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Research Article

Formulation Development and Evaluation of Leaf Extract of *Ficus benghalensis* for Antidiabetic Activity

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ABSTRACT

Herbal products are known for their inherent property i.e. comparatively safe and economic. In present study, leaf extract of *Ficus benghalensis* was evaluated for antidiabetic activity. The aim of the research work was to formulate and evaluate capsule dosage form of ethanolic extract. Leaves of *Ficus benghalensis* collected from local area of Ahmednagar district and shade dried. Ethanolic, Hydroalcoholic and petroleum ether extracts were prepared using soxhlet apparatus. Extracts were screened for antidiabetic activity using alloxan induced diabetes in rats. Oral glucose tolerance test was measured as parameter to check antidiabetic activity. Ethanolic extract was found most effective among them. Granules were prepared using ethanolic extract and filled in capsule. Capsule were evaluated for parameters including uniformity of weight, disintegration time.

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1. INTRODUCTION

Ficus benghalensis is an indigenous plant belonging to family moraceae. It is commonly known as banyan tree or bargad or bar.⁽¹⁾ It is reported to have antidiabetic activity.⁽²⁾ Many diseases that are caused due to genetically disorders and one of this is diabetes Mellitus. Diabetes is a disorder of metabolism (the way our bodies use digested food for growth and energy). After digestion, the glucose passes into blood stream where it is available for body cells to use for growth and energy. Glucose gets into the cells in presence of insulin, a hormone produced by the pancreas.⁽³⁾ Diabetes is not a single disease it's group of heterogeneous syndromes such as heart attack, stroke and peripheral vascular disease.⁽⁴⁾ There are more than 125 million people with diabetes in the world today and this number is expected to approach 220 million. It is also estimated that there are 30-33 million diabetics in India now, and every fourth diabetics in the world today is an Indian. Indians are genetically more susceptible to diabetes and WHO predicts the number of diabetes in India would group to 80 million by 2030. The lack of documentation and stringent quality control are the key of obstacles, have hindered the acceptance of the alternative medicines in developed countries. In recent times, many

studies have been carried out in the search of a proper plant drug that could be effective in diabetes mellitus.⁽⁵⁾

2. MATERIAL AND METHODS

2.1 Collection of plant material

Leaves of *Ficus benghalensis* were collected from the local area of Ahmednagar district in Maharashtra.

2.2 Extraction process

Leaves of *Ficus benghalensis* were collected, then pulverized in electrical grinder. About 140 gm of powdered leaves were used for extraction, powder was passed through 120 mesh sieve to remove fine powder and coarse powder and coarse powder was used for extraction.⁽⁶⁾ Three different solvents were used for extraction namely; Petroleum ether, Ethanol and Hydroalcoholic (7:3).

Technique: Soxhlet apparatus

The powdered leaves of *Ficus benghalensis* were extracted with solvent for removal of coloring matter by defatting process using continuous soxhlet extraction method. After complete defatting the defatted powder were condensed with solvent for 30 hrs. Extraction temperature was maintained at 50° c. The extract was filtered and

concentrated to get thick paste and after it freeze dried to get powder. The extract was stored in air tight container. (7)

2.3 Experimental models:

2.3.1 Experimental animals:

Wistar albino rats weighing between 150-180 gm were obtained from Laxmi bio farms private limited, Pune. The rats were housed in cleaned metallic cages and kept in well ventilated room and allowed to acclimatized to the laboratory condition for one week before being used. They were fed with standard animal pellet and had free access to water and libitum. The animal were randomly divided into six groups. The protocol of the experiment (1942/PO/Re/S/17/CPCSEA/2018/02/01) was approved by Institutional Animal Ethics Committee (IAEC) of Pravara Rural College of Pharmacy, Loni and were conducted in accordance with permission from Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA).

2.3.2 Oral Glucose Tolerance Test in Normal Rats (OGTT)

Rats were divided into six groups (n=6). They were fasted overnight and accessed to water only. Blood samples were taken retro-orbital route and blood sugar levels were initially monitored. 1st group were treated with a control vehicle, 2nd was diabetic control and 3rd to 6th were treated with extract (300mg/kg, p.o., each) after that animals were treated with 5% dextrose orally. (8)

2.3.3 Induction of Diabetes Mellitus

Alloxan monohydrate was used to induce diabetes in rats. Diabetes was induced by injecting a dose of 120 mg/kg of alloxan monohydrate intraperitoneally. The alloxanized rats were kept for 7 days with free access to food and water. The rats were fasted 8th day for 12 hours and their blood glucose levels were determined. Rats with glucose levels above 250 mg/dl were used for study. (9)

2.3.4 Treatment protocol

The diabetic rats were randomly divided into six groups (n=6/ groups). Total 36 Rats.

