



Formulation And Evaluation Of Antidiabetic Herbal Capsule

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ABSTRACT

The work presented here deals with formulation and evaluation of herbal antidiabetic capsule containing dried powder of Momordica Charantia Fruit. Medicinal plants are commonly known for their therapeutic value and free from side effects. Keeping this in view, the development of antidiabetic drug from the natural plants being a major thrust area has drawn the attention of the researchers in the field of natural product research because synthetic drugs may cause unwanted side effects. But the lack of complete evaluation for herbal formulations is the most important challenges faced. So, the quality control evaluation is necessary to ensure the quality of the herbal formulations. Hence the present study was aimed to formulate the herbal capsules using the dried powder of Momordica Charantia fruits and evaluated the pharmaceutical quality of herbal capsules formulated. The evaluation parameters include weight variation, disintegration time and uniformity of weight tests. The herbal capsules formulated were achieved the criteria within permitted range for conventional dosage forms as per pharmacopoeial standards. The findings suggested that the formulated herbal capsules of dried powder of Momordica Charantia fruits have passed through all the evaluation parameters .

Keywords: Bitter gourd, Diabetes Mellitus , Herbal Capsule, Evaluation.

INTRODUCTION

Diabetes Mellitus is a syndrome characterized by chronic Hyperglycemia and disturbances of carbohydrate, fat and protein metabolism associated with absolute or relative deficiencies in insulin secretion and/or insulin action. Diabetes mellitus is considered as one of the 5 leading cause of death in the world diabetes mellitus is a major global health concerning with its projected rise in prevalence from 171 millions in the 2000 to 366 million in 2030.

There are 3 types of diabetes

1.Type 1 Diabetes Mellitus

2.Type 2 Diabetes Mellitus

3. Type 3 Diabetes Mellitus

Type 1 diabetes mellitus is also known as insulin dependent diabetes. is an auto immune disorder in which antibody destroy the beta cells of the islets of langerhance in pancreas cause an insulin deficiency i.e pancreas fails to produce an enough Insulin.

Type 2 diabetes mellitus is also known as non insulin dependent diabetes. Type 2 - Non-Insulin Dependant Diabetes Mellitus (NIDDM) is an adult onset diabetes. Most of patients are obese. There is an reduced sensitivity of tissue to insulin.

Type 3 Gestational Diabetes Mellitus, which occurs around 20-24 weeks of pregnancy during which placental hormone are raising and responsible for Insulin resistance.

Plant based medicine has been use cost effectively worldwide to treat diabetes In fact in many parts of the world, especially poor countries this may be the only form of therapy available to treat diabetic patients. Diabetics Mellitus is a group of chronic metabolic disorder caused by due to high blood sugar levels over an prolonged period. Diabetes Mellitus caused by either the pancreas not producing enough Insulin or the cells of the body not responding properly to the insulin produced.

Pathophysiology

There is direct association between hyperglycemia and the physiological responses. The brain recognizes the hyperglycemia and send a message via nerve impulses to pancreas to decrease its effect. Figure (1)

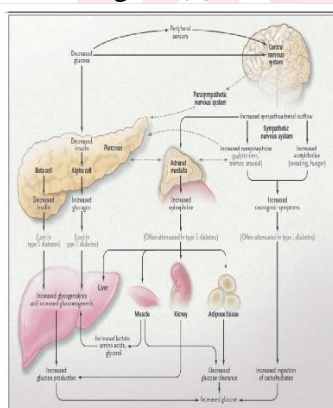


Figure 1 the physiological response to hyperglycaemia

Type 1 diabetes mellitus

Type 1 diabetes mellitus is known by autoimmune reduction of insulin producing cells in the pancreas by $CD4^+$ and C T cells and macrophages which infiltrates the islets. Various features classify type 1 diabetes mellitus as an autoimmune disease: complex and human leucocyte antigen.

