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Research Article

Formulation And Evaluation of Polyherbal Capsules for Antidiabetic Activity

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ABSTRACT

Herbal formulation is a dosage form consisting of one or more than fresh herbs of processed herbs in particular quantities to provide specific nutritional, cosmetics benefits and are meant to diagnose, treat, alleviate disease of human being. Poly herbal capsule is a form of ayurvedic medicine that is defined as totally dried raw materials which is powdered very minutely to a small size and then filtered to obtain fine powder and made as granules and filled in capsules. It is used to treat variety of diseases and conditions. The Aim of the present work is to reveal the pharmacognostic, phytochemical, antidiabetic activity for the formulation and evaluation of polyherbal capsules. The required materials were collected from Kasaragod and subjected to successive solvent extraction. Later pharmacognostic studies like microscopical evaluation, ash value and extractive value were carried out. The preliminary phytochemical studies were carried out in different solvents like Water, Petroleum ether, Chloroform, Ethanol, Methanol and Ethyl acetate. Water and ethanolic extract was used for the study of antidiabetic activity.

INTRODUCTION

Medicinal plants are one of the sources of natural products for the treatment and management of debilitating diseases. Plants which have one or more of its parts having substances that can be used for treatment of diseases, are called Medicinal plants. Medicines derived from plants

are widely famous due to their safety easy availability and low cost.

HERBAL MEDICINE

Herbal medicine is defined as a branch of science in which plant based formulations are used to alleviate diseases. It is also known as botanical medicine or phytomedicine. Later phytotherapy

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has been introduced as a more accurate synonym of herbal or botanical medicine. With the advent of the allopathic system of medicine, herbal medicine gradually lost its popularity among people. The WHO has recently defined Traditional medicine (including herbal drugs) as comprising therapeutic practices that have been in existence, often for 100 of years, before the development and spread of modern medicine and as still un used today. Traditional medicine is a synthesis of therapeutic experience of generations of practicing physicians of indigenous system of medicines. Traditional preparations comprise medicinal plants, minerals and organic matter etc. Herbal drugs constitute only those traditional medicines which primarily use medicinal plant preparation for therapy. Herbal medicines are complex compound with multiple synergistic mechanisms of action that modulate pathophysiological function. It has become a popular form of health care. Even though several differences exist between herbal and conventional pharmacological treatment, herbal medicine can be tested for efficacy using conventional trial methodology. Several specific herbal extracts have been demonstrated to efficacious for specific conditions.

2) POLYHERBAL FORMULATIONS

Polyherbal formulation refers to a medicinal preparation that contains a combination of two or more herbs or herbal extracts. These formulations are created by blending multiple herbs with complementary or synergistic properties to enhance therapeutic efficacy or address multiple health concerns simultaneously. Polyherbal formulations plan has been utilized generally around the earth because of its restorative and remedial application. Polyherbalism confers some benefits not available in single herbal formulations it is evident that better therapeutic effect can be reached with a single multi constituent formulation. For this, a lower dose of herbal

preparation would be needed to achieve desirable pharmacological action, thus reducing the risk of deleterious side effects. Besides, PHF'S bring improved convenience for patients by eliminating the need of taking more than one different single herbal formulation at a time, which indirectly leads to better compliance and therapeutic effect. All these benefits have resulted in the popularity of PHF in the market when compared to single herbal formulation

MATERIALS AND METHODS

Collection of plant materials

The fresh leaves of *Andrographis paniculata*, *Syzygium aqueum*, *Passiflora edulis* and *Tamarindus indica* were collected from Kasargod and Kannur district, Kerala (India) in the month of April 2024.

Authentication of plant material

The plant material was identified and authenticated by Smitha K o Assistant professor (Horticulture), college of Agriculture, Kerala Agricultural university, Padannakad, Kasargod, Kerala.

Extraction of plant material

Extraction of *Andrographis paniculata*, *Tamarindus indica*, *Passiflora edulis* and *Syzygium aqueum* was carried out separately by maceration. The coarsely powdered leaves of *Andrographis paniculata*, *Tamarindus indica*, *Passiflora edulis*, *Syzygium aqueum* were macerated with solvents like petroleum ether, ethanol, water separately. The extract obtained after maceration process was then used for phytochemical studies to choose the most suitable solvent for extraction.

Preliminary phytochemical screening

The extracts of selected plants were subjected to preliminary phytochemical screening to detect the various phytoconstituents such as alkaloids, glycosides, flavonoids, phenols, tannins, proteins and amino acids.

Formulation of polyherbal antidiabetic capsule



Antidiabetic capsules containing leaf extract were prepared by manual capsule filling method. Other ingredients such as lactose used as diluents, Magnesium stearate as lubricant and Microcrystalline cellulose act as diluents and disintegrants. Methyl Paraben act as preservatives. All the excipients along with API weighed as

shown in table and passed through sieve no.44. Then, all ingredients were mixed following geometric mixing excluding glidant and lubricant thoroughly for 15 minutes. Glidant and lubricant were later added and pushed to a capsule having size "0" and have an average net content weight of 400mg.

