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FABRICATION AND EVALUATION OF ANTI DIABETIC POLYHERBAL TABLETS

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ABSTRACT

Medicinal plants have played a crucial role in human civilization by providing essential resources, including medicines, for thousands of years. Their rich contents of bioactive secondary metabolites, such as alkaloids, glycosides, tannins, and lignans, contributes to various therapeutic properties, including anti-inflammatory, antioxidant, and antidiabetic effects. Given the increasing prevalence of diabetes mellitus and the side effects of synthetic drugs, there is growing interest in plant-based treatments. The study investigates the potential of six medicinal plants *Trigonella foenum-graecum* (Fenugreek), *Moringa oleifera* (Moringa), *Nigella sativa* (Black seed), *Linum usitatissimum* (Flaxseed), *Cinnamomum zeylanicum* (Cinnamon), and *Macrotyloma uniflorum* (Horse gram) for their antidiabetic properties. The research involves the collection, freeze-drying, and formulation of these plant extracts into a polyherbal tablet using methanolic extracts. Pre-formulation studies, including bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio were conducted to evaluate powder flow properties. Additionally, formulated tablets were subjected to quality assessment tests such as weight variation, friability, and disintegration time. The aim of the study is to contribute the growing body of evidence supporting the integration of medicinal plants into modern healthcare systems for diabetes management.

KEYWORDS: Medicinal plants, Bioactive compounds, Antidiabetic properties, Pre-formulation studies, Polyherbal tablet, Diabetes.

INTRODUCTION

Plants have played a vital role in human civilization, providing essential resources such as food, medicine, clothing, and shelter.[1] Natural products derived from plants have been widely explored for drug discovery, with medicinal plants being used for over 5,000 years.[2] Even today, nearly 70-90% of people in developing countries rely on traditional plant-based medicines.[3] Recognizing the value of these ancient remedies is crucial, as scientific validation can help integrate them into modern healthcare systems and open new possibilities for alternative treatments.[4]

One of the key reasons for the therapeutic potential of medicinal plants is their rich content of secondary metabolites.[5] These natural compounds including alkaloids, glycosides, tannins, and lignans offer a wide range of health benefits, such as anti-inflammatory, antioxidant, antitumor, and antidiabetic properties.[6] Many modern drugs have been developed directly or indirectly from plants, demonstrating their enduring significance in medicine.[7]

Diabetes mellitus, a condition that continues to rise globally, has led researchers to seek better treatment options, including herbal remedies.[8-15] The World Health Organization has recognized the importance of plant-based medicines, particularly in regions with limited access to conventional diabetes treatments.[16] Given the side effects of synthetic drugs like insulin and oral hypoglycemic agents, there is growing interest in natural antidiabetic compounds. Studies indicate that over 400 plant species possess hypoglycemic properties, yet many remain unexplored.[17] This study focuses on six medicinal plants inclosing *Trogonella foenum*, *Moringa oleifera*, *Nigella sativa*, *Linum usitatissimum*, *Cinnamum zeylanicum* and *Macrotyloma uniflorum*.[18]

Table 1: Phytochemical Aspects Of The Herbs Used In Formulation.[19-23]

S. No.	Local Name	Botanical Name	Family	Active Constitution	Mechanism Of Action
1	Fenugreek seed	*Trogonella foenum*	Fabaceae	Cinnamaldehyde	Increased insulin secretion and sensitivity
2	Moringa	*Moringa oleifera*	Moringaceae	Quercetin and chlorogenic acid	Inhibition of α-amylase and α-glucodase activities
3	Black seed	*Nigella sativa*	Ranunculaceae	Thymoquinone	Enhancing glucose tolerance, reducing hepatic gluconeogenesis
4	Flax seed	*Linum usitatissimum*	Linaceae	α-Linolenic Acid (ALA), omega-3 fatty acid, lignan	Improve insulin sensitivity, anti-inflammatory properties, Antioxidant
5	Cinnamon	*Cinnamomum zeylanicum*	Lauraceae	Cinnamaldehyde	Activating glycogen synthase, Inhibition of Alph-amylase
6	Horse seed	*Macrotyloma uniflorum*	Fabaceae	Aescin	Slow carbohydrate absorption, insulin receptor activators and stimulators of glucose uptake.

MATERIALS AND METHODS

The plant extracts used in this study were sourced from local traders. All the ingredients used as the excipients in the formulation of polyherbal tablets were of analytical grades. These plant materials were chosen based on their traditional medicinal value and potential therapeutic benefits.[24-25] The plant extracts were subjected to freeze-drying process. Each extract was separately dried for an appropriate duration based on its specific drying rate.

