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FORMULATION AND EVALUATION OF HERBAL CAPSULE CONTAINING PANEER DODI AND FENUGREEK FOR THE TREATMENT OF DIABETES

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ABSTRACT
Withania coagulans is commonly known as Paneer Dodi belonging to family Solanaceae is a well -known plant in herbal medicinal systems having great potential against diabetic disease by improving the secretion of insulin. In addition, Trigonella Foenum Graecum plant is also known as a Methi or fenugreek which is used as ayurvedic medicines for antidiabetic, anti hypercholesterolemic, anti-toxic and immunomodulatory activity. It was though worthwhile to explore its application into our body to treat type-2 diabetes, it acts on the insulin receptors for the better consumption of insulin. The objective of present study was to formulate a dosage form of antidiabetic herbal capsule dosage form having higher efficacy, less side effect and dose accuracy. Our study focuses on preparation of herbal capsule that consist of antidiabetic activity by combination of Paneer Dodi with Fenugreek. The equal proportion of Paneer Dodi and Fenugreek powder (Biherbal powder) is dried & triturate for increase the surface area of powder during dissolution. The Biherbal powder prepared have lack of dose accuracy and bitter taste during consumption thus to overcome this both limitations Powder is filled in Capsule shell which can retain the 300mg of powder. To achieve 1gm dose per day the capsule is given thrice a day. The capsule is disintegrated in 3.5 to 4 minutes and the drug is released and dissolve within a period of 1 hour.
KEY WORDS: *Anti-diabetic, Withania coagulans, Trigonella Foenum Graecum*

INTRODUCTION
Introduction to Disease.
A chronic condition of the metabolism of proteins, lipids, and carbohydrates is known as DIABETES MELLITUS. One defining characteristic of diabetes mellitus is an impaired or insufficient insulin secretory response, which results in impaired use of carbohydrates (glucose). The most prevalent endocrine disorder, diabetes mellitus (DM), is frequently caused by an insufficient or absent supply of insulin or, less frequently, by an impairment of insulin activity (insulin resistance). Diabetes mellitus is also known as "sugar" in popular culture. The International Diabetes Federation (IDF) estimates that there are currently 40.9 million diabetics in India, with a projected increase to 69.9 million by the year 2025. The pancreas produces both the glucagon and insulin hormones. The beta (ß) cells in the islets of Langerhans release insulin, whereas the alpha (α) cells in the same organelles secrete glucagon. By facilitating glycogenesis and delivering glucose to the muscles, liver, and adipose tissue, insulin lowers blood sugar levels. While alpha (α) cells play a significant role in managing blood glucose by generating glucagon, which raises blood glucose levels by speeding glycogenolysis, erythrocytes and neural tissue do not require insulin to use glucose.

The risk of obesity, metabolic, and cardiovascular diseases as well as cancer in the fetus's future life after birth are all elevated. In between 80% and 90% of cases of diabetes mellitus, type II diabetes is present. The severity of the issues and total morbidity and mortality might vary depending on the location. Additionally, those with diabetes who engage in modest levels of physical exercise had a negligibly decreased chance of passing away than sedentary people. It is now widely accepted that for such an occurrence to occur, a particular genetic constitution is needed. One of the biggest health obstacles to the growth of the economies of WHO African Region members is the rising burden of non-communicable illnesses like diabetes.