SL NO.	INGREDIENTS	F1	F2	F3
1	Drug	400	400	400
2	Microcrystalline cellulose	14	12	11
3	Magnesium stearate	25	27	23
4	Methyl paraben	0.2	0.3	0.5

Physical characteristics:

Bulk density, Angle of repose, Hausner's ratio, Carr's index, and particle size distribution was determined for evaluating the physical characteristics of the powder.

a. Bulk density

10g of mixture was taken in a graduated measuring cylinder and tapped on a wooden surface. Bulk density is calculated by using the formula Bulk density= weight taken/ bulk volume Tapped density= weight of churna taken volume/ (tapped)

b. Angle of repose

Angle of repose was determined by using funnel method. The powder was allowed to flow through a funnel fixed on a stand to form a heap. The height and the radius gives the angle of repose. Angle of repose $\tan \Theta = \tan (h/r)$ Where, h =height of heap, r =radius of heap

c. Compressibility/Carr's Index

This is calculated using the formula: Carr's Index= Bulk density (Tapped)- Bulk density (Untapped)/Bulk density (Tapped) * 100

d. Hausner's Ratio

The formula used to determine Hausner's ratio is Hausner's ratio = Bulk density (tapped) /Bulk density (untapped)

INVITRO ANTIDIABETIC ACTIVITY

Inhibition of alpha-amylase enzyme

A starch solution (0.1% w/v) was obtained by stirring 0.1g of potato starch in 100 ml of 16mM

of sodium acetate buffer. The enzyme solution was prepared by mixing 27.5 mg of alpha-amylase in 100 ml of distilled water. The colorimetric reagent is prepared by mixing sodium potassium tartrate solution and 3, 5- dinitro salicylic acid solution 96mM. Both control and plant extracts were added with starch solution and left to react with alpha-amylase solution under alkaline conditions at 25°C. The reaction was measured over 3 times. The generation of maltose was quantified by the reduction of 3, 5- dinitro salicylic acid. This reaction is detectable at 540 nm.

Calculation of 50% Inhibitory concentration (IC50)

The concentration of the plant extracts required to scavenge 50% of the radicals (IC50) was calculated by using the percentage scavenging activities at five different concentrations of the extract. Percentage inhibition (1%) was calculated by,

$$I\% = (A_c - A_s) / A_c \times 100, \text{ (Shai et al., 2010).}$$

Where A_c is the absorbance of the control and A_s is the absorbance of sample.

EVALUATION OF POLYHERBAL CAPSULE

a) Weight variation test

weight variation test is used to determine the variation in the amount of powder contained in each herbal capsule. Twenty capsules were taken and weighed. The average weight is calculated and



compared with individual capsule weight. Percentage variation was calculated as per USP (2010) specification. The herbal capsule should not be less than 90% and not more than 110% of theoretically calculated weight of each unit.

b) Disintegration test

It is the measurement of time required under a given set of conditions in which the selected capsules were disintegrated into the particles that pass through 10 mesh screens within a specific time.

c) Determination of moisture content

Loss on drying is a test that determines the presence of moisture or volatile matter in sample. An excess of water will encourage microbial growth. Presence of moisture content provides the information concerning shelf life and quality of drug.

Moisture content % = (Final weight of sample / initial weight of sample) x 100

d) Determination of pH

1g of capsule powder was taken and dissolved in 100ml of demineralised water. The pH value of solution is determined by using digital pH meter. The electrodes were immersed in the test solution and the pH was measured.

RESULT AND DISCUSSION

Extraction of plant material

The extraction of dried leaves of *Andrographis paniculata*, *Syzygium aequum*, *Tamarindus indica*, *Passiflora edulis* were carried out by maceration process by using suitable solvent. The extracts obtained were collected and concentrated which then weighed and kept in a desiccator until it was used for further studies.

Preliminary phytochemical screening

Phytochemicals present in water and ethanolic extracts of the crude drug.

Physical Evaluation: Results of the moisture content of the crude drug.

SL NO	Plant	Plant part	Loss on drying (g)	Percentage loss on drying (%w/w)
1	<i>Andrographis paniculata</i>	Leaf	10.64±0.36	8.70±0.54
2	<i>Tamarindus indica</i>	Leaf	30.54±2.47	24.92±1.28
3	<i>Syzygium aequum</i>	Leaf	31.40±2.87	20.60±1.54
4	<i>Passiflora edulis</i>	Leaf	29.30±1.41	25.44±0.45
5	<i>Polyherbal mixture</i>	Leaf	13.50±0.11	10.15±0.25

Results of Total ash value, Acid insoluble ash value and Water-soluble ash value of crude drug.

