Chapter 2: Background

India is a country with an enviable treasure of ancient knowledge and diverse variety of flora and fauna. Indian system of medicine i.e. Ayurveda has been in use for more than 4000 years and it stood the test of time. Even today, considerably large number of people use herbal or traditional drugs in one form or the other.

Ayurveda: Life, Health and Longevity

Several traditional healthcare systems exist in India from centuries and out of all the traditional practices, Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy are the official traditional systems of medicine. These systems are collectively known as Indian Systems of Medicine (ISM), and are currently called as an acronym AYUSH for Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homoeopathy. They collectively provide healthcare to the vast majority of people of India and neighboring countries. WHO has listed over 21000 plant species used around the world for medicinal purpose, out of which 2500 are used in India.¹

Ayurveda is a well-known healing art. In olden times, vaidyas used to treat patients on individual basis, and prepare dosage form according to the requirement of the patient. But the scenario has changed now; herbal medicines are being manufactured on a large scale in mechanical units. They are getting popularized in developing and developed countries owing to their natural origin and lesser side effects.²

Herbal formulation has gained great importance and rising global attention recently. This scenario is obvious as major increase in the herbal formulation usage has been observed during the last few years in developed world, where market expansion occurred in European countries and USA.³ The World Health Organization (WHO) estimates that 80% of the world’s inhabitants still rely mainly on traditional medicines for their health care.⁴
Some diseases still do not yield to treatment under allopathic system of medicine but the treatment for the same are available in the Traditional medical system (TMS) which is more rational, more effective and cheaper because of the local availability of herbs.

Moreover, the people in the developed world strive to stay healthy in the face of chronic stress and pollution and to treat illness with medicines that work in concert with body’s own defenses.

Modern research is adding to our knowledge of the healing power of plants. At least, 35,000 plant species growing in the developing countries are estimated to have medicinal value. More than 7000 medicinal compounds in the modern pharmacopoeia are derived from plants. The current accepted modern medicine or allopathy has gradually developed over the years by scientific and observational efforts of scientists. However, the basis of its development remains rooted in traditional medicine and therapies. Ancient wisdom has been the basis of modern medicine and will remain as one important source of future medicine and therapeutics. Commercially, these plant-derived medicines are worth about US$ 14 billion a year in the United States, and US$ 40 billion worldwide.\(^5\)

**Concept of Poly herbal formulations:**

Drug formulation in *Ayurveda* is based on two principles: Use as a single drug and use of more than one drugs, in which the latter is known as poly-herbal Formulation. This key traditional therapeutic herbal strategy exploits the combining of several medicinal herbs to achieve extra therapeutic effectiveness, usually known as polypharmacy or polyherbalism.

Historically, the Ayurvedic literature “*Sarangdhar Samhita*” dated centuries ago in 1300 A. D., has highlighted the concept of polyherbalism in this ancient medicinal system.\(^6\) In the traditional system of Indian medicine, plant formulations and combined extracts of plants are chosen rather than individual ones.\(^7\)

Even though the active phytochemical constituents of individual plants in many formulations have been well established, they are usually present in minute amounts.
and mostly, they are insufficient to achieve the desirable therapeutic effects. Scientific studies have revealed that these plants of varying potency when combined may theoretically produce a greater result, as compared to their individual effect or the sum of their individual effect. This phenomenon of positive herb-herb interaction is known as synergism. Certain pharmacological actions of active constituents of herbs are significant only when potentiated by those of other plants, but not evident when used alone.

Due to synergism, polyherbalism confers some benefits not available in single herbal formulation. It is evident that better therapeutic effect can be reached with a single multi-constituent formulation. For this, a lower dose of the herbal preparation would be needed to achieve desirable pharmacological action, thus reducing the risk of deleterious side-effects. Besides, poly-herbal formulations bring improved convenience for patients by eliminating the need of taking more than one different single herbal formulation at a time, which indirectly leads to better compliance and therapeutic effect. All these benefits have resulted in the popularity of poly-herbal formulations in the market when compared to single herbal formulations.  

**Need for standardization of herbal drugs**

The practice of Ayurveda practice continues today to treat human diseases and provide positive health benefits to the people. Ayurvedic formulations [such as solid (vati, churna), semisolid (avaleha, ghrita), liquid (asava, arishta) dosage forms] have numerous uses in Ayurveda. They affect or help to rectify the three doshas in the body, and restore homeostatic balance that builds up in the body’s digestive system and spreads to the tissues. Considering the widespread use and popularity of Ayurveda, proper standardization and validation methods are being developed for promoting Ayurvedic drugs.

At present no official standards are available for ayurvedic preparations. Manufacturers fix their own parameters for testing their formulations and these are only preliminary in
nature. At present it is very difficult to identify the presences of all the ingredients claimed in a poly-herbal formulation.

Various chromatographic and spectrophotometric methods and evaluation of physicochemical properties can be tried to evolve pattern for identifying the presence of different ingredients. Wherever possible, these methods can be applied for quantitative estimation of bioactive groups of compounds like alkaloids, flavonoids, polyphenolic components or for estimation of a particular compound. But, in polyherbal Ayurvedic formulation it is very difficult to estimate each and every ingredient. Combined, well-coordinated efforts from scientific workers of different disciplines are required for this purpose.

Addressing issues of standardization is vital and needs broader consideration. Ayurvedic medicine was developed at times of limited access to technologically variable norms of standardization. The dynamic process of evolution could alter and affect the identity and structure of natural materials. For commercialization, correct identification and supply of raw material to avoid adulteration has become a challenge. Additionally, some botanical species might have been extinct.

Quality controls of synthetic drug offer no problems with very well defined parameters of analysis. In contrast, herbal products represent a number of unique problems when quality aspects are considered. These are because of the nature of the herbal ingredients present therein, which are complex mixtures of different secondary metabolites that can vary considerably depending on environmental and generic factors.

Furthermore, the constituents responsible for the claimed therapeutic effects are frequently unknown or only partly explained. These complex positions of quality aspects of herbal drugs are further complicated by the use of combination of herbal ingredients as are being used in traditional practice. It is not uncommon to have as many as five different herbal ingredients in one product. Thus batch to batch variation starts from the collection of raw material itself in the absence of any reference standard for identification. These variations multiply during storage and further processing.
The existing knowledge of Ayurveda and ethnic medicines are being validated through newer guidelines of standardization, manufacture, quality control and modern technique.\(^\text{10}\) The World Health Organization also has recognized the importance of traditional medicine and has been active in creating strategies, guidelines and standards for botanical medicines.\(^\text{11,12}\)

Standardization and analysis of the chemical markers of the Ayurvedic and other poly herbal formulation has always been a concern.\(^\text{13}\) Herbal drug development includes various steps, starting from collection of raw materials, correct identification, pharmacognostic and chemical quality standardization, safety and preclinical pharmacology, clinical pharmacology and randomized, controlled clinical trials.