Treatment was given in following manner

Table.1 Treatment protocol

Sr.No.	Name of groups	Treatment
1.	Vehicle control	Normal saline injection
2.	Diabetic control	Normal saline injection
3.	Standard	Metformin 600 mg/kg of body weight
4.	Test I (Pet. Ether extract)	Pet ether extract 300 mg/kg
5.	Test II (Hydroalcoholic extract)	Hydroalcoholic extract 300 mg/kg of body weight
6.	Test III (Ethanolic extract)	Ethanolic extract 300 mg/kg of body weight

2.3.5 Analysis of blood sugar levels

Blood samples were collected by retro-orbital plexus at the intervals of 0hr, 1hr, 3hr, 5hr, 3rd day, 5th day, and 7th day. The blood glucose level in the samples was estimated.

2.4 Formulation of capsule:

Table.2 Formula for Granules

SR. No.	Name of Ingredients	Quantity
1.	<i>Ficus benghalensis</i> extract	10gm
2.	Starch	600mg
3.	Lactose	3.5gm
4.	Starch	600mg
5.	Water	q.s
6.	Gelatin	150mg
7.	Propyl paraben	20mg
8.	Methyl paraben	40mg
9.	Magnesium stearate	90mg

2.5 Evaluation:

2.5.1 Evaluation of powder blend: (10)

a. Angle of repose:

10 gm of powder was passed through funnel and pile was formed. Height and radius of pile was measured and angle of repose was calculated by using following formula

$$\text{Angle of repose } (\theta) = \tan^{-1} (h/r)$$

H= height

R=radius

Table.3 Relationship between angle of repose (θ) and powder flow (11)

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

b. Bulk density

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

$$\text{Bulk density} = \text{Weight of the powder/volume of the powder}$$

c. Tapped 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.

$$\text{Tapped density} = \text{Weight of the powder/volume of the tapped powder}$$

d. Compressibility index

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

$$\text{Compressibility index } (\%) = (\text{Tapped density} - \text{Bulk density}) \times 100 / \text{Tapped density}$$

Table.4 Grading of powders for their flow properties ⁽¹²⁾

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

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= Tapped Density – Bulk Density

2.5.2 Physical evaluation of capsule

All the formulated capsules were subjected to following evaluation parameters:

a. Color and appearance

The compressed tablets were examined for their color and appearance. Color and appearance of tablets were determined by visual method.

b. Weight variation test

20 capsules were randomly selected and weight to determined average weight and were compared with

individual capsule weight. The deviation from the average weight in each case was calculated and expressed as a percentage. Not more than two of the capsules from the sample size deviate from the average weight by a greater percentage and none of the capsule deviate by more than double that percentage. ⁽¹³⁾

c. Disintegration test

Generally, the test is useful as a quality assurance tool for conventional dosage forms. The efficacy of a drug or dosage form is solely dependent on the rate which formulation (capsule) disintegrates in the patient's gastrointestinal tract. For performing disintegration test six randomly selected capsules were taken. The tablet disintegration test apparatus was used. The disintegration assembly was maintained at temperature $37 \pm 2 \text{ }^\circ\text{C}$. The capsule was placed in each tube which was then suspended in the beakers which contains simulated gastric fluid (SGF, pH 1.2, without pepsin) to move up and down for 30 minutes. The disintegration test is a measure of the time required under a given set of conditions in which selected capsules were disintegrated into particles, which will pass through a 10 mesh screen within a specified time. ⁽¹⁴⁾

3. Statistical analysis

Data obtained were analyzed using One Way Analysis (ANOVA) followed by dunnet test and expressed as mean \pm SEM. Differences between means were regarded significant at $P < 0.001$.

