

FORMULATION AND EVALUATION OF HERBAL ANTI- DIABETIC TABLET

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ABSTRACT

Diabetes mellitus is a heterogeneous group of disorders characterized by increasing blood glucose level caused by lack of insulin hormone. One of the plants that were often used as traditional medicine for diabetes in Indonesia was bhendi (*Malachra capitata*) fruit. *Malachra capitata* belonging to family Malvaceae is very common erect or underground shrub. It grows up to 1.5 metres tall. *M. Capitata* is planted as fibre plant in India, formerly also in Cuba. The fiber is excellent, 8-9 feet long, and that experts have declared it little, if at all, inferior to jute. The antidiabetes activity of okra fruit extract. The study was divided into several steps: a preliminary study of anthyperglycemia of bhendi fruit after glucose, sucrose, and amylum administration; antidiabetic activity in insulin deficiency animal model developed by aloxan administration and insulin resistance animal model developed by lipid emulsion administration, and in vitro study of α -glucosidase and α -amylase enzyme inhibition activity. The plant is used medicinally; especially the root extracts and seeds are reported to be used medicinally as compared to other parts. Diabetes mellitus is a long-term metabolic condition that has significant social, health, and economic ramifications. The two main causes of the increase are ageing and obesity. The several kinds of diabetes and their associated complications including immune system problems, periodontal disease, retinopathy, nephropathy, somatic and autonomic neuropathy, cardiovascular disorders, and diabetic foot-are introduced in this chapter. Additionally included are emerging therapeutics, existing management, and treatments. Numerous compounds have been isolated and identified from the genus *Malachra* L including flavonoids, steroids, triterpenes, anthocyanins, leuco anthocyanins, saponins, carbohydrates, phenols, glycosides, and alkaloids.

KEYWORDS: Antidiabetic Activity, *Malachra Capitata*, Malvaceae

RATIONALE AND OBJECTIVE:

RATIONALE : Formulation and evaluation of herbal tablet use in treatment of diabetes mellitus.

OBJECTIVE OF THE STUDY:

- To prepare a Novel, cost-effective, non-toxic, and green way to hypoglycemic preparation
- It is advised along with existing oral hypoglycemic drugs. And is known to prevent diabetic complication.
- Antidiabetic drugs are medicines developed to stabilise and control blood glucose levels amongst people with diabetes
- To investigate curative effect of MALACHRA CAPITATA on Diabetes maliatus
- The objective of this study is to formulate tablet that can treat diabetes and it's easy to administrate
- To show the herbal product are cheaper and easily available.
- To understand the quality, safety, efficiency of herbal tablet in treatment.
- The objective of study was to formulate and evaluate the antidiabetic tablets by wet granulation methods and to study the effect of it.

INTRODUCTION

Diabetes:

Diabetes is the most common disease. Firstly the presence of Sugar in the urine of diabetes was demonstrated by Dabson in 1755. In 1989 von Mering and Minkowski that pancreatectomized dose become diabetic in addition to developing digestive disturbances. It is a group of metabolic disorder characterized by high blood sugar level (Glucose).

Diabetes by the Numbers More than 37 million US adults have diabetes, and 1 in 5 of them don't know they have it. Diabetes is the seventh leading cause of death in the United States. Diabetes is the No.cause of kidney failure, lower-limb amputations, and adult blindness. In the last 20 years, the number of adults diagnosed with diabetes has more than doubled

Types of Diabetes:

There are three main types of diabetes: type 1, type 2, and gestational diabetes (diabetes while Pregnant)

A. Type 1 Diabetes Mellitus:

Type 1 diabetes is thought to be caused by an autoimmune reaction (the body attacks itself by mistake) This reaction stops your body from making insulin. Approximately 5-10% of the people who have diabetes have type 1.

