

Naavudi[®]

FIRST NATURAL
INSULIN-MIMETIC

Information
Booklet

Preface

Diabetes Mellitus (DM) represents a major medical problem affecting millions of people all over the world. Diabetes is a metabolic disorder in which the body does not produce or properly use insulin, a hormone responsible for converting sugar, starch and fats into energy needed for daily life.

The two distinct forms of DM are, Type I, juvenile or Insulin Dependent Diabetes Mellitus (IDDM – an auto immune disease in which body does not produce any insulin) and Type II, adult onset or Non Insulin Dependent Diabetes Mellitus (NIDDM – a metabolic disorder resulting from the body's inability to make sufficient or properly use insulin).

However, since there are more adult onset cases (NIDDM-90-95%) than juvenile ones (IDDM-5-10%); Type II needs more attention.

Despite a significant improvement over the past two decades in our understanding and treatment of Diabetes Mellitus many aspects about the subject need to be elucidated, because the management and treatment of Diabetes Mellitus still remains one of the major challenges for the medical profession.

Looking at the inconveniences and agony of persons suffering from diabetes and trying out various medicaments, developing diabetic neuropathy, increasing renal load and various other complications like haematological disorders, cardiovascular complications, weight loss, lactic acidosis and retinopathy etc., the Research and Development team of Naavudi started working on herbal remedy for diabetes.

On a prolonged study it was found that 'Epicatechin' which is found in abundance naturally in wood commonly known as Vijaysar, (*Pterocarpus marsupium*) mimics insulin in its action. Encouraged by the finding, the team continued to work on developing a combination of herbs and natural products which would be synergistically beneficial to a diabetic patient as a whole. The objective was not only to take care of blood glucose level but also to take care of other peripheral problems associated with it, which cause major distress to the patient.

Standardization of Herbal Formulation

Naavudi has been standardized in terms of "Epicatechin", an active principle of this formulation.

The first step adopted towards attaining quality and consistency is the strict adherence to the rigorous standardized procedure that are followed in the collection of *Pterocarpus marsupium*. Proper identification and selection of the herb, proper time of the year for harvest, proper maturity of the bark of the plant used are the three most important specifications set, that are used for the collection and standardization of all the herbs used.

After proper selection of the herbs, each and every herb is subjected to the rigid standards like assessment of foreign organic matter, water soluble extractive, ethanol soluble extractive, moisture content, microbial contamination and chromatographic finger printing. After proper quality assessment of each and every ingredient, they have to undergo processing. Processing of the herb and active ingredient involve proprietary know-how. In **Naavudi** the active ingredient has been extracted, processed concentrated by a unique technique so that the goodness of whole constituent is incorporated in one capsule.

After successfully developing the combination (formulation), Naavudi was standardized in terms of moisture content, total extractable component, foreign organic and inorganic impurities, total microbial load, active principle 'Epicatechin'; distintegration time, weight variation of the capsule etc.. To make the consistency of the formulation (which is the major problem in herbal formulation) 'finger printing' of the formulation has been developed in terms of specific marker, which is the 'key' of the formulation. Apart from this, the formulation has also been tested in terms of its 'efficacy' under different stressed conditions.

Institute of Toxicological Research Centre, Lucknow for acute toxicity studies and has been found totally free from any side effects.

Formulation

Naavudi capsule has been scientifically formulated to create a better, balanced, complementary and non toxic medicine.

