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FORMULATION AND CHARACTERIZATION OF POLYHERBAL EXTRACT BLEND FOR THE MANAGEMENT OF DIABETES

A. Veenadevi*, P.Srinivasa Babu, S. Aswini, M. Padma Sai Sree, Busi Divyasri

Department of Pharmaceutics, Vignan Pharmacy College, Vadlamudi, Guntur, AP, India.

A. Veenadevi

Assistant Professor

Vignan Pharmacy College

Corresponding author email.id: veenadeviavanigadda@gmail.com

Abstract:

Herbal antidiabetic agents play an important role in the management of diabetes by reducing blood glucose levels and enhancing insulin secretion with minimal adverse effects. The present study aimed to formulate and evaluate polyherbal sustained-release antidiabetic tablets using extracts of Annona squamosa, Psidium guajava leaves, and Trigonella foenum-graecum seeds. The plant materials were collected locally, shade-dried, powdered, and extracted separately using water and methanol. Polyherbal matrix tablets were prepared by the wet granulation method using starch as a binder and varying concentrations of HPMC K100 as a hydrophilic matrix-forming polymer. Five formulations were developed and evaluated for preformulation and post-compression parameters such as weight variation, hardness, friability, thickness, and disintegration time, which were found to be within pharmacopoeia limits. Dissolution studies demonstrated sustained drug release, with approximately 50% of the drug released within 6 hours. The in-vitro antidiabetic activity was assessed using the α-amylase inhibition assay, which showed a concentration-dependent increase in inhibition from 60.90% at 50 µg to 84.20% at 1000 µg. The inhibitory activity was comparable with standard drugs Metformin (85.81%) and Acarbose (75.72%) at 1000 µg, indicating significant antidiabetic potential. Overall, the formulated polyherbal tablets exhibited satisfactory physicochemical properties, sustained drug release, and promising antidiabetic activity, suggesting their potential application in the management of diabetes mellitus.

Key words: Polyherbal tablets; Sustained-release; Antidiabetic activity; α-Amylase inhibition assay; HPMC K100.

Introduction:

Over 100 million people worldwide, or roughly 6% of the total population[1], suffer from diabetes mellitus, a common endocrine disorder. The number of affected people is expected to increase fivefold over the course of the next ten years. Globally, diabetes is a major public health concern[2]. Diabetes mellitus is characterized by hyperglycemia, which can be caused by either decreased insulin receptor sensitivity, insufficient insulin production, or both[3]. This illness has grown to be a significant global health issue. Over the past 40 years, the prevalence of diabetes has rapidly increased worldwide[4]. The World Health Organization wants to cut the number of diabetes cases and premature deaths by one-third by 2030, but there hasn't been much progress[5]. According to recent estimates, the number of adults with diabetes between the ages of 20 and 79 will rise from 41 million in 2010 to 51 million in 2030, impacting roughly one in ten adults[6]. Although they may have a number of negative effects, insulin and oral antidiabetic medications are frequently used in allopathic medicine to treat diabetes complications and successfully lower blood glucose levels[7]. The effectiveness of several herbal remedies and minerals in managing diabetes mellitus has been reported in the literature[8]. Because they have fewer adverse effects than traditional allopathic medications, herbal remedies are frequently regarded as safer[9].

Materials and Methods :

The study utilized leaves of Annona squamosa and Psidium guajava, along with fenugreek seeds, which were obtained from local vendors. The plant materials were dried, powdered, and subjected to ethanol extraction. The excipients used in the formulation included Hydroxypropyl Methylcellulose (HPMC K100M), lactose monohydrate, and starch, all procured from Thermo Fisher Scientific India Pvt. Ltd.. Talc was obtained from Loba Chemie Pvt. Ltd., and magnesium stearate was sourced from SD Fine-Chem Limited. These materials and excipients were used in the preparation of the polyherbal tablet formulation.