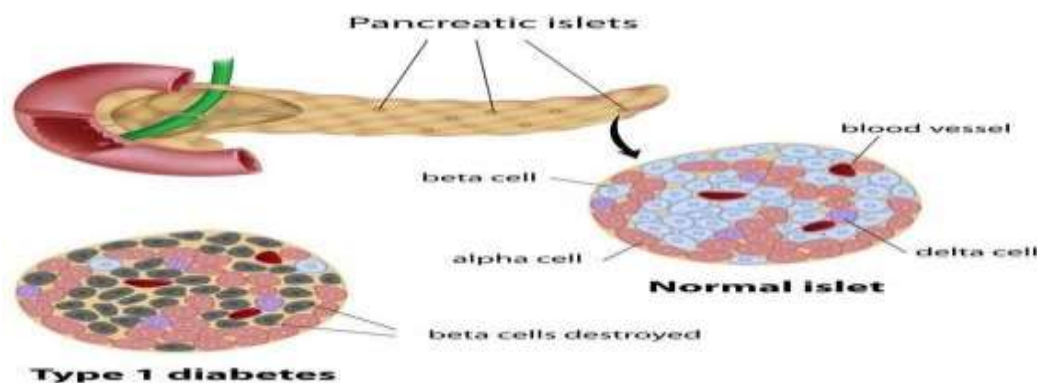


Fig no 1 : type 1 diabetes mellitus

Symptoms of type 1 diabetes often develop quickly. It's usually diagnosed in children, teens, and young adults. If you have type 1 diabetes, you'll need to take insulin every day to survive. Currently, no one knows how to prevent type 1 diabetes. This form was previously preferred to as -insulin dependent diabetes mellites (IDDM) or -juvenile diabetes this is autoimmune destruction of pancreatic beta cells individual as an absolute insulin deficiency and no longer produces insulin such patients are absolutely depend on exogenously administered insulin for survival.

B. Type 2 Diabetes Mellitus:

According to World Health Organization in 2014 it is found that 422 million adults are affected by diabetes. It causes 1.5 million deaths in 2012 and it is seen that the majority of population are mainly affected by type 2 diabetes.it also found that previously type 2 diabetes was diagnosed among adults but now it occurs in children also.

