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FORMULATION AND EVALUATION OF ANTIDIABETIC POLYHERBAL TABLETS OF HYLOCEREUS POLYRHIZUS & SYZYGIUM CUMINI

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ABSTRACT

The diabetes has been increasing throughout the globe with an alarming rate due to Lifestyle changes and it has become a global burden requiring attention of the most Populated countries, where its incidence is ever increasing. This research gives Information regarding the herbal drugs will cure the diabetic complication in patient. Herbal antidiabetic drug Treat diabetic mellitus by lowering glucose level in blood and they increase the insulin amount secreted by the Pancreases. Polyherbal formulations enhance the therapeutic action and reduce the Concentrations of single herbs, thereby reducing adverse events. The study focuses on polyherbal formulations Of two different medicinal fruits used for the treatment of Type II diabetic patients.

The peel of red dragon fruit (Hylocereus polyrhizus) had been proven to have a total polyphenol content And total flavonoids 2 to 3 times more than its flesh. These components could reduce oxidative stress and maintain the Function of pancreatic beta cells, which could affect blood sugar levels. Dragan fruit have property to reduce blood sugar level.

This review delineates the utility of Jamun, Syzygium cumini in the treatment of Diabetes And hyperlipidemia. Diabetes is A common disorder inflicting children and adults equally. Jamun or Syzygium cumini belongs to family Myrtaceae and bears sweet fruits that are eaten as such or used to prepare juice, jam, and Cookies. Jamun contains Cardiac glycosides, anthraquinones, catechins, alkaloids, flavonoids, glycosides, steroids, Phenols, tannins, and saponins.

INTRODUCTION

Diabetic mellitus is a systemic metabolic disorder which Is characterized by hyperglycaemia (increase amount of Glucose in blood), Hyperlipidaemia (increase amount of Lipids in blood),

Hyperinsulinemia (Decrease secretion Of insulin in blood) (Chandraprakash Dwivedi, 2013). In This research we were prepared antidiabetic tablet which Is used to cure the diabetic disorder. In the diabetic Disease the insulin secretion and its action are diminish. Chronic hyperglycaemia of diabetes is associated with Long term damage, Dysfunction and failure of various Organ specially the eyes, Kidney, nerves, heart and blood Vessels. Diabetic mellitus are occurs due to alteration of Metabolism of carbohydrate, lipid and proteins. In this Preparation of tablet we were selected two herbal drugs Such as red dragon fruit (**HYLOCEREUS POLYRHIZUS**) & jamun seed (**SYZYGIUM CUMINI**) There are main two type of Diabetic mellitus disorder They were classified depending upon the insulin Dependency.

Type 1. Insulin dependent diabetic mellitus.
Type 2. Non-Insulin dependent Diabetic mellitus.

Type 1:

This type of diabetic mellitus is occur due to Autoimmune disease of beta cell. Due to the destruction Of beta cells of pancreases the circulation of insulin in Blood is not regulated. They are occurs in between the Age of 30 years. In that the beta cells fails to respond to normal stimuli.

Type 2:

This type of diabetic mellitus is not depend on the insulin. Obesity is the major cause of this type of Diabetic mellitus. In that the beta cell count are decrease. This type of diabetic are occurs in age onward 40 year. Symptoms – Polyuria, Polydipsia, Polyphagia, Fatigue And Long term diabetes may causes Gangrene and Myocardial infraction.

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Red Dragon fruit (RDF) is a fruit source that is rich in natural antioxidants, namely betacyanin, flavonoids, polyphenols, ascorbic acid, and also fiber 1. The main antioxidant content in RDF is flavonoids. Flavonoids have a polyphenolic structure which is found in many fruits 2. Increasing RDF flesh consumption leaves the skin that is currently not used optimally.

Apart from the flesh, RDF skin can also be used as an alternative because of its nutritional content and antioxidant effects 3. The total content of polyphenols and flavonoids from 80% methanol extract of RDF skin is three times higher than RDF flesh. The total phenolic content extracted from the skin and flesh is 14.82 ± 1.07 and 4.91 ± 0.55 mg Gallic Acid Equivalent (GAE) / 100g 4.

In type 2 diabetes mellitus (T2DM), hyperglycemia is caused by the inability of Insulin to mobilize blood glucose into cells due to insulin receptor resistance 5. Hyperglycemia increases the autooxidation of glucose from free radicals. In hyperglycemia conditions, the formation of free radicals or Reactive Oxygen Species (ROS) comes from glucose oxidation, on-enzymatic glycosylation of proteins, and oxidative degradation of glycolic proteins 6. The increase in intracellular glucose causes an abundance of electron donors to be generated during the Kreb cycle, thereby pushing the potential of the inner mitochondrial membrane upward - a condition associated with mitochondrial dysfunction and increased production of ROS 7. In addition, ROS will increase the expression of Tumour Necrosis Factor-α (TNF-α) and exacerbate oxidative stress. TNF-α can result in insulin resistance through decreased autophosphorylation (auto-phosphorylation) of insulin receptors 8,9. These oxidative stress markers can be measured using Malondialdehyde (MDA) 10.



