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REVIEW ARTICLE

FORMULATION AND EVALUATION OF NUTRACEUTICAL MIX

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ABSTRACT

Aswagandha is a medicinal herb widely used by the people to treat various disorders like diabetes, mental disease, asthma, inflammation, arthritis and tuberculosis. The plant *Withania coagulans* commonly called as aswagandha belongs to the family *Solanaceae* and is a rare, endangered and endemic plant species of India. The curative properties of the plant have ascribed to the presence of complex chemical substances such as alkaloids, glycosides, steroids, flavonoids, essential oils etc. which are secondary metabolites synthesized from intermediate metabolism. Hence a study was conducted with the objective of assessing the "Effect of medicinal plants on type II diabetes ''.The effect of medicinal plants was studied by formulation and evaluation of nutraceutical mix. The study was carried out in the Department of Pharmacology, home science college and research institute, Madurai. The utraceutical formula was developed and organoleptically evaluated by a panel of diabetics using nine point hedonic rating scale. Based on the organoleptic evaluation it was observed that the patient hesitate to take the nutraceutical formula in the form of powder because of mixed strong flavour and bitter taste. Hence, the nutraceutical formula was given in the form of capsule. Both the extracts of AF&SAFJA were mixed in the proportion of 40:200 and then dried under sunlight with lid. Dried extract was powdered and filled in the empty gelatin capsule at 2.5 mg dosage level. The extracts proved the considerable glucose reduction and hence the capsule named as glucodip. The glucodip capsules were packed in plastic bottles, pet jars and 400 gauge polyethylene bag which were stored at ambient condition to study their storage behaviour (changes in moisture and microbial load). The capsules were drawn from each packaging material and analyzed for their quality for a period of 180 days at 30 days interval. Glucodip capsule showed a gradual and marked decrease in blood sugar & urinary sugar level during the study period. This reduction was a significant decrease. Production cost of glucodip capsule was Rs. 5.00 per capsule.

INTRODUCTION

It has been pointed out by the World Health Organization that nearly 60 per cent of the global deaths are mainly due to non communicable disease like cardiovascular diseases, respiratory disorder, diabetes mellitus, hereditary ailments mental and neurological disease (Sativa and Mani, 2001). According to Kowsalya *et al*. (1995) the use of oral hypoglycemic drugs and insulin therapy have been considered as an effective treatment to control diabetes. But prolonged courses may cause undesirable changes to the body. They suggested that controlling diabetes through selective medicinal herbs could be the effective management of diabetes. Aswagandha is one of the medicinal herb widely used by the people to treat various disorders like diabetes, mental disease, asthma, inflammation, arthritis and tuberculosis. The plant *Withania coagulans* commonly called as aswagandha belongs to the family *Solanaceae* and is a rare, endangered and endemic plant species of India.

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The curative properties of the plant have ascribed to the presence of complex chemical substances such as alkaloids, glycosides, steroids, flavonoids, essential oils etc. which are secondary metabolites synthesized from intermediate metabolism (Arora, 2004). The local name Asgandh seems to be derived from the Sanskrit name Aswagandha. Ashwa means horse and gandha means fragrance – smelling like a horse and it literally means "the sweat of horse"which indicates the property of strength and the sexual vitality of the horse. Mostly the roots and occasionally the leaves and seeds of the plant are used in medicinal preparations fruits are very rarely used. The major biochemical constituents of aswagandha from which its primary medicinal properties emanate, are based upon the actions of certain steroidal alkaloids and steroidal lactones in a class of constituents called withanolides . These serve as an important hormone precursors which the body is then able, as needed, to convert into human physiological hormones. If there is an excess of a certain hormone, the plant based hormone precursors occupy the so-called hormone receptor sites, without converting to human hormones, to block absorption. In this way, Aswagandha, like other adaptogenic tonic herbs, is

amphoteric and can serve to regulate important physiological processes, increasing or decreasing as needed (Subramanian, 1984) WHO approves the use of plant drugs for the different diseases including diabetes as well. (Habib *et al*, 2005). Therefore studies with plant extract are useful to know their efficacy, mechanism of action and safety. Hence a study entitled on "Effect of medicinal plants on type II diabetes '' was planned with following objectives:

OBJECTIVES

- Standaradization of herbal formula for type II diabetes.
- Analyze the quality characteristics of herbal formula initially and on storage

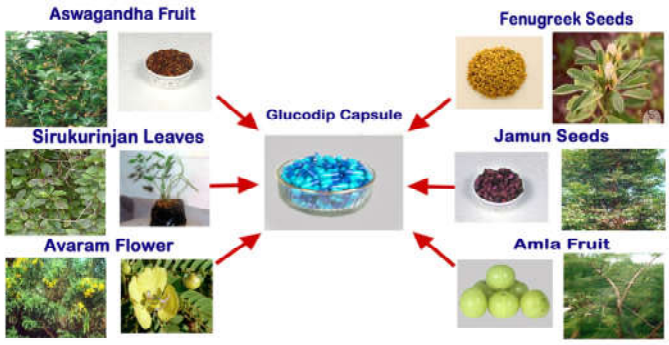
MATERIALS AND METHODS

This chapter deals with the materials and methods adopted for the study on the formulation and evaluation of nutraceutical food mix.The study was conducted in the Department of Food Science and Nutrition, Home Science College and Research Institute, Tamil Nadu Agricultural University, Madurai.

Materials

Ingredients used for capsule formulation

Fig 4. Ingredients used in Glucodip Capsule



Chemicals used for the laboratory estimation

The chemicals and reagents used for the study were of laboratory reagent (LR), analytical reagent (AR) or guaranteed reagent (GR) grade.

Capsule

Capsule made of gelatin was used for packing the glucodip capsule.

Packaging materials

The capsules were packed in plastic bottles, pet jars and 400 gauge poly ethylene bag.

Preparation of plant extract

Aswagandha Fruit (AF), Sirukurinjan leaves, Avaramflower, Fenugreek seeds, Jamun seeds and Amla fruit (SAFJA) were cleaned, washed dried and powdered. Sirukurinjan leaves, Avaramflower, Fenugreek seeds, Jamun seeds and Amla fruit (SAFJA) were mixed with equal amount and named as SAFJA extract.

Aswagandha fruit powder and SAFJA powder (1:2) was extracted in boiling water for 2 hrs and concentrated to half of the volume by double boiling method. Then it was cooled and filtered thorough Whatman No 1 filter paper. The filtrate was centrifuged at 10000 rpm in Sorvall centrifuge at room temperature (32ºc) and the supernatant of the extract was concentrated up to 100ml.The concentrated crude extract was dried and made in to powder and used for the study.

Acceptability trial of nutraceutical formula

The results indicated that group III (40:200) had higher hypoglycemic activity when compared to other groups. The nutraceutical formula (40:200 proportion of AF & SAFJA) organoleptically evaluated by a panel of diabetics by using nine point hedonic rating scale. Based on the organoleptic evaluation it was observed that the patient hesitate to take the nutraceutical formula in the form of powder because of mixed strong flavour and bitter taste. Hence, the nutraceutical formula was given in the form of capsule for diabetic patients. K.S Variar Astanga Ayurvedics Pvt ltd, at Trichy and used for further study (capsule formation).

Storage studies

The glucodip capsules were packed in plastic bottles, pet jars and 400 gauge polyethylene bag and stored at ambient condition to study their storage behaviour by observing changes in moisture and microbial load. The capsules were drawn from each packaging material and analyzed for their quality for a period of 180 days at one month interval

Chemical analysis for the capsules

The procedures adopted to analyze the chemical composition of the capsules are given below