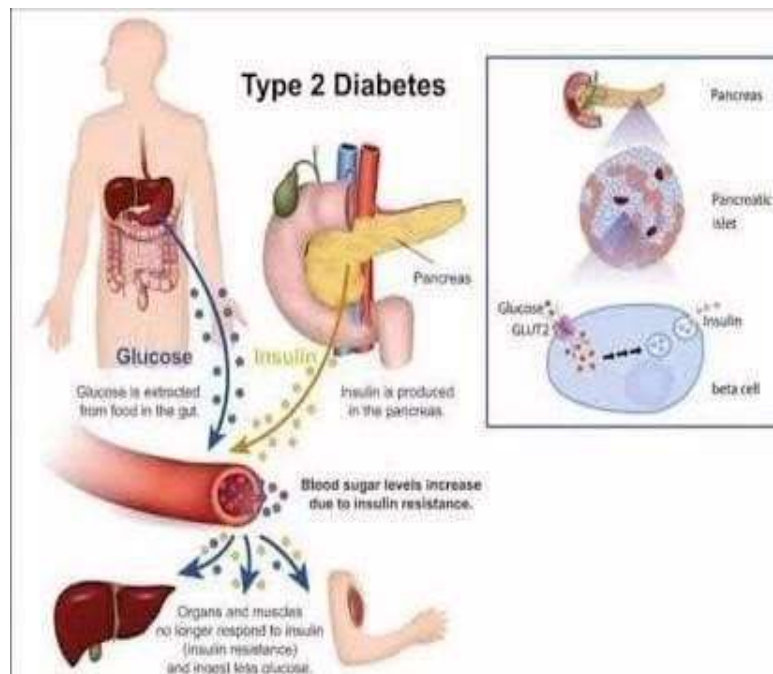


Fig No 2: Type 2 Diabetes Mellitus

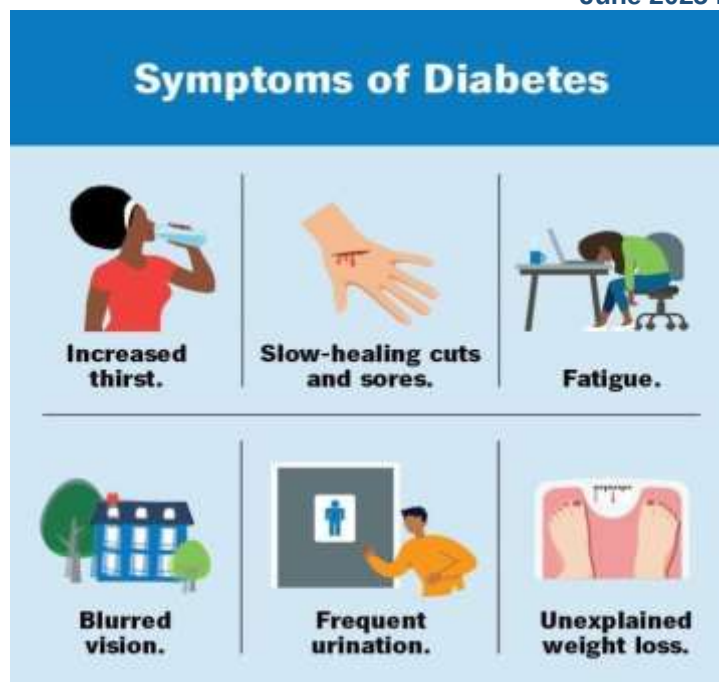


Fig No 3: Symotoms Of Diabetes

Anti-Diabetes Drugs:

The most common and effective antidiabetic medicinal plants of Indian origin are Babul (*Acacia arabica*), bael (*Aegle marmelose*), church steeples (*Agrimonia eupatoria*), onion (*Allium cepa*), garlic (*Allium sativum*), Ghrita kumara (*Aloe vera*), neem (*Azadirachta indica*), ash gourd (*Benincasa hispida*), Beetroot (*Beta vulgaris*), Fever nut (*Caesalpinia bonducella*), bitter apple (*Citrullus colocynthis*), ivy gourd (*Coccinia indica*), eucalyptus (*Eucalyptus globules*), banyan tree (*Ficus benghalensis*), gurmar (*Gymnema sylvestre*), gurhal (*Hibiscus rosa-Sinesis*), sweet potato (*Ipomoea batatas*), purging Nut (*Jatropha curcas*), mango (*Mangifera indica*), karela (*Momordica charantia*), mulberry (*Morus alba*), kiwach (*Mucuna pruriens*), tulsi (*Ocimum sanctum*), bisasar (*Pterocarpus marsupium*), anar (*Punica granatum*), jamun (*Syzygium cumini*), giloy (*Tinospora cordifolia*), and Methi (*Trigonella foenum-graecum*). All these plants are a rich source of phytochemicals. Diabetes mellitus (DM) is a prevailing global health metabolic disorder, with an alarming incidence rate and a huge burden on health care providers. DM is characterized by the elevation of blood glucose due either to a defect in insulin synthesis, secretion, binding to receptor, or an increase of insulin resistance. The internal and

external factors such as obesity, urbanizations, and genetic mutations could increase the risk of developing DM. Flavonoids are phenolic compounds existing as secondary metabolites in fruits and vegetables as well as fungi. Their structure consists of 15 carbon skeletons and two aromatic rings (A and B) connected by three carbon chains. Flavonoids are furtherly classified into 6 subclasses: flavonols, flavones, flavanones, Isoflavones, flavanols, and anthocyanidins. Naturally occurring flavonoids possess anti-diabetic effects. As in vitro and animal model's studies demonstrate, they have the ability to prevent diabetes and its complications. The aim of this review is to summarize the current knowledge addressing the antidiabetic effects of dietary flavonoids and their underlying molecular mechanisms on selected pathways: Glucose transporter, hepatic enzymes, tyrosine kinase inhibitor, AMPK., PPAR, and NF-kB. Flavonoids improve the pathogenesis of diabetes and its complications through the regulation of glucose metabolism, hepatic enzymes activities, and a lipid profile. Most studies illustrate a positive role of specific dietary flavonoids on diabetes, but the mechanisms of action and the side effects need more clarification. Overall, more research is needed to provide a better understanding of the mechanisms of diabetes treatment using flavonoids.