Fig. no. 1

Kingdom	*Plantae*
Order	*Caryophyllales*
Family	*Cactaceae*
Subfamily	*Cactoideae*
Tribe	*Hylocereae*
Genus	*Hylocereus*
Species	*H. undatus*[5]

Table 1: Taxonomical Classification

Syzygium cumin (Family-Myrtaceae) The WHO predicts that diabetes will be the 7th leading cause of death in 20301 India leads the world in the number of diabetics who experience the dubious diversity of so-called "diabetic world capital". is increasing worldwide, the prevalence of type 2 diabetes is rising dramatically, perhaps due to obesity, declining employment rates as countries develop economically and as a result of aging. Over time, diabetes can increase the risk of developing health problems, including blindness, kidney damage, nerve damage, amputation, and cardio vascular disease.

Although diabetes cannot be cured, the disease can be controlled by non-pharmacological and pharmacological strategies, where the development of glycemic control factors is important factors in delaying the onset and progression of diabetes-related complications. A great way to manage diabetes can be achieved through diet, exercise and / or treatment instead of insulin.[1] In the modern medical system, managing diabetes without side effects remains a challenge. In India's traditional medicine program, more than 100 diabetic herbs are mentioned where more than one herb combined is used to treat health problems and this herbal extract extracted in the form of a tonic or blend shows better results. [2] Diabetes is a metabolic disorder characterized by hyperglycemia and glucose intolerance.

Pancreas dysfunction is a major cause of these metabolic disorders. This may be due to a lack of insulin production, insulin dysfunction or both. Diabetes is of four types depending on the etiology and presentation of the clinic. Insulindependent diabetes mellitus (IDDM, Type I) and insulin-dependent diabetes mellitus (NIDDM, Type II). Other types of diabetes include gestational diabetes, and certain types.

Diabetes I (IDDM) is an autoimmune disease caused by ly-cell destruction of the Langerhans islands by T lymphocytes leading to local intrusion and suppression of insulin production and this requires treatment instead of insulin. It is characterized by increased peripheral insulin resistance and impaired production of insulin by pancreas. It is more common than type I. People with type II diabetes suffer from intermediate stages of glucose fasting disorders and improper glucose tolerance and hence it is also known as prediabetes. Obesity is one of the leading causes of type II diabetes and 90% of patients with diabetes fall under this category.

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Fig. no. 2

1	Domain	Eukaryota
2	Kingdom	Plantae
3	Phylum	Spermatophyta
4	Subphylum	Angiospermae
5	Class	Dicotyledonae
6	Order	Myrtales
7	Family	Myrtaceae
8	Genus	Syzygium
9	Species	Syzygium cumini

Table :2 Taxonomical classification

OBJECTIVES

1. Blood Sugar Control: To help regulate blood sugar levels and improve insulin sensitivity.
2. Antidiabetic Efficacy: To provide a natural and effective alternative to conventional antidiabetic medications.
3. To formulate herbal antidiabetic tablet by using herbal ingredients such as Dragan fruit & Jamun seed.
4. Evaluation of herbal antidiabetic tablet such as disintegration, dissolution, hardness and friability etc.
5. Reduce blood sugar levels in people with type 2 diabetes.

MATERIAL AND METHODS

a) Material:

1. Syzygium Cumini

1.1. Raw material procurement

The jamun fruits were obtained from the local market. The reagents (analytical and HPLC grade) and standards were pur chased from Merck (Merck KGaA, Darmstadt, Germany) and Sigma– Aldrich (Sigma–Aldrich Tokyo, Japan). Male Sprague Dawley rats used in the bio evaluation trials were obtained from National Institute of Health (NIH), Islamabad. The Diagnostic Kits used for various analyses were from Sigma–Aldrich, Bioassay (Bioassays Chemical Co., Germany) and Cayman Chemicals (Cayman Europe, Estonia).

1.2. Sample Preparation

Jamun fruit was washed and then fruits and seeds were separated. The fruits and seeds were then dried in tunnel drier at 40 C for 24 h. The dried fruits and seeds were ground to a fine powder using a grinder (PHILIPS 600W Type HR 2068). The resultant powders were packed in air tight glass jars and stored in laboratory cabinet at room temperature of 25–30 C for further investigations.

