labs.

Soft loans, speedy clearances, etc. for agencies trying to enter this field should be provided immediately.

3. Drug Regulatory Policy.

Without a stringently written and implemented regulatory policy on Ayurvedic quality control, there will never be adequate motive for private initiative in this field. Government should ofcourse first create the public and private infrastructure needed to fulfill the requirements then religiously implement the provisions of schedule T of the Drugs and Cosmetics Act and Rules. Private investment in this area will then automatically follow.

4. Consumer Awareness Program

Having the infrastructure and Drug Administration in place, a consumer awareness program to be launched. This will ensure that private companies tighten up and deliver quality at affordable prices.

5. International Promotion Program

After having done the good work, the industry and particularly the government can and should tell the whole world about the modern quality standards that our “traditional” medicines adhere to. The Korean Government has done wonders with the public knowledge they have generated for marketing of their national product ginseng. Today, although we have superior herbs in our country, we have no Indian equivalent to the brand equity that the Korean Ginseng enjoys worldwide.

6. Intellectual Property Strategy

No research program is complete without first a sound Intellectual Property (IP) Strategy in place. This should not be under-estimated and training to be imparted to all scientists to think commercially as well.

CONCLUSION

Standardization of Ayurvedic products is a much needed public and private effort which will help in elevating Ayurveda to the levels it truly deserves in this country and abroad.

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