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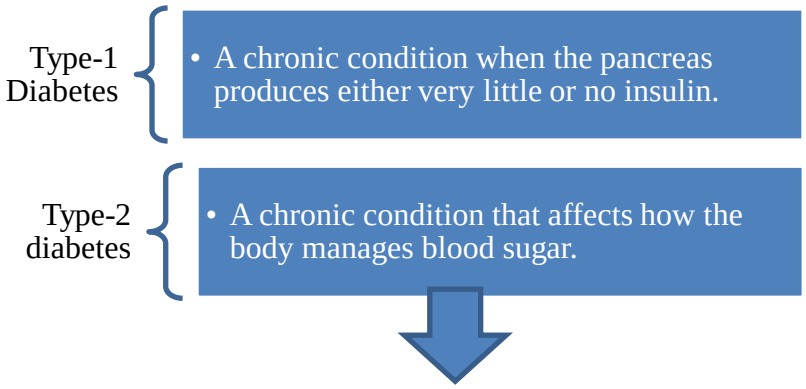
Diabetes is characterized by an abnormality in either the synthesis or secretion of insulin, as seen in Type 1 diabetes mellitus (T1DM) and pancreatic duct stenosis, or by the emergence of insulin resistance or its abnormal production, as seen in Type 2 diabetes (T2DM) and certain secondary diabetes.

1.2 INTRODUCTION OF DISEASE

Diabetes mellitus, a group of disease that results in too much sugar in the blood.



Sugar builds up in the bloodstream because the pancreas doesn't produce enough insulin.
Both type-1 and type-2 diabetes may cause by a combination of genetic or ecological factor.

Type-2 Diabetes

Cells in the liver, fat, and muscles develop insulin resistance. The cells don't take in enough sugar as a result. The pancreas cannot produce enough insulin to maintain appropriate blood sugar levels.

1.3 INTRODUCTION OF DOSAGE FORM

Capsule

Capsules are solid preparation with hard and soft of various shapes and capacities, usually containing a single dose of active ingredients.

- **Hard gelatin capsule**
- **Soft gelatin capsule**

Hard gelatin capsule: It contains medicine in the form of dry powder or very small pellets and granules. There is various size of capsule available 000, 00,0,1,2.

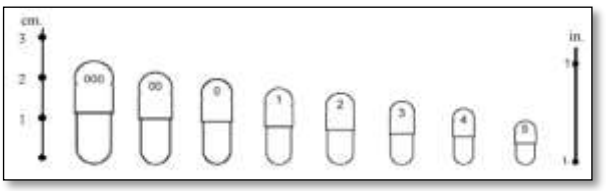


Figure 1.1 Capsule Size

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Table 1.1 Capsule Size

Size	Outer diameter(mm)	Height or locked length(mm)	Actual volume(ml)
000	9.97	26.14	1.37
00	8.53	23.30	0.95
0	7.65	21.7	0.68
1	6.91	19.4	0.50
2	6.35	18.0	0.37
3	5.82	15.9	0.30
4	5.31	14.3	0.21
5	4.91	11.1	0.13

1.3.1 Advantages and Disadvantages of Capsule

Advantages

Fast acting: Capsules tend to break down more quickly than tablets. They may offer faster relief from symptoms than tablets.

Tasteless: Capsules are less likely to have an unpleasant taste or odor.

Tamper-resistant: They're often made so that it's not as easy to split them in half or crush like tablets. As a result, capsules may be more likely to be taken as intended.

Higher drug absorption: Capsules have higher bioavailability, which means that more of the drug is likely to enter your bloodstream. This could make capsule formats slightly more effective than tablets.

Disadvantages

Less robust: Tablets are typically more stable than capsules. They may react to environmental conditions, particularly humidity.

Shorter shelf life: Capsules expire more quickly than tablets.

More expensive: Capsules that contain liquids are generally more expensive to manufacture than tablets and may cost more as a result.

May contain animal products: Many capsules contain gelatin sourced from pigs, cows, or fish. This may make them unsuitable for vegetarians and vegans.

Reduced doses: Tablets can hold twice the amount of medication that capsules can. You might need to take more to receive the same amount as you would in a tablet.

1.4 INTRODUCTION OF DRUG

PANEER DODI also called Withania coagulans is a small shrub and belongs to the family Solanaceae. It is commonly known as 'Paneer Dodi' or 'Indian cheese Malor'.

