2.1 AIMS AND OBJECTIVES

Herbal medicines as the major remedy in traditional system of medicine have been used in medical practices since antiquity. The use of herbal medicine due to toxicity and side effects of allopathic medicines, has led to sudden increase in the number of herbal drug manufactures.

In olden times, vaidyas used to treat patients on individual basis, and prepare drug according to the requirements of the patient. But the scenario has changed now; herbal medicines are being manufactured on the large scale in Pharmaceutical units, where manufacturers come across many problems such as availability of good quality raw material, authentication of raw material, availability of standards, proper standardization methodology of single drugs and formulation, quality control parameters.

The quality control of crude drugs and herbal formulations is of paramount importance in justifying their acceptability in modern system of medicine. But one of the major problems faced by the herbal drug industry is non-availability of rigid quality control profile for herbal material and their formulations.

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 task of defining standards for quality control of herbal crude and their formulation involves biological evaluation for a particular disease area, chemical profiling of the material and laying down specification for the finished product. Therefore, in case of herbal drugs and product, the word “Standardization” should encompass entire field of study from cultivation of medicinal plant to its clinical application.

Plant material and herbal remedies derived from them represent substantial portion of global market and in this respect internationally recognized guidelines for their quality assessment and quality control are necessary. WHO has emphasized a need to ensure quality control of medicinal plant products by using modern technique and by applying suitable parameters and standards. And to ensure quality control of medicinal plant products we need to know the phytochemical constituents along with the pharmacological actions of the respective compounds of the medicinal plants.

To comply with any monograph standard, there is a need for appropriate analytical methods for determining identity, quality, and relative potency using these compounds. Nowadays, with the use of sophisticated methods of analysis like TLC, HPTLC, HPLC, it is possible to isolate and set up certain standards for analysis of a particular constituent from Ayurvedic formulation.
One of the methods of standardization is “Marker Based Standardization” with one or more constituents present in the drugs as standards for quantitation. This method is more convenient, reliable and once developed and validated as per guidelines, can very well adapted for routine analysis irrespective of number of samples. The well structured SOPs can be framed with this method of standardization.

Thus the aims and objectives of the present research work are:

- To develop simple, convenient and reproducible methods for standardization of different Ayurvedic / herbal formulations with the marker compounds by the modern analytical techniques such as HPTLC and HPLC.
- To apply the developed and validated chromatographic methods for study and determination of stress degradation of the marker compound/s.
- To extend application of the validated method for pharmacokinetic study of marker compound/s in rats.