DIABETES MELLITUS

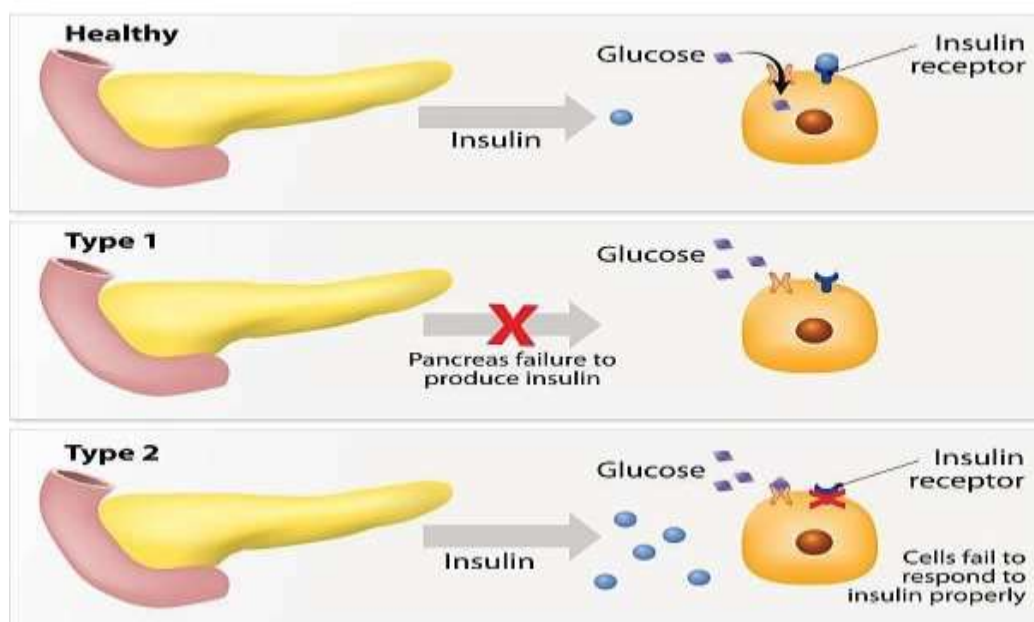


Fig No 4: Diabetes Mellitus diagram

PLAN OF WORK

- Literature Survey
- Selection Of Herbal Drug
- Determine Active Constituent of Herbal Drug
- Selection of Excipients
- Selection Of Material & Equipment's
- Selection Method For Extraction
- Identification Test For Extraction
- Prepare Granules With Extract
- Pre-compression Test
- Compression Tablet
- Post-Compression Test

Literature Review :

Sr.No	Article Title	Brief Description	Author Name	Journal Name And Ref.No
1	Preliminary Phytochemistry and Anti-Microbial Activity of Malachra Capitata Plant.	Methanolic, Chloroform and Benzene extract of the leaves of Malachra Capitata was screened for its phytochemical and antibacterial properties on E. Coli and Listeria monocytogenes at varying concentrations	Naik RM et al	American Journal Of Pharmtech Research
2	Antibacterial Activity Of Malchra Capitata L.	The stem and root extracts of Malachra capitata were active against all the test organisms while the leaf extract was effective against Micrococcus species and Escherichia coli only.	Bhowal M. And Yawalikar N.	Indian Journal of Plant Sciences ISSN: 2319-3824(Online
3	Isolation and Study of β -sitosterol the Unsaponifiable Matter from the Plant Malachra capitata (Linn)	The fat obtained from the shade dried plant Malachra capitata (Linn) was saponified and the unsaponifiable matter was isolated.	Raina Jadhav and Sageeta Parihaar	Biomedical & Pharmacology Journal Vol. 7(1), 285-287 (2014

4	An Overview of Genus Malachra L. Ethnobotany, Phytochemistry, and Pharmacological Activity	In this review, we consider the conservation of these species to save the ancestral knowledge of their traditional use in populations, and their pharmacological potential for future studies in search of alternatives for solutions to diseases in humans and animals and tools for the design and search of potential bioactive compounds against infectious and non-infectious agents.	Leonor Cervantes Ceballos, Jorge Sanchez Hoyos	Advance In Research On Plants and Natural Products. Plants 2022, 11(21), 2808
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Table no 1:Literature review

MATERIAL AND METHOD:

1. Material

- Plant material taken from Village area generally from farm.
- The plant were separated and clean dust from it
- The neem leaves of plant were separated, washed with tapped water.
- Dried and homogenized fine powder being in close Container.

2. Methodology

Method Of Preparation:

1.Direct Compression Method

2.Dry Granulation Method

3. Wet Granulation Method

1.Direct Compression Method:

- This method involves directly mixing the API with excipients and then
- compressing the mixture into tablets. It's a simple and efficient method, often used when the API and excipients have good flow and compression properties.

