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ORIGINAL ARTICLE

Pharmacognostic Standardization of Some Herbal Antidiabetic Drugs in Polyherbal Formulation

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ABSTRACT
In order to assess a drug's quality, purity, safety, and effectiveness, the quantity of active components in its herbal formulations must be standardised. Standardizing commercial polyherbal formulations is the aim of the current effort. Polyherbal formulations have been standardised based on organoleptic characteristics, physical characteristics, and physicochemical qualities and quality control parameters.
Keywords; *Diabetes, Herbal plants, Polyherbal Formulation, Standardization*

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INTRODUCTION

India has a long history of embracing traditional medicine, which includes the Ayurveda, Siddha, and Unani (ASU) health care systems. These treatment modalities include a sizable proportion of botanical ingredients (1). In addition to aiding to perpetuate the traditional culture, the safety, effectiveness, and quality of these conventional medical practises will also help to justify the usage of ecosystem commodities and services in healthcare. (2,3). Historically, medicinal plants have been very important to human life. Due to the growth of revolutionary medications, several plants have established their identities. Although synthetic medications have swept over the health care industry and are highly effective, they can have dangerous adverse effects. The sole solution to this issue is natural medication sources, which may be found by looking for medicinal plants with potential therapeutic efficacy. As they develop up in the body, superoxide (SO) ions, hydroxyl radicals, and hydrogen peroxide are examples of reactive oxygen species (ROS) start a number of pathological or degenerative processes such as diabetes, atherosclerosis, Alzheimer's disease, cancer, heart disease, and Alzheimer's disease (4). Due to relatively minimal detrimental reactions and low cost, herbal formulations are becoming more prevalent presently, in particular for the management of Type II Diabetes mellitus. Poly herbal formulations are precisely what their name suggests—multiple components with various herbal origins. There might be a many biological activities in the plant components (5). The primary uses of polyherbal formulations are to increase activity or mitigate the harmful effects of chemicals derived from other plants. This review compares an appropriate polyherbal formulation with a monoherbal formulation to show the impact of polyherbal formulations on antidiabetic efficacy (6). Despite polyherbal treatments have been practised in Chinese medicine for many decades, there's still yet no empirical proof of their treatment response. In opposed to a singlemedicines or a mixture of drugs frequently show promise in the treatment of illnesses. In Western medicine, the concept of pharmacological combinations is well-established, and it has seen incredible success over the years (7).

The World Health Organisation (WHO) has contributed to the development of guidelines to help member states develop national traditional medicine policies and explore their practical opportunities, including evaluation, safety, and efficacy. The WHO places a strong emphasis on the potential benefits of medicinal plants for society healthcare in developing countries (8). The effort to systematize the plant exploited as

medication has evolved to be of paramount importance. Pharmacognostic studies have the potential to standardise processes in some kind of a step-by-step manner (9). Traditional herbal therapy is thriving, as due to their natural sources and competitive prices, these therapies are growing more and more popular in both industrialized and developing nations (10). With this in mind as substantiation, the present investigation was conducted in order of standardising some available on the market polyherbal antidiabetic medications based on their physicochemical properties. For this study, we chose two available on the market polyherbal formulations, Formulation A and Formulation B, respectively. The current study describes the standardisation of herbal anti-diabetic drugs based on organoleptic characteristics, physical attributes, and physicochemical properties.

MATERIAL AND METHODS

Marketed samples

Two marketplace samples have been selected and collected from the local market of Nashik, Maharashtra. Formulation A and Formulation B were subjected to evaluation of following Pharmacognostic and quality control parameters:

Qualitative Parameter, Organoleptic evaluation, Physicochemical evaluation and Preliminary phytochemical evaluation

Qualitative Parameter

The quality control parameters such as pH, weight variation test, friability test, hardness, disintegration test were performed according to the Indian Pharmacopeia.

Organoleptic evaluation

Senses were utilized in order to appraise the powder's appearance, flavor, texture, smell, and colour.

Physicochemical evaluation

The determination of physicochemical constants such as pH, Loss on drying, total ash, water-soluble, and acid-insoluble ash values, Water and alcohol extractive values was evaluated.

Ash Value

Determination of Total Ash:

A tared silica crucible was filled with 2.5 g of precisely weighed powdered drug, which was then burned until it was carbon-free at a maximum temperature of 450oC, after cooling, it was weighed. If this method failed to produce carbon-free ash, the burnt material was put out with hot water, the residue was collected on ashless filter paper, and the residue was burned using filter paper. The addition of filter, dried by evaporation, at a temperature, and ignited of no more than 450^{o}C. Calculations were made to determine the ash percentage in relation to the air-dried medication (11).