SL NO	Plant	Plant part	Total ash value (%w/w)	Acid insoluble ash value (%w/w)	Water soluble ash value (%w/w)
1	<i>Andrographis paniculata</i>	Leaf	8.62±0.76	2.10±0.55	1.50±0.67
2	<i>Tamarindus indica</i>	Leaf	7.95±0.63	0.516±0.18	5.25±0.92
3	<i>Syzygium aequum</i>	Leaf	15.8±0.12	13.2±0.88	3.8±0.47
4	<i>Passiflora edulis</i>	Leaf	6.1±0.52	2.9±0.54	3.29±0.14

The results of extractive values

SL NO	Plant	Plant part	Water soluble extractive value (%w/w)	Alcohol soluble extractive value (%w/w)

1	<i>Andrographis paniculata</i>	Leaf	88.27±0.78	55.47±0.89
2	<i>Tamarindus indica</i>	Leaf	30.22±5.40	25.82±4.77
3	<i>Syzygium aqueum</i>	Leaf	83.6±0.30	67.58±0.72
4	<i>Passiflora edulis</i>	Leaf	21.94±0.85	18.46±0.98

Fluorescence analysis

The fluorescence analysis was determined as described earlier and the results are

Name of plant	Before treatment			After treatment with 50% HCL			After treatment with 50% NAOH		
	Ordinary light	Short UV	Long UV	Ordinary light	Short UV	Long UV	Ordinary light	Short UV	Long UV
<i>Andrographis paniculata</i>	Light green	Colourless	Light yellow	Light green	Colourless	Light green	Light green	Colourless	Light Brown
<i>Tamarindus indica</i>	Yellowish brown	Light brown	Dark brown	Brownish yellow	Light yellow	Colourless	Dark red	Light yellow	Yellowish brown
<i>Syzygium aqueum</i>	Yellowish brown	Light green	Dark brown	Dark brown	Light Brown	Black	Light orange	Light yellow	Colourless
<i>Passiflora edulis</i>	Light green	Light yellow	Yellowish green	Dark brown	Dark green	Light green	Yellowish green	Light yellow	Dark green
<i>Polyherbal mixture</i>	Olive green	Light yellow	Colourless	Dark brown	Colourless	Colourless	Light orange	Light yellow	Fluorescent Green

Physical characteristics

Evaluation of physical properties of polyherbal formulation

SL.NO	Parameters	Observation
1	Bulk density	0.3615±0.013
2	Tapped density	0.4032±0.002
3	Angle of repose	32.56±0.142
4	Carr's index	10±0.341
5	Hausner's ratio	1.11±0.013

Evaluation of polyherbal capsule

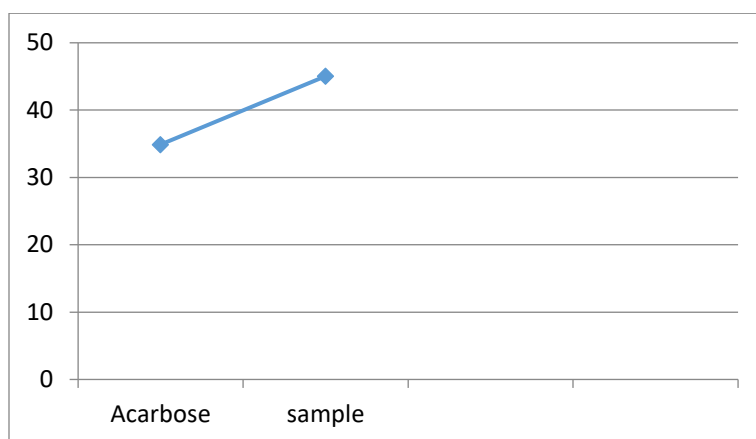
SL NO	FORMULATION	WEIGHT VARIATION	pH	MOISTURE CONTENT	DISINTEGRATION TIME (MIN)
1	PHF1	441mg±0.22	6.10	13.21±0.01	13.15±0.01
2	PHF2	443mg±0.01	6.3	13.50±0.02	13.26±0.02
3	PHF3	445mg±0.02	6.25	15.50±0.04	13.56±0.01

Anti-diabetic Activity

In vitro antidiabetic activity from alpha amylase method.

SL.NO	Sample	IC50 values (µg/ml)
1	Acarbose (standard)	34.89 (µg/ml)
2	Formulation	45.04 (µg/ml)





DISCUSSION

Herbs play a major role in the treatment than allopathic medicines because of fewer side effects, low cost and easy availability. The research work was done on that basis and the selected plants for the formulation was literally proved for the therapeutic use of antidiabetic purpose. The present study was undertaken with an intention to develop an antidiabetic polyherbal capsule.

Diabetes mellitus is a chronic disorder found in all parts of the world and is becoming a serious threat to mankind. The leaves of *Andrographis paniculata*, *Tamarindus indica*, *Syzygium aqueum* and *passiflora edulis* were collected from Kasargod district, Kerala, India in the month of March 2023. The capsule having fine powder of herbs in appropriate ratio was subjected standardisation by means of various physical and chemical methods. The pH was determined in order to avoid any irritation and moisture content was determined to find any increase in weight caused by moisture absorption. Finally the value obtained was within the standard.

The antidiabetic activity can be measured by inhibition of alpha amylase enzyme. From this investigation by considering the results, it was found to be effective for the treatment of diabetes.

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