2.Dry Granulation Method

- This method involves compacting powder mixtures into large pieces (slugs), which are then broken down into granules.
- The granules are then compressed into tablets

3. Prepare By Using Wet Granulation Method

- In this method the solvent were used for dump mass.
- All ingredient were weighed & triturate by mottar 4 pestle & individually. Using mass through sieve no. 8
- The herbal drug. Starch (half quantity) & preservative (methyl parabean) mixed with sufficient quantity water and form dump mass.
- The mass was passed through sieve no. 16 to form granules and granules were dried at 50-60°C for 15 min. In hot air oven.
- In that dried granules remaining quantity of talc, magnesium stearate were added mix with spatula.
- At least prepared granules were passed for compression by single punching machine.

DRUG PROFILE:**1) Malachra Capitata :**

COMMON NAME: Ran bhendi **SCIENTIFIC NAME:** Malachra Capitata **FAMILY:**

Malvacaee

KINGDOM: Plantae



Fig No 5: Malachra Capitata

Mechanism of action :

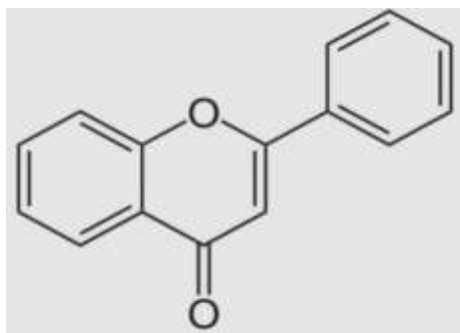
Ran bhendi had a high fiber content, which helps stabilize blood sugar by regulating the rate of sugar absorbed from the intestinal tract. Because of these fiber and other nutrients, okra had activity in minimizing blood sugar levels in diabetics.

Uses :

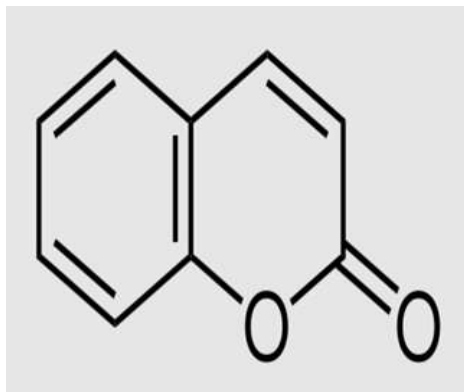
- In the treatment of diabetes.

Chemical Constituents:

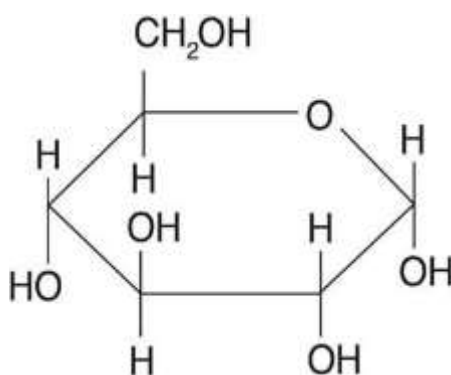
1) Flavonoids



2) Coumarins



3) Carbohydrate



NEEM:

SYNONYM: Neem tree, Margosa.

FAMILY: Meliaceae

PART TO BE USE: Leaves

Mechanism Of Action:

The neem phytochemical nimbidin (200 mg/kg) significantly delayed the rise in blood glucose after oral glucose administration. It reveals the antihyperglycemic benefits of neem (9). The use of neem lowered blood glucose levels considerably.



Fig No 6: Neem

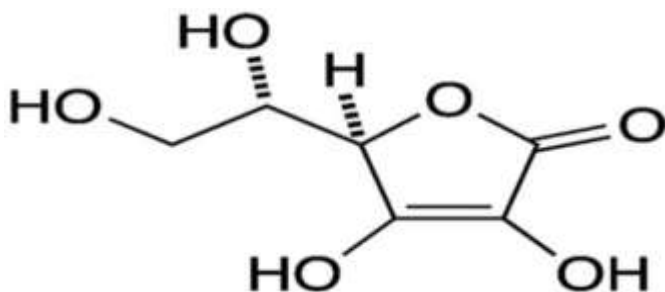
MEDICINAL USES :

The chemical compounds present in neem have following uses :