Composition

Proprietary Blend across Composition

Role of Herbal Ingredients

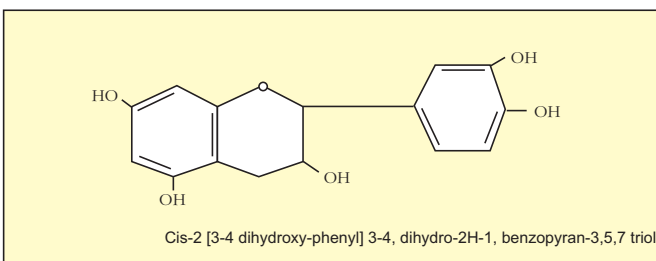
Pterocarpus marsupium	:	Regenerates β cells, mimics insulin, checks blood sugar level.
Momordica charantia Linn	:	Astringent, controls blood sugar level.
Cinnamomum tamala	:	Diuretic, increases blood insulin, stimulates pancreas.
Eugenia jambolana	:	Diuretic, antidiabetic. It diminishes the quantity of sugar in urine; allays the unquenchable thirst.
Melia azadirachta	:	Checks basal metabolism and body sugar level.
Picrorrhiza kurrooa	:	Checks basal metabolism, bitter tonic, corrects the function of liver and kidney.
Ocimum sanctum	:	Diaphoretic, stimulant, anti-stress, adaptogenic.
Gymnema sylvestre	:	Hypoglycemic agent, diuretic, have an oxidase action on glucose solution and shows glycolysis.

The whole formulation of **Naavudi** is based on an active principle 'Epicatechin' which is at the core of the total product. *Other ingredients are added to prevent and cure the different complications of diabetes.* It controls the metabolic derangements rather than mere control of blood sugar level.

Physiology & Pharmacology of Active Principles

Epicatechin the active principle of **Naavudi** is extracted from the bark of *P.marsupium* in a highly scientific manner.

Epicatechin is a benzopyran having the following organic structure.



This active principle controls diabetes in the following manner:

- Ⓐ Epicatechin increases the cAMP content of the islet which is associated with increased insulin release.
- Ⓑ Epicatechin plays a role in the conversion of proinsulin to insulin by increasing cathepsin β activity.
- Ⓒ Epicatechin plays an insulin-mimetic effect on osmotic fragility of human erythrocytes.
- Ⓓ Epicatechin inhibits Na/K ATPase activity on patient's erythrocytes, an effect similar to that of insulin.

First Natural Insulin Mimetic

Clinical Trial Report

A clinical trial has been conducted to evaluate the efficacy of Naavudi in the treatment of Non Insulin Dependent Diabetes Mellitus (NIDDM) at Sir Sunder Lal Hospital by Dr. K.N. Devendra, Consultant – Diabetic Clinic (I.M.), Institute of Medical Sciences, Banaras Hindu University, Varanasi. Dr. K.N. Devendra is a member of Diabetic Association of India (DAI), Research Society for Study of Diabetes in India (RSSDI) and Indian Society of Wound Management (ISWM).

A number of diagnosed patients of Non Insulin Dependent Diabetes Mellitus (NIDDM) were selected for present study from the Out Patient Department (OPD) and In-door of the diabetic clinic, (Indian Medicine), Sir Sunderlal Hospital, Institute of Medical Sciences, Banaras Hindu University, Varanasi.

All the patients were examined clinically for the signs and symptoms of Diabetes Mellitus and subjected for routine Bio-chemical investigations as per clinical protocol. Self control method was used in this clinical trial.

Follow-up Studies

All the patients were assessed on clinical and bio-chemical parameters periodically at the interval of one month, two months & three months.

PARAMETERS OF ASSESSMENT

Assessment was done on objective and subjective parameters.

Parameters of Objective assessment were:

- ▶ Reduction in Fasting and Post-Prandial Blood Sugar Level
- ▶ Desirable change in the status of Body Mass Index (BMI)
- ▶ Changes in Haemoglobin Level
- ▶ Changes in Levels of Serum Cholesterol
- ▶ Changes in Levels of Blood Urea and Serum Creatinine

Parameters of Subjective assessment were:

- ▶ The gentle hypoglycemic activity by natural ingredients

DOSAGE

All the patients were given 1 **Naavudi** capsule twice daily 30 minutes before meals.