FENUGREEK also called Trigonella Foenum graecum is a seed and belongs to the family Leguminosae. It is commonly known as 'Fenugreek' or 'Methi'.

Paneer Dodi and fenugreek is an effective ayurvedic herb used to manage blood sugar levels.
In diabetes, beta cell become damaged and cannot produce insulin. This combination corrects the beta cell of pancreas leads to better use of insulin.
Aim: Formulation and Evaluation of Herbal Capsule Containing Paneer Dodi and Fenugreek for the Treatment of Diabetes.

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Objectives

- To Develop Novel Oral Drug Delivery System.
- Dose Accuracy.
- Patient More Compliance.
- Act as Taste Masking.
- Capsule Over Tablet.

Rationale

Type-2 Diabetes is a Chronic Condition.
Cell in muscle, fat and the liver become resistant to Insulin. As a result, the cells don't take in enough sugar.
The pancreas can't make enough insulin to keep sugar levels within a healthy range.

Paneer Dodi stimulates the pancreas β- cells and facilitates better insulin secretion and makes proper use of insulin, while the fenugreek reduce the insulin resistance and reduce fasting blood glucose level and improve glucose tolerance in patient. Paneer Dodi and fenugreek is an effective ayurvedic herb used to manage blood sugar levels. In diabetes beta cell become damaged and cannot produce insulin additionally the patient having resistance to insulin thus this combination corrects the beta cell of pancreas and also leads to better use of insulin but reducing insulin resistance

Material Used

Table 5.1 Materials

SR. NO.	COMMON NAME	CATEGORY	QUANTITY	FIGURE
1	PANNER DODI	ANTI DIABETIC	25 gm	
2	FENUGREEK	ANTI DIABETIC	25gm	

Method of Preparation

A) Collection of Drugs

Primarily we obtain two drugs one is Panner Dodi which is flower portion and another is Fenugreek which is seed portion.

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Figure 5.3 Raw Drug

B) Drying of Drugs:- Dry both the Drug Fenugreek and Panner Dodi in hot air oven at 150 degree C individually.

Figure 5.4 Drying Method

C) Triturate of Drugs:- Triturate both Panner Dodi and fenugreek in a mortar pastel individually.

Figure 5.5 Trituration Process

D) Sieving of Powder

After Trituration process both drug powder is passing through different number of sieves 100, 80, 60 to obtain different size of drug particle (Fine powder).

Figure 5.6 Sieving of Paneer Dodi

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Figure 5.7 Sieving Process of Fenugreek Seed

E) Mixing of Powder

Subsequently, 1:1 ratio of Panner Dodi and Fenugreek powder is added. Both the drug are mixed manually.

Figure 5.8 Mixing of Powder

F) Capsule Filling

Weigh 300mg of drug and then filled it manually (hand filling) in capsule shell of size #1. Then place the capsule cap over the body and lock the capsule.

Figure 5.9 Weighing

Figure 5.10 Capsule Filling

G) Packaging and Storage

Strip packaging is a unit-dose packaging in which a semi-rigid blister/cavity previously formed is filled with product and lidded with heat-sealable backing material.

Different packaging strip is used like aluminum foils, cellophane, polyethylene.

Capsule is filled between 2 aluminum foil heat is applied on the foil for sealing.

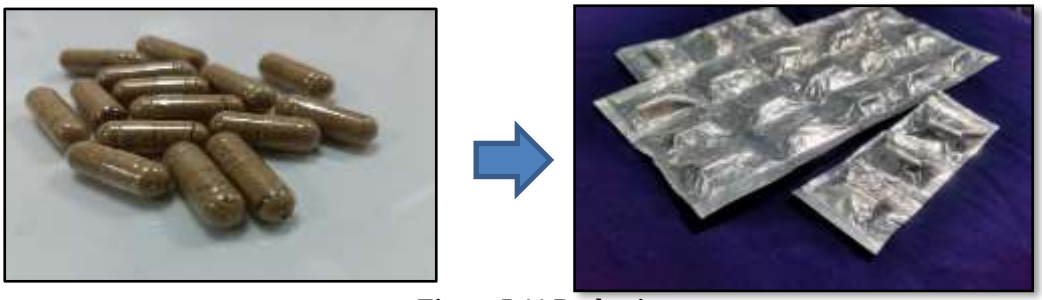

Figure 5.11 Packaging

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5.3 Direction for Use

Maximum 1gm of dose is required per day to treat diabetes.