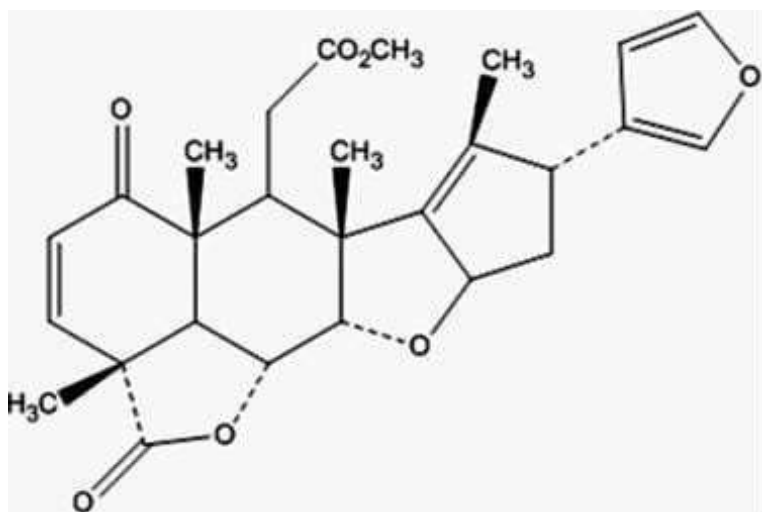
- 1) anti-diabetic
- 2) antiarthritic
- 3) antipyretic

Chemical constituents:

1) Ascorbic Acid



2) Nimbin



EXCIPIENTS (INGREDIENTS) USED IN MANUFACTURING OF HERBAL TABLETS FOR DIABETES

- Excipients Used In Manufacturing Of Herbal Tablets For Diabetes

Sr..No	Ingredientsn	Uses
1	Malachra Capitata	Antidiabetic
2	Neem Powder	Antihypoglycemic
3	Starch	Disintegrent
4	Talc	Glident
5	Methyl Parabean	Preservative
6	Acacia	Stablizer
7	Vanilla Powder	Flavouring Agent
8	Magnesium sterate	lubricant

Table No 2: Excipients

TABLET PUNCHING:

Wet about 250mg of granules and places in punching mould and required quantity of tablet where punch using hand operating Tablet punching machine.

Step 1:

Fig No 7: API+Excipient

Step 2:

Fig No 8: Seive no 8

Step 3:

Fig No 9: Dump Mass Particle

Step 4:

Fig No 10:Dried Granules

Step 5:

Fig No 11: Seive NO 16

Step 6:

Fig No 12: Punching Machine

Step 7:

Fig No 13:Herbal Anti-Diabetic Tablet

Evaluation Parameter**Pre-Compression Test Angle of repose:**

Determined by using the funnel method. Accurately weighed granules were taken in a funnel and the height of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap. The granules were allowed to flow through the funnel freely onto the surface. The diameter of the powder cone was measured and angle of repose was calculated from the following formula.

$$\tan \theta = h/r$$

Where,

θ = angle of repose, h = height of powder r = radius of powder cone

Loose Bulk density (LBD):

Determined by pouring a weighed quantity of granules into a graduated cylinder and measuring the volume and weight.

$$\text{LBD} = \text{Weight Of Powder} / \text{Volume Of The Packing}$$

Tapped bulk density (TBD):

Determined by placing a graduated cylinder, containing a known mass of granules. The cylinder was allowed to fall under its own weight onto a hard surface from the height of 10 cm at two second intervals. The tapping was continued until no further change in volume was noted

$$\text{TBD} = \text{Weight Of The Powder} / \text{Volume Of The Packing}$$

Hausner ratio:

It is the measurement of frictional resistance to the drug. The ideal range should be 1.2- 1.5 determined by using the following formula

$$\text{Hausner ratio} = \text{TBD} / \text{LBD}$$

Compressibility index:

The Compressibility index of the blends was determined by the Carr's compressibility index

$$\text{Compressibility Index (\%)} = (\text{TBD} - \text{LBD}) \times 100 / \text{TBD}$$

Loss on drying:

One gram of granules was transferred into a dried, glass stoppered shallow weighing bottle. The contents were distributed evenly and placed in the drying chamber. The stopper was removed from the bottle and the contents were dried for a specified time to achieve a constant weight

$$\text{Loss on drying (\%)} = [(\text{Initial weight} - \text{Final weight}) / (\text{Initial weight})] \times 100$$

Post-compression Test**Weight Variation:**

The average weight was determined by randomly selecting and weighing 20 tablets. Each tablet was also weighed individually. The deviation from the average weight in each case was calculated and expressed as percentage. Not more than two of the tablets from the sample size can deviate from the average weight by a greater percentage and none of the tablets deviate by more than double that percentage.