The majority of islet antibodies are move against glutamic acid decarboxylase(GApancreatic beta cells; a deficiency in insulin secretion, which leads t metabolic derangement linked with type 1 diabetes mellitus. Beside the loss of insuli secretion, the main function of pancreatic alpha cells seems abnormal which leads to excessive secretion of glucagon. In the normal cases,hyperglycemia results in reduction of glucagon secretion, although, type 1 diabetes mellitus patients, the glucagon secretion is not suppressed by hyperglycemia. Therefore, the result is inappropriate elevation of glucagon which exacerbate metabolic

defects because of the insulin deficiency. However insulin deficiency consider as the primary defect in type 1 diabetes mellitus, also it was found that there is a defect in administration of insulin. From the consequences of insulin deficiency uncontrollable lipolysis and elevation in free fatty acids in the plasma, which lead to suppression in glucose metabolism especially in peripheral tissues, for instance, skeletal muscle. Thus, this mainly impairs the proper utilization of glucose and insulin deficiency, also reduce their function to express which present in the liver only and has its main function in storage of glucose as glycogen, which aids in phosphorylation of glucose to enter glycolysis and gain more ATP. In addition, it results in poor expression of GLUT 4 class of glucose transporters which present in the adipose tissue. (Figure2)

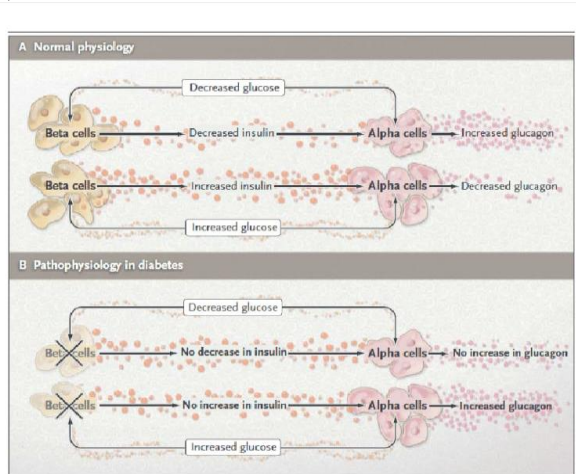


Figure 2 in figure 2a it shows the normal physiological effect of reduction in insulin linked with a low glucose concentration which leads to stimulate of alpha cell glucagon secretion .

Type 2 diabetes mellitus

These mechanisms are break down in type 2 diabetes, the main consequences in the pathology of type 2 diabetes are impaired insulin secretion via a dysfunction of the pancreatic beta cells, in addition, impairment of insulin action through insulin resistance. In cases where the insulin resistance dominates, the mass of beta cells been transformed and has the capability to increase the insulin supply, compensation for the excessive and Figure 2 .

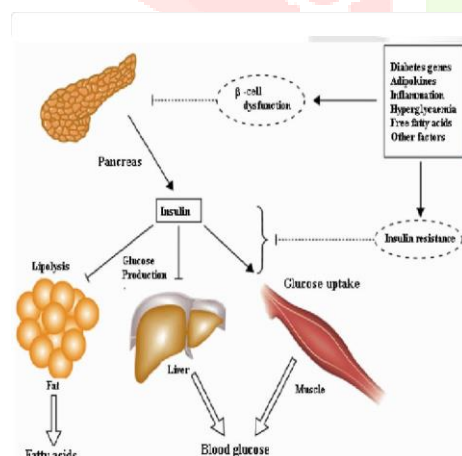


Figure 3 Pathophysiology of hyper glycemia and increased fatty acids in type 2 diabetes

Insulin resistance

It is believed through the primary events, that there is initial deficit in insulin secretion and mainly this relative insulin deficiency associated with peripheral insulin resistance. The significant resistance to the insulin leads to impaired insulin mediated glucose uptake in the peripheral, in addition, incomplete suppressed hepatic glucose output and impaired triglyceride uptake by fat. In order to overcome the insulin resistance, a significant increase

in islet cells leads to increase in amount of insulin secreted. Patients with type 2 diabetes has elevated and accelerated endogenous glucose production or impairment in fasting glucose. As this increase happens in hyper insulinemia.

Clinical symptoms and signs

The majority of symptoms are typical in both types of diabetes, but they may vary in the degree and development, as they more severe in type 1 than type 2. (Figure 4)