1.3. Preparation of Jamun Extracts (Syzygium Cumin)

The jamun extracts were prepared using binary solvent i.e. aqueous ethanol (50% v/v). About 50 g sample was added in volumetric flasks followed by the addition of solvent. Afterward, the volumetric flasks were placed in orbital shaker operating at 280 rpm and 50 C at temperature for a time length of 45 min. Later on, all extracts were filtered. The filtrate was then evap orated using Rotary Evaporator (Eyela, Japan) at 40 C under reduced pressure for the removal of solvent. The extracts were then stored in sealed bottles for future use.

2. Hylocereus Polyrhizus

Pitaya [Hylocereus polyrhizus (F.A.C. Weber) Britton & Rose] was obtained from Frutacor, which is located in Vale do Jaguaribe - CE (05º 53’ 26” S; 38º 37’ 19” W). The fruits were washed, sanitized, and processed in Embrapa Agroindústria Tropical (Fortaleza-CE). Thus, the pitaya was processed using a pulp-finisher (ITAMETAL/BONINA 0.25 DF) equipped with sieves of different meshes (2.5 and 0.8 mm) to separate the pulp (containing seeds) and the peel, which was discarded. In the end, the pulp and seed (edible portion) was obtained, frozen at −20 °C, lyophilized (LIOTOP LP 510) and tritured using and a mortar/pestle. This lyophilized material was used in all the experiment.

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Sr.no.	Ingredients	Quantity	Role
1	Dragon fruit extract (Hylocereus polyrhizus)	10 g	Api
2	Jamun fruit extract (Syzygium cumin)	10 g	Api
3	Lactose	3.5 g	Diluent
4	Starch	1.75 g	Disintegrant
5	Magnesium Stearate	0.35	Lubricant
6	Talcum powder	0.35	Glidants
7	Accacia	3.5	Binder
8	Methyl paraben	0.30	Preservative
9	Vanillin	0.25	Flavourant

Table No. 3 Ingredients

3. Formulation of tablets

The herbal antidiabetic tablet were prepared by using wet granulation method. In this method the solvent were used for the [reparation of damp mass. All the ingredient were weighed and triturated by using mortar and pestle and this mass was passed through sieve no.8 individually. In the next step the herbal drug, starch (half quantity) and Preservatives (Methyl paraben) mixed with sufficient quantity of water along with small amount of gelatine to form dump mass i.e. coherent mass. The mass was passed through sieve no.16 to form granules and the granules were dried at 500C-600C for 15 min in hot air oven. In that dried granules, remaining quantity of starch, Talc, Magnesium stearate were added mixed with spatula. At the last prepared granules were passed for compression by single punching machine.

b) Method

Wet granulation technique:

Wet granulation is most used process of granulation in pharmaceutical industry during tablet manufacturing. The formulation of granules also helps to reduce segregation and improve the content uniformity of the final product. The effect of formulation and process variable on powder behavior in the granulator can be better understood once the main phenomena involve in the granulation are determined . Tablet represent the most popular drug delivery system . It has been reported that wetting and nucleation and thereby granule attributed were influenced by parameters like nature and amount of liquid binder and its properties like viscosity, density, wettability solidliquid contact angle, liquid droplet size.

Merits

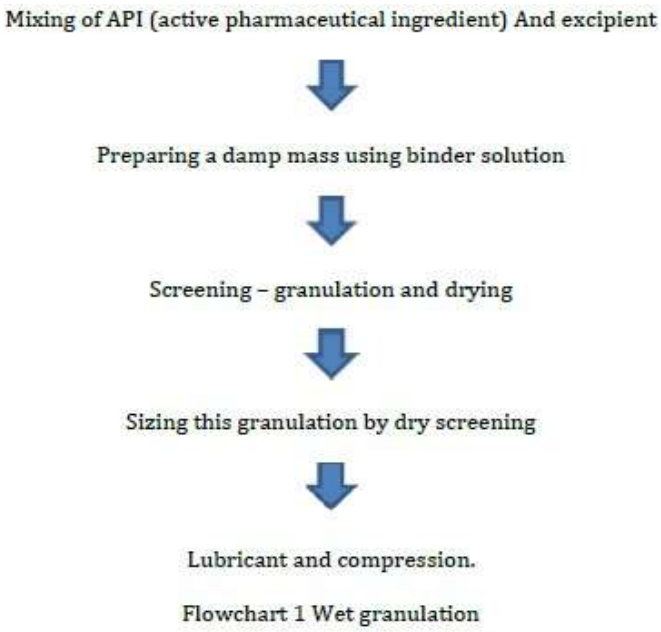
a) It improve flow property and compression characteristics and increase density of granule.
b) Better distribution of color and soluble drug if added in the binding solution. c) It reduce dust hazards.
d) Prevent segregation of powders.
e) Makes hydrophobic surface more hydrophilic.

