CHAPTER-3
OBJECTIVE &
PLAN OF STUDY
3. Rationale of the study and plan of work

3.1. Rationale of the study

Herbal medicines have a strong potential in the primary health care. Most Ayurvedic and Unani traditional products are marketed as dietary supplements worldwide. Although herbal medicinal products have been perceived by the public as relatively low risk, there has been more recognition of the potential risks associated with this type of product as the use of herbal medicines increases. Potential harm can occur via inherent toxicity of herbs, as well as from contamination, adulteration, plant misidentification, and interactions with other herbal products or pharmaceutical drugs. Quality control is crucial to ensure the safety and correct handling of herbal medicines. There have been numerous reports on the toxicity, the misidentification and substitution of plant species. Herbal medicines have been reported to contain heavy metals and synthetic prescriptions or non-prescription drugs. The prevalent use of herbal medicines due to their easy availability has raised concerns over their quality, efficacy and safety. Many herbal products are sold even without prescriptions and consist of a decoction of several herbal materials defined in a formula. As a result, the clinical application of a particular herbal medicine is the synergistic effect of multiple chemical compositions. In this case, the pharmaceutical approach of analyzing a single ingredient cannot be applied to discern the quality of herbal preparation. Thus, quality control methods which reflect the holistic approach of complementary medicine have to be developed in order to determine the chemical basis of herbal medicines. Current herbal standardisations are often based on the quantitative analysis of a single compound, which may not reflect the total characteristic, bioactive and toxic nature of the herbs or products. Therefore, there is a need to establish internationally recognised methodology for quality standardisation of traditional herbal medicines like multiple marker based quantification, determination of total metabolite content or application of hyphenated techniques such as LC-PDA, LC-MS or GC-MS which will give better understanding of bioactive multi component herbal formulations (Priti and Rajani, 2010; Rajani and Kanaki, 2008). Hence, in the present investigation an attempt had been made for quality control of compound traditional Unani formulations using multiple marker based analysis by HPLC/HPTLC/GC-MS methods in addition to additional quality control parameters.
3.2. Plan of work

- Selection of formulations.
- Physico-chemical evaluation of formulations.
  - Description
  - Loss on drying
  - Moisture content determination by Karl-Fischer method
  - Total ash
  - Acid insoluble ash
  - Water soluble ash
  - pH of 1% solution
  - pH of 10% solution
  - Extractive value determination by Successive Extraction Method
  - Alcohol soluble matter
  - Water soluble matter
  - Total phenolic contents by UV spectrophotometer
  - Determination of sugar content by Anthrone Method
  - Dimensional variation
  - Disintegration test
- Determination of contaminants
  - Chemical contaminants (Heavy metal, Pesticides residues)
  - Fungal contaminants (Aflatoxins)
- Development of HPTLC fingerprinting.
- Development of fingerprint profile by GC-MS
- Development of analytical methods for the quantification of marker constituents (HPLC/HPTLC/UPLC-MS/GC-MS).
- Validation of the developed method.