

## ISSUES ARISING IN CASE OF SAFETY AND EFFICACY OF AYURVEDIC FORMULATIONS – A REVIEW

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### ABSTRACT

Huge range of formulations Ayurveda has been practiced since ages and stood the taste of time. In spite of this long traditional history, their scientific pedestals time demanding. Several reports had documented that not all herbs are safe, as per general belief and some are quit toxic, having adverse effect. As a result the quality, Safety and Efficacy of these formulation have become an important concern for both consumer and health authorities, so there is need to reassess the issues regarding safety and efficacy of Ayurvedic formulation. Safety of Ayurvedic formulation can be determined by identifying Contamination, Misidentifications, Substitution and Adulteration of raw drug material. Pharmaceutical assessments, Toxicity assessment and Risk assessment approach also final Product and their bioavailability are important factors deciding safety of drugs. The efficacy of Ayurvedic formulations is measure by only its ability to improve health of well-being. To overcome all these issues and proves the safety and efficacy of Ayurvedic formulations, the pharmacovigilance study, proposed safety index and Ayurpharmaco-epidemiology is needed. The review article enlightens all these issues with positive approaches. All these steps are useful and must be taken for the betterment of Ayurvedic formulations with respect to its safety and efficacy regarding welfare of global health.

**KEYWORDS:** Ayurvedic formulation, Pharmaco-vigilance, Safety index, Ayurpharmaco-epidemiology, etc.

### INTRODUCTION

In India, system of Ayurvedic medicine is time tested traditional system originated about 5000 year's back.<sup>1</sup> It is an effective and potential alternative system of treatment in case of diseases like Neurological disorders, Cancers, Skin diseases, Diabetic militias, Hepatic as well as renal impairment, Obesity, Infertility, Sexual weakness, etc., where modern system has limitation. In current scenario, various

Ayurvedic formulation are being used by the peoples of various Asian developing countries.<sup>2</sup> This fact is recognized by WHO in the early 1970 and decide to encouraged respective governments to effectively utilize local knowledge of traditional medicines for disease prevention as well as health promotion of mankind.<sup>3</sup> However, the Ayurvedic formulations suffers from a range of short comings such as unacceptable as

well as insufficient evidences of safety, efficacy, standardization of raw material and end product, in consistent production practices, etc.<sup>3</sup>

With this huge range of formulations Ayurveda has been practiced since ages and stood the taste of time. This efficacy and safety of these formulations are already proven through clinical expertise through decade. This proves its evidence.<sup>4</sup> In spite of this long traditional history, their scientific pedestals time demanding with the advancement of medical, Biological and Pharmaceutical Sciences meantime, several reports had documented that not all herbs are safe, as per general belief and some are quit toxic, having adverse effect.<sup>5</sup> It has been also reported that some products are not of described quality due to absence of regulatory standers. As a result the quality, Safety and Efficacy of these formulation have become an important concern for both consumer and health authorities.<sup>6</sup> For wider applicability and acceptance of these formulations in current sophisticated era, there is need to reassess the issues regarding safety and efficacy of Ayurvedic formulation. Such novel issues are discussed in this review article to conclude the importance of pharmacovigilance study of Ayurvedic formulation as well as Safety index and Ayurpharmaco-epidemiology in assessing the safety and efficacy of Ayurvedic Formulation.

This critique study is mainly based upon various classical texts, books related to modern science and research articles published in renowned journals. After studies these particulars, obtained novel issues regarding safety as well as efficacy of

Ayurvedic formulation are enlisted as follows

**(1) Safety issues** – Safety issue of Ayurvedic formulation in various cases the toxicity of formulations has been traced to contaminants and adulterations. However some toxic plants and minerals are used in preparation of Ayurvedic formulation.

As a whole these formulation have a risk of adverse effects and drug- drug and drug – food interactions if not properly assessed. The toxicity effect of these formulations may be attributed mainly to inherent toxicity of plant constituent and ingredient and secondary manufacturing malpractices and contamination. Detailed photochemical as well as pharmacological studies are required to evaluate toxic effect of formulation some basic issues regarding safety are as follows.

1.1) Contamination in raw material (basically in herbal substance) Potential contamination of raw material includes micro-organisms, microbial toxins, pesticides, fumigation agents, radioactivity and the presence of toxic compounds of toxic metals.<sup>7</sup>

1.2) Misidentifications of raw substances – Huge number of formulation are described by various authors in the Ayurvedic classic these authors follow individual system of describing these formulation, they use particular synonyms of various ingredients. They only explain the properties and therapeutic uses of particular herbal drugs, devoid of morphological characteristic. Due to this exact identification of the particular ingredient is not possible in current scenario which leads to misidentification

1.3) Commercial use of substitutes gives rise to faulty preparations. Sometime plant of similar morphological characteristics are

substitute or cheaper alternative are used by manufactures leads to toxicity of formulation

1.4) Adulteration – intended addition an accidental contamination via processing gives rise to adverse effects

1.5) Regulatory approaches for pharmaceutical assessments – The risk associated with use of these formulations are mainly associated with failure of good handling and manufacturing of products. Strict compliance of GMP should require for manufacturing which is not followed<sup>3</sup>

1.6) Toxicity assessment –Toxico-dynamic and Toxico-kinetic, Toxico-genomic studies is needed to assess the toxicity of Ayurvedic formulation at cellular level which is not done in present situation

1.7) Risk assessment approach - Assessment of risk depends upon hazard identification dose-response assessment and exposure assessment. In the risk assessment process studies need to take into account formulation of the herbal

1.8)Product and their bioavailability there is necessary to combine quality application data with chronic toxicity data which is rarely available.

