1. INTRODUCTION

Diabetes is a chronic disorder of carbohydrate, fat and protein metabolism characterized by increased fasting and postprandial blood sugar levels. The global prevalence of diabetes is estimated to increase from 4% in 1995 to 5.4% by the year 2025 [WHO, 1999] has predicted that the major burden will occur in developing countries. Studies conducted in India in the last decade have highlighted that not only the prevalence of diabetes is high but also increasing rapidly in the urban population. It is estimated that there are approximately 33 million adults with diabetes in India. This number is likely to increase to 57.2 million by the year 2025 [Ramachandran et al., 2002].

As diabetes is a multifactorial disease leading to several complications and therefore demands a multiple therapeutic approach. For example, to manage post-prandial hyper-glycaemia at digestive level, glucosidase inhibitors such as acarbose, miglitol are used. These inhibit degradation of carbohydrates thereby reducing the glucose absorption by the cells. To enhance glucose uptake by peripheral cells biguanide such as metformin is used. Sulphonylurease like glibenclamide is insulinotropic and works as secretagogue for pancreatic cells. Although several therapies are in use for treatment, there are certain limitations due to high cost and side effects such as development of hypoglycemia, weight gain, gastrointestinal disturbances, liver toxicity etc [Dey, 2002]. The hypoglycemic effect of some herbal extracts has been confirmed in human and animal models of type 2 diabetes.

Diabetes mellitus is a serious global health problem and more than 240 million people suffered from this disease. The prevalence rate of the disease varies from country to country being more in India. Diabetes is the name for a group of chronic or lifelong disorders with different causes, clinical features and outcomes. It affects the way the body uses food to make the energy necessary for life. Primarily, diabetes is a defect in carbohydrate (sugar and starches) metabolism that also affects fats and proteins. There are two main types of diabetes: Insulin dependent diabetes mellitus (IDDM) or type 1 diabetes and Non-insulin dependent diabetes mellitus (NIDDM) or type 2 diabetes.
Diabetes mellitus, long considered of minor significance to world health, is now emerging as one of the main threats to human health in the 21st century (Zimmet, 2000). Several epidemiological diseases globally and it is the fourth or fifth leading cause of death. The diabetes epidemic relates particularly to NIDDM which is a complex, constitutional multifactor disorder and recognized antiquity, affecting human society at all stages of development and is present both in developed and developing nations.

In the developed nations, only ageing and the increase in population size will produce a relatively small increase in the further prevalence of NIDDM. However, in developing nations urbanization is occurring rapidly and is producing lifestyle changes, which adversely affect metabolism and are there by causing a large increase in the number of diabetic patients. In the developing countries NIDDM occurs at relatively younger age (30 - 64 years) and in developed countries, it generally occurs in individuals over 65 years.

However, most of these cases are a direct result of poor eating habits, higher in their body weight and lack of exercise. Genetic and environmental factors contribute to the pathogenesis of NIDDM among subjects at high risk because of inherited susceptibility (Groop et al., 1997). The development of NIDDM below 25 y of age is classified as maturity onset diabetes of the young (MODY). They do not require insulin for the control of diabetes for a varying period from the time of detection. They do not have Islet cell antibodies (ICA). Glucokinase deficiency is a marker of MODY.

Type 2 diabetes is caused by a combination of genetic and lifestyle factors (Kaprio et al., 1992). Although genes that predispose an individual to diabetes are considered to be an essential factor in the development of the disease, activation of a genetic predisposition requires the presence of environmental and behavioral factors, particularly those associated with lifestyle. The most significant factors are overweight, abdominal obesity and physical inactivity (Stumvoll et al., 2005). Intrauterine and early childhood influences may also play a role.

The rapidly increasing prevalence of type 2 diabetes demonstrates the important role played by lifestyle factors and provides the potential for reversing the global epidemic of type 2 diabetes. The most dramatic increases in type 2 diabetes have occurred in populations where there have been rapid and major lifestyle changes. These
include changes in diet and reductions in physical activity with consequent increases in the prevalence of overweight and obesity (Zimmet et al., 2001). Risk factors for type 2 diabetes can be classified as non-modifiable and modifiable.

Ramachandran et al. (2002) studied that the various metropolitan cities in India, the prevalence of diabetes in the country is frightening. Nearly 12 percent of the adult population in Delhi and Kolkata, nearly 10% in Mumbai, 12.5% in Bangalore, 13.5% in Chennai and nearly 16% in Hyderabad are patients of diabetes. The number speaks of the magnitude of the problem. According to WHO, (2006) prevalence is due to the adoption of a sedentary life style, smoking, high fat diet and lack of exercise. Therefore India is expected to confront an enormous health care burden due to a large number in the population suffering from this chronic disorder and its sequel.

