PREAMBLE

Ayurveda the Science of life bestowed health and longevity in the form of preventive and curative measures. The preventive measures deals with the treatment without medicines, where as curative aspects are mainly covered by drugs i.e. Dravya. In ancient treatise we find a vivid description of drugs and disease solely attributed to metabolic derangement along with genetic predisposition. It believes in Swasthaparayanata, which means maintenance of health on one hand and treatment of disease on the other. Ayurvedic drugs have made a dent in the international markets, which are looking towards alternative medicine for the cure of ailments to which even modern system has no answer. These ailments include metabolic or degenerative disorders like arthritis, diabetes, cancer, dementia, age related disorders, immunological and gynecological problems.

In Ayurveda, presently there are about 1000 single drugs and 8000 compound formulations. Holistic approach of Ayurveda in regard to preventive, promotive and curative measures with due consideration of health and disease is well established. The aim of medical science is to provide better health to every human being so as to have a nice tomorrow. Different medical sciences with various principles and fundamentals are trying their best for one common goal i.e. health for all. To achieve this goal, the science should be able to eliminate the disease without any side effects. Even though many research is going on but in spite of all sorts of advancements of science, in this world, man is not able to sail himself in the boat of happy and healthy life. Unnatural ways of life style, increased population and moreover the world of machines have created unlimited desires in human mind on one hand; while on the other hand, directly or indirectly it has originated anxiety, anger, hostility and grief. So, many diseases are influenced by unnatural dietary habits, restless lifestyle and stress, one of them is diabetes.

Diabetes mellitus is a major health problem for the world in the 21st century. In the year 2000, India, China, United States, Pakistan and Japan with 32.7 million, 22.6 million, 15.3 million, 8.8 million & 7.1 million diabetics respectively, are the countries having largest numbers of diabetic persons. At least 50% of all people with diabetes are
undiagnosed even though there is quite advanced medical research. It still remains a burning problem. Recent studies reveal that the prevalence rates are 10-18% in the urban Indian adult population and there is also evidence that the prevalence of type-2 diabetes is increasing in rural population too.

Diabetes mellitus can be correlated under the umbrella of Prameha. In the management of Prameha many single and compound formulation were described in Ayurvedic Text. However lot of research work already have been conducted various herbs for their antidiabetic activity. Some of the plants like Guduchi, Neem, Karavellaka, Kumari, etc. In Bhavaprakash Nighantu Kakamachi is explained as Mehajeeta. It is Tikta Katu Rasa, Ushna Veerya and Katu Vipaka in Nature. Kakamachi was screened for various activities like antimicrobial, anti fungal, hepato-protective, anticancer, antioxidant, etc. Surprisingly its antidiabetic activity is yet been explored. Hence for the present study it has been selected for antidiabetic activity in NIDDM (Type 2).

Numerous therapies have been advocated by ancient Acharyas (Philosophers) in the management of each and every disease, but their efficacy needs re-establishment by means of thorough and intensive researches. Ayurvedic science has its foundation in the doctrine of Tridosha - Vata, Pitta and Kapha (wind, bile and Phlegm). Ayurvedic treatment can differ for the same disease from individual to individual, which are standardized and express the mode of action of drug (Aushadha) in terms of Rasa, Guna, Veerya, Vipaka and Prabhava. This concept forms the basis for the selection of particular drug for the specific disease / disorder. Other concept of Ayurveda includes D.hatu, Prakriti, Vikriti, Agni, Ama, Pathya, and Apathya etc. Most of the traditional medicines were standardized based on the traditional concepts mentioned above instead of instruments, so any method of quality-control should support above parameters with evidence based documents for its standardization then only drug’s efficacy and efficiency can be considered as proved and will be helpful in another area drug discovery.

Though the use of many indigenous drugs has been described in classics and in practice for the treatment of Diabetes, still there is a need for more effective drug, which can cure or control the disease promptly. In the country like India many people are below the poverty line and cannot afford the expensive treatment for diabetes. In such condition there is heavy need of such a drug that should be effective, cheap, abundant and easily
available to a common person. Hence the selection of Kakamachi was done for the study entitled “Study of the Antidiabetic Effect of whole plant of Kakamachi (Solanum nigrum Linn.)”.

