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Research Paper

Formulation & Evaluation of Polyherbal Antidiabetic Tablet

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ABSTRACT

A chronic condition with long-term complications is diabetic mellitus. Herbal antidiabetic medications reduce blood glucose levels and increase the amount of insulin released by the pancreas to treat diabetes mellitus. In this study, we attempted to create and assess a herbal pill that contained dried plant extracts of Asparagous racemosus, Syzygium cumini, and Gymneme sylvestre. Additionally, the produced tablets' weight fluctuation, friability, hardness, and disintegration time are evaluated. The formulation has a decent level of hardness (2.98 ± 0.21), which helps with its quick disintegration. The formulation has a decent level of hardness (2.98 ± 0.21), which helps with its quick disintegration. All of the values were determined to be within acceptable bounds. The tablets' mechanical stability was demonstrated by their friability (0.52±0.04). The pills weighed 550 mg on average, with a ±5% weight variation. The weight variation test was successful. Excipients and extracts do not interact, according to FTIR research. This polyherbal pill may be regarded as a herbal therapy for diabetes mellitus based on the findings achieved.

INTRODUCTION

The primary foundation for biocultural and ecosystem conservation, as well as for additional pharmacological, phytochemical, toxicological, and ecological research, is the traditional knowledge of medicinal plants.[1] Approximately 40% of all medical care is provided via the use of traditional medicinal herbs.[2] The area of herbal medicine has experienced exponential expansion in recent years, and due to their natural origin and fewer side effects, these herbs are becoming more and more well-liked worldwide. Many nations have found success with herbal remedies, and because of their potential, scientific research into medicinal plants has begun.[3] In scientific inquiry, ethnobotanical knowledge and traditional medicine are crucial.[4,5] In India indigenous medicines have been used in the treatment of

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Diabetes mellitus since the time of Charaka and Sushruta (6th century BC).[6] According to WHO estimations, more than 80% of the world population depends on traditional medicinal practice for primary health care needs.[7] Over 75% of the world population is depending on local health practioners and traditional medicines for their primary needs.[8] Traditional ethonobotanical studies have received much attention in recent years due to their wide acceptability and clues for new or lesser – known medicinal plants.[9] A number of reviews have been published in the last three decades on plants pharmacological activities. Very recently, two exhaustive reviews have been published based on the global literature survey on 150 plants and 343 plants in different part of the world [10-25].

Diabetic mellitus

Hyperglycemia (an rise in blood glucose), hyperlipidaemia (an increase in blood lipids), and hyperinsuliemia (a decrease in blood insulin production) are the hallmarks of this systemic metabolic disease. We created an antidiabetic medication for this study, which is used to treat diabetes. Insulin secretion and action are reduced in diabetes illness. Diabetes-related chronic hyperglycemia is linked to long-term harm, failure, and dysfunction of many organs, including the kidney, heart, blood vessels, nerves, and eyes. Changes in the metabolism of proteins, fats, and carbohydrates lead to diabetic mellitus [26].

Types of Diabetic mellitus :

There are main two type of Diabetic mellitus disorder they were classified depending upon the insulin dependency [27].

Type 1: Diabetes mellitus that is insulin-dependent (IDDM)

This kind of diabetes mellitus is brought on by a beta cell autoimmune illness. The breakdown of pancreatic beta cells results in an unregulated blood insulin circulation. They take place between the ages of thirty and forty. The beta cells are unable to react to typical stimuli.

Type 2: Diabetes mellitus that is not insulin-dependent (NIDDM)

Insulin is not necessary for this kind of diabetes. Obesity is the major cause of this type of diabetic mellitus. Because of this, the number of beta cells is declining. This form of diabetes are occurring at age onward 40 year.

Table 1. Plant Profile Used in Formulation [28,29]

Herbal Ingredient	Biological Source	Family	Chemical Constituents	Uses
Syzygium Cumini 	Dry seeds of *Syzygium Cumini*	Myrtaceae	Alkaloid – Jambosin, Glycoside-Jamboline	Jamun fruit seeds are very effective to lower blood glucose levels in the diabetic. Inhibition of glucose absorption Antioxidants.

ASPARAGUS RACEMOSUS 	Dried roots of Asparagus Racemosus	Zingiberaceae	Sarsaspogenin, shatavarin I-IV	Asparagus racemosus is an adaptogenic herb that primarily vitalizes the body. It is use in Ayurveda. Besides helping the body maintain a healthy level of blood sugar. Shatavari also helps keep you calm, has antioxidant and anti-inflammatory properties.
Gymneme sylvestre 	It consist of leaves of woody climber plant known as Gymneme Sylvestre	Apocynaceae	Gymnemic acid, tartaric acid , gumarin ,choline	Lower blood sugar Reduce the amount of sugar absorbed by the intestines Lower LDL cholesterol

MATERIALS AND METHODS

Plant Materials collection and Extraction

Figure_4 Soxhlet extraction

Gymneme sylvestre, Syzygium cumini, and asparagus racemosus leaves were gathered locally, dried, and ground into powder for use in this investigation. Ethanol is used as a solvent in the Soxhlet extractor to extract the powdered plant components individually. The solvent in the extractor is collected, evaporated, and the extracts are stored for later use.[31–32]

Excipients used to formulate tablets : In this formulation Lactose, Starch, Di calcium phosphate, Acacia, Magnesium stearate, Methyl paraben, used to compose tablets. Di calcium phosphate and Lactose used as Bulking agents, Acacia and Starch used as granulating agents, Magnesium stearate use for lubrication and Methyl paraben, used as preservatives.[33-35]

In the present study dried ethanolic extracts of *Gymneme sylvestre, Syzygium cumini, Asparagous racemosus* was formulated into tablet dosage form by direct compression] Formulation has the following composition as depicted in the method. [36] table 2.