Observations & Result

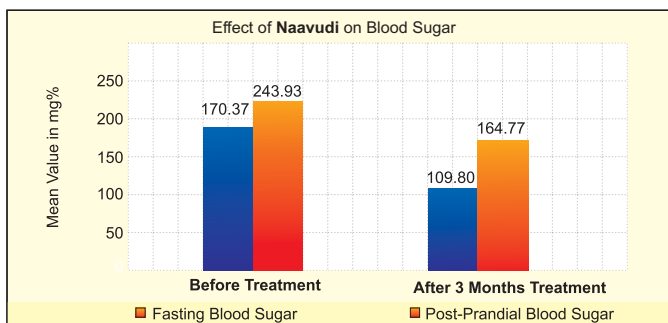
EFFECT OF NAAVUDI ON BLOOD GLUCOSE LEVEL

It was observed that among all the patients who completed 3 months treatment, the Blood Glucose Level fell significantly.

T A B L E - 1

	Blood Glucose Level	Before Treatment	After 3 Months Treatment	P. Value
1.	Fasting Blood Sugar (Mean Value in mg%)	170.37	109.80	<0.001
2.	Post-Prandial Blood Sugar (Mean Value in mg%)	243.93	167.77	<0.001

FIGURE - 1



The Post-Prandial Sugar Level which was 243.93 mg% (Before treatment) was reduced by **Naavudi** to 164.77 mg% at the end of three months therapy which falls within the normal range. The statistically significant efficacy of the drug is evident by its P value (<0.001).

It was observed that, **Naavudi** has moderately good hypoglycaemic action exhibiting persistent glycaemic control with a slow onset of action thus keeping away the danger of drug induced-hypoglycaemia. It is notable that **no case of drug induced-hypoglycaemia was observed during the trial.**

Thus **Naavudi** is very much useful in controlling Blood Glucose Level without any side effects in cases of maturity onset Non-Insulin Dependent Diabetes Mellitus of mild to moderate severity.

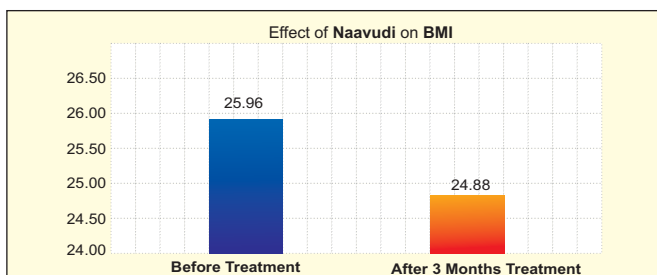
Effect of Naavudi™ on Body Mass Index

Body Mass Index (BMI) is a number calculated by looking at weight in relation to height and is the most common parameter to define obesity which is a most prevalent risk of Diabetes Mellitus.

TABLE - 2

	Before Treatment	After 3 Months Treatment	P. Value
Body Mass Index (BMI)	25.96	24.88	<0.001

FIGURE - 2



As evident from the Table - 2 & Figure - 2, the mean Body Mass Index (BMI) of the patients was 25.96 indicating that majority of the patients were overweight. **Naavudi** reduced their BMI up to a mean of 24.88 indicating a reduction in BMI value towards normal range. P value (<0.01) depicts that **Naavudi is statistically significant in reducing the BMI.**

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Effect of Naavudi on Serum Cholesterol

TABLE - 3

	Before Treatment	After 3 Months Treatment	P. Value
Serum Cholesterol Mean Value in mg%)	229.90	194.03	<0.001

FIGURE - 3

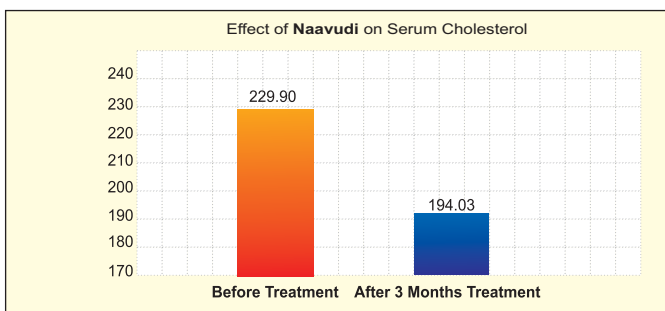


Table – 3 & Figure – 3 shows that Serum Cholesterol level was significantly reduced by **Naavudi** in three months from a mean value of 229.90 mg% to 194.03 mg% thus it also reduces the chance of Ischaemic Heart Disease among diabetic patients. Reduction in Serum Cholesterol level show that **in addition to hypoglycaemic action Naavudi also has Cardio-protective benefits.**

