ORIGINAL ARTICLE

Formulation and Evaluation of Antidiabetic Polyherbal Tablets

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Abstract

Aim: The goal of this study is to create and test antidiabetic polyherbal tablets made from several extracts of the chosen plant. Plants are usually a good source of medication. In reality, many currently accessible medications were produced from plants, either directly or indirectly. The anti-diabetic activity of a solid pharmaceutical dosage formulation containing a unique dry plant extract and several excipients such as starch, microcrystalline cellulose, and talc was reported to be statistically significant. **Materials and Methods:** The evaluation of prepared tablets is also discussed in this letter (weight variation, friability, hardness, and disintegration time). **Results and Discussion:** All of the values were within acceptable limits, according to the results of the preformulation experiments. The formulation has a fair amount of hardness (3.250.57), which aids in its rapid disintegration. The formulation's friability (0.290.03) revealed that the tablets were mechanically stable. Because the average weight of the tablets was 340 mg, a weight variation of 7% is permissible. **Conclusion:** As a result, the weight variation test was passed on the full formed tablet. The mixtures took more than a minute to disintegrate finally, it may be concluded that the formed tablet requires additional research to properly understand the underlying mechanism of action, as well as long-term toxicity tests.

Key words: Disintegration, polyherbal formulation, preformulation study

INTRODUCTION

Plants are usually a good source of medication. In reality, many currently accessible medications were produced from plants, either directly or indirectly. Organic compounds abound in the plant kingdom, many of which have been employed for medical and other purposes.[1]

Hyperglycemia, hypertriglyceridemia, and hypercholesterolemia are all symptoms of diabetes mellitus. Synthetic hypoglycemic medicines have major adverse effects such as hematological effects, liver, renal, and coma sickness, among others. Plant-derived drugs, on the other hand, are generally believed to be less toxic and have less side effects. As a result, the hunt for a more effective and safer herbal antidiabetic drug has become a priority.[2] According to the World Health Organization, botanical medicines are used by 80% of the world's population for primary healthcare. The use of ethnobotanicals for the treatment of blood sugar disorders has a long legendary history. In type 2 diabetes, an unhealthy diet, physical inactivity, a deficiency in insulin production in response to meals, and diminished sensitivity of the target tissues to insulin action combine to cause a rise in blood glucose levels.[3,4] By 2025, the global prevalence of chronic metabolic disorders, which currently affects roughly 150 million individuals, will have risen to 300 million.[5] Synthetic oral anti-diabetic medications and insulin, which are now used to control diabetic complications, are successful in lowering blood glucose levels, but they have a variety of adverse effects and do not control diabetic problems.[6] Traditional medicinal plants are utilized to treat a variety of diabetic issues around the world. For the treatment of diabetes mellitus, various herbal medications and minerals have been documented in olden traditional literature. Herbal medications are thought to be safe and have fewer adverse effects than synthetic drugs.[6] Exploring the hypoglycemic

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potential of medicinal plants has thus become critical to give mankind with a safer herbal medicine alternative.

Polyherbal compositions may increase pharmacological action while lowering single herb concentrations, decreasing unwanted effects. Entire plant extracts and plant formulations have been utilized as drugs rather than individual plants. It is still difficult to find a medicine that is effective against diabetes, either alone or in combination. As a result, we decided to create a polyherbal antidiabetic formulation combining *Momordica charantia*, *Azadirachta indica*, *Eugenia jambolana*, *Phyllanthus amarus*, *Glycyrrhiza glabra*, and *Piper nigrum* extract.

MATERIAL AND METHOD

Collection and authentication of plant materials

Buldana, a local market, provided the plant material. Dr. M.R. Bhise, Department of Botany, L.K.D. K Banmeru Science College, Lonar Dist-Buldana (MS), authenticated the plants with reference letter no. DOB/2018-19/01. The plant parts were separated, thoroughly washed with tap water, shade dried, and homogenized to a fine powder before being stored in a closed container for future research.

Extraction of plant material

The plant materials of *M. charantia, A. indica, E. jambolana, P. amarus, G. glabra,* and *P. nigrum* were cut into slices and shade dried ground to a coarse powder and passed through a 80 mesh sieve. The powdered plant materials were subjected to extraction using different extraction methods such as Soxhlet apparatus, maceration, percolation using different solvents, and subjected to phytochemical screening and further study.

Formulation of antidiabetic tablet

In the present study, dried powder of extract was formulated into tablet dosage form by direct compression method. Formulation has the following composition: *M. charantia*, *A. indica, E. jambolana*, *P. amarus, G. glabra, P. nigrum* (in ratio 1:1) Starch (15 mg), magnesium stearate (33 mg), microcrystalline stearate (2 mg), and talc (2.5 mg).

Preformulation studies[7]

A. Angle of repose

The angle of repose was calculated using the fixed height approach to estimate the flow parameters of the physical mixtures in all formulations. A funnel with a 10 mm inner diameter stem was suspended from the platform at a height of 2 cm. About 10 g of sample was progressively transferred along the funnel's wall until the tip of the pile developed and came into contact with the funnel's steam. The radius of the powder cone was estimated by drawing a crude circle around the pile base. The following formula was used to compute the angle of repose from the average radius.

$$\theta = \tan^{-1}(h/r)$$

Where,
θ = Angle of repose
h = Height of the pile
r = Average radius of the powder cone

B. Loose bulk density

Bulk densities of all types of granules were assessed by gently pouring 25 g of material into a 100 ml graduated cylinder through a glass funnel. The sample's volume was measured and recorded. By pouring a weighed quantity of mix into a graduated cylinder and measuring the volume and weight, the apparent bulk density was established.