Moisture

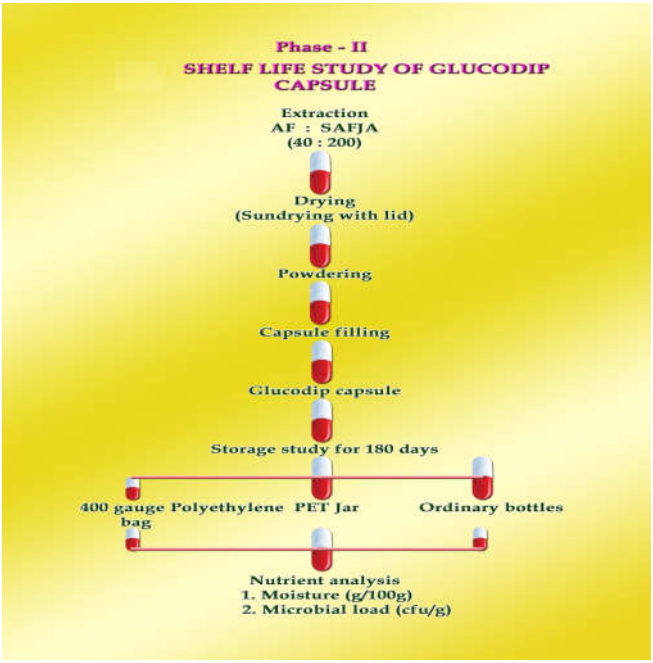
The moisture content of formulated capsule was estimated by the air-oven method suggested by Ranganna (1995). The sample was dried at 110°C and the drying was continued till a constant reading was obtained. The moisture content was expressed as percentage.

Microbiological examination

Microbiological examination of capsules was carried out by the method prescribed by Istavankiss (1984). Approximately 1 g of the sample was taken in a 9 ml sterile water blank and thoroughly mixed in a rotary shaker for 10 minutes. From the solution, a series of 10^6 to 10^4 dilutions were obtained by using serial dilution techniques. The dilutions 10^6, 10^4 and 10^3 were used for bacteria, fungi and yeast respectively. From the respective dilutions, 10 ml of sample was poured in a petri plate and rotated clockwise and anti-clockwise for uniform spreading of the sample. Sterilized and cooled (40^0c), respective medium was poured into petri plates and allowed to solidify. After solidification, the plates were incubated at room temperature (28± 2^0C) for 2 days for bacteria, 2 to 3 days for fungi and 5 days for yeast.

Economic feasibility analysis

To analyze the economic feasibility of the processing plant project, four criteria were considered, viz.,



- Internal-rate of return,
- Benefit-cost ratio,
- Payback period and
- Break-even point (Rajan, 1984**).**

Processing

Cost and returns of a mini value added processing unit

The feasibility of organizing small processing units as a cooperative venture was examined by analyzing the cost and returns from a hypothetical processing plant with a capacity of processing 100 capsules /day for 300 days. The capital components were divided into initial investment cost, variable cost and fixed cost. The initial investment cost included the value of land, buildings, machineries and equipments and the charge for provision of facilities. The variable cost in the case of capsule production included cost of raw materials, packing material cost, cost of fuel, electricity charges, labour charges i.e., technical, skilled and unskilled, other contingent expenses and cost of other raw components. The fixed cost in the case of capsule production included the administrative and supervisory charges, telephone and advertisement charges, interest on total investment, annual depreciation on machineries and equipments and depreciation on office equipments.

Annual total cost of production

It was estimated by adding annual total fixed cost and to the variable cost.

Gross return

It was worked out by multiplying the annual production and prevailing product market price per unit.

Profit

It was obtained by deducting annual total cost of production from gross return.

RESULTS AND DISCUSSION

Using acceptable, safe and economically feasible methods traditional medicine is becoming one of the surest means to achieve total health care coverage for the world's populations. In the next millennium traditional medicine would take a position as a back bone of biomedical research. In this chapter the results obtained from the present study on the formulation and evaluation of nutrceutical mix are highlighted and discussed under the following headings. Acceptability trial of nutraceutical formula among diabetes

Quality evaluation of glucodip capsule on storage

Acceptability trial of nutraceutical formula for diabetes

The developed nutraceutical formula organoleptically evaluated by a panel of diabetics using nine point hedonic rating scale and the scores obtained for the formula is presented in table