Effect of Naavudi™ on Serum Creatinine & Blood Urea

Increased Serum Creatinine & Blood Urea leads to Nephropathy which is one of the major consequences of Diabetes Mellitus.

TABLE - 4

Sl. No.	Parameters	Before Treatment	After 3 Months Treatment	P. Value
1.	Blood Urea (Mean Value in mg%)	38.23	33.23	<0.001
2.	Serum Creatinine (Mean Value in mg%)	1.57	1.32	<0.001

FIGURE - 4 (A)

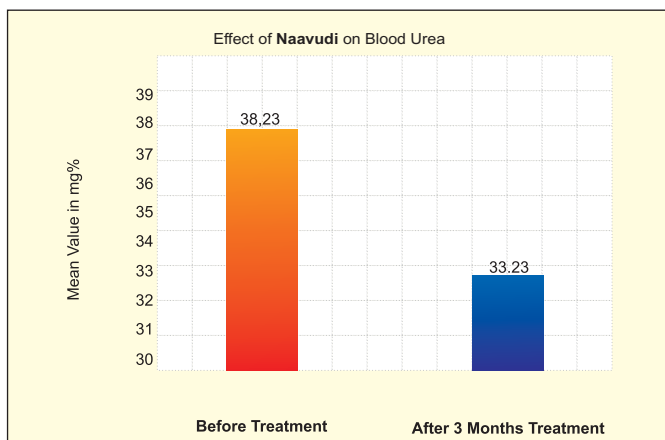
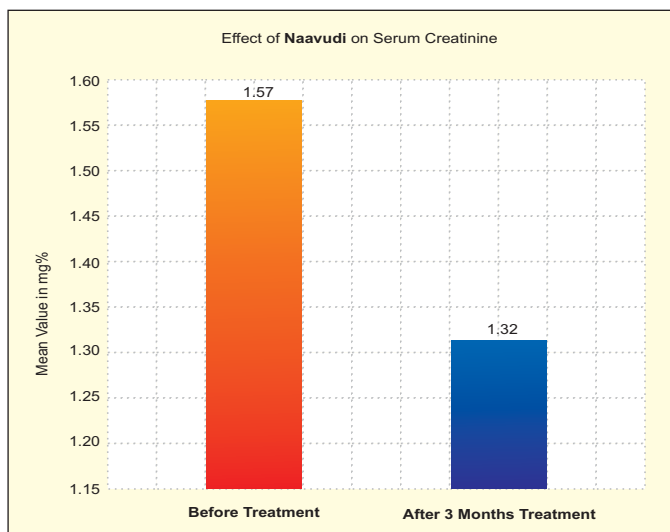


FIGURE - 4 (B)



As it is evident from the Table – 4 and Figure 4 & 5; that the Blood urea level 38.23 mg% which was towards external limit of normal range was reduced significantly up to the level of 33.23 mg% at the end of three months. This is indicative of **Naavudi's** efficiency to improve the functions of kidney as well as its reno-protective action. In addition to above, reduction of the Serum Creatinine value from 1.57 mg% to 1.32 mg% again depicts **Naavudi's** role in reno-protection and in the improvement of renal function

Effect of Naavudi™ on Haemoglobin

TABLE - 5

	Before Treatment	After 3 Months Treatment	P. Value
Haemoglobin (Mean Value in gm%)	11.58	13.27	<0.001