**(2) The efficacy of Ayurvedic medicine –** The central issue in the modern debate about herbal medicine is that the efficacy of Ayurvedic formulations is measure by only its ability to improve health of well-being and not by scientific assessment criteria age old wisdom does not necessarily guarantee the product is question is efficacious with reasonable specificity. On the other hand modern medicines are more focused and studies on particular diseases based on specific Etiopathological entities.

For testing efficacy the tools like anecdotal reports, case reports, case series and random clinical trials<sup>8</sup> are used. The Ayurvedic treatment is mainly based upon Dashvidha Pariksha Bhavaas - Prakruti, Vikruti, Sara, etc. which indicates individually of the patient.<sup>9</sup> Because of this to study the efficacy of Auyrvedic formulation on mass level is quiet impossible.

### **OBSERVATIONS**

Impotent component of Indian health care i.e. Ayurveda is based upon its own strong basic concept along with philosophy old observation of centuries, rich traditional wisdom Ayurvedic formulation are prepared by using different part of plants, incorporation with metallic and non-metallic substances. Sometimes this formulation are combined with some material of animal origin as milk, ghee, honey, bile, etc. this system provides vast resources of formulation from purely herbal (plant origin), or herbo-mineral, which are preferably used as a single or polyhedral or herbo-mineral compounds.

To overcome all these issues and proves the safety and efficacy of Ayurvedic formulations, the pharmaco-vigilance study is needed each of them. There is need to train Ayurvedic experts in the science of pharmaco-vigilance and include them not only in reporting of adverse reaction but also in its assessments.<sup>10</sup> In this modern age, scientific evidence is very much essential for better acceptability of a therapeutic agent along with the history of traditional medicine, so establishment of such evidence and their documentation in a scientific way must be done. Extensive researches based on scientific methods on Ayurvedic

formulations and their reporting through international journals are very much important and time demanding. To prove the efficacy of Ayurvedic poly-herbal or herbo-mineral formulations extensively in the vitro and vivo study, clinical trials, observational study reports are badly needed along with their publication in international platform. The proposed safety index is prudent to add that the index is to find favours with medicine like modern one. The safety index is based upon an unmet need to integrate the seriousness as well as the intensity of drug toxicity into a quantity of drug toxicity and further capture mild side effect, still further study is required.<sup>11</sup>

‘Ayurpharmaco-epidemiology’ is a newly developed field by synergy of the fields such like clinical pharmacology, epidemiology and Ayurveda. It will be used in case of deciding the effects of Ayurvedic formulations on large populations to describe and analyse the practices, evaluate the safety and efficacy, and carry out medico economic evaluations. This research is one such technique that can be implemented to acquire facts about Ayurvedic formulations practice and safety without having to invest in large clinical trials. This type of study can be less expensive and provide some evidence as to the use and safety of Ayurvedic formulations in large populations. further attentions to the special needs of the Ayurveda, Siddha and Unani fields are necessitated.<sup>12</sup>

### **DISCUSSION AND CONCLUSION**

Basically, Ayurvedic formulations are very cheap and can be affordable for poor people in the developing countries. Traditionally, Ayurvedic formulations are based on

scientific Dashavidha Parikshya Bhaava are more effective for the treatment of certain diseases without or with minimum adverse effects compared to modern medicines. Now only needs scientific evidences in support of their therapeutic effectiveness and safety of particular Ayurvedic formulations. If these can be done in a scientific manner, then Ayurvedic formulations may be considered as a potential source of alternative treatment in case of the failure or less effectiveness of modern medicines. In summary, it can be concluded that Ayurvedic formulations has glorious traditional background for the treatment of all diseases with minimization/without adverse effects. To keep faith on Ayurvedic treatment as well as in Ayurvedic formulations and to spread its popularity all over the world, extensive preclinical, clinical and observational studies in vivo and in vitro for the efficacy and safety of those formulations as well as publications of those results in the international platform are very much needed and also time demanding. Positive results of the investigations may be highly accepted by physicians, scientists, practitioners, and other people including the international community. But, in case of negative findings for therapeutic efficacy, toxicity, adverse-effects, etc. the effective steps should be taken along with the modification of the formulation, manufacturing, administration and doses of that specific preparation. All the above steps are useful and must be taken for the betterment of Ayurvedic formulations with respect to its safety and efficacy regarding welfare of global health.

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Source of support: Nil,

Conflict of interest: None Declared

### Cite this article as

Pravin K Koparde: Issues Arising in Case of Safety and Efficacy of Ayurvedic Formulation – A Review *ayurpub*; III(1): 705-709