

Research Article

Formulation and Evaluation of Poly Herbal Nutraceutical Gummies for Diabetes

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Abstract

In this study due to the Changes in human lifestyle can have a profound impact on health, leading to a range of disorders. Poor diet, insufficient exercise, smoking, and excessive drinking are associated with chronic illnesses such as heart disease, diabetes, and some types of cancer. Nutraceuticals, which blend nutrition with pharmaceuticals, are foods or food components that are vital in altering and sustaining normal physiological functions crucial for human health. The growth of the global nutraceutical market is primarily driven by current demographic and health trends. Nutraceuticals sourced from both plants and animals present promising opportunities for the food industry to develop innovative food products in the future. In this study, we created nutraceutical gummies designed to address diabetes. These gummies were crafted using four plants known for their antidiabetic effects: panner Doda, star fruit, noni fruit, and the insulin plant.

Keywords: Nutraceuticals, Diabetes, Nutrition, Gummies.

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1 Introduction

A nutraceutical serves as an alternative to traditional medication, offering physiological advantages. The core principle of nutraceuticals is prevention, echoing the words of Hippocrates, the father of medicine, who advised, "Let food be your medicine." Jellies or gummies are clear or semi-clear, oil-free, semisolid formulations suitable for both internal and external use. Oral gummies are derived from water-soluble bases like tragacanth, gelatin, pectin, alginate, and boro glycerin [1]. Their appealing appearance makes them particularly suitable for both young and elderly patients. Furthermore, oral gummies are well-received by individuals with diabetes, as well as by geriatric and pediatric populations. They can be utilized in the oral cavity for both local and systemic treatments [2]. Oral gummies enable the quick breakdown of drugs using saliva, eliminating the need for water, and allow for rapid drug absorption through the buccal mucosa, thereby reducing the first-pass effect. This results in a significantly faster onset of action and more efficient drug absorption compared to the tablets currently available. Herbal medicines and supplements are gaining popularity in the market due to their minimal side effects and traditional applications.[3], [4], [5]

2 Method

Collection of Plant Material:

The star fruit powder was purchased from kr impex enterprises 208 east Mohan nagar, amrisar, The noni fruit powder was purchased from Shree ram online, bolangir, odisha, The paneer Doda powder was purchased from mandore industries area jodhpur, The insulin plant powder was purchased from 208 east Mohan nagar, amrisar.

Extraction Of Plant Material:

100 grams of powdered samples of each plant were extracted using a Soxhlet equipment for 24 hours using 1:1 ethanol and acetone as a solvents. A rotary evaporator was used to concentrate the extracts, and any remaining extracts were then dried. Until they were used, the extracts were kept in a refrigerator at 5°C. [6]

Selection of gelatine as a base:

For the preparation of gummies, gelatin were used as a jelling agent. To achieve optimal consistency in the nutraceutical gummies, a series of concentration of gelatin 5, 10, 15, 20, 25, 30 were used. The effect of gelatin concentration on the textural properties of the gummies was evaluated and the results showed that 25 grams of gelatin yielded the most desirable consistency.

Method of preparation:

The four formulations F1, F2, F3, F4 were prepared. In each formulation contained a combination of four plants, while three plants maintain at a constant concentration, and one plant concentration was varied at a lower level across a four formulations, the formulations as shown in the table no 1.

Table 1. formulation of gummies

Ingredients	F1(gm)	F2(gm)	F3(gm)	F4(gm)	Uses
Gelatin	12.5	12.5	12.5	12.5	Gelling agent
Insulin plant extract	2.75	3.25	3.25	3.25	Active ingredient
PaneerDoda extract	3.25	2.75	3.25	3.25	Active ingredient
Noni fruit extract	3.25	3.25	2.75	3.25	Active ingredient
Star fruit extract	3.25	3.25	3.25	2.75	Active ingredient
Stevia powder	6	6	6	6	Sweeting agent
Chocolate essence	0.1	0.1	0.1	0.1	Flavour agent
Citric acid	0.1	0.1	0.1	0.1	Acidifier
Propylene glycol	2	2	2	2	Humectant
Water	Q.s	Q.s	Q.s	Q.s	Vehicle