Table 2 Composition on formulation ingredients for poly herbal anti diabetic tablets

Sr.no	Ingredients	Composition (mg)	Uses
1.	Gymneme sylvestre	60	Antidiabetic

2.	Syzygium cumini	40	Antidiabetic
3.	Shatavari	40	Antidiabetic
4.	Lactose	100	Binder
5.	Starch	100	Disintegrant
6.	Di calcium phosphate	180	Bulking agent
7.	Acacia	10%	Thickining agent
8.	Magnesium sterate	20	Lubricant
9.	Methyl paraben	0.1%	Presevative

Tablet Preparation By Direct Compression:

Figure_5 Formulated Tablet

Direct compression was used to create a herbal tablet that contained Gymneme sylvestre, Syzygium cumini, and Asparagus racemosus. By understanding their characteristics, other components such as lactose, starch, acacia, calcium phosphate, magnesium stearate, methyl paraben, and propyl paraben are employed as excipients. Every excipient and API was weighted according to Table No. 7 and then passed through Sieve No. 20. After that, for fifteen minutes, all of the ingredients—aside from the lubricant and glidant—were fully combined using geometric mixing. A single rotatory punching machine (CMD3-16, S.No-A/1882/94, Cadmac) was used to compress the powder blend into a 550 mg tablet after it had been fully combined with talc and magnesium stearate.

Evaluation

Preformulation studies

Preformulation studies were performed before formulating the tablets powders were subjected to following evaluation parameters.

Angle of repose

Angle of repose was determined by using funnel method; in a funnel the accurately weighed blend was taken. The funnel height was arranged in a manner that the funnel tip just touches the "apex of the heap" or "head of blend". Through the funnel "the drug excipient blend" was allowed to flow freely on to the surface. Table 3 shows the relationship between Angle of Repose and Powder Flow. The diameter of the powder cone and angle of repose were calculated by using the following equation.

$\tan \theta = h/r$

Where h = height of powder cone formed

r = radius of the powder cone formed.

Table 3. Relationship between angle of repose (θ) and powder flow.

Angle of Repose(θ)	Type of Flow
25	Excellent
25-30	Good
30-40	Passable
>40	Very poor

Bulk Density

By pouring the weighed quantity of blend into graduated cylinder and measuring the volume.

$$\text{Bulk Density} = \frac{Weight\ of\ Powder}{\text{Volume of packing}}$$

Tapped Density

A known mass of drug excipient blend was placed in a graduated cylinder. The cylinder was tapped on to a hard surface from the height of 10 cm at two second interval. Tapping was continued, "Until no further change in volume was noted".

$$\text{Tapped Bulk Density} = \frac{Weight\ of\ powder}{Volume\ of\ tapped\ packing}$$

Compressibility index

The Compressibility index of the blends was determined by Carr's compressibility index. **Table 3 shows grading of powders for their flow properties.**

$$\text{Compressibility index (\%)} = \frac{Tapped\ Density - Buik\ Density}{Tapped\ Density}$$

Table 4- Grading of powders for their flow properties.

Consolidation Flow index (Carr's index)	Flow
5-15	Excellent
12-16	Good
18-21	Fair to passable
23-25	Poor
33-38	Very Poor
>40	Very Very Poor

FTIR Evaluation

Fourier transform infrared (FTIR) spectrum of herbal extracts was subjected to determine the identification of the compound and compatibility of the extract with other excipients used in the formulation of polyherbal tablets. The spectrum of IR helps in the identification of a compound based on the existence of different functional groups.

Physical evaluation of Tablets

Tablets were subjected to following evaluation parameters.

Colour and appearance

For the colour and appearance the tablets were visually examined.

Weight variation test

For variation 20 tablets average weight was determined. Individually each tablet weight was examined. In each case deviation from the average weight was calculated and expressed as percentage. Not more than two of the tablets from the sample size deviate from the average weight by a greater percentage and none of the tablets deviate by more than double that percentage.

Hardness

Hardness of tablet was measured by Monsanto Hardness Tester.

Fig _6 Monsanto hardness tester

Friability test

Friability tests were performed for the tablets using Roche friabilitor (4 min at 25 rpm) .

Thickness

By using Vernier calipers was used to evaluate thickness of tablets. Thicknesses were evaluated.