Determination of Acid Insoluble Ash:

The insoluble material was then gathered on ashless filter paper, rinsed with hot water, and burned to a constant weight after the collected ash was heated for 5 minutes in 25 cc of diluted hydrochloric acid. Calculations were done to figure out how much acid-insoluble ash there was compared to the air-dried medicine (11).

Water Soluble ash: After the ash was heated with 25 ml of water for 5 minutes, the insoluble material on the ash-free filter paper was collected, washed with hot water, ignited, cooled in a desiccator, and weighed. The weight of the insoluble material was subtracted from the overall ash weight to get the weight of the water-soluble ash. The air-dried medicine served as a baseline for quantifying the amount of water-insoluble ash (12).

Extractive values

Water soluble extractive:

For 24 hours, 5 gm of coarsely powdered, air-dried medicine was macerated with 100 ml of water in a closed conical flask. After a 6-hour period of regular stirring, the mixture was let to stand for an additional 18 hours. This was filtered via grade 100 Whatman filter paper. A petri dish containing the filtrate's 25 millilitres was dried at 105 °C before being weighed. The amount of extractive that is water soluble is calculated in respect to material that has been air-dried (11).

Alcohol soluble extractives:

In a closed conical flask, 5 G of coarsely ground, air-dried medication was 100 ml of 70% ethanol were used to macerate the ingredients. for 24 hours, with regular shaking during the first 6 hours, then left to stand for 18 hours. In order to prevent ethanol loss, this was filtered quickly. On a petri dish, 25 mL of the filtrate were evaporated to dryness, 105°C drying, then weighed. The proportion of extractive that is soluble in alcohol was calculated with reference to the air-dried medicine (11).

Preliminary phytochemical evaluation

Standard methods were used to conduct an initial qualitative phytochemical examination of all the Formulations.

Test for Alkaloids:

Dragendorff's test: Dragendorff's reagent should be added in a few drops to 2 ml of the test solution. Forms an orange-brown ppt (11).

Test for Flavonoids:

Shinoda Test: A few drops of strong HCl and 5 ml of 95% ethanol were added to the sample. Magnesium turnings weighing 0.5 g were added to this solution. The presence of flavonoid was revealed by the pink colouring (13).

Test for Glycoside:

Legal's test: Pyridine was used to dissolve in the test solution of 1 ml. 1 ml of sodium nitroprusside solution was added, and 10% sodium hydroxide solution was used to make the solution alkaline. The development of pink to blood red hue denotes the presence of cardiac glycosides (14).

Test for Tannins:

Lead acetate test: With distilled water, one millilitre of the extract was dissolved. The lead acetate solution was added in small amounts to this solution. There are phenolic chemicals present because white precipitate is forming (14).

Test for Triterpenoid:

Libermann-Burchard test: acetic anhydride, a few drops of H2SO4, and chloroform were used to treat 1 ml of the extract; the production of a dark green hue, which shows that terpenoids are present, was then seen (15).

Test for Saponin:

Foam test: The presence of saponins was detected after a tiny quantity of extract was violently shaken with water (15).

OBSERVATIONS AND RESULTS

Qualitative parameters

Three distinct PHFs were used, and all in vitro testing were carried out in accordance with the IP 2014. The weight variation, hardness, disintegration, and friability tests are among those performed.

Weight variation test

Twenty tablets and capsules from each PHF were taken out and weighed, and their average weight was computed. Formulation A and Formulation B were found to be within the established limits respectively 7.5% and 5%. The outcomes of the weight variation test are shown in Table 1.

Hardness test

The Monsanto hardness tester was used to determine hardness, and the strength of the individual tablet for Formulation B was examined. Table 2 shows the hardness test results.

Friability test

The test for friability was conducted using the Roche friabilator. The test involved selecting and weighing 20 pills from Formulation B. As the tablets fall from a height of 6 inches, they were shocked. The weight was measured again after the 100^{th} revolution. This test has an acceptable limit of less than 0.8 percent. Table 3 shows the friability test results.

Disintegration test

Six capsules and six tablets from Formulation A and Formulation B, respectively, were used in the disintegration test, and the test was carried out. For this test, the temperature was kept at 37 °C. Table 4 shows the results of the disintegration test.

Organoleptic evaluation:

Organoleptic characters colour, odour, texture and Solubility of Formulation A and Formulation B are shown in Table 5.

Physicochemical analysis:

Table 6 includes percentages for drying loss, total ash, acid insoluble ash, water soluble ash, alcohol soluble extractive value, water soluble extractive value, etc.