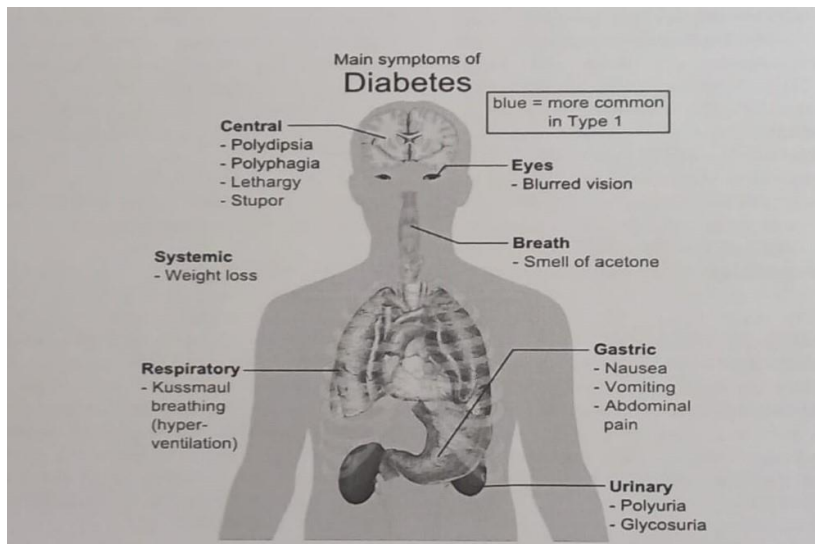


Figure 4 Clinical symptoms and signs of diabetes mellitus

Clinical picture of type 1 diabetes

- Weight loss
- Polyuria
- Polydipsia
- Constipation fatigue
- Blurred vision
- Letharg
- Hyperventilation
- Smell of acetone

Clinical picture of type 2 diabetes

- Atherosclerosis
- Hyperlipidemia
- Hypertension
- Obesity
- Cardiovascular complications

Capsule

Capsule are solid dosage form in which the drug or a mixture of drug is enclosed in a hard gelatin capsule shells in soft soluble shells of gelatin or in hard or soft shells of any other suitable material of various shapes and capabilities. Inside the empty shell of the capsule the powder of *Momordica charantia* is filled. The powder is prepared and filled inside it .

Advantages

1. Capsule mask the taste and odour of unpleasant drugs and can be administered.
2. They are attractive in appearance.
3. They are economical.
4. They are easily swallowed and quickly dissolved in stomach.

Disadvantages

1. Not suitable in emergency and unconscious patients

PLANT PROFILE

KARELA:

Synonyms: bitter gourd , bitter melon

Scientific name : momordica charantia l

Biological source; karela consist of fresh green fruits of the plant known as momordica charantia belonging to family Cucurbitaceae.

Chemical constituents : charantin, momordicin, other constituents the drug are carbohydrate minerals alkaloid glycoside proteins lipid and phenolic compound .



Figure 5 Bitter gourd

TULSI :

Synonyms: holy basil , sacred basil

Scientific name : ocimum sanctum linn

Biological source : tulsi constint of fresh and dried leaves of ocimum sanctum linn . belonging to family labiatic.



Figure 6 Tulsi

MATERIAL AND METHOD

Formulation Table :-

Table 1 : Active Ingredients

Sr.No.	Ingredients	Each capsule 500 mg contains	For 80 capsule batch
1	Bitter gourd	450 mg	36 gm
2	Tulsi	50 mg	4 gm

Equipments :-

Hand operated capsule filling machine

Weighing balance

Dissolution test apparatus

Disintegration test apparatus.

7.1 Preparation of *Momordica charantia* powder:-

Wash and Slice: wash the bitter gourds thoroughly and slice them into thin pieces. You can remove the seeds if you prefer a milder taste.

- **Drying :** Sun-dry the bitter gourd slices until they are crisp and have lost all moisture. This may take several days, depending on the weather.
- **Grinding:** Once completely dried, grind the slices into a fine powder using a grinder or blender. You can sift the powder to ensure a finer consistency.
- **Storage:** Store the karela powder in an airtight container in a cool, dry place.



Figure 7 momordica charantia powder

Phytochemical screening of herbal drugs:

Sr. No	Phyto constituents	Chemical Test	Inference	Result
1	Alkaloids Test	Mayer's test	Appearance of Yellow cream Ppt	Positive
		Wagner's test	Reddish Brown Precipitate	Positive
		Mayer's test	Formation of yellow white ppt	Positive
		Dragendroff test	Red ppt	Positive



Sr. No	Phytoconstituents	Chemical Test	Inference	Result
2	Glycoside	Legal test	Pink to red colour form	Positive
		Baljet test	Yellow orange colour	Positive
		Keller-killani test	Reddish Brown colour	Positive



Sr.No	Phytoconstituents	Chemical Test	Inference	Result
3	Triterpenoids	Liebermann-burchard test	Formation of deep red colour	Positive

Procedure:-

Preparation of capsules of *Momordica charantia*.

