INTRODUCTION:

Ayurveda is a holistic eternal healing science that existed in the universal consciousness. It is a science that deals not only with treatment of some diseases but is a complete way of life (Rangari V. D. 2008). Ayurveda - a traditional medicine system of India is originated over 6000 years ago (Bansa A. et al 2001). It 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 (tridosha). Tridosha are in harmony with each other, but in every human being one of them is dominating witch, in turn is called as the Prakruti of that person. Tridosha exist in human body in seven forms called saptadhatu like Rasa, Rakta, Meda, Mamsa, Majja, Shukra and Asthi. These tissues are subject to wear and tear so that mala is formed from them. When tridosha, saptadhatua and mala are in poise with each other, it is called as healthy condition while imbalance causes a pathological condition (Kokate C. K. et al 2009).

Formulations of Ayurveda are herbal, mineral/metal and animal origin, which are processed pharmaceutically for their therapeutic effects. In today’s scenario, major population depends on herbal drugs. According to WHO, Ayurvedic medicines come under traditional medicines and refers to health practices, approaches knowledge and beliefs incorporating plant, animal and mineral based medicines, spiritual therapies, manual techniques and exercises (Yoga and Pranayam), applied singularly (Herb) or in combination (Polyherb) to treat, diagnose and prevent illnesses or maintain well-beings (Payyappallimana U. 2010).

Despite of tremendous advancement in Allopathic system of medicines, there are many areas in which allopathic medicines have failed to prove its effectiveness. Main drawback of allopathic system is its side effects, high cost of drugs as well as treatment, lack of curative treatment for
chronic diseases and reoccurrence of disease after stoppage of medication. People are losing their faith towards allopathic medicines and going towards the use of Traditional medicines, Unani system of medicines, Sidha system of medicines and Naturopathy. As per the WHO, about three-quarters of the world’s population currently use herbs and other forms of traditional medicines to treat their disease (The truth behind herbal drugs 2012). Herbal products are natural and people believe it as a safe medicine. Due to wide range of biological activities, higher safety margins and lesser costs has set aside herbal medicine in high demand both in the developed and developing countries (Parmar S. et al 2011).

In recent past there are occurrences of some doubt on safety and efficacy of herbal formulations as it is marked as a dietary supplement and they are regulated under the Dietary Supplement Health and Education Act of 1996 (DSHEA – US FDA), which does not require proof of safety and efficacy. Herbal products can be as toxic as or even more toxic than prescription medicines. Due to wrong interpretation and question of safety and efficacy of the product, people are afraid of using herbal medicines. A good efficacy is assumed as self-evident, and therapeutic benefit without risks is expected. Many users prefer natural medicine instead of synthetic remedies. Therefore, it is necessary to access the quality of drugs based on the active ingredient and safety and efficacy of the product as per the WHO guidelines for formulation and raw material (Bhushan P. et al 2004).

Major drawback associated with herbal product is the lack of evidence based on its standard profile and quality and safety aspects of herbal formulations. There is a lack of data supporting the efficacy of clinical trials in traditional medicines. Other major problem associated with herbal formulation is the loss of genetic biodiversity or risk of annihilation (Raj S. et al 2011). Heavy metal (HM) toxicity is another safety issue in herbal formulations and it is essential to evaluate them for their content.
Ayurvedic literature emphasizes the use of heavy metals in their formulation due to their particular biological properties for curing. Ayurveda has described specific physiochemical processes like sublimation, heating etc. to detoxify the metals and to avoid its toxicity. Heavy metals in Ayurvedic medicines include not only lead and mercury but other metals such as chromium, iron, zinc, nickel, cadmium, arsenic and tungsten. Amount of heavy metals and trace elements in Ayurvedic preparation depends on the geographical location, varying according to the quality of the soil, water or air pollution (Alwakeel S. S. 2008). The American medical research community has sounded a heavy metal warning against Ayurvedic cures. Herbal products from the Indian system of medicine sold in the US contain dangerous levels of lead, mercury & arsenic. (Shukla K., Jain V. 2006). Environmental impact of heavy metals such as Cd, Pb, Hg and As causes serious concern on the health of individuals (Borkowski B. 1994, Ernst E. 2001).

Herbal product cannot be considered scientifically valid if the drug tested has not been authenticated and characterized in order to ensure reproducibility in the manufacturing of the product. Moreover, many dangerous and lethal side effects have recently been reported, including direct toxic effects, allergic reactions, effects from contaminants, and interactions with herbal drugs. (Vaidya A. D. B., Devasagayam T. P. A. 2007). Therapeutic activity of an herbal formulation depends on its phytochemical constituents. The development of authentic analytical methods which can reliably profile the phyto-chemical composition, including quantitative analyses of marker/bioactive compounds and other major constituents, is a major challenge to scientists. For this reason, standardization is an important step for the establishment of a consistent biological activity, a consistent chemical profile, or simply a quality assurance program for production and manufacturing of an herbal drug (Patra K. C. et al 2010). WHO specific guidelines, for the evaluation of the safely, efficacy and quality of herbal medicines as a prerequisite for global
harmonization are of extreme importance. Extraction and characterization of herbal medicines, increased bioavailability of phytosomes, bhasma as a metal nano carrier drug delivery system, DNA based molecular markers in distinguishing adulterants and SCAR markers for authentication and discrimination of herbs from their adulterants are reported. (Amartya Bose et al 2012).

The public belief that herbal and natural products are safer than synthetic medicines can only be ascertained by implementing standard operating procedures (SOP) leading to Good Agricultural Practice (GAP), Good Laboratory Practice (GLP), Good Supply Practice (GSP) and Good Manufacturing Practice (GMP) for producing medicinal products from herbal or natural sources (Chan K. 2003).

Ayurveda utilizes the potential of various herbs as drugs and play important role in modern health care, particularly where satisfactory treatment is not available. Recently the clinical importance of herbal drugs has gained substantial attention. The present work was designed to standardize the herbo-mineral formulation and prove its clinical efficacy which has not been carried out yet.