Demerits

c) Processes is expensive because of labor, space, time, special equipment and energy requirement.
d) Multiple processing steps involved in the process and complexity.
e) Loss of material during various stages of processing.
f) Moisture sensitive and thermolabile drugs are poor candidate.
g) Any incompability between the formulation components is aggravated during the processing.

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Steps



Flowchart 1 Wet granulation

EVALUATION OF TABLET

1. Preformulation study

A. Angle of repose: Angle of repose is were used to check the flowability of the granules in hopper before compression of tablet. Fixed funnel method is used to check the angle of repose. At the specific height the funnel was fixed on the graph paper which is placed horizontally at surface.

Then the granules was passed to the funnel until the apex of the pile touched to the tip of the funnel. Radius was measured by using scale and determined the angle of repose by using following formula.

$\theta = \tan^{-1}(h/r)$

Where,

θ - Angle of Repose h – Height of pile r – Radius of pile

B. Bulk Density: A known amount of granules was transferred into a 25ml of measuring cylinder, carefully level the powder without compacting and measure the bulk volume.

Bulk Density = weight of powder / Bulk Volume

C. Tapped Density: Tapped density is the ratio of weight of powder to theTapped volume. It was determined by tapping a measuring cylinder containing fixed quantity of powder for the specific period of time. The tapped density was calculated by using following formula.

Tapped Density = Weight of Powder / Tapped

D. Hausner Ratio: It was determined after the measuring of Tapped density and bulk density. It is the densitification of the herbal powder mixture which may result from the vibration of the feed hopper which was calculated by using below formula Hausner Ratio = Tapped Density / Bulk Density

E. Carr's Index: Carr's index was used to check the compressibility and flow of the granules from hopper. It is expressed in percentage. Carr's index was calculated by using following formula. Carr; s Index = Bulk Volume – Tapped volume / Bulk volume × 100

2. Hardness: The Hardness of the Tablet is also called as Tablet Crushing strength. Harness test is used to check the hardness of the prepared tablet. In this test we can measured the force which is required for the breaking of the tablet. Monsanto tablet hardness tester is used to check the hardness of the tablet. The hardness is express in Kg/cm2.

3. Weight Variation: It is also called Uniformity of weight. In this evaluation test twenty tablet were weighed separately and then average weight was determined. The percentage deviation was calculated and check for weight variation as per IP.

4. Friability Test: The friability test is used to check the combined effect of abrasion and stock. This test is used to check the tablet is suitable for transportation or not for that purpose Roche Friabilator is used it is laboratoryfriability tester. In that the preweighed antidiabetic tablet sample is placed in the friabilator which consist of plastic chamber that operate 100 revolution for 4 min means 25 rpm. The tablet are then dusted and reweighed. Conventional compressed tablet that loses less than that 0.5-1.0 % of their weight are generally acceptable Fig.4: Friability test

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5. Dissolution Test: Dissolution is the process by which a solid solute enters in the solution. It may be defined as the amount of drug substance that goes into solution per unit time. The disintegration test simply identified the time required for the tablet to break up under the condition of test and all the particles are passed through mesh no.10 screen. The rate of drug absorption of acidic drug is high in GIT. So for that purpose the rate of dissolution is determined. For determination of dissolution rate of tablet we were take 900ml of 0.1N HCL in basket of dissolution apparatus and which were rotated at 50 rpm and time limit of 20 min. The accepted amount dissolution limit for 20 min is not less than 80%.

RESULT

Natural remedies are more acceptable as they are safer with fewer side effect than synthetic once, so an herbal antidiabetic tablet is nontoxic, safe, Efficacious and improve patient compliance as it contains herbal ingredient. This herbal antidiabetic tablet were evaluated for various evaluation test such as preformulation study (Angle of repose, bulk and Tapped density, Carr's index, Hausners ration), Hardness test, Weight variation test, Friability test and Dissolution test and they full fill the value.

Table.2: Result of Antidiabetic test.

Sr.no.	Evaluation parameters	Value
1	Angle of repose	27
2	Bulk density	2.9
3	Tapped density	3.7
4	Hausner's ratio	1.2
5	Carr's index	20
6	Hardness	3.5kg/cm^2
7	Weight	Two tablets were varied in weight
8	Friability	Weight loss 0.55% of its initial weight
9	Dissolution	18 min
10	Disintegration	14 min

CONCLUSION

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

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