Approximately 75-80 percent of people with diabetes die of cardiovascular disease (CVD) (Tuomilehto et al., 2004). People with type 2 diabetes have a two to four times higher risk of coronary heart disease (CHD) than the rest of the population, and their prognosis is poorer. The risk of cardiovascular and peripheral vascular disease is also significantly higher.

Patients with diabetes develop clinical cardiovascular diseases they sustain a worse prognosis for survival than do CVD patients without diabetes (Singer et al., 1989). Both IDDM and NIDDM are independent risk factors for CHD (Wilson et al., 1998 and McGill et al., 1998). One reason for the poor prognosis in patients with both diabetes and Ischemic Heart disease seems to be an enhanced myocardial dysfunction leading to accelerated heart failure. Several factors probably underlie diabetic cardiomyopathy are: severe coronary atherosclerosis, prolonged hypertension, chronic hyperglycemia, micro vascular disease, glycosylation of myocardial proteins and autonomic neuropathy.

Type 2 diabetes develops when the production of insulin is insufficient to overcome the underlying abnormality of increased resistance to its action. The early stages of type 2 diabetes are characterized by overproduction of insulin. As the disease progresses, insulin levels may fall as a result of partial failure of the insulin producing β cells of the pancreas. Complications of type 2 diabetes include blindness, kidney failure, foot ulceration which may lead to gangrene and subsequent amputation and appreciably increased risk of infections, coronary heart disease and stroke. The
enormous and escalating economic and social costs of type 2 diabetes make a compelling case for attempts to reduce the risk of developing the condition as well as for energetic management of the established disease (King et al., 1998 and Amos et al., 2010).

Mortality from stroke is increased almost three fold in patients with diabetes than those without diabetes (Stampler et al., 1993). Prospective studies (Gotzsche et al., 1996; Spector, 1998 and McGill et al., 1998) indicated that all of the major cardiovascular risk factors such as: cigarette smoking, hypertension and high serum cholesterol continue to act as independent contributors to CVD in patients with diabetes. Atherogenic dyslipidemia is characterized by three lipoprotein (the Lipid Triad) abnormalities like: elevated VLDL, small LDL particles and low HDL Cholesterol.

Type 2 diabetes is associated with defects in both insulin secretion and insulin action. Endogenous insulin may be normal, depressed, or elevated. However, insulin levels are inadequate to overcome coexisting insulin resistance. Insulin is released by the pancreas in two phases, and persons with type 2 diabetes lose the initial sharp acute release of insulin (first phase insulin release). As a result, insulin levels may be normal, but the effectiveness of insulin is decreased. Resistance to insulin may result from either a post receptor or a cellular receptor defect in peripheral tissues and occurs early in the disease process. At the cellular level, there is a decrease in glucose uptake and utilization, which is reflected by an increase in postprandial glucose levels.
There may also be an increase in hepatic glucose production, especially in the early morning. Hepatic release of glucose is the primary determinant of fasting glucose levels. Fasting hyperglycemia appears to occur somewhat later in the progression of diabetes. Initially, type 2 diabetes may be well controlled by medical nutrition therapy.
alone, but as the disease progresses from insulin resistance to insulin deficiency, medications are needed in addition to medical nutrition therapy. Oral medications may be prescribed as mono therapy or in combination. However, after approximately 10y; 40-50% of the individuals with type 2 diabetes will require exogenous insulin for adequate glycemic control and to prevent complications of diabetes (National Institutes of Health, 1995).

Most of the patients with atherogenic dyslipidemia are insulin resistant (Grundy, 1998; Mostaza et al., 1989). Atherogenic dyslipidemia also have an elevated serum total apolipoprotein B. Severe elevations in LDL cholesterol can produce full blown atherosclerosis and premature CHD in the complete absence of other risk factors. It is true that most patients who have diabetes do not have marked elevations of LDL cholesterol, but these patients nonetheless carry high enough levels to support the development of atherosclerosis. Improved glycemic control, better control hypertension and prevention of atherosclerosis with cholesterol lowering therapy may prevent or mitigate diabetic cardio myopathy.

Oxidative stress in cells and tissues results from the increase generation of reactive oxygen species and from decreases in antioxidant defense potential system (Gumieniczek et al., 2002). Several hypotheses have been put forth to explain the genesis of free radicals in diabetes. These include oxidation processes of glucose; the non-enzymatic and progressive glycation of proteins with the consequently increased formation of glucose derived advanced glycosylation end products (AGEs), and enhanced glucose flux through the polygon pathway (Oberley, 1988; Tiwari and Rao, 2002). Elevated generation of free radicals resulting in the consumption of antioxidant defense components may lead to disruption of cellular functions and oxidative damage to membranes and may enhance susceptibility to lipid peroxidation (Baynes, 1991). Under physiological conditions, a widespread antioxidant defense system protects the body against the adverse effects of free radical production (Halliwell and Gutterridge, 1994).

