3. AIM OF WORK

3.1 Aim and Objective

The use of herbal medicine has sudden increase due to toxicity and side effects of allopathic medicines throughout the industrialized and developing world as home remedies and over the counter drugs. Rural populations in the developing world depend on medicinal herbs as their main source of primary healthcare. In olden times, vaidyas treat patients by preparing drug according to the requirements of the patient on individual basis. But the scenario has changed now; herbal medicines are manufactured on the large scale in Pharmaceutical units. The quality control of crude drugs and herbal formulations is of paramount importance in justifying their acceptability in modern system of medicine. Manufacturers come across problems such as availability of authenticated quality raw material, availability of standards and non-availability of rigid standardization methodology of single drugs, formulation and quality control parameters. The nature of the herbal ingredients 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 common to have five or more herbal ingredients in one product. Thus batch to batch variation starts from the collection of raw material. These variations multiply during storage and further processing.

The word “Standardization” for herbal drugs and product covers entire field of study from cultivation of medicinal plant to its clinical application. Plant material and herbal remedies derived from herbal drugs represent substantial portion of global market. This necessitates internationally recognized guidelines for their quality assessment and quality control. WHO has emphasized a need to ensure quality control of medicinal plant products by using modern technique and by applying suitable parameters and standards. 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. ‘Marker based Standardization’ is the standardization methods with one or more
constituents present in the drugs or formulation as standards for quantitation. The method is more convenient, reliable and once developed and validated as per guidelines, can be adapted very well for routine analysis irrespective of number of samples. The well-structured SOPs can be framed with this method of standardization.

The aim and objective of the present work is to develop simple, convenient and reproducible validated methods for standardization of herbal raw materials and formulations with the marker compounds; berberine, curcumin, glycyrrhitin acid, piperine, embelin, l-dopa, diosgenin and withaferin A using HPLC, a modern analytical technique, as per ICH guidelines.

3.2 Plan of Work

1. Review of literature
2. Collection and authentication of plants
3. Evaluation of physicochemical parameters like ash values, extractive values, loss on drying, pH value, Microbial contamination etc.
4. Preliminary phytochemical screening
5. Collection of reference standards
6. Preparation of extracts and polyherbal formulation
7. Selection of wavelength
8. Selection and optimization of mobile phase
9. Preparation of standard and sample solutions
10. Preparation of calibration curves
11. Validation of developed HPLC method