Chapter 2.

AIMS and OBJECTIVES.

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Mahamrutyunjaya rasa is an ayurvedic herbo-mineral formulation often used to treat cardiac disorders. It has been prescribed in the *A.S.S. Rasa-Rasayana Prakarana* as a *Hrydayottejaka.* Ayurvedic literature records the formula of *Mahamrutyunjaya rasa* as: 1 part each of powdered purified *Aconitum ferox, Solanum indicum, Piper nigrum* and *Piper longum,* sieved and then mixed with 1 part each of purified sulphur and purified sodium metaborate. To this mixture 2 parts of purified cinnabar was added and mixed uniformly.

It was observed that the formulation contains a number of contituents which have a very narrow therapeutic index. Further, studies on such ayurvedic cardioactive formulations is of important consideration, since cardiovascular remedies are usually taken for long periods of time. The presence of large number of minerals further complicates the issue of safety of such formulations. Thus, development of quality control methods and safety as well as efficacy studies are important for such muti-component therapies in the present scenario.

Although, the physical parameters prove to be important standardization tools, the quantitative assessment of bioactive molecules (marker compounds) have been empirically and scientifically proven to be better standardization parameter. Therefore, there is an urgent need to develop analytical methods for quantification of the active constituent in the polyherbal formulations.

The present study is thus aimed at developing new standardization tools for assessment of safety, quality and efficacy of *Mahamrutyunjaya rasa.* The present study was planned in the following manner:

1. Quality control of crude drug materials.
2. Isolation of the Chemical Markers and their characterization.
3. Selection of marketed formulation.
4. Preparation of laboratory formulation.
5. Standardization of the procedure for formulation preparation.
   - Collection of intermediate samples during processing *(Shodhana).*
   - Study the physico-chemical changes using XRD, IR, DSC and HPTLC studies.

6. Physical Standardization of the formulations on the basis of IP and WHO guidelines.
7. Chemical Standardization of the formulations.
   - Development of Analytical methods using sophisticated techniques like spectrophotometry, spectrofluorimetry, HPLC, HPTLC, voltammetry and ICP.
   - Validation of the developed methods
   - Development of stability indicating methods for the marker components.
   - Development of analytical methods for simultaneous estimation of the active constituents.
8. Biological Standardization of the formulations
   - Toxicity studies
   - *In vitro* cell viability studies
   - Studies on the cardio-active activity using Isoproterenol induced myocardial infarction in rats.