Literature abounds with information that nutrient and non-nutrients components including oxidants like β - carotene (Johnson, 2002), vitamin C and vitamin E and a number of carotenoids, polyphenols and flavonoids occurring in plant food possess antioxidant property (Venson, 2002) that can offer a protective shield
against various degenerative diseases. Adequate intake of micronutrients within the range of dietary references intake (DRI) prevents deficiency disease and is important in maintaining the health and well being of patients with diabetes (Mooradian, 1999).

Rhodes and Price (1997) reported that whole grains contain dietary fiber and many health promoting components such as vitamins, minerals and phytochemicals, which includes phenolic compounds have antioxidant properties and can protect against degenerative disease (Harborne and Williams, 2000). Research has shown that whole grain consumption helps to lower the risk of cardiovascular disease, ischemic stroke, type II diabetes, metabolic syndrome (Jones et al., 2002).

In the preview of above mentioned background and context of the precarious prevalence of diabetes. Prevalence of diabetes, particularly of type 2 diabetes, the investigator has recognized the significance and need for the present study, which is discussed below.

**Significance and need of the study:**

Type 2 diabetes is a significant health concern. In keeping with the scenario of the prevalence of diabetes, India has long passed the stage of a diabetic epidemic. The problem has now reached, in scientific language, “Pandemic” proportions growing astronomically year after year (WHO, 2000). There are nearly 171 million diabetics in the world, out of which nearly 31.7 million are in India and by the year 2030, there will be 366 million individuals affected by diabetes worldwide out, of which over 79.4 million will be in India. It is now India has the dubious distinction of being home to largest number of people with diabetes. Recent studies revealed that the mortality due to the problems associated with this disease is at alarming rate and hence there is a need to put more research efforts in preventing the diabetes and to find therapeutic measures with safe, cheap and locally available food materials having diabetes controlling efficiency.

In this context analytical study on of the situation of diabetic patients with regard to health is of prime importance and this exercise may be repeated any number of times if resources permit. Use of sample, objective indicators of health has great significance when the assessment is to be made on experimental groups. Diabetes has been proposed as a suitable indicator which suits the public health problem. This
exploration of the data not only on herbal drug supplementation but also regarding body composition, physical activity patterns have been shown because physical activity in diabetes plays a major role. Different levels of energy intakes and energy expenditure and nutritional counseling were also focused. There is a need to examine these aspects in the Indian context.

Herbal Supplementation Capsules formulated with locally available natural food materials and to know the efficacy of such natural food supplementation in controlling obese NIDDM patients. In order to carry out a systematic study, regular obese NIDDM patients from two hospitals in Guntur City, Andhra Pradesh, India were selected. The work was carried out with the following objectives.

**Aims and objectives of the research project:**

- The aim of the study intends to focus on the impact of the herbal Supplementation capsules prepared from herbal products on selected parameters of obese NIDDM patients.

- **To achieve the aim the following objectives were selected:**
  - To examine the socio- demographic data and genetic influences in relation to family history of obese Non –Insulin Dependent diabetes mellitus patients.
  - To study the Antimicrobial activity of leaf products used in supplementation and to evaluate the supplementation impact on obese NIDDM patients.
  - To evaluate the anthropometric measurements and characteristics including height, body weight, BMI and waist hip ratio and body density, fat mass, free fat mass and lean body mass index before and after supplementation.
  - To assess the clinical symptoms and health complications, Micro and macro vascular complications, average food intake dietary pattern and nutrition counseling, energy intakes and energy expenditure with reference to physical activity before and after supplementation of obese NIDDM patients.
  - To examine the physiological assessment including systolic and diastolic blood pressure of obese NIDDM patients before and after supplementation.
  - To analyze the biochemical parameters including fasting blood glucose, post prandial blood glucose, glycosylated hemoglobin, serum creatinine and blood urea nitrogen, Total cholesterol, HDL-cholesterol, LDL-cholesterol, VLDL-cholesterol,
triglycerides and serum antioxidant levels of obese NIDDM patients before and after supplementation.

It is, thus felt, it will be useful to study the selective parameters such as physical, nutritional, clinical, physiological, metabolic, biochemical, microbiological and health care system, examining the impact of Herbal supplementation capsules on diabetic patients.