Method of preparation of gummies:[7], [8], [9]

1. The process of making gummies involves creating two separate solutions: one of water and sugar, and another of gelatin and water.
2. In a beaker, combine stevia and water. This mixture is heated on medium-high while stirring with a glass stirrer.
3. Adjust the temperature to ensure it does not exceed 130°C.
4. Continue heating until a clear solution is achieved.
5. In a different beaker, mix gelatin with water and heat gently for a few minutes.
6. Then, pour the warm sugar solution into the gelatin mixture, mix thoroughly, and heat the combined mixture briefly to 70°C.
7. Add varying concentrations of plant extracts from paneer doda, noni fruit, star fruit, and the insulin plant to the mixture, stirring to achieve a uniform solution. Then, incorporate flavoring agents and preservatives.
8. Coat the silicone mold with glycerine to prevent sticking. Pour the warm mixture into the mold and tap it on the shelf to level the fillings.
9. Remove and clean any excess solution from the mold.
10. Allow the mold to sit in a safe place at room temperature for 60 minutes.

Evaluation tests:[9], [10], [11], [12], [13], [14], [15], [16]

Physical appearance/visual inspection:

The formulation prepared was evaluated for clarity, texture, odour, taste, colour.

Determination of pH:

A 10% v/v Gummy solution was constituted in distilled water, and the pH of the solution was measured using a calibrated pH meter.

Solubility test:

Solubility was obtained by adding the solute in a small amount to a fixed volume of solvents like water, ethanol, ether, and 0.1 N HCl during the pre-formulation solubility analysis.

Stability study:

The stability of the formulation was studied for a period of 4 weeks by keeping it at a temperature of 25–30 °C.

Moisture content:

One gummy was weighed and then crushed in a mortar and pestle. From there 1g of the sample was weighed and dried for 24hrs in desiccator. The sample is weighed after 24hrs.

% moisture = $\frac{\text{initial wet weight} - \text{dry weight}}{\text{dry weight}} \times 100$

Stickiness:

The texture of the medicated gummy in terms of stickiness had been evaluated by visual inspection of the product after mildly rubbing the gummy sample between two fingers.

Spread ability:

The ability of the gummy to spread was evaluated by placing it between two slides, with a 1000 g weight applied on top of the upper slide, and pressing it for 5 minutes to achieve uniformity. The area over which the gummy spread was then calculated using the formula ($A = \pi r^2$), which denotes the area of a circle.

Weight variation:

The gummy were removed from the moulds and weighed. The observed data was reported as mean standard deviation, with the average weight of 10 gummy being used as the reference point.

Weight variation = $\frac{\text{individual weight} - \text{average weight}}{\text{average weight}} \times 100$

Syneresis Test:

Syneresis occurs when water drains from a contracting or shrinking structure by extraction or expulsion, potentially reducing the gummies quality. This test was performed at room temperature ($25 \pm 5^\circ\text{C}$) by weighing the samples. First, an absorbent paper was attached to the surface of each gummies, and then

the final weights of the preparations were observed. A significant difference between the initial and final weights indicates syneresis.

% syneresis = $\frac{\text{initial weight} - \text{final weight}}{\text{final weight}}$

Thickness test:

The gummy thickness is measured by using the verniers callipers, the each recipe will be checked for thickness to determine the thickness.

Alpha amylase inhibition activitys:

α -amylase is an enzyme that hydrolyses the polysaccharides such as starch, glycogen into glucose and maltose. α -amylase inhibitors bind to α - bond of polysaccharide and prevent the breakdown of polysaccharide into mono and disaccharide. By means of inhibiting the α -amylase, the glucose formation from the glycogen and starch will be reduced. Alpha-amylase activity can be measured in-vitro by hydrolysis of starch in presence of α -amylase enzyme. This process was quantified by using iodine, which gives blue colour with starch. The reduced intensity of blue colour indicates the enzyme- induced hydrolysis of starch in to monosaccharides. α -Amylase was premixed with formulation F1, F2, F3, F4 separately and 0.5% starch solution was added at 37°C for 5 min to start the reaction and terminated by addition of 2 ml of 3,5-dinitrosalicylic acid The reaction mixture was heated for 15 min at 100°C and diluted with 10 ml of distilled water in an ice bath α -Amylase activity was determined by measuring spectrum at 540 nm. Acarbose was used as standard α -amylase inhibitor.