Extraction of annona squamosa leaves powder:

The plant materials were initially collected and authenticated to verify their botanical identity. Once dried, the materials were ground into a fine powder and sieved to achieve a uniform particle size. The powders were then accurately measured and combined in a fixed ratio. Extraction was performed using the maceration method with water as the solvent. 75 g of the powdered drug, 750 mL of solvent was added and stirred occasionally. The mixture was filtered on the 8th day. The mixture was heated on a hot plate, filtered, and the solvent was evaporated to yield the crude extract. This extract was further heated until it formed a semi-solid mass, which was then dried in a vacuum dryer to produce a powdered form of the extract[10].

Extraction of psidium guajava leaves powder:

Fresh guava leaves were collected and authenticated, then thoroughly washed to remove impurities and shade-dried to preserve their active compounds. Once dried, the leaves were ground into a fine powder and sieved to ensure uniform particle size. 20 grams of powder was boiled at 90ºC in 100 ml of double distilled water in a sterile flask for 30 minutes. Mixture was centrifuged at 4000 rpm for 10 minutes (Remi elektrotechnik ltd). the supernatant was separated at stored at 4ºC for further study and concentrated by evaporating the solvent on a water bath until a semi-solid mass was formed. Finally, the concentrated extract was dried in a vacuum dryer to yield a powdered form suitable for further study[11].

Extraction of fenugreek seeds powder:

The dried seeds were ground into a coarse powder using a mechanical grinder. A measured amount of this powder was subjected to cold maceration with a mixture of ethanol and water as the extraction solvent for 48 to 72 hours, with occasional stirring to enhance the extraction of phytoconstituents. After the extraction period, the mixture was filtered through muslin cloth, and the filtrate was concentrated by evaporating the solvent on a hot plate until a semi-solid extract was obtained. The concentrated extract was then collected, dried, and stored in an airtight container for further phytochemical analysis and formulation studies[12].

Formulation of tablet:

Accurately weighed quantities of custard apple, guava, and fenugreek powders were measured using a calibrated digital balance and checked for uniformity before blending. The powders were transferred to a clean mortar and thoroughly mixed to create a homogeneous herbal blend. Starch was added as a disintegrant, lactose as a diluent, and hydroxypropyl methylcellulose (HPMC) as a binder to enhance cohesion. All excipients were uniformly mixed with the herbal powders, and a suitable amount of liquid was gradually added to form a smooth dough. The dough was properly kneaded, allowed to rest for adequate binding, and then passed through a No. 10 sieve to produce wet granules. These granules were dried in a hot air oven at a controlled temperature until the desired moisture content was achieved. The dried granules were cooled, passed through a No. 22 sieve to ensure uniform particle size, and any oversized lumps were removed. Finally, magnesium stearate and talc were incorporated as lubricants and glidants, and the mixture was uniformly blended to prepare it for tablet compression & quantities of ingredients used in the formulation was shown in below table-1[13].

Table no: 1 Formulation table for polyherbal tablet

S.no	Ingredients	F1	F2	F3	F4	F5
1.	Custard apple leaves extract	75mg	75mg	75mg	75mg	75mg
2.	Guava leaves extract	75mg	75mg	75mg	75mg	75mg
3.	Fenugreek seeds	50mg	50mg	50mg	50mg	50mg
4.	Hydroxypropyl methylcellulose	75mg	100mg	125mg	150mg	175mg
5.	Lactose monohydrate	175mg	150mg	125mg	100mg	75mg
6.	Starch	35mg	35mg	35mg	35mg	35mg
7.	Talc	10mg	10mg	10mg	10mg	10mg
8.	Magnesium stearate	5mg	5mg	5mg	5mg	5mg

Evaluation of powders:

Pre compression parameters of powder blend:[14]

Angle of Repose:

The angle of repose was determined using the fixed height method to evaluate the flow properties of the powder blend. About 10 g of the sample was allowed to flow through a funnel fixed at a height of 2 cm to form a conical heap. The height (h) and radius (r) of the powder cone were measured, and the angle of repose (θ) was calculated using the formula.

$$\theta = tan^{-1}\frac{h}{r}$$

Where, ɵ = Angle of repose

h = Height of the pile

r = Average radius of the powder cone

Bulk Density:

Bulk densities of all types of granules were assessed by gently pouring 25g of material into a 100 ml graduated cylinder through a glass funnel. The sample's volume was measured and recorded. By pouring a weighed quantity of mix into a graduated cylinder and measuring the volume and weight, the apparent bulk density was recorded.

