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Formulation and Evaluation of Anti - Diabetic Pastilles

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ABSTRACT:

Background and objectives: The main objective of this current research work is to formulate and evaluate an anti – diabetic, herbal pastilles. Pastilles, derived from the Latin word pastilles which was from panis, meaning loaf. They are pill shaped lump of condensed herbs which was ignited to release its medicinal properties. They are formulated by discharging a thick viscous liquid into a solid mold and allow it to solidify. The drug release takes place by chewing them. The herbs, *Gymnema sylvestre* powder and *Costus speciosus* used in this formulation have shown proven activity in the treatment of type 2 diabetes mellitus.

Materials and methods: Pastilles are known for its convenient, palatable solid dosage administration. This abstract provides an overview of formulation and evaluation of pastilles containing antidiabetic herbs such as *Gymnema sylvestre, Costus speciosus*. The pastilles are formulated using 0.5g and 1g of *Gymnema sylvestre* and *Costs speciosus* with agar as thickening agent. Honey and peppermint oil were added as sweetening and flavoring agent.

Results and Discussion: Results proved that with the increase in the quantity of agar and acacia gradually, pastilles satisfy all the evaluations successfully. Among the five formulations, formulation two and five showed successful in all aspects.

Keywords: *Pastilles, Gymnema sylvestre, Costus speciosus, Diabetes mellitus.*

INTRODUCTON:

Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Treatment of diabetes involves a multifaceted approach such as dietary changes, pharmacotherapy and continuous monitoring. However, the complexity of treatment regimens often leads to issues of therapeutic non-compliance among patients, compromising the effectiveness of diabetes management. In pursuit of addressing this challenge, the present research delves into the formulation and evaluation of anti-diabetic pastilles as a novel and patient-friendly dosage form.[1]

Pastilles, or medicated lozenges, have gained attention as a promising drug delivery system due to their ease of administration, palatability, and potential for controlled drug release. This research aims to explore the development of anti-diabetic pastilles containing pharmacologically active agents with proven efficacy in diabetes management. The formulation will be designed to enhance patient adherence by providing a convenient and pleasant means of medication intake.[7]

MATERIALS AND METHODS:

The pastilles are formulated using 0.5g, 1g, 1.5g, 2g and 2.5g of *Gymnema sylvestre* and *Costus speciosus* with agar and acacia as thickening agents. Honey, jaggery and peppermint oil were added as sweetening and flavoring agent. They are formulated using mold injection method by discharging a thick viscous liquid into standard pastilles molds of 2ml capacity allowed it to solidify at room temperature. The drug release takes place by chewing them.[1]

Table 1: Composition of herbal anti - diabetic pastilles

Formulation code	*Gymnema sylvestre* (g)	*Costus speciosus* (g)	Agar (g)	Acacia (g)	Honey (g)	Jaggery (g)	Water
01	0.5	0.5	1.5	0.25	2.5	2.5	Q.S.
02	1	1	1.0	0.25	2.5	2.5	
03	1.5	1.5	1.5	0.5	2.5	2.5	
04	2.0	2.0	3.0	1.5	2.5	2.5	
05	2.5	2.5	3.5	2.0	2.5	2.5	