AIMS AND OBJECTIVES:
- To authenticate and standardize the herb by modern techniques
- To assess the experimental and clinical efficacy of Kakamachi in Diabetes Mellitus (NIDDM- Type-2)
- To specify the mode of action of Kakamachi in Diabetes Mellitus Type 2
- To assess the adverse effect of the drug if any in Kakamachi

MATERIALS AND METHODS:
The entire study was conducted in the following stages-
- Collection of genuine herbs from their habitat and collection of market samples.
- Standardization of the Drugs-
  This has been done to confirm for identity, purity, and quality of the drug. The focus is to be given on the standardization of Kakamachi by means of various parameters like microscopic, macroscopic, determination of ash content, HPLC, Heavy metal, etc.

Safety study
- This has been done to ensure the safety of the drug and conducted in Swiss albino rats as acute and sub-acute toxicity study.

Clinical Study-
Clinical study conducted to ensure the efficacy of Kakamachi in the 90 patients of Diabetes Mellitus type-2, NIDDM. Permission and no objection certificate of the Institutional Ethical Committee (IEC) have been taken prior to the trials. These patients of the disease have been divided into three groups by random sample method by including minimum 30 patients in each group. These three groups are as follows-
- Group A- Kakamachi whole plant powder.
- Group B- Sulphonylurea group medicine.
- Group C- Kakamachi whole plant Powder with Sulphonylurea group medicine.
Dose of 3 gm two time a day for 12 week was given and same dietary regime and daily regime was advised in all the groups.

The present study carries a clinical screening of a drug for its antidiabetic property as supposed to be mentioned in traditional textbook. It is also concentrated on clinical study of Kakamachi as antidiabetic effect by investigating various parameters like, Blood Sugar, complete Lipid Profile, Liver Function Test and Kidney Function Test, as a safety assessment.

PRESENTATION-

To fulfill the aim and objectives, the study plan was divided into VI Chapters.

The First Chapter, Drug Profile consists of detailed conceptual studies about Kakamachi \( (\text{Solanum nigrum} \ \text{Linn.}) \) from the Ayurvedic Text as well as Modern Literature. This chapter deals with historical background. Nirukti of the Kakamachi, synonyms and their interpretations, literature identity in Ganas. Vernacular names, taxonomy, ecology, part used, properties, therapeutic uses, formulations, and review of previous work, etc.

The Second Chapter consists of Disease Profile which deals with historical aspects of correlation with Diabetes in the form of Prameha. Definition, meaning, relation with Prameha, review of antidiabetic Karma in Ayurveda, assessment of antidiabetic action / pramehaghnna action, pharmacodynamics of antidiabetic action, list of some pramehaghna drugs Ayurvedic review of diabetes, historical review, modern review of literature on etio-pathological aspects of Diabetes Mellitus.

The Third Chapter deals with the Standardization by means of Pharmacognostic and toxicity study as a pre-clinical study by analytical and experimental manner on Solanum nigrum. This study is carried out as macroscopical, microscopical characteristics of plant, evaluation of different ash contents, extractives, fluorescence study, phytochemical study, chromatographic study, Heavy metal analysis, acute and sub-acute toxicity study, etc.

The fourth Chapter deals with the Clinical study carried out for its antidiabetic activity. This includes activity of Kakamachi on various parameters like symptomatology of Prameha Vyadhi as a subjective and Blood sugar levels, lipid profile, glucose tolerance test, etc as objective parameters. The liver function test, kidney function test are also
carried out to assess the toxicity of the drug on the vital organs and confirm its safety levels.

The Fifth Chapter deals with Discussion and Conclusion about the entire work under the title. There is discussion on the drug literature, its analytical and experimental study, disease profile and clinical study, and at last conclusion of the entire work.

The Sixth Chapter gives a brief Summary of the present study.

At last the bibliography and annexure along with the consent form was included.