$$Bulk\ Density = \frac{\text{Weight of the powder}}{\text{volume of Packing}}$$

Tapped Density:

By gently pouring 25g of material through a glass funnel into a 100ml graduated cylinder, the tapped densities of all types of granules were calculated. From a height of 2 inches, the cylinder was tapped until a steady volume was reached. The sample's volume after tapping was measured, and the tapped density was determined. The tapping was kept going until there was no more change in volume.

$$\text{Tapped Density} = \frac{Weight\ of\ powder}{Volume\ of\ Tapped\ Packing}$$

Compressibility Index:

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

$$\text{Compressibility index (\%)} = \frac{Bulk\ density - Tapped\ density}{Tapped\ density} * 100$$

Hausner's Ratio:

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

$$Hausner\ Ratio = \frac{Tapped\ Density}{Bulk\ Density}$$

EVALUATION STUDIES:

Post compression parametrs of tablets:

1. Physical evaluation test:
The overall look of the tablet was visually examined in terms of shape, colour, texture and odour. Vernier callipers were used to determine the thickness of the tablet. The tablet was placed vertically between two jaws, and the thickness was measured in millimetres. Six tablets were utilised for this test [15]

2. Weight variation test:.
For the weight variation test, the average weight of 20 tablets was determined. Each tablet was weighed individually, and the deviation from the average weight was calculated and expressed as a percentage. According to the criteria, no more than two tablets from the sample may deviate from the average weight by more than the specified percentage, and none of the tablets should deviate by more than twice that percentage.

3. Hardness :

Tablet hardness was measured using a Monsanto hardness tester. The tablet was positioned lengthwise between the upper and lower plungers, and force was applied by turning a threaded bolt until the tablet fractured. The hardness was then recorded in kg/cm.[16]

4. Friability:

Friability was assessed using a Roche friabilator, which subjects a sample of tablets to combined abrasion and shock by rotating a plastic chamber at 25 rpm, causing the tablets to fall from a set height during 100 revolutions. Pre-weighed tablets were dusted and then reweighed, with the friability expressed as the percentage weight loss. According to established limits, the friability should be less than 1%.[17]

It is calculated using a formula-

$$\% \, Friability = \frac{Initial\,Weight - Final\,Weight}{Initial\,Weight}$$

***5. In Vitro* drug release:**

The dissolution test for the polyherbal formulated tablets was conducted using the USP Apparatus Type II (paddle method). Nine hundred milliliters of pH 6.8 potassium phosphate buffer served as the dissolution medium, maintained at a temperature of 37 ± 0.5°C. The paddle speed was set to 50 rpm. One tablet was placed in each vessel, and samples were withdrawn at 5, 15, 30, 45 minutes, 1 hour, 1.5 hours, and 2 hours (extended up to 6 hours for extended-release formulations). After each sampling, an equal volume of fresh dissolution medium was added to maintain the volume. The samples were filtered and analyzed using a UV spectrophotometer at 271 nm. The percentage of drug release was then calculated. Dissolution testing was also performed on a standard marketed metformin tablet, and its drug release data were compared with that of the polyherbal tablets. [18]

6. Disintegration time:

Disintegration apparatus containing plastic tube measuring 80–100 mm in length, with an internal diameter of 28 mm and Six tablets were placed inside the tube, which was then repeatedly raised and lowered at a rate of 28 to 32 cycles per minute. The tablets were considered disintegrated when no particles remained above the wire gauze and all had passed through a 10-mesh screen[19].

7. Kinetics studies of drug release data:

Kinetic models are primarily used to describe the drug release from dosage forms. In vitro dissolution data were utilized to predict and develop sustained-release formulations. The mechanism of drug release and kinetic data for the prepared polyherbal tablet formulations were analyzed using model-dependent methods based on mathematical models such as zero-order, first-order, and Higuchi models. Additionally, Peppas plots were generated to further characterize the release kinetics. The various mathematical models analyzed included:

$$\text{Zero order: } C = C_0 - Kt$$

$$\text{First order: } \text{Log } C = LogC_0 - \frac{kt}{2.303}$$

$$\text{Higuchi model : } C = Kt^{1/2}$$

$$\text{Peppas model: } C = Kt^{n}$$

In kinetic studies, the following terms are commonly used: C represents the drug concentration at a given time interval t, C_0 is the initial drug concentration, K denotes the rate constant, and n is the release exponent indicating the drug release mechanism.

