3. SCOPE AND OBJECTIVES

Traditional medicines are used by about 60% of the world's population. Current estimates indicate that about 80% of the people in developing countries still rely on traditional medicines based largely on various species of plants and animals for their primary healthcare. Although medicinal plants are used as remedies for various diseases worldwide, standardization, quality control, safety and efficacy remains a big challenge in the herbal drug discovery and development. Therefore, medicinal plants should be explored in various aspects of phyto-pharmaceutical research such as applications of hyphenated techniques for quality control, discovery of new chemical entities, novel pharmaceutical formulation development, etc. Despite of the fact that Gymnema sylvestre extract has been widely explored for its chemistry, preclinical and clinical pharmacology for its antidiabetic activity in Type I and Type II diabetes, as prerequisite, there was a need of more detailed and interdisciplinary research on Gymnema sylvestre extract. Further, a cursory review of literature available also indicated that there is no direct published report or claim on the anti-diabetic and anti-hyperlipidaemic activity of its hydrolyzed product; gymnemagenin (GMG). Therefore, the aim of the study is to explore newer approaches in herbal drug discovery and development with special emphasis on quality control, standardization, bioavailability, antidiabetic activity of GMG, novel formulation development and herb-drug interactions taking Gymnema sylvestre as a case example.

The objectives of the present study were as follows;

- To develop a novel, selective and sensitive method for quantitative estimation of gymnemagenin from various Gymnema sylvestre formulations and extract using HPLC-ESI-MS/MS as a quality control tool.
- To isolate, and characterize GMG from Gymnema sylvestre extract.
- To perform the safety assessment of Gymnema sylvestre extract and isolated GMG as per OECD guidelines.
To determine absolute bioavailability of gymnemagenin (GMG) after oral and iv. administration.

To develop, optimize and characterize of *G. Sylvestre* extract and GMG loaded polymeric nanoparticles.

To study comparative bioavailability of developed polymeric nanoformulations with *G. sylvestre* extract and GMG.

To prepare & characterize sodium and potassium salts of isolated GMG.

To compare anti-hyperglycemic potential of GMG, GMG sodium, GMG potassium salts, and GMG nanoparticles with *G. sylvester* extract in streptozotocin induced diabetic rats.

To study the antiproliferative effects of GMG using MTT assay.

To study *in silico*, pharmacokinetic and pharmacodynamic interactions of *G. sylvestre* extract with selected conventional drug; Glimepiride.