In size #1 capsule 300mg is filled.

So, Dosage Frequency is Thrice Capsule per Day.

Phytochemical Screening

Table 6.1 Result of Phytochemical Screening

Tests for Phytochemical	Chemical test	Fenugreek	Paneer Dodi	Combination
Carbohydrate	Molish Test	+ve	+ve	+ve
	Benedict Test	+ve	+ve	+ve
Protein	Biuret Test	-ve	-ve	-ve
Amino Acid	Ninhydrin Test	-ve	-ve	-ve
Glycoside	Killer-Killani Test	+ve	+ve	+ve
Steroid	Salkowski Test	+ve	+ve	+ve
Alkaloid	Dragendroff Test	+ve	+ve	+ve
	Mayer Test	+ve	+ve	+ve
	Wagner Test	+ve	+ve	+ve
Flavonoid		+ve	+ve	+ve

Test of Combination (Paneer Dodi & Fenugreek)

Pre- compressional Parameters

Table 6.3 Result of Micromeritic Properties of Powder

Sr no.	Parameters	Fenugreek	Paneer Dodi	Combination
1.	Bulk volume	25	27	27
2.	Tapped volume	20	19	19
3.	Bulk Density	0.4	0.37	0.37
4.	Tapped Density	0.5	0.5	0.52
5.	Angle of repose	13.42	11.347	12.65
6.	Hausner's ratio	1.25	1.43	1.405
7.	Carr's index	0.2	0.301	0.307

Post Evaluation Parameter

6.4.1 Dissolution Test

Preparation of Phosphate Buffer pH 7.2: -

Dissolve 1.404gm of sodium hydroxide and 6.795gm potassium dihydrogen phosphate in sufficient water to produce 1000ml

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Table 6.4 Trial Batch

Time(min)	I	II	III
0	0	0	0
5	0.077	0.073	0.070
10	0.133	0.132	0.130
15	0.173	0.177	0.179
20	0.184	0.189	0.190
25	0.210	0.201	0.200
30	0.224	0.221	0.229
35	0.250	0.246	0.248
40	0.276	0.274	0.278
45	0.301	0.310	0.309
50	0.345	0.349	0.340
55	0.457	0.459	0.458
60	0.492	0.498	0.496
65	0.523	0.524	0.588
70	0.625	0.520	0.582

Data of Dissolution Study

Time (min)	STDEV	Mean aborbance	conc(ug/ml)	Conc (mg/5ml)	cummulative release	Conc (mg/900ml)	corrected cr	%Drug release
0	0	0	0	0	0	0	0	0
5	0.004	0.073	0.973	0.005	0.009	0.875	0.884	8.844
10	0.002	0.132	1.929	0.010	0.019	1.736	1.755	17.547
15	0.003	0.176	2.661	0.013	0.032	2.395	2.427	24.270
20	0.003	0.188	2.847	0.014	0.046	2.562	2.608	26.085
25	0.006	0.204	3.109	0.016	0.062	2.798	2.860	28.601
30	0.004	0.225	3.454	0.017	0.079	3.108	3.187	31.872
35	0.002	0.248	3.836	0.019	0.098	3.452	3.551	35.506
40	0.002	0.276	4.295	0.021	0.120	3.866	3.985	39.852
45	0.005	0.307	4.798	0.024	0.144	4.318	4.462	44.617
50	0.005	0.345	5.421	0.027	0.171	4.879	5.049	50.494
55	0.001	0.458	7.279	0.036	0.207	6.551	6.758	67.580
60	0.003	0.495	7.891	0.039	0.247	7.102	7.348	73.482
65	0.037	0.545	8.705	0.044	0.290	7.834	8.125	81.245
70	0.053	0.576	9.208	0.046	0.336	8.287	8.623	86.230