Zero-order drug release is analyzed by plotting the cumulative amount of drug released against time. First-order kinetics are evaluated by plotting the logarithm of the cumulative percentage of drug remaining versus time. The Higuchi model is assessed by plotting the cumulative percentage of drug released against the square root of time. The Korsmeyer-Peppas model is examined by plotting the logarithm of the cumulative percentage of drug released against the logarithm of time [20].

8. In vitro screening test:
In the in vitro α-amylase inhibitory screening test, α-amylase was initially dissolved in a phosphate buffer (pH 6.8) at a concentration of 0.1 mg/ml. The sample solution was then added to the α-amylase solution and incubated at 37°C for 5 minutes. Following this incubation, the reaction was started by adding 0.1 ml of a 1% w/v starch solution. The mixture was incubated further at 37°C for 3 minutes. The reaction was stopped by adding DNS (3,5-dinitrosalicylic acid) solution to the samples. The samples were then boiled at 100°C for 5 minutes, cooled to room temperature, and their absorbance was measured at 572 nm using a spectrophotometer [21].

Results and Discussion :

Evaluation of powder blends-

The table 2 summarizes the evaluation of powder blends (F1–F5) based on bulk density, tapped density, Carr's index, Hausner's ratio, and angle of repose, which collectively reflect the flow properties of the formulations.

Table no 2: Evaluation of powder blends

Formulation	Bulk Density (gm/ml)	Tapped Density (gm/ml)	Carr's Index (%)	Hausner's Ratio	Angle of Repose
F1	0.50	0.60	16.68	1.32	26.78
F2	0.54	0.58	11.67	1.20	28.80
F3	0.48	0.54	10.76	1.17	25.77
F4	0.44	0.62	12.00	1.18	22.90
F5	0.52	0.53	14.72	1.12	20.89

EVALUATION OF POLYHERBAL TABLET:

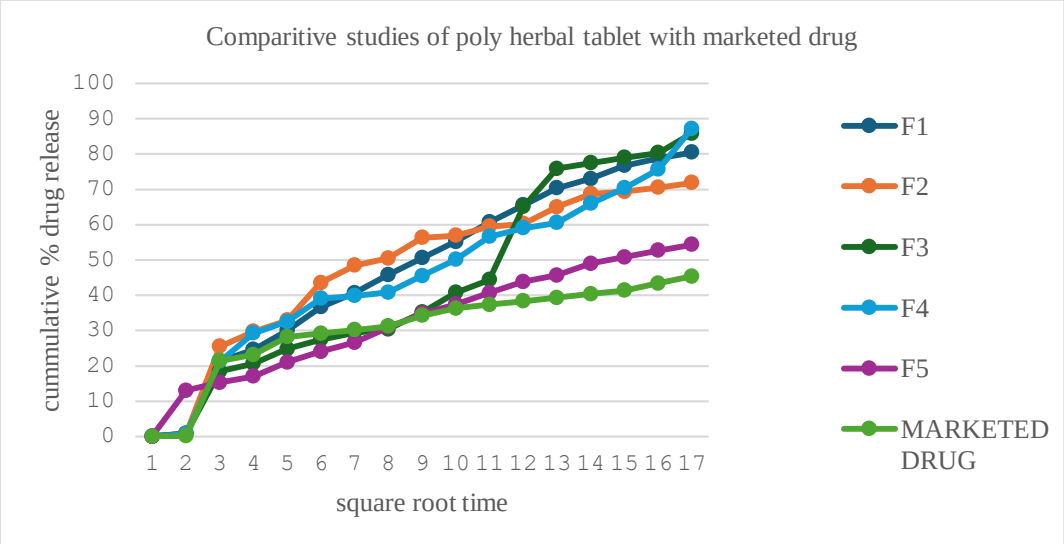
The polyherbal tablets (F1–F5) demonstrated uniform weight ranging from 470 to 503 mg, adequate hardness between 4.2 and 5.5 kg/cm², and consistent thickness of 7.03 to 7.09 mm. Friability values were below 1%, indicating good mechanical strength. Disintegration times ranged from 12.17 to 30.3 minutes, reflecting acceptable tablet performance.