LBD = Weight of the powder/volume of the packing

C. Tapped bulk density

By gently pouring 25 g of material through a glass funnel into a 100 ml graduated cylinder, the tapped densities of all types of granules were calculated. From a height of 2 inches, the cylinder was tapped until a steady volume was reached. The sample's volume after tapping was measured, and the tapped density was determined. A graduated cylinder containing a known mass of medicine excipient blend was used to determine it. At 2-s intervals, the cylinder was permitted to fall from a height of 10 cm onto a hard surface under its own weight. The tapping was kept going until there was no more change in volume.

TBD = Weight of the powder/vol of the tapped packing

D. Compressibility index

The compressibility index of the blends was determined by Carr's compressibility index.

$$\text{Compressibility index (\%)} = (\text{TBD-LBD}) \times 100/\text{TBD}$$

E. Hausner's ratio

It is the measurement of frictional resistance of the drug. The ideal range should be 1.2–1.5. It is determined by using the following formula:

$$\text{Hausner's ratio} = \text{TBD/LBD}$$

F. Loss on drying

A well-mixed granules (1 g) was placed in a shallow weighing bottle with a dry glass stopper. The materials were uniformly

dispersed and put into the drying chamber (Sartorius moisture balance). The bottle's cap was removed, and the contents were dried for a set amount of time to achieve a consistent weight.

Loss on drying (%) = ([Initial weight – Final weight]/[Initial weight])×100

Evaluation of tablets

All the formulated tablets were subjected to following evaluation parameters:

a. Color and appearance

The compressed tablets were examined for their color and appearance.

b. Weight variation test

20 pills were randomly chosen and weighed to establish the average weight. Weighing each tablet separately was also done. In each example, the percentage variation from the average weight was computed. Only two of the sample size ton's tablets stray from the average weight by a bigger percentage, and none by more than double that amount.

c. Hardness and friability test

The hardness and friability were tested for the tablets using calibrated hardness tester (Monsanto) and Roche friabilator (4 min at 25 rpm) tests, respectively.

d. Disintegration test for tablets

A rust-proof wire gauge disc is placed at the lower end of a glass of plastic tube 80–100 mm long with an internal diameter of about 28 mm and an external diameter of 30–31mm. Six pills were inserted in the tube, and the tube was raised and lowered so that the entire up and down movement was repeated 28–32 times/min. When no particles remain above the gauge, which easily pass through mesh, the tablets are dissolved (10 mesh screen).

e. Thickness

The thicknesses of the tablets were evaluated by Vernier calipers.

f. Stability studies

The stability study of the formulated tablets was carried out at 40°C and 75% relative humidity using a stability chamber for 2 months.

RESULTS AND DISCUSSION

All of the physical attributes of the granules, such as bulk density, tapped density angle of repose, Carr's index, and Hausner's ratio, were determined to be within acceptable limits, indicating that the granules have adequate flowability. Tables1-4 shows that the angle of repose, Carr's index, and

Table 1: Grading of powders for their flow properties

Carr's index	Flow
5–15	Excellent
15–16	Good
18–21	Fair to passable
23–25	Poor
33–38	Very poor
<40	Very very poor

Table 2: Relation between angle of repose and powder flow

Carr's index	Flow
<25	Excellent
25–30	Good
30–40	Passable
>40	Very poor

Table 3: Result of preformulation studies

Parameter	F1	F2
Bulk density	0.48	0.44
Tapped density	0.52	0.53
Angle of repose	11.30	14.03
Hausner's ratio	1.08	1.13
Carr's index	7.6	12

Table 4: Evaluation of tablet

Parameter	F1	F2
Texture	Smooth	Smooth
Color	Light brown	Light brown
Odor	Characteristic	Characteristic
Taste	Bitter	Bitter
Size	14.75 mm	14.85 mm
Shape	Round, Biconvex	Round, Biconvex
Thickness	5.12 mm	5.12 mm
Weight variation	2.34	2.20
Hardness	2.98±0.21	2.91±0.20
Friability	0.50	0.52
Disintegration time	12.15±0.21	13.20±0.21

Table 5: Stability study of tablet

Storage condition	Description	Average wt (mg)	Hardness (kg/cm²)	Disintegration time (Min)	Friability (%)
Initial	Color: Light brown Odor: Characteristic	650	2.91	13.20	0.52
1 month at 45°C/75%RH	Color: Light brown Odor: Characteristic	650	2.91	13.20	0.53
2 month at 45°C/75%RH	Color: Light brown Odor: Characteristic	650	3.00	13.20	0.51

Hausner's ratio are all in the range of 21–24, 11.45–14.42, and 1.10–1.17, respectively.

The polyherbal antidiabetic pills were tested for color, average weight, hardness, friability, and disintegration time, all of which were found to be acceptable according to Pharmacopeia criteria. The tablets were determined to have a hardness of between 9.000.02 and 12.500.003 kg/cm^2. The tablet's friability was determined to be <1%, suggesting good mechanical resistance, and the disintegration time of all batches was found to be between 100.012 and 380.011 min. Formulation was chosen as the optimal batch based on several requirements [Table 5].

The physical properties of the final formulation have not changed much, according to stability assessments. There was a slight rise in moisture content and hardness, but no change in friability, indicating that the alterations were within the prescribed limits [Table 5].

CONCLUSION

Based on the results of the powder preformulation study and the standardization parameter of the formulated tablet, it is concluded that all of the parameters evaluated were within the acceptable range. Physical testing revealed that the formulation had acceptable hardness, friability, and disintegration time. In conclusion, it can be stated that the formulated tablet necessitates additional research to fully investigate the underlying mechanism of action, as well as long-term toxicity studies.

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