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Time(min)	%Drug release
0	0.00
5	8.84
10	17.55
15	24.27
20	26.08
25	28.60
30	31.87
35	35.51
40	39.85
45	44.62
50	50.49
55	67.58
60	73.48
65	81.25
70	86.23

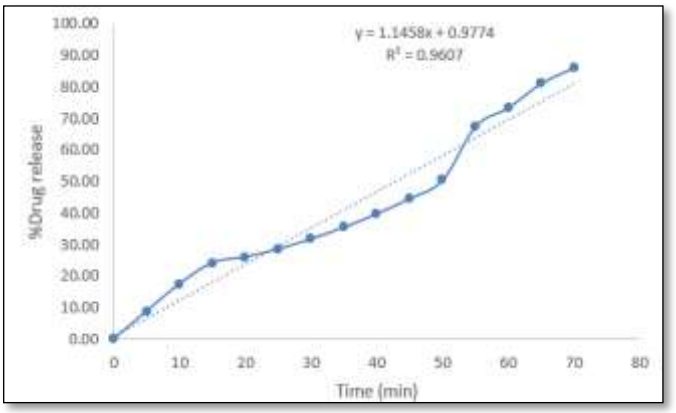

Figure 6.8 Dissolution Apparatus

Disintegration Test

Preparation of Phosphate Buffer pH 6.8: -

Dissolve 0.896gm of sodium hydroxide and 6.795gm of potassium dihydrogen phosphate in sufficient water to produce 1000ml.

Disintegration Time

In Phosphate Buffer: - 3 minutes

In Water: - 4 minutes

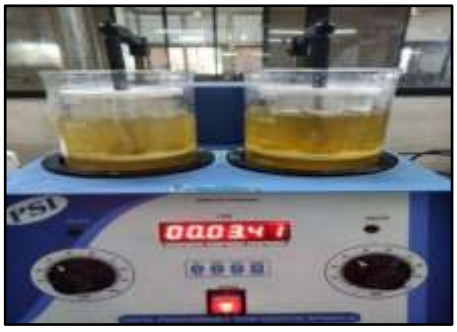

Figure 6.10 Disintegration Time in Phosphate Buffer

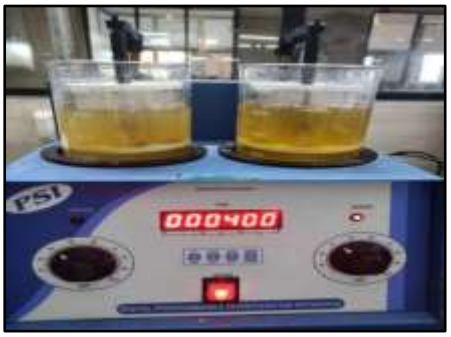

Figure 6.11 Disintegration Time in Water

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RESULT AND CONCLUSION

7.1 RESULT

TEST	RESULT
Color	Transparent
odor	odorless
Size of capsule	#1
Dissolution Time	1hr
Disintegration Time	3-4 min
Therapeutic Effect	Anti- diabetic
Drug Content in Each Capsule	300mg
Dosage Frequency	3 times per day

7.2 CONCLUSION

Our present work is to formulate Anti-Diabetic Drug to treat Type-2 Diabetes with the use of Panner Dodi and Fenugreek. So, it has negligible side effect and contain herbal product with no excipient.
So, we can conclude that herbal capsule with least side effect which can impart the required proportion to heal the Diabetes.

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