Preparation Of Granules By Wet Granulation Method

Diluents such as microcrystalline cellulose, magnesium stearate, were also dried to get the better formulation. The active ingredients were accurately weighed according to the formulation and combined with microcrystalline cellulose, followed by the addition of diluents and a glidant along with magnesium stearate as a lubricant.[26] Acacia binding solution was prepared using the necessary amount of water. The measured excipients were thoroughly blended with the extract, and the Acacia solution was gradually incorporated until the mixture formed a damp mass. This damp mass was then passed through a sieve with a mesh size of 16 and dried in an oven at 105°C until the granules were adequately dried. Subsequently, the dried granules were sifted through a sieve with a mesh size of 20 and prepared for lubrication. Magnesium stearate were thoroughly mixed and passed through a sieve with a mesh size of 40 before being combined with the dried granules.

Formulation of Polyherbal Tablets From Processed Granules

The polyherbal extract was accurately weighed and passed through sieve No. 20 to ensure uniform particle size. A granulating paste was then prepared. This paste was combined with excipients to form a wet, coherent mass, which was subsequently passed through sieve No. 22 to produce granules. The formed granules were then dried in an oven at a controlled temperature of 40-45°C, ensuring proper moisture removal while preserving the integrity of the active ingredients.[27] Finally, the tablets were compressed using 17mm punches on a single punch machine.[28] The blended powder from each trial batch was evaluated for flow characteristics, including bulk density, tapped density, compressibility index, and angle of repose.[29]

Table 2: Composition of Polyherbal Antidiabetic Tablets.

S. No.	Ingredients	Weight (mg)
1	Polyherbal extract	200
2	Microcrystalline cellulose	100
3	Magnesium Stearate	5
4	Acacia	10%
5	Propyl paraben	0.1%
6	Purified water	q.s

EVALUATION OF POLYHERBAL ANTIDIABETIC TABLETS

Pre Formulation Studies

1. Bulk density (ρb)

The bulk density was assessed by utilizing a graduated cylinder containing a weighed powder mixture of known volume. The bulk density is found by dividing the weight of the powder mixture by the volume occupied by its packing.

$$\rho b = M/V_o$$

2. Tapped density (ρt)

The powder blend was poured into a graduated cylinder that was then tapped on a hard surface. The tapping was carried on until there was no noticeable change in the volume of the powder blend within the cylinder. Tapped density is determined by calculating the ratio of the weight of the powder blend to the volume of the tapped

packing.

$$\rho t = M/V_t$$

3. Angel of repose

The precisely measured powder mixture was positioned in the funnel. The funnel's height was modified to ensure that its tip made contact with the peak of the powder heap. The powder mixture was permitted to flow freely through the funnel onto the surface. The diameter of the dust cone was recorded, and the angle of repose was determined using the formula:

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

Where, h = height of the pile, r = radius of the pile.

4. Compressibility index[30]

The bulk and tapped densities were measured, and Carr's index of the powder blend was calculated using the formula:

Compressibility index (%) = (Tapped density - Bulk density) × 100/ Tapped density

5. Hausner's ratio[31-32]

It is the measurement of frictional resistance of the drug. The ideal range should be 1.2-1.5. Hausner's Ratio is calculated using the formula:

$$(Vo - Vi) \times 100 / Vo$$

Where,

Vo= untapped density

Vi = tapped density.

Post Formulation Studies

1. Color and appearance

The color and appearance of the formulated tablets underwent a visual inspection.

2. Weight variation test

20 tablets were randomly selected and weighed individually to determine the average weight. The deviation from the mean weight of the tablets was then calculated and expressed as a percentage.

3. Friability test

Friability assesses the overall impact of shock on tablets. The friability test was conducted in accordance with pharmacopeial standards using the Roche friabilator, which involved 100 revolutions at a speed of 25 rpm. For the tablets to be deemed acceptable, the friability must not exceed 1.0%. The calculation for friability was done using formula

$$\% \text{ friability} = [W_0 - W_t / W_0] \times 100$$

Where, W_0 = initial weight of tablet

W_t = final weight of tablet

4. Thickness

Vernier calliper was used to measure the thickness of each tablet, 20 tablets from the batch was sampled and the average thickness of all the tablets was computed.