FIGURE - 5

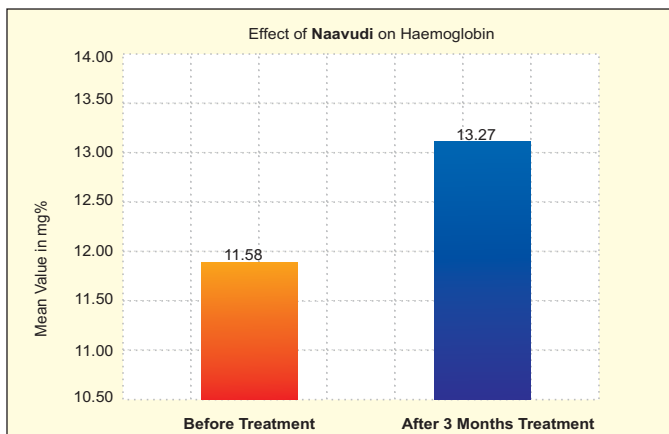


Table – 5 and Figure – 6 illustrates that haemoglobin level was significantly improved by **Naavudi** from a mean value of 11.58 gm% to 13.27 gm% during three months therapy which indicates restoration of positive health of the patient.

Effect of Naavudi™ on Subjective Symptoms

TABLE - 6

S.No.	Symptoms	Percentage Improved
1.	Polyuria	100
2.	Polydipsia	100
3.	Increased appetite	100
4.	Weakness	90
5.	Fatigue	90
6.	Feeling of cold in hand and feet	100
7.	Burning sensation	89
8.	Numbness	100
9.	Paraesthesia	80
10.	Muscular pain	100

Above table shows that there was marked improvement in subjective symptoms. Besides this, a better sense of well being was observed in all the patients. On the basis of the above results this can be concluded that **Naavudi** can also be used in Insulin Dependent Diabetes Mellitus (IDDM) as an adjuvant which in turn will be helpful in reducing the dosage of Insulin and other hypoglycaemic drugs.

Marked improvement in symptoms along with a better sense of well being was experienced by all the patients. This may be due to better glycaemic control exerted by **Naavudi** or we may say that these are the specific Ayurvedic natural constituents of **Naavudi** which in addition to adequate glycaemic control, induces a better sense of well being.

PRESENTATION: Strips of 10 capsules.

Safety

- **Naavudi** is derived from vegetable and herbal sources and manufactured in a highly scientific manner, hence it is very safe for persons of any age.
- Acute oral toxicity study of **Naavudi** has been conducted at Institute of Toxicological Research Centre (I.T.R.C.), Lucknow.

Dosage (mg/kg)	Dead/Dosed	Death	Signs of Toxicity
5000	0/5	NIL	NIL

Naavudi at a limit dose of 5000 mg/kg has not produced any signs of poisoning or death of animals. Autopsy of the surviving animal at the end of the observation period did not indicate any gross pathological changes.

As is evident from the Table - 1 & Figure - 1, that the Fasting Blood Sugar Level was reduced by Naavudi from the pre-treatment value of 170.37 mg% to the level of 109.80 mg% at the end of three months therapy. The P value (< 0.001) shows statistically promising significance of the drug in reduction of Fasting Blood Sugar Level.

Precautions

- Avoid Sweets, Creams, Butter, Cheese, Jams, Pastry & Jellies.
- Avoid taking fatty and fried food stuff with excessive spices.
- Regular morning walk and mild exercise like yoga helps in effective control of diabetes.
- Blood sugar levels should be monitored periodically.

Multicentric trial in NIDDM patients

Encouraged by the results of clinical evaluation of the beneficial role of NAAVUDI in the management of diabetes in NIDDM patients at IMS, B.H.U, Varanasi, NAAVUDI was offered to many doctors in different cities for first hand evaluation of the novel concept of 'Insulin mimetic effect of naturally found Epicatechin'. Doctors who were looking for a natural alternative to modern OHD available because of long term side effects being observed by them accepted NAAVUDI and tried on their patients who were either new cases not responding to dietary controls and exercises or who were on different OHD, singularly or in mixed dose regimen. The data received by these doctors was statistically analysed which presents a very satisfactory finding that NAAVUDI is quite effective in those cases also where the patients were on modern OHD and ultimately leading to total elimination of the dependence on modern OHD to NAAVUDI which being a naturally derived product is free from any long term side effects and on the contrary patients reported distinctive improvement in 'quality of their life'.