Figure 1: Pastilles by injection method in silicon moulds

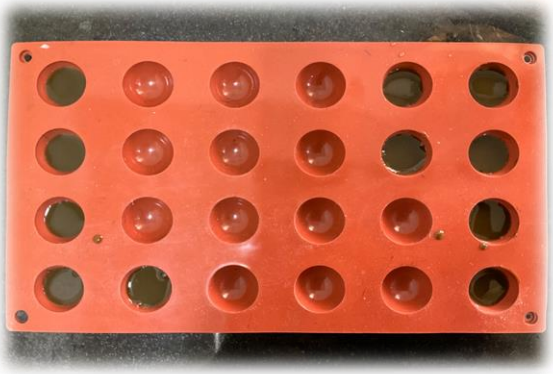
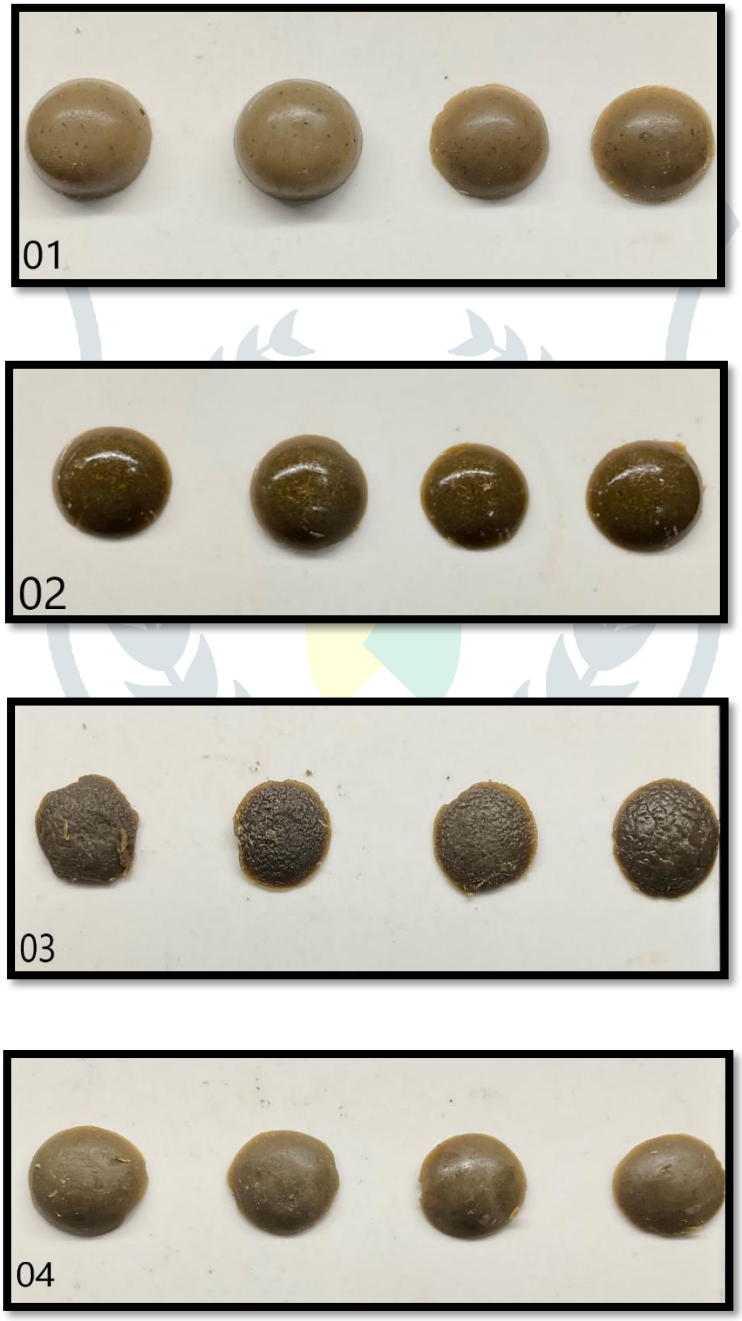


Figure 2: Pastilles of different formulations



Evaluation of the Soft Pastilles

The prepared pastilles were studied for their physiochemical properties like weight variation, Hardness, Thickness, Diameter and Friability.

Weight Variation test

Ten pastilles were taken from each formulation (1 to 5) and measured individually using digital weighing balance. The average weight of one pastille is calculated by using the formula[1]

$$\text{Weight variation} = \frac{\text{Individual weight} - \text{Average weight}}{\text{Average weight}} \times 100$$

Hardness

The hardness of pastilles was determined using Monsanto hardness tester.[1]

Thickness

The thickness and diameter of the pastilles was determined using vernier caliper and ruler of 30cm.[2]

Friability

The Roche Friability apparatus was used to determine the friability of the pastilles. The pastilles were first weighted (initial weight). The initial weight was noted. The weighed pastilles were put in the apparatus and was rotated at 100 revolution or for 4 minutes. Then again, the pastilles were weighed individually and the difference is noted.[2]

The percentage of friability is calculated using the formula

$$\text{Friability (\%)} = \frac{\text{Initial weight of tablets} - \text{final weight of tablets}}{\text{Initial weight of tablets}} \times 100$$