Preliminary phytochemical study:

The presence or absence of specific phytochemical elements in Formulation A and Formulation B was revealed by preliminary phytochemical screening findings in Table 7.

DISCUSSION

Selected Formulation A and Formulation B have major indications in diabetes and are frequently marketed formulations for diabetes, but their standardization has not been documented, thus an attempt has been undertaken in the current study. Folk medicine is one of the earliest forms of healthcare, and it has withstood the test of time. Folk medicine now has a potential to be identified on a worldwide basis, thanks to the increased interest in searching out natural sources of health treatment. Pharmacognostic assessments, such as values of ash are used to calculate the purity and quality of the medicine. It displays the existence of numerous contaminants such as carbonates, oxalates, and silicates. The quantity of inorganic chemicals is determined using water-soluble ash. The silicates are mostly determined by acid-soluble ash. The pharmacognostic assessment findings show that medications are typically impurity-free. All of the metrics demonstrated their use, with total ash value showing the total quantity of inorganic material remaining after burning and acid insoluble ash indicating silicate contaminants that may have been introduced during improper raw material washing. The quantity of moisture in the drug is indicated by the loss on drying value, which may lead to enzymatic activity that weakens the finished product. A certain solvent's extractive value indicates how much medicine is soluble in it. In the pharmaceutical company's quality control or quality assurance laboratory, the material's purity and potency as well as any formulations created after the procedure may be checked. The ash value is used to determine the validity and purity of the sample. It also acts as a critical quality indicator. A high ash value indicates that the pharmaceutical or drug combination was inadequately prepared for commercialization, whether by adulteration, contamination, replacement, or adulteration. Quality control measures like as hardness, friability, and disintegration also show that PHFs are of consistent quality. The quality control testing results showed that the tested medications are of acceptable quality. More study is needed to confirm the potential advantages of PHFs. Because many existing studies are of low quality, this must be addressed by introducing corrective methods for research trials. Controlling the quality and standardization of herbal medicines is achievable but challenging. Herbal diabetic medicines exist in a number of ways. When compared to synthetic drugs, it's a win-win situation. Aside from that, herbal compositions are controlled differently across the country.

CONCLUSION

The current study revealed various qualitative and pharmacognostic parameters such as hardness, friability, weight variation, disintegration time, pH, organoleptic properties, total ash, insoluble acid ash, water, alcohol, extractive value- alcohol soluble extractive value, water soluble extractive value, moisture content, and other physicochemical criteria and preliminary phytochemical study. It may be determined that it meets all of the standardization parameters.

Table 1: Result of weight variation test of Formulation A and Formulation B

Sr.No.	PHF	Average weight	Average Deviation	Limit
1	Formulation A	0.5505	0.0412875	7.5%
2	Formulation B	0.452	0.0226	5%

Table 2: Result of hardness test of Formulation B

Sr.No.	PHF	Average Hardness (kg/cm2)
1	Formulation B	15

Table 3: Result for friability of Formulation B

Sr.No.	PHF	% Weight Loss
1	Formulation B	0.03

Table 4: Result for Disintegration test

Sr.No.	PHF	Average disintegration time (Minutes)
1	Formulation A	3.20
2	Formulation B	23.17

Table 5: Result for Organoleptic Characteristics of Formulation A and Formulation B

Parameter	Formulation A	Formulation B
Colour	Greenish	Orange
Odour	Bitter	Bitter
Texture	Course	Fine
Solubiliy in Water	Partially soluble	Partially soluble
Solubiliy in Alcohol	Partially soluble	Partially soluble

Table 6: Result for Physico-chemical parameters

Sr. No.	Particular	Formulation A	Formulation B
1.	% Loss on drying (SEM)	7.46 ±0.12	5.65 ±0.048
2.	% Total Ash (SEM)	5.33 ± 0.19	6.56 ± 0.84
3.	% Acid insoluble Ash	0.556 ±0.2	1.56 ±0.38
4.	% Water soluble Ash	0.56 ±0.19	1.78 ±0.77
5.	% of Alcohol soluble extractive value	11.47±0.92	9.87±0.27
6.	% of Water soluble extractive value	11.73 ± 0.46	12.27±0.46

Table 7: Result for Preliminary phytochemical tests of Formulation A and Formulation B

Phytochemical constituent	Test	Formulation A	Formulation B
Alkaloid	Dragendorff's test	+	--
Flavonoid	Shinoda Test	+	--
Glycoside/Sugar	Legal's test	--	--
Tannin	Lead acetate test	+	+
Triterpenoid	Libermann Burchard test	+	+
Saponin	Foam test	--	--

+ Presence, --Absence

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