Multicentric trial of NAAVUDI in newly diagnosed NIDDM, with mild to moderate blood sugar levels

Sixty patients with a mean blood sugar level of 172 mg / dl (fasting) and 264 mg / dl (post prandial) were put on NAAVUDI one capsule b.i.d. half an hour before meals. Fall in blood sugar level was seen from the first month of therapy and at the end of third month blood sugar level came down to normal. None of the patients had reported any side effects.

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Evaluation of NAAVUDI as adjuvant to OHD (Oral Hypoglycaemic Drugs)

NAAVUDI was added in the drug-regimen in patients who were not responding to OHD (Pioglitazone, Metformin, Glibenclamide, Gliclazide taken alone or as combination of these drugs). The hypoglycaemic effect of NAAVUDI is established since addition of NAAVUDI with OHD brought down the blood sugar level to normal with tapering of OHD requirement to almost half within 2 months.

T A B L E - 9*

Dt. of Testing	Treatment	Total Daily Dose	Blood Sugar Level mg%	
			Fasting	P.P
01.01.2002	Pioglitazone 30mg Melformin 500mg TDS	30mg 1500mg	154	203
25.02.2002	Naavudi 1 BD Pioglitazone 15 mg OD Metformin 500mg OD	2 Caps. 15 mg 1000mg	122	178
05.03.2002	Naavudi 1 BD Pioglitazone 15mg OD Metformin 500mg OD	2 Caps 15mg 500mg	95	150

Dr. Prakash Sharma, M.B.B.S
New Colony, Pratapgarh-230 001

T A B L E - 10*

Dt. of Testing	Treatment	Total Daily Dose	Blood Sugar Level mg%	
			Fasting	P.P
15.11.2001	Glibenclamide 5 mg BD	10 mg		292
31.12.2001	Glibenclamide 5 mg OD Naavudi 1 BD	5 mg 2 Caps.		201
01.02.2002	Glibenclamide 2.5 mg OD Naavudi 1 BD	2.5 mg 2 Caps.		150
02.03.2002	Glibenclamide Naavudi 1 BD	Nil 2 Caps.		126

Dr. Zameer Ahmed, B.Sc.; M.B.B.S
Turkmanpur, Gorakhpur-273 005

Observation

NAAVUDI has hypoglycaemic effect in NIDDM cases. By adding NAAVUDI to the therapy the dose of oral hypoglycaemic drugs is reduced or the same can be discontinued depending upon individual patient.

Doctor's Observations on NAAVUDI in Diabetes Mellitus

"It does not increase weight rather it decreases B.M.I. It decreases significantly PPBS in type II Diabetes Mellitus. It decreases the requirement of O.H.Ds / Insulin if used in combination."

— **Dr. Chakrapani Pandey**, M.D., F.C.C.P.
1, M.P. Building Golghar Gorakhpur

"The response of NAAVUDI on the patients is satisfactory. During treatment there was no hypoglycemia or any other complication."

— **Dr. Chakrapani Pandey**, M.D., F.C.C.P.
1, M.P. Building Golghar Gorakhpur

"My blood sugar fasting before NAAVUDI (treatment) was 265 mg%. After one month blood sugar was 180 mg%. Now blood sugar is normal."

— **Dr. Z.A. Noor**, B.M.S.
Dhampur Road, Nehtaur, Distt. Bijnore

"I tried NAAVUDI capsules on my mother. She was taking glybenclamide 5 mg. OD and metformin 500 mg BID half an hour before meals. She is normal from 1st day (of treatment with NAAVUDI) and physically fit."

— **Dr. Fahimuddin Ansari**, B.Sc.; B.A.M.S.
Raja Ka Tajpur, Distt. Bijnore 246735

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