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RESEARCH ARTICLE

FORMULATION AND EVALUATION OF HERBAL ANTIDIABETIC TABLET

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ABSTRACT

Phytomedicines based on principles of Ayurveda are need of the hour and is more feasible than allopathic drugs which is not only more expensive in terms of "leads" but is also associated with many unwanted effects. Ethnopharmacological usage and the literature review revealed that the *Alangium salvifolium* seeds (Ankola) have significant antidiabetic activity. After the detailed study of powder of ethanolic extract of seeds of *Alangium salvifolium* Linn., a formulation using the plant material was prepared, to made the formulation more acceptable and justified for diabetics, an excipient having nutraceutical value like soy was also incorporated, the formulation was evaluated and standardized as per the pharmacopoeial standards. The results of preformulation studies revealed that all the values were within acceptable limit. Formulation showed appreciable hardness characteristics (3.25 ± 0.57), which facilitates its fast disintegration. The friability (0.29 ± 0.03) of formulation indicated that the tablets were mechanically stable. As the average weight of tablets was 340 mg, the acceptable weight variation range is $\pm 7\%$. Hence the entire formulated tablet passed the weight variation test. The disintegration time of formulations was more than 1 minute. Thus the claims made by the traditional Indian systems of medicine regarding the use of this plant in the treatment of diabetes stands confirmed. The final conclusion drawn from the above mentioned data is that the possible use of these economical and relatively non toxic, non-hazardous natural remedies of plant origin may further be explored as they are devoid of major side effects associated with synthetic agents.

Keywords: *Alangium salvifolium*, Disintegration, Preformulation study

INTRODUCTION

The *Alangium salvifolium* (Alangeaceae) also called as Ankola and extensively cultivated in India. It is a popular folk medicine and has been studied for its anti-inflammatory, antimicrobial, antifertility and cardiogenic activities. Its dried seeds, has traditionally been used to treat various ailments in Asia. Traditionally *Alangium salvifolium* seeds have been reported to exhibit a variety of biological activities, including antidiabetic, anticancer, diuretic, anti-inflammatory, antimicrobial, laxative, and antiepileptic activity⁽¹⁻⁴⁾. The World Health Organization has estimated that 80% of the world's population use botanical medicines for their primary healthcare needs. The use of ethnobotanicals has a long folkloric history for the treatment of blood sugar abnormalities. Diabetes mellitus is a group of metabolic diseases characterized by hyperglycaemia, hypertriglyceridaemia and hypercholesterolaemia⁵. The synthetic hypoglycemic agents have serious side effects like haematological effects, disease of liver, kidney and coma etc., Plant derived drugs are mostly considered to be less toxic and with fewer side effects. Therefore, search for more effective and safer herbal antidiabetic agent has become an area of active research.

MATERIALS AND METHODS

Plant Materials

Alangium salvifolium seeds were collected, authenticated (NBRI/CIF/Re/08/2008/32), powdered, extracted with ethanol, concentrated by using Buchi rota evaporator and stored in desiccators for further studies. The antidiabetic activity by using alloxan induced diabetic model was carried out⁶.

Formulation of antidiabetic tablet⁷

In the present study dried powder of ethanolic extract of *Alangium salvifolium* seeds was formulated into tablet dosage form by wet granulation method. Formulation has the following composition: *Alangium salvifolium* (210mg), *Glycine max* (50mg), Starch (40mg), Sodium benzoate (5mg), Gelatin (5mg), Microcrystalline cellulose (10mg), Talc (15mg) and Magnesium stearate (5mg/kg).

Preparation of granules by wet granulation method:

1. Starch was weighed and made into granulating liquid with water and the preservative sodium benzoate was added.
2. The starch emulsion along with preservative was cooked well on a water bath until translucent semisolid mass was formed.
3. The gelatin paste was prepared by using required quantity of water separately.
4. The weighed quantities of excipients were mixed thoroughly with extract; the cooked starch and gelatin paste were added slowly till the powder became a damp mass.
5. This damp mass was passed through sieve number 20 and dried in an oven at a temperature of 60°C for 3h, until granules were properly dried.
6. Then the dried granules were passed through sieve number 20 and were subjected to lubrication.

Lubrication

All the ingredients mentioned as lubricating agents were mixed thoroughly and sieved through Sieve No.100 and

mixed with the dried granules. Finally the tablets were compressed by using single punch machine.

EVALUATION OF FORMULATED TABLET

Preformulation studies⁷

a. Angle of repose

Angle of repose was determined by using funnel method. The accurately weighed blend was taken in a funnel. The height of the funnel was adjusted in such a way that the tip of the funnel just touches the apex of the heap or head of blend. The drug excipient blend was allowed to flow through the funnel freely on to the surface. The diameter of the powder cone was measured and angle of repose was calculated using the following equation:

$$\tan \theta = h/r$$

Where h = height of powder cone formed

r = radius of the powder cone formed

Table 1: Relationship between angle of repose (θ) and powder flow

Angle of Repose (θ)	Type of flow
<25	Excellent
25-30	Good
*30-40	Passable
>40	Very poor

*Adding the glidant e.g. 0.2% aerosol, may improve flow

b. Loose bulk density

Apparent bulk density was determined by pouring a weighed quantity of blend into graduated cylinder and measuring the volume and weight.