Table 1. Mean score value for the developed nutraceutical formula

Characteristics	Nutraceutical formula
Colour and Appearance 9 8 7 6 5 4 3 2 1	9
Flavour 9 8 7 6 5 4 3 2 1	3
Texture 9 8 7 6 5 4 3 2 1	7
Taste 9 8 7 6 5 4 3 2 1	3
Overall Acceptability 9 8 7 6 5 4 3 2 1	3

From the table it was found that colour and appearance scored 9 and texture scored 7. Though these two qualities scored good scores, all the other criteria were found to be not acceptable. Based on the organoleptic evaluation it was observed that the patient hesitate to take the nutraceutical formula in the form of powder because of mixed strong flavour and bitter taste. Hence, the nutraceutical formula was given in the form of capsule for diabetic patients. The capsule was prepared with AF: SAFJA extract (40:200) powder in K.S Variar Astanga Auyrvedics Pvt ltd, at Trichy and used for further study.

Quality evaluation of glucodip capsule on storage

Glucodip capsule was assessed for its quality characteristics before conducting clinical trial and discussed below.

Moisture

The capsules were packed in pet jar, 400 gauge poly ethylene bag and ordinary bottles stored at ambient conditions.

Table 2. Changes in moisture content (g/100g) of the glucodip capsule during storage

Days	Moisture content of the glucodip capsule (g/100g)		
	Pet jar	400 gauge polyethylene bag	Ordinary bottles
0	3.2	3.2	3.2
30	3.2	3.2	3.2
60	3.2	3.2	3.4
90	3.2	3.2	3.4
120	3.2	3.4	3.6
180	3.4	3.6	3.8

	SED	CD (0.05)	CD (0.01)
T	0.64612	0.42246	1.11925 NS
B	1.30445	0.85325	2.25892 NS
TB	1.74323	1.14112	3.01968 NS

Table 3. Changes in microbial load of the glucodip capsule during storage

	Microbial load of the glucodip capsule (cfu/g)								
Days	Pet jar			400 gauge polyethylene bag			Ordinary bottles		
	Bacteria	Fungi	Yeast	Bacteria	Fungi	Yeast	Bacteria	Fungi	Yeast
0	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL
30	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL
60	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL	2
90	BDL	BDL	BDL	BDL	BDL	BDL	BDL	BDL	2
120	BDL	1	1	1	1	1	2	2	2
180	2	2	2	2	2	2	3	3	3

The changes in moisture content of the glucodip during storage are presented in table 2

There was a slight increase was noticed during storage period which was increased from 3.2 to 3.8 g/100g. Because the outer covering of the capsule coated with preservative materials (MPS). Minimum changes were observed during storage. The statistical analysis also showed that the changes were not significant.

Microbial load

Microbial population of glucodip capsule during storage was assessed and are presented in table 3. A slight increase in the microbial load was noticed during storage period. Among the packaging materials, capsule stored in pet jar and 400 gauge polyethylene bag showed a good results when compared to capsule stored in ordinary bottles. The initial microbial count of all the samples were found o be below detectable level. The bacterial count had increased during the storage period. The presence of bacteria was not detectable initially but increased to $2X10^6$ cfu/g at the end of the storage period.

An increasing trend was noted in fungal population in the capsule stored in ordinary bottles during storage period. The fungal population in capsule stored in pet jar and 400 gauge polyethylene bag was found to be low when compared to the capsule stored in ordinary bottles. Yeast was found to be below detectable level initially in the capsule stored in all the packaging materials which had increased to $2X10^3$ in pet jar and 400 gauge poly ethylene bag where as in ordinary bottles $3X10^3$ at the end of the storage period.

Economic feasibility analysis of the glucodip capsule production

Economics of glucodip capsule production

Annual Processing Expenditure

Economics of glucodip capsule production @ 100 capsules / day production capacity and operating season of 300 days in a year are furnished in Table 4. The initial investment expenditure was Rs. 1,35,000 for the above mentioned plant. The total annual fixed cost was Rs. 50,200 for the processing plant. The annual variable cost or running cost was worked was Rs. 58,512. The annual total annual processing expenditure was Rs. 1,14,112 as could be seen from Table 4.