3 Result and Discussion

The wide literature survey carried out for the present research work, to formulate the herbal nutraceutical gummies. This study focus on the development of nutraceuticals gummies utilizing four plants renewed for their antidiabetic properties, panner Doda, star fruit, noni fruit and insulin plant. These plants have been traditionally employed in various cultures to manage blood sugar levels. Paneer Doda, for intense, has been shown to possess alpha glucose inhibitory activity, while star fruit flavonoids and phenolic acids have been found to exhibit anti-oxidant and anti-diabetic effects. Noni fruit which composition of anthraquinones, flavonoids, and phenolic acids has been linked to improve glucose metabolism, where has insulin plant bio active compounds have been reported to stimulate insulin secretion and enhance glucose uptake in muscles. The combining these plants into a nutraceutical gummy formulation, these study aims to create a novel, natural, and effective product for diabetes management. To investigate the synergistic effects of the four plants, four nutraceutical gummy formulations F1, F2, F3 and F4 were developed. Each formulation contained a combination of four plants, while three plants maintain at a constant concentration, and one plant concentration was varied at a lower level across a four formulation the formulations as shown in the table no 1. This deliberate variation a loud us to assess the individual contribution of each plant to the overall anti-diabetic efficacy of the formulations, while also evaluating the synergistic interaction among the plant extract.

Physical appearance.

Table 2. physical parameters of gummies

SI.no	Parameter	F1	F2	F3	F4
1	Colour	Brown	Brown	Brown	Brown
2	Odour	Chocolate	Chocolate	Chocolate	Chocolate
3	Texture	Soft	Soft	Soft	Soft
4	Clarity	Transparent	Opaque	Opaque	Opaque
5	Taste	Light sweet	Light sweet	Light sweet	Light sweet
6	Consistency	Semisolid	Semisolid	Semisolid	Semisolid
7	Shape	Heart shape	Heart shape	Heart shape	Heart shape
8	Chewiness	Easily chewable	Easily chewable	Easily chewable	Easily chewable
9	Stickiness	Non-sticky	Non-sticky	Non-sticky	Non-sticky

pH determination:

Table 3. Determination of pH

Formulations	pH
F1	6.7
F2	6.7
F3	6.9
F4	6.8

Solubility:

Table 4. Determination of solubility

Solvent	F1	F2	F3	F4
Water	Sparingly soluble	Sparingly soluble	Sparingly soluble	Sparingly soluble
Ethanol	Insoluble	Insoluble	Insoluble	Insoluble
Ether	Slightly soluble	Slightly soluble	Slightly soluble	Slightly soluble
0.1N HCL	Easily soluble	Easily soluble	Easily soluble	Easily soluble

Moisture content:

Table 5. Determination of moisture content

Formulation	Moisture content (gm)
F1	0.16
F2	0.13
F3	0.14
F4	0.14

Spread ability:

Table 6. Determination of spread ability

Formulation	Initial area cm ²	Spread ability (cm ²)
F1	1.6 cm ²	3.8 cm ²
F2		3.6 cm ²
F3		3.5 cm ²
F4		3.6 cm ²

Weight variation:

Table 7. Determination of weight variation

Formulation	Average weight
F1	2.01 gm
F2	2.02 gm
F3	2.07 gm
F4	2.1 gm

Syneresis Test:

Table 8. Determination of syneresis test

Formulation	Initial weight	Final weight	Syneresis (%)
F1	2.02	1.89	0.13
F2	2.10	1.68	0.42
F3	2.40	2.10	0.30
F4	2.09	1.19	0.9