LBD = Weight of the powder / volume of the packing

c. Tapped bulk density

It was determined by placing a graduated cylinder, containing a known mass of drug excipient blend. The cylinder was allowed to fall under its own weight on to a hard surface from the height of 10 cm at two second intervals. The tapping was continued until no further change in volume was noted.

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.

Compressibility index (%) = (TBD-LBD) x 100 / TBD

Table 2: Grading of powders for their flow properties

Consolidation index (Carr's index)	Flow
5-15	Excellent
12-16	Good
*18-21	Fair to Passable
*23-35	Poor
33-38	Very poor
<40	Very Very poor

*Adding the glidant should improve the flow

e. Hausner 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:

Hausner ratio = TBD / LBD

f. Loss on drying

A well-mixed granules (1g) was transferred into a dried, glass stoppered shallow weighing bottle. The contents were distributed evenly and placed in the drying chamber (Sartorius moisture balance). The stopper was removed from the bottle and the contents were dried for a specified time to achieve a constant weight.

$$\text{Loss on drying (\%)} = [(Initial\ weight - Final\ weight) / (Initial\ weight)] \times 100$$

Physical 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

The average weight was determined by randomly selecting and weighing 20 tablets. Each tablet was also weighed individually. The deviation from the average weight in each case was calculated and expressed as percentage. Not more than two of the tablets from the sample size ton deviate from the average weight by a greater percentage and none of the tablets deviate by more than double that percentage.

C. Hardness and Friability test

The hardness and friability were tested for the tablets by using calibrated hardness tester (Monsanto) and Roche friabilitor (4 minute at 25 rpm) tests respectively.

D. Disintegration test for tablets

A glass of plastic tube 80-100 mm long with an internal diameter of about 28 mm and external diameter 30-31mm fitted at the lower end with a disc of rust proof wire gauge. Six tablets were placed in the tube, raise and lower the tube in such a manner that the complete up and down movement is repeated 28 to 32 per minute. The tablets are disintegrated when no particles remains above the gauge, which readily pass through mesh (10 mesh screen).

E. Thickness

The thicknesses of the tablets were evaluated by Vernier calipers.

RESULTS AND DISCUSSION

The result of the pharmacological study revealed that ethanolic extract of seeds of *Alangium salvifolium* has potent antidiabetic activity. After the detailed study of crude drug, extracts and solvent evaporated powder of ethanolic extract of *Alangium salvifolium* Linn., a single drug formulation using the plant extract was prepared and the formulation was evaluated and standardized as per the pharmacopoeial standards.

The dried granules of powder of seeds of *Alangium salvifolium* was prepared and characterized on the basis of preformulation studies including parameters like angle of repose, loose bulk density, tapped bulk density, loss on drying, compressibility index and hausner ratio etc. Preformulation study of granules prepared by wet granulation method showed that all the parameters which were evaluated were within the acceptable limit. The tablets were evaluated for their hardness, thickness, friability, weight variation, moisture content and *in-vitro* disintegration time.

The hardness of formulation was measured in kg/cm^2 with the help of Monsanto tester. Formulation showed appreciable hardness characteristics (3.25 ± 0.57), which facilitated its fast disintegration. The friability (0.29 ± 0.03) of formulation indicated that the tablets were mechanically stable. As the average weight of tablets was 340 mg, the acceptable weight variation range is $\pm 7\%$. Hence the entire formulated tablet passed the weight variation test. The disintegration time of formulations was more than 1 minute.

Table 3: Preformulation studies of dried granules

S. No.	Parameters	Result
1	Angle of repose	26.3 ⁰
2	Loose bulk density	0.28 g/cm^3
3	Tapped bulk density	0.37 g/cm^3
4	Compressibility index	29.72%

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5	Hausner ratio	1.32
6	Loss on Drying	0.98%

Table 4: Standardization of formulated antidiabetic tablets

S.N.	Parameters	Observations
1.	Color	Light brown
2.	Weight variation test	± 4.24
3.	Hardness	3.25 ± 0.57
4.	Friability	0.29 ± 0.03
5.	Disintegration time	3.02 ± 1.2
6.	Thickness	0.37 ± 0.02

Results of preformulation study of granules and standardization parameter of formulated tablet showed that all the parameters which were evaluated were within the acceptable limit. Results of physical evaluation concluded that formulation had acceptable hardness, friability and disintegration time. In conclusion, it can be stated that formulated tablet of ethanolic extract of *Alangium salvifolium* seeds demands further investigations to fully explore the underlying mechanism of action along with long term toxicity studies.