Disintegration test for tablets

Glass of plastic tube [80-100 mm] long with an internal diameter [28 mm] and external diameter [30-31mm] fitted at the lower end with a disc of rust proof wire gauge. Six tablets were placed in the tube, the tube was raised and lowered in such a manner that the complete up and down movement was repeated [28 to 32] per min.

Fig_7 Disintegration Apparatus

The tablets were disintegrated when no particle remains above the gauge, which readily pass through mesh (10 mesh screen).

RESULT AND DISCUSSION

Preliminary phytochemical analysis was done for extracts of Gymneme sylvestre, Syzygium cumini, Asparagous racemosus from that we can conclude the presence of various phytoconstituents for e.g. Alkaloids, Glycosides, Tannins, Flavonoids which is responsible for therapeutic use.

Table 5. Preliminary Phytochemical test was conducted on extracts

Sr.	**constituents**	***Gymnema sylvestre***	***Syzygium cumini***	***Asparagous racemous***
1	Alkaloid	+	-	+
2	Glycoside	+	-	+
3	Tannin	+	+	+
4	Saponin	+	+	+
5	Steroid	+	+	+
6	Flavonoids	+	+	+
7	Carbohydrates	-	-	+

Formulations prepared by direct compression method were tested for the preformulation studies for potential evaluation to tablet compression. All the evaluated Preformulation parameters are shown in table no.9. Based on the preformulation studies powder flow properties are good.

Table 6. Preformulation parameters of powder

Sr. No.	**Parameter**	**Results**
1.	Angle of Repose	28.18 ^{0}
2.	Bulk Density	0.35 g/cm^3
3.	Tapped Density	0.38 g/cm^3
4.	Compressibility index	20.33%

FTIR:

Table 7. FTIR Data of Extract

Sr. No.	Functional Group	Wave No. (Cm^{-1})	IR Range
1	-CO	1025	900-1300
2	-NH (strech)	3296	3000-3700
3	-C-C	1616	1600-1700

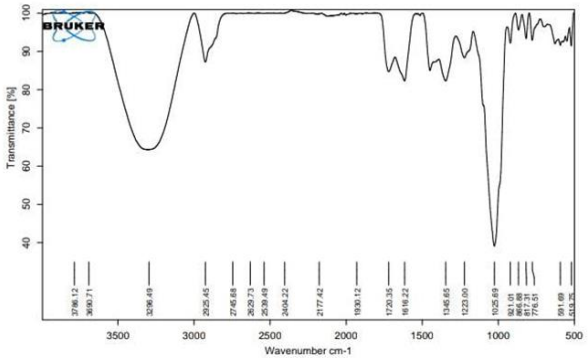
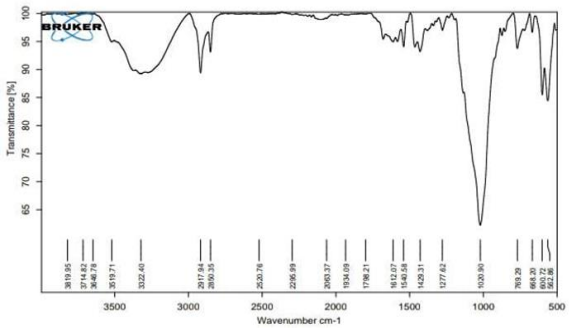


Table 8. FTIR data of Extract +Excipients

Sr. No.	Functional Group	Wave No. (Cm^{-1})	IR range
1	-CH	2917	2700-3300
2	-CO	1020	900-1300
3	N-H	769	700-900
4	C-Br	562	500-600



Then the process is continued with compression of tablet by direct compression method, after compression tablets were evaluated by Physical parameters observed were displayed on below table no.12. The finished tablets colour was Greenish White; Weight variation was ± 5%, Hardness, Friability are respectively 2.98 ± 0.21, 0.52 ± 0.04 Kg/cm2 . Thickness was measured as 3 ± 0.02 mm and Disintegration time 7 ± 0.54 min are good for stability to consume for human use.

Table 9. Physical parameters for poly herbal anti diabetic tablets.

Sr. No.	**Parameter**	**Results**
1	Colour	Greenish white
2	Weight variation test	±5%
3	Hardness(kg/cm2)	2.98 ± 0.21
4	Friability (%)	0.52 ± 0.04
5	Thickness(mm)	3 ± 0.02
6	Disintegration(min)	7 ± 0.54

CONCLUSION

All the three plants used in the work was gymneme sylvestre ,syzygium cumini, asparagus racemosus leaves was extracted by using ethanol and that extracts were used to formulate tablets. All the ingredients were passed through mesh no.20.The powder mixture possesses good flow properties additives like bulking agents, glidents, binders, lubricants, adsorbents were used for formulation evaluation of tablets was performed. Different parameters of evaluation like Appearance, hardness, percentage weight variation, friability, disintegration were performed and results were noted . It can be concluded that the powders of all extracts and compression method were suitable for the formulation of the tablet. Preformulation study and Physical Parameter revealed that all the values were within acceptable limit. Based on results it is concluded that the formulation and evaluations

are good. But still there is need to do accelerated stability study to determine shelf life of product.

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