Hardness test:

The Hardness of the Tablet is also called as Tablet Crushing strength. Hardness test is used to check the hardness of the prepared tablet. In this test we can measure 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 expressed in Kg/cm^2 .

Friability test:

The friability test is used to check the combined effect of abrasion and shock. This test is used to check the tablet is suitable for transportation or not for that purpose Roche Friabilator is used it is laboratory friability tester. In that the preweighed antidiabetic tablet sample is placed in the friabilator which consists of plastic chamber that operates 100 revolutions for 4 min means 25 rpm. The tablets are then dusted and reweighed. Conventional compressed tablets that lose less than 0.5-1.0% of their weight are generally acceptable.

Disintegration test:

A glass of plastic tube 80-100 mm long with an internal diameter of about 28 mm and external diameter 30-31 mm fitted at the lower end with a disc of rust proof wire gauge. Six tablets were placed in the tube, raised and lowered the tube in such a manner that the complete up and down movement is repeated 28 to 32 per minute. The tablets are disintegrated when no particles remain above the gauge, which readily pass through mesh (10 mesh screen).

Color And Appearance:

The compressed tablets were examined for their color and appearance.

Thickness:

The thicknesses of the tablets were evaluated by Vernier calipers.

RESULT

Table no 3: formulation designing

Sr. no	Ingredients	F1	F2	F3
1	Malachra Capitata Powder	100mg	100mg	100mg
2	Neem Powder	40mg	40mg	40mg
3	Starch	30mg	30mg	30mg
4	Talc	10mg	10mg	10mg
5	Methyl Paraban	10mg	10mg	10mg
6	Acacia	20mg	20mg	20mg
7	Vanilla Powder	40mg	40mg	40mg
	Total	250mg	250mg	250mg

Table No 4: Pre Formulation Study Of Powder Sample

Sr.no	Evaluation parametere	F1	F2	F3
1	Angle of repose(θ)	27	26	27
2	Bulk density(g/ml)	0.29	0.28	0.27
3	Tapped density(g/ml)	0.36	0.35	0.37
4	Carrs index(%)	19.37 %	19.36%	19.34%
5	Hausner ratio (%)	1.24	1.25	1.26

Table No 5: Preliminary Test For Tablet

Sr.No	Physical Appearance	F1 To F3
1	Colour	Green
2	Odour	Pungent
3	Taste	Bitter
4	Shape	Round
5	Diameter(cm)	0.8
6	Width(cm)	0.4

Table No 6: Post Compression Test

Sr.no	Evaluation parameter	F1	F2	F3
1	Weight Variation(Gm)	0.028	0.026	0.027
2	Friability(%)	0.31	0.32	0.34
3	Hardness Test(Kg/Cm2)	4.25	4.27	4.28
4	Thickness Test (Mm)	0.00633	0.00634	0.00635
5	Disintegration Time (Min)	15	18	20
6	Dissolution Time (Min)	18	22	25

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 fewer side 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 the treatment of diabetic patient. The present study highlights for the antidibetic and hypoglycemic potential of malachra Capitata seeds against diabetes. The chemical constituent present in the fruits of the plant shows antidibetic property

FUTURE SCOPE :

The future scope for formulation and evaluation of herbal tablets in diabetes treatment includes:

Future Directions:

1. **Advanced extraction techniques:** Utilizing modern extraction methods to improve yield and purity of bioactive compounds.
2. **Nanotechnology:** nano-formulations Developing to enhance bioavailability and efficacy.
3. **Personalized medicine:** Tailoring herbal tablets to individual patient needs and genetic profiles.
4. **Combination therapy:** Investigating combinations of herbal extracts with conventional medications.
5. **Clinical trials:** Conducting large-scale, well-designed clinical trials to establish efficacy and safety.

Potential Benefits:

1. **Improved glycemic control:** Enhanced management of blood sugar levels.
2. **Reduced side effects:** Minimized adverse effects compared to conventional medications.
3. **Increased patient compliance:** More patients may adhere to treatment regimens.

Challenges and Opportunities:

1. **Regulatory frameworks:** Establishing clear guidelines for herbal product development.
2. **Quality control:** Ensuring consistency and quality of herbal extracts.
3. **Collaboration:** Fostering partnerships between researchers, clinicians, and industry stakeholders.

By addressing these challenges and opportunities, herbal tablets can become a valuable addition to diabetes management strategies.

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