Swelling index

Initial weight of the pastilles from each batch is noted. One pastille from each formulation is kept in the measuring cylinder of 50ml each [5 numbers] which is filled by 20ml water each and kept it aside for 24 hours. After 24 hours again it is weighed and the weight is noted.[1]

Invitro drug release studies

Dissolution conditions:

- **Apparatus** USP 2 paddle apparatus
- **Dissolution medium** 200ml of pH 6.8 phosphate buffer
- **Temperature** 37 degree Celsius
- **Rotating speed** 100 rpm
- **Sample time interval** 10,20,30 minutes
- **Detection** UV Visible spectrophotometer at wavelength 273nm

The samples were withdrawn at 10,20,30 minutes and analyzed using UV at 273nm respectively.[2]

RESULTS AND DISCUSSION:

Results:

Table 2: In process quality control tests (IPQC)

All

Formulation code	Weight variation(g)	Hardness (kg/cm^2)	Thickness (mm)	Diameter (cm)	Friability (%)
01	1.42 ± 0.10	2.20±1.19	7.12 ±0.01	2.1	0.42± 0.04
02	2.14±0.22	2.47±1.43	7.25± 0.04	1.96	0.79± 0.01
03	1.97±0.32	3.50±1.72	7.29± 0.05	2.22	0.63± 0.06
04	1.7±0.17	5.43± 1.10	7.30± 0.02	2.0	0.59± 0.04
05	1.07±0.22	4.03±1.52	7.32±0.04	1.98	0.58 ±0.08

prepared formulations underwent physical-chemical evaluations such as weight variation, thickness, hardness, friability, drug content, disintegration test, and wetting time to determine the formulation's suitability for the dosage form and intended therapeutic use.[5] The weight variation was within ± 2% of variation. The hardness of each formulation was estimated and found to be in acceptable range of 5 to 5.5 kg / cm2. The thickness of lozenges was nearly similar across all formulations, falling between 7.10 mm and 7.30 mm. Friability was discovered to be less than 1%, which is regarded satisfactory in the range of 0.08 to 0.01%.

Table 3: Dissolution profile of pastilles

Formulation code	Time (mins)	Absorbance at 273nm
1	10	0.204
	20	0.233
	30	0.246
2	10	0.251
	20	0.265
	30	0.292
4	10	0.145
	20	0.154
	30	0.185
5	10	0.139
	20	0.156
	30	0.208

The manufactured sugar-free lozenges were tested for dissolution time. The samples were withdrawn at pre-determined time points, diluted appropriately, and analysed. spectrophotometrically at 273 nm.[2]

Swelling index:

Table 4: Swelling index profile of pastilles

Formulation code	Observation (20 ml)
1	No change
2	No change
4	Increased by 0.5 ml
5	Increased by 1 ml

Appearance:

The pastilles, except for batches F3 and F4 showed smooth appearance and no cracks were found while inspecting using magnifying glass (5X and 10X) with very smooth flat surface and light brown colour with aromatic fragrance with mild sweet taste

DISSCUSSION:

The anti-diabetic herbal pastilles were formulated and evaluated. Results proved that with the increase in the quantity of agar and acacia gradually, pastilles satisfy all the evaluations successfully. The formulation with 1 & 2.5 gm quantity of *Gymnema sylvestre*, *Costus speciosus* complied with the tested evaluation parameters. This formulation passes the tests as per the Indian Pharmacopeial (IP) procedures. Further justification in terms of its pharmacological and therapeutic activity such as anti-diabetic and anti-oxidant potential could be exhibited with further studies.

CONCLUSION:

In conclusion, the formulation and evaluation of anti-diabetic pastilles containing Gymnema sylvestre and Costus speciosus have shown promising results. The pastilles demonstrated favorable physiochemical properties and drug release characteristics. Formulations two and five in particular showed success in all aspects of evaluation. This research signifies the potential of pastilles as a novel and patient-friendly dosage form for the management of diabetes. Further studies and clinical trials could validate the effectiveness and patient compliance of these anti-diabetic pastilles, paving the way for a convenient and palatable medication option for individuals with diabetes mellitus.

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