- 1) Weigh the required quantity of drug .
- 2) Moisture content should be less than 1.5%
- 3) Bitter gourd and tulsi should be dried and seved though 100 # , moisture less than 1.5
- 4) Mix all the ingredients uniformly using mortar and pestle.
- 5) Empty capsule shells of number "0" is selected and for filling the content in capsule shell hand operated capsule filling machine is used.

Filling of capsules :

Hand Operated Hard Gelatin Capsule Filling Machine

The empty capsules are filled into the loading tray which is placed over the bed. By opening the handle, the bodies of the capsules are locked and capsule separated in the loading tray itself, which is then removed by operating the lever. The weighed amount of the drug was mixed with sufficient quantity of excipients to be filled in the capsules and placed in powder tray already kept in position over the bed. The powders are spreaded with the help of a powder spreader so as to fill the bodies of the capsules uniformly to get 200 capsules. The excess of the powder is collected on the platform of the powder tray. Lowered the pin plate and moved it downward so as to press the powder in the bodies. The powder tray is removed and placed the caps on the holding tray in position. The caps are pressed with the help of plate with rubber top and operated the lever to unlock the cap and body of the capsules. The loading tray is removed and the filled capsules are collected in a tray.



Figure 8 Hand operated capsule filling machine

EVLUATION PARAMETERS

1 weight variation test:-

First of all randomly 20 filled capsules was selected. Weighted the all 20 capsules collectively, and find out average weight by applying this formula.

$$\text{Average weight} = \frac{\text{wt. of 20 capsule}}{20}$$

20

Then weighted each 20 capsules one by one and note down their respective weights then Find out percentage weight variation for each capsule with using formula.

$$\% \text{ Weight Variation} = \frac{\text{Real wt.} - \text{Avg. wt}}{\text{Avg. wt}} \times 100$$

Avg. wt .

Maximum positive to maximum negative range was selected.

2 uniformity of weight:-

Twenty capsules were selected. Each capsule was weighed on an analytical balance, carefully emptied of its content, the shells reweighed and the weight of content determined. The collective weight of content, average weight of content per capsule and the deviations (%) of individual content weights from the mean were calculated.

3 Disintegration Test for Capsule

Disintegration test was performed with the help of the digital microprocessor based disintegration test apparatus by Electro Lab. One capsule was introduced into each tube and added a disc to each tube. The assembly was suspended in the water in a 1000 ml beaker. The volume of water was such that the wire mesh at its highest point is at least 25 mm below the surface of the water, and at its lower point was at least 25 mm above the bottom of the beaker. The apparatus was operated and maintained the temperature at $37.50 \pm 0.5^\circ\text{C}$. The time required to disintegrate all capsules and pass through wire mesh .

4. pH

1 g of capsule powder was taken and dissolved in 100 ml demineralized water. The pH value of the solution was determined by means of a digital pH meter. The pH meter was calibrated using buffers of 4, 9 and 7 pH. The electrodes were immersed in the test solution and pH was measured.

RESULT AND DISCUSSION**1) phytochemical screening test**

Sr.no.	Chemical constituent	Test	Observation	Result
1	Alkaloid	Mayer's test	Appearance of yellow cream ppt	positive
		Wagner's test	Reddish brown ppt	positive
		Hager's test	Formation of yellowish white ppt	positive
		Drangendorff's test	Red ppt	positive
2	Glycosides	Legal test	Pink to red colour form	positive
		Keller kilani test	Formation of deep red colour	positive
3	Triterpenoids	Libermann burchard test	Formation of deep red colour	positive

2) Evaluation parameter test

Sr. no.	Evaluation parameter	Result
1	Weight variation test	497±5%
2	Content uniformity test	Evaluated
3	Disintegration test	Capsule disintegrated within 12 minutes
4	pH	7.33

SUMMARY AND CONCLUSION

The main aim of formulated herbal antidiabetic Capsule was to cure or treat the Diabetic patient. It was concluded that the hebal antidiabetic Capsule which are prepared from natural sources they shows fewerside effect as compared to Capsule which are prepared from synthetic compound. The prepared herbal antidiabetic Capsule was evaluated using various parameter and was found to be satisfied for for the treatment of diabetic patients.

Herbal medicine are still widely using for Primary health care in so many countries because of cultural acceptability, compatibility with human being and with lesser side effects than Synthetic one.

In this study are prepare Antidiabetic Herbal capsule by using bitter gourd fruit, theses herbs possess an potent Antidiabetic activity.

Nowadays, increasing demand for herbal medicine has been Increased People may like to accept the herbal medicine due to their lesser side effects

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