

Fifty percent of all prescribed drugs throughout the world are derived or synthesized from natural products, the only available sources for which are animals, marine, plants and micro-organisms. It is considered that because of the structural and biological diversity of their constituents, plants offer a unique and renewable resource for the discovering of potential new drugs and biological entities. Between 1983 and 1994, 41% of new approved drugs have natural products as their source, which indicates that natural products still play a very important role in the development of new medicine.

Many clinical disorders are associated with the immune system. Suppression of the immune system is required in the management and treatment of inflammation and allergic diseases, while stimulation is highly desirable for the treatment of HIV, immunodeficiency and infectious diseases.

At the time of starting this project H<sub>1</sub>N<sub>1</sub> virus and AIDS were considered a universal threat and sincere efforts were being made everywhere to find the means to control the epidemic. Several reports were then published indicating the anti HIV properties of several herbal extracts. The drugs selected for the present study are reported to show strong activity against HIV and HSV, but due to unavailability of suitable model these activities could not be tested and efforts were made to develop a standardized polyherbal formulation for immunomodulatory activity of these drugs using a modern approach.

The present work therefore aimed to evaluate and standardize the selected plant drugs such as *Glycyrrhiza glabra*, *Nelumbo nucifera*, *Prunella vulgaris* and *Zizyphus jujube* for the claims made under traditional systems for their antioxidant and immunomodulatory activities and prepare polyherbal formulations.

It was observed that herbal formulations contain a number of constituents which have a very narrow therapeutic index. Thus, development of quality control methods and safety as well as efficacy studies are important for such multi-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 for polyherbal formulation. The present study was planned in the following manner:

The specific aim of the work undertaken was:

1. Preliminary pharmacognostical parameters:
  - a) Collection and authentication of plant materials.
  - b) Morphological and microscopical identification.
  - c) TLC fingerprinting of different components.
2. *In-vitro* antioxidant activity of extracts.
3. Preparation and optimization of formulation by *in vitro* antioxidant activity using Design of experiment.
4. Development of standardization techniques in terms of
  - a) Physical standardization according to WHO guidelines.
  - b) Phytochemical standardization: Chemical tests and TLC studies.
  - c) Chemical standardization: Method development and validation for the quantitative analysis of active constituents using UV, HPLC, HPTLC, Spectrofluorimetric and other methods.
  - d) Biological standardization: Toxicity studies, pharmacological activity and cell viability studies.