Table 3 Evaluation Parameters of tablets after post compression.

Formulation	Average weight (mg)	Hardness (kg/cm^2)	Thickness (mm)%	Friability	Disintegration Time (min)
F1	470	5	7.03	0.56	15.24
F2	503	4.5	7.05	0.45	16.20
F3	502	4.2	7.09	0.85	12.17
F4	495	5.5	7.04	0.58	16.12
F5	497	5.3	7.08	0.76	30.3

DISSOLUTION STUDIES:

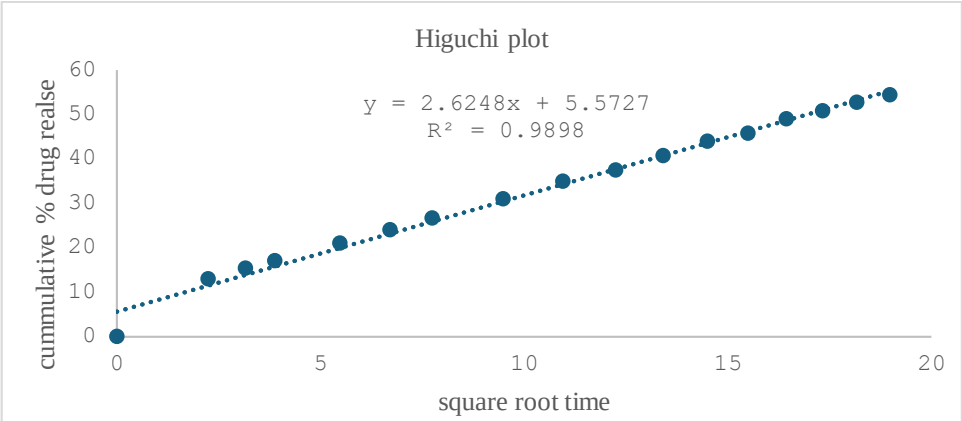
The dissolution study demonstrated a gradual increase in drug release over time for all formulations (F1–F5). Among these, F1 showed the highest drug release, while F5 exhibited the lowest, indicating a slower and more controlled release profile. This suggests that F5 offers superior sustained drug release compared to the other formulations. HPMC serves as a hydrophilic matrix polymer that forms a gel barrier upon hydration, regulating water penetration and drug diffusion. Drug release primarily occurs through diffusion and matrix erosion, extending the drug's action for approximately 8–12 hours. The Higuchi model further supports that the formulation follows a diffusion-controlled mechanism, confirming its sustained release characteristics was shown in comparative graph no-1.



Graph –1 Comparative studies of Poly herbal tablet with marketed formulation.

KINETIC STUDIES:

The Higuchi plot shows a linear drug release pattern for all formulations, indicating diffusion-controlled release. F1 showed slightly higher release, while others demonstrated sustained release behaviour. The graph of formulation F5 shows a steady increase in cumulative drug release with time. The linear pattern indicates a controlled and diffusion-based drug release mechanism. This suggests sustained release behaviour of the formulation. Huguchi plot for optimized formulation was shown in graph-2



Graph 2 Huguchi plot for optimized formulation

INVITRO ANTIDIABETIC ACTIVITY:

The in-vitro antidiabetic activity shows that percentage inhibition increased with increasing drug concentration (50–1000 µg). The highest inhibition was observed at 1000 µg (84.204%), indicating concentration-dependent enzyme inhibitory activity compared to the control was shown in below table no 4

Table no 4 Alpha amylase activity of Polyherbal Extract

Compound	concentration	Absorbance(s)	S-c	S-c/s	%inhibition
Extract	50µg	0.348	0.212	0.60962	60.902
	100µg	0.526	0.390	0.74	74.12
	250µg	0.664	0.528	0.79	79.52
	500µg	0.710	0.574	0.80	80.84
	1000µg	0.861	0.725	0.84	84.20
Control(c)		0.136			