5. Disintegration Time

The disintegration time was assessed using a disintegration test apparatus maintained at a temperature of 37±0.5 °C for the immersion liquid. The time taken for complete disintegration was recorded. Tablets were considered disintegrated when no particles were visible above the specified gauge and when they passed swiftly through a 10mesh screen.[33]

6. *In vitro* Dissolution test

The study utilized a basket-type tablet dissolution testing apparatus. A dissolution medium was prepared by adding 0.1 M hydrochloric acid to the vessel, resulting in a total volume of 900 mL. The medium was then heated to a temperature of 37±1°C and agitated at a rate of 50 rpm for a period of 1 hour. At designated time intervals, 10 mL samples were taken from a location midway between the surface of the dissolution medium and the top of the rotating blade. Following each sample extraction, an equal volume of fresh dissolution medium, kept at the same temperature, was added back into the system. The samples were analyzed using a UV-visible spectrophotometer to determine the absorbance at a wavelength of 250 nm. The cumulative percentage of drug release was calculated using an equation based on a standard curve.[34]

RESULTS

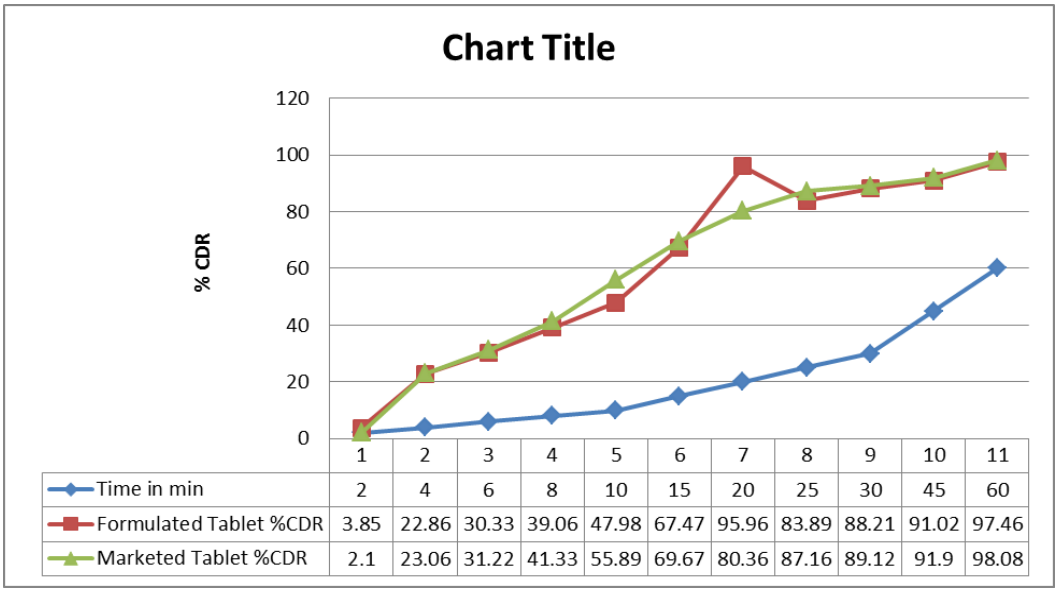
The results of the evaluation was seems to be within the prescribed limit. The results were been highlightened in the table 3 and 4

Table 3: Preformulation studies of Herbal Dried Extracts.

S. No.	Parameters	Observation
1.	Bulk Density (gm/ml)	0.52
2.	Tapped Density ((gm/ml)	0.53
3.	Angle of Repose	32
4.	Compressibility Index (%)	14.72
5.	Hausner's ratio	1.12

Table 4: Post Compression Evaluation Studies.

S. No.	Parameters	Observation
1.	Colour and Appearance	Dark Brown and round shape
2.	Weight variation	305.2
3.	Friability	0.87
4.	Thickness	4.09
5.	Disintegration Time	15.30



	1	2	3	4	5	6	7	8	9	10	11
Time in min	2	4	6	8	10	15	20	25	30	45	60
Formulated Tablet %CDR	3.85	22.86	30.33	39.06	47.98	67.47	95.96	83.89	88.21	91.02	97.46
Marketed Tablet %CDR	2.1	23.06	31.22	41.33	55.89	69.67	80.36	87.16	89.12	91.9	98.08

Figure 1: *In vitro* Drug Release Studies.

CONCLUSION

The polyherbal tablets being formulated by the wet granulation method shows good results. The formulated tablets were evaluated and the results were within the prescribed limits of Pharmacopeia. The preformulation studies also suggested that the flow properties and the other parameters are in accordance with the specified limits. However, still the further investigation needed to be carried out to specify the action of drug against diabetes. The *in vitro* drug release study indicates that the drug is being released from the formulated tablets in the much specified manner are in accordance with the marketed formulation as specified in literature. Moreover, the polyherbal formulations may also demonstrate synergistic effect which is the prime parameter in deciding the dose.

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