Economic analysis of glucodip capsule Production

The gross return was estimated for glucodip capsule production accounting for Rs. 1,50,000. Here the market price of glucodip capsule (Rs.5.00/ capsule) was used to arrive the gross return. (Table 5)In nutshell, it was found that annual processing expenditure of glucodip capsule production per capsule was arrived at Rs.3.80. Further the profit per glucodip capsule was *estimated as Rs. 1.20.*

Economic analysis of glucodip capsule Production

S.No	Particulars	Amount
I	Total annual processing cost (Rs)	1,14,112
2	Production/year (capusules) @ 100 capsules/day for 300 days	30,000
3	Price/ capsule (Rs)	5.00
4	Gross income /year (Rs)	1,50,000
5	Profit /Year (Rs)	35,888
6	Cost of production /capsule (Rs)	3.80
7	Profit /capsule (Rs)	1.20

Economics of glucodip capsule production

Economics of glucodip capsule production @ 100 capsules / day production capacity and operating season of 300 days in a year are furnished in Table 28. The initial investment expenditure was Rs. 1,35,000 for the above mentioned plant.

Table 6. Economic Feasibility Analysis of glucodip capsule Production

1	Internal Rate of Return	24.61 %
2	Benefit -cost ratio	1.30
3	Break-even point	16461 capsules/year
4	Pay back period	4 years

The total annual fixed cost was Rs. 40,000 for the processing plant. The annual variable cost or running cost was worked was Rs. 58,512. The annual total cost of processing expenditure was Rs. 1,14,112 as could be seen from Table 26. The gross return was estimated for 100 capsule for glucodip capsule production accounting for Rs. 1,50,000. Here the market price of glucodip capsule (Rs.5.00/ capsule) was used to arrive the gross return. In nutshell, it was found that annual processing expenditure of glucodip capsule production per capsule was arrived at Rs.3.80. Further the profit per glucodip capsule was estimated as Rs. 1.20.

Summary and Conclusion

A summary of the results obtained from the study is presented in this chapter. Data regarding Quality evaluation of glucodip capsule from AF & SAFJA extracts on storage had been summarized.

Acceptability trial of nutraceutical formula for diabetes

Based on the organoleptic evaluation it was observed that the patient hesitated to take the nutraceutical formula in the form of powder because of strong flavour and bitter taste. Hence, the nutraceutical formula was given in the form of capsule for diabetic patients. The capsule was prepared with AF: SAFJA extract (40:200) powder and used for further study.

Quality evaluation of glucodip capsule on storage

The capsules were packed in plastic bottles, pet jars and 400 gauge poly ethylene bags. Changes in moisture and microbial load were observed.

Moisture

During the storage period, there was a slight increase in moisture content of glucodip capsule packed in polyethylene bags while negligible change was observed when packed in 400 gauge poly ethylene bag and pet bottles.

Microbial load

A slight increase in the microbial load was noticed during storage period. Among the packaging materials, capsule stored in pet jar and 400 gauge polyethylene showed a good results when compared to capsule stored in ordinary bottles.

Cost Analysis

Cost of the prepared glucodip capsule was worked out and the cost is Rs 5.00 per capsule.

Conclusion

Valid conclusions drawn from this study are follows.

- Pet bottles and 400 gauge polyethylene bags were found to be more suitable for storing glucodip capsule.
- Glucodip capsule had good keeping quality upto 180 days.
- Production cost of glucodip capsule was Rs. 5.00 per capsule.

Future Thrust

- Further study on clinical trial could be undertaken with larger samples for a longer period of time.
- Glucodip capsules is made up of natural extracts of AF & SAFJA powder, hence shelf life study for longer period could be undertaken.
- Further studies on hypolipidaemic patients could be carried out as the extracts showed good results for the lipid profile change in rats.

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