The table shows that α-amylase inhibition by Metformin increased with concentration (50–1000 µg). The highest inhibition (85.841%) was observed at 1000 µg was show in below table 5

Table no 5 Alpha amylase activity of Metformin

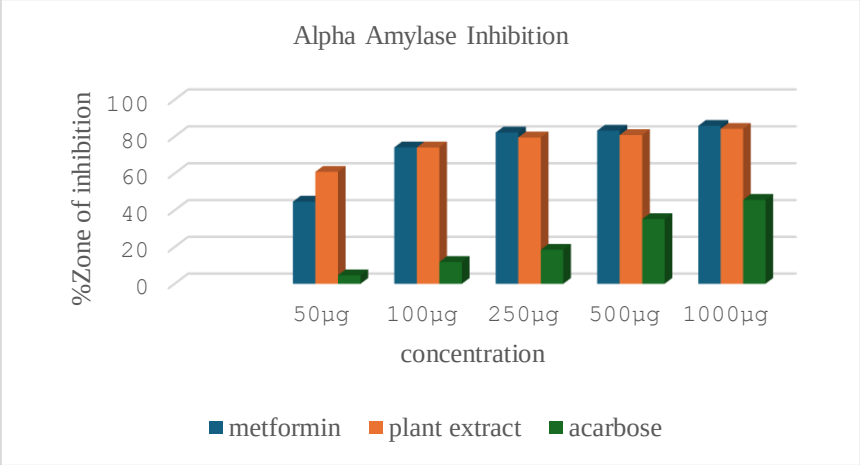
Compound	concentration	Absorbance(s)	S-c	S-c/s	%inhibition
Metformin	50µg	0.236	0.10	0.44	44.72
	100µg	0.526	0.39	0.74	74.14
	250µg	0.764	0.62	0.82	82.19
	500µg	0.810	0.67	0.83	83.21
	1000µg	0.961	0.82	0.85	85.84
	control	0.136			

The table shows the α-amylase inhibition activity of Acarbose, which was taken as the standard drug in this study. The percentage inhibition increased with concentration from 4.62% at 50 µg to 45.71% at 1000 µg, indicating a dose-dependent effect was shown Table 6

Table no 6: Alpha amylase activity of Standard Acarbose

Compound	concentration	Absorbance(s)	S-c	S-c/s	%inhibition
Acarbose	50µg	0.190	0.006	0.046	4.623
	100µg	0.210	0.021	0.129	11.891
	250µg	0.230	0.044	0.175	18.52
	500µg	0.278	0.2	0.392	35.20
	1000µg	0.329	0.146	0.427	45.71
Control(c)		0.182			

The graph represents the alpha-amylase inhibition activity of metformin, the test drug, and acarbose at different concentrations (50–1000 µg). The percentage of inhibition increases with increasing concentration for all samples, indicating a dose-dependent effect was shown in below Graph no 3.



Graph 3 Comparitive Graph Alpha Amylase Inhibition

Conclusion:

The research presents a promising polyherbal formulation derived from the synergistic combination of Psidium guajava (Guava), Trigonella foenum-graecum (Fenugreek), and Annona squamosa (Custard Apple), specifically designed to combat diabetes mellitus. The core strength of this treatment lies in its multi-targeted approach; rather than relying on a single pathway, it utilizes enzyme inhibition—likely targeting \alpha-amylase and \alpha-glucosidase—to slow carbohydrate digestion and prevent post-meal glucose spikes. By combining these three distinct botanical extracts, the formulation achieves a synergistic effect, meaning the collective therapeutic impact is significantly more potent than the results produced by any of the plants used in isolation. Furthermore, the study confirms that the resulting polyherbal tablet is not only pharmacologically effective but also biologically safe and chemically stable, making it a viable candidate for long-term oral administration. This identifies the formulation as a highly accessible, cost-effective, and natural alternative to synthetic oral hypoglycemic agents, offering a sustainable strategy for chronic disease management in diverse populations.

The formulation was found to be safe, stable, and suitable for oral administration. Overall, the developed polyherbal tablet shows strong potential as a natural, economical, and effective therapeutic option for the management of diabetes mellitus.

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