Alpha Amylase Inhibition Test

Alpha-amylase activity can be measured *In-vitro* by hydrolysis of starch in presence of α -amylase enzyme. This process was quantified by using iodine, which gives blue colour with starch. The reduced intensity of blue colour indicates the enzyme- induced hydrolysis of starch in to monosaccharides. α -Amylase was premixed with formulation F1, F2, F3, F4 separately and 0.5% starch solution was added at 37°C for 5 min to start the reaction and terminated by addition of 2 ml of 3,5-dinitrosalicylic acid The reaction mixture was heated for 15 min at 100°C and diluted with 10 ml of distilled water in an ice bath α -Amylase activity was determined by measuring spectrum at 540 nm. Acarbose was used as standard α -amylase inhibitor. [17]

Table 9. Alpha amylase inhibitory activity

Formulation (500mg/ml)	Percentage of inhibition (%)
Standard (Acarbose)	81.69
F1	55.45
F2	58.14
F3	69.23
F4	62.55

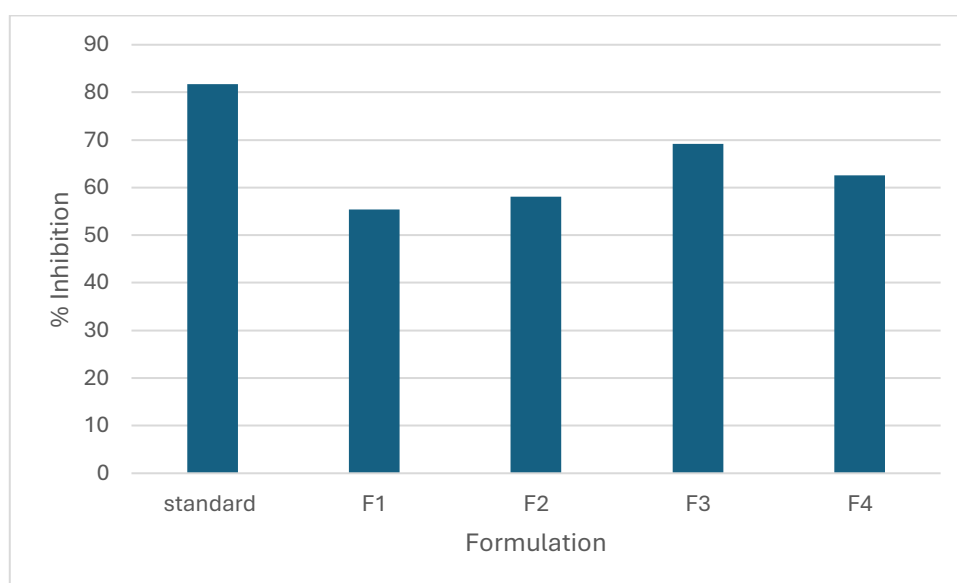


Fig 1. Alpha amylase inhibitory activity

The alpha-amylase inhibitory activity was performed on the four formulations F1-F4. The most potent action was shown by Formulation F3 despite having a lower concentration of noni fruit extract, which suggests a strong synergistic effect among the herbal components. The overall order of increasing anti-diabetic activity was F3 > F4 > F2 > F1.

4 Conclusion

In this study, poly herbal nutraceutical gummies for diabetes management were successfully formulated and evaluated [1]. The formulations F1, F2, F3, F4 were developed using four plants with established antidiabetic properties: paneer Doda, star fruit, noni fruit, and the insulin plant². The core of the study involved varying the concentration of one plant extract across the four formulations to investigate the synergistic effects of the herbal combination³. All four formulations showed positive alpha-amylase inhibitory activity, a mechanism that reduces blood glucose by preventing the breakdown of starch and glycogen into simple sugars [4]. This effect is likely due to the plants' rich phytoconstituents, such as alkaloids, tannins, and flavonoids, which inhibit amylase activity [5]. Notably, Formulation F3 demonstrated the most potent action, despite having a lower concentration of noni fruit extract compared

to the other constant extracts [6]. This superior efficacy strongly suggests a significant synergistic effect among the combined herbal extracts, validating the potential of these poly herbal gummies as an effective, natural approach to diabetes management [7].

5 Declarations

5.1 Author contributions

The names of the authors listed in this journal contributed to this research.

5.2 Conflict of Interest

The authors declare no conflict of interest.

5.3 Funding Statement

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