Preface

In spite of the rapid advancement in modern medicine and understanding the etiopathogenesis of Non-Insulin Dependent Diabetes Mellitus (NIDDM), there is an alarming rise in the insulin resistance cases and failure of Oral hypoglycemic agents (OHA’S). Increasing intake of non dietary constituents of food and drinks and the increased use of fertilizers, chemicals, pesticides and insecticides in production sector causing an altered glycemic state due to declined glycogenesis and increased gluconeogenesis in addition to decreased pancreatic beta cell activity, ultimately resulting in Diabetes mellitus. And it is squeal due to varying glycemic state even with antidiabetic regime. Various herbs have been found beneficial in the management of NIDDM and are gaining considerable recognition in the management of NIDDM worldwide. In Ayurvedic Material Medica, mention of several plants has been made for the control of Diabetes. The exhaustive phytochemical research has revealed several phytoconstituents having antidiabetic activity. Keeping in mind about the multifactorial and complex etiology of NIDDM and its alarming growing incidence, it is necessary to consider herbal therapy along with synthetic drugs as mono\combo therapy. This will enable us to manage early diabetic stage and secondary failure in diabetic patients.
Taking lead from the aforesaid facts, an attempt has been made in the present study to formulate and standardize an effective new herbal formulation using the plants, which are perennial, widely grown, economical and easily available. As per folkloric claims and Ayurvedic texts the plants selected for study were known to possess the antidiabetic property. Two such herbs (*Alternanther sessilis* and *Caralluma attenuate*) were selected for the investigation. It is found that so far no systematic work has been carried out on these two plants. Both the herbs were phytochemically tested for the presence of active constituents and the plants were extracted by soxhlet method with water and ethanol and subjected to column chromatography for isolation of various active constituents. The UV, IR, $^1$H NMR, MASS, LCMS, HPLC and TLC techniques were performed to confirm the presence of various phytochemical constituents and for their structural characterization.

Extracts of both the herbs were subjected for hypoglycemic, antidiabetic, sub acute toxicity and insulin secreting activity tests on rats. And the extracts of both the herbs were formulated into granules with widely used cereals and pulses for Diabetes like, ragi, channa, soya along with other ingredients like, skimmed milk powder, guar gum and sweetener. The process of germination was used to increase the nutrient content of ragi,
channa and soya. The formulation was standardized by various physical, chemical, microbiological and chromatographic parameters, stability studies were conducted as per the ICH guidelines for a period of six months. Further, the antidiabetic and hypoglycemic activity of the formulation was carried out on rabbits. Effectiveness of the formulation in regulating the sugar levels was tested in selected group of patients by administering 15 g of formulation twice daily for four weeks, selected subjective parameters such as generalized weakness, fatigue, leg cramps, burning sensation in hands and soles, constipation were also evaluated during the course of investigation.

The entire work has been presented in four chapters, the first chapter contains introduction and scope of the study with comprehensive literature relating to the present investigation. The second chapter deals with the materials used and the methods adopted for the present study. The results obtained in the present study are incorporated in the third chapter followed by summary and conclusion in the fourth chapter. The results presented in various chapters are summarized for providing comprehensive information on formulation and development of a new herbal drug for control of Type-II Diabetes.
Lastly I regret for any grammatical and typographical errors in the thesis as a consequence of oversight and I request for condonation of the same.

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