4. RESULTS AND DISCUSSION**4.1 Evaluation of powder blend:****Table.5 Evaluation of powder blend**

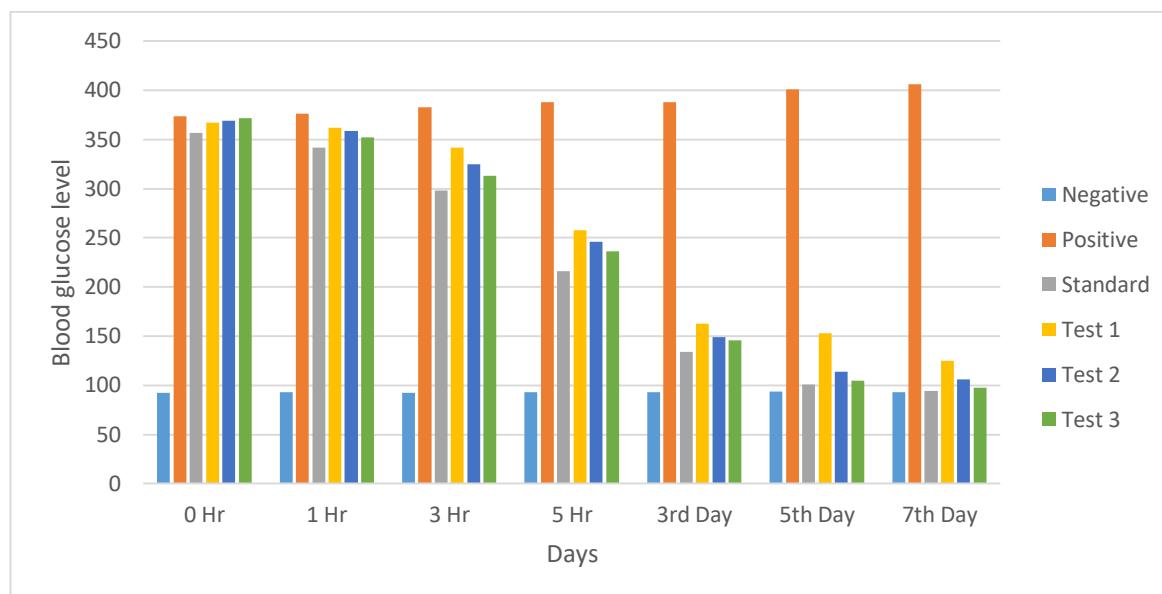
Sr.No.	Parameters	Results
1.	Bulk density (gm/ml)	0.50
2.	Tapped density (gm/ml)	0.6
3.	Carr's index (%)	15
4.	Hausner ratio	1.17
5.	Angle of repose ($^\circ$)	28.36

4.2 Evaluation of capsule:**Table.6 Evaluation of capsule**

Sr.No.	Parameters	Results
1.	Weight variation test ($\pm 5\%$)	± 2.48
2.	Disintegration time (min)	20

4.3 Estimation of blood glucose levels**Table.7 Effect of *Ficus benghalensis* leaf extract on alloxan induced diabetic rats**

Treatment Groups	Blood sugar level (mg/ml)					
	Vehicle control	Diabetic control	Metformin	Pet. Ether extract	Hydroalcoholic extract	Ethanollic extract
0 Hr	92.6 \pm 0.39*	374 \pm 0.93*	357 \pm 1.08***	367 \pm 1.19***	369 \pm 0.93*	372 \pm 0.78*
1 Hr	93 \pm 0.34	376 \pm 0.47	342 \pm 0.49***	362 \pm 0.62***	359 \pm 0.65***	352 \pm 0.68***
3 Hr	92.3 \pm 0.26*	383 \pm 0.61*	298 \pm 0.63***	342 \pm 0.75***	325 \pm 0.44***	313 \pm 0.65***
5 Hr	92.9 \pm 0.25*	388 \pm 0.63*	216 \pm 0.43***	258 \pm 0.68***	246 \pm 1.05***	236 \pm 0.62***
3 rd Day	93 \pm 0.25	388 \pm 0.31	134 \pm 0.48***	163 \pm 0.47***	149 \pm 0.73***	146 \pm 0.43***
5 th Day	93.7 \pm 1.10	401 \pm 0.84	101 \pm 0.38***	153 \pm 0.41***	114 \pm 0.72***	105 \pm 0.38***
7 th Day	93.0 \pm 0.33**	406 \pm 1.21**	94.4 \pm 0.92***	125 \pm 1.43***	106 \pm 0.31***	97 \pm 0.32***



Graph.1 Graphical representation of effect of *Ficus benghalensis* extract on blood glucose level

Effect of the ethanolic extract of *Ficus benghalensis* on blood glucose levels in alloxan induced diabetic rats is shown in Table- 7. The initial blood glucose levels of diabetic rats selected for the study were in the range of 300 to 500 mg/dl. In untreated control (diabetic) rats the blood glucose levels increased to 352 mg/dl on the seventh day. In ethanolic extract (300 mg/kg) treated rats, the blood glucose levels steadily decreased and it was 97 mg/dl on the 7th day. Thus the drug treatment restored the blood glucose levels almost nearer to normal values.

5. DISCUSSION

The preliminary phytochemical analysis of *Ficus benghalensis* extracts showed the presence of Steroids, flavonoids and tannins. In our study the difference observed between the initial and final fasting plasma glucose levels of different groups under investigation revealed a significant elevation in blood glucose in diabetic control group as compared with normal animals at the end of the 7- day experimental period. Our investigations indicate the efficiency ethanol extract in maintenance of blood glucose level in alloxan induced diabetic rats. Administration of ethanolic extract of *Ficus benghalensis* to diabetic rats showed a significant decrease in levels of blood glucose.

6. CONCLUSION

Herbal medicine can play, treatment of diseases than allopathic medicine because of less side effect and easy availability. Leaves of *Ficus benghalensis* were extracted by using petroleum ether, ethanol and hydroalcoholic solvent (7:3) and extract was used to formulate capsule. Capsules were evaluated for physical parameter and standardize as per pharmacopeia standards. Preformulation study and physical parameters result revealed that all the values within acceptable limits.

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