JETIR.ORG ISSN: 2349-5162 | ESTD Year : 2014 | Monthly Issue

JOURNAL OF EMERGING TECHNOLOGIES AND INNOVATIVE RESEARCH (JETIR)

An International Scholarly Open Access, Peer-reviewed, Refereed Journal

FORMULATION AND EVLUATION OF HERBAL ANTIDIABETIC TABLETS

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ABSTRACT: Herbal Medicine is the oldest form of healthcare. The objective ofthis research was to formulate and evaluate anti-diabetic herbal tablet from *Amaranthus viridis* extract. The leaves of *Amaranthus viridis* exhibit strong Antidiabetic effect, according to the literature study. The herbal tablets were made utilizing a binder solution including starch and a wet granulation process. The purpose of the Preformulation research was to examine powder properties. The findings indicate that the powder mixes have acceptable flow characteristics. According to the results of the Preformulation studies, all of the values were within acceptable limits. Post-compression parameters such as description, hardness, thickness, weight variation, friability, and disintegration time were used to assess the herbal tablets produced. The formulation also has an intriguing impact on diabetic rats caused by streptozotocin. For formulation f4, all other metrics were within acceptable pharmacopoeial norms. The short-term stability testing yielded results that were equivalent to the initial formulation and determined to be good. As a result, the herbal formulation f4 can be employed as a reliable, patient-friendly, and cost-effective herbal dosage form. As a result, future research into the creation of a strong herbal Antidiabetic medicine based on the current plant offers a lot of potential.

Key Word: Diabetes mellitus, Amaranthus Viridis extract, herbal tablets.

I. INTRODUCTION

Diabetes is a metabolic endocrine condition characterised by high blood sugar levels. Hyperglycemia is caused by insulin insufficiency, either absolute or relative, or cellular resistance to insulin. Diabetes is becoming more common all across the world at an alarming rate. With the biggest number of diabetessubjects, India ranked 1. The most distressing illness trend is a shift in disease beginning age of ten years sooner. Long-term uncontrolled hyperglycemia can increase the risk of diabetic problems later in life. There are a variety of current drugs available for glycemic management, but the main disadvantage is the long-term negative effects. In both developed and developing countries, herbal medications are in high demand. According to a WHO estimate, 80 % of the people in underdeveloped nations still rely on herbal products for their primary treatment. Potent herbal formulations have re-emerged as a safer medicine for numerous health concerns, including many chronic disorders. In this work, we sought to make a herbal solid form of the above-mentioned extract, i.e. tablets.

The use of relationship between people and plant has a long history for the treatment of uncontrolled blood sugar level abnormalities. Diabetes mellitus causes hyperglycemia, hyperglyceridaemia, and hypercholesterolemia. Synthetic anti-diabetic drugs include serious side effects such kidney failure, coma, and liver damage, among others. Plant-based medicines are typically considered safe and have few side effects. As a result, the search for a safer herbal Antidiabetic medicine that is also more

effective has become a popular issue. *Amaranthus viridis* is a worldwide annual herb because of its traditional therapeutic significance in the treatment of diabetes and other ailments.

II. MATERIAL AND METHODS

Collection and Authentication: Whole plant of *Amaranthus viridis* leaves were collected from Akole, Maharashtra, in the month of March-May. The plant was authentified by Dr., M. S. Khyade, professor at Sangamner Nagarpalika Arts, D.J. Malpani Commerce & B. N. Sarada Science College, Sangamner 422 605(Voucher No. 115).

Extract preparation: The plant's leaves were cleaned and coarsely pulverised before being dried in ambient air in a room free from direct sunlight. 50g of leaf powder was macerated for 48 hours in 1.0 L distilled water with micro vortex stirring at 355 rpm, and then macerated for another 24 hours in 0.50 L distilled water. After that, the macerate is filtered through cloth and Whatman Filter Paper No. 1 before being baked in a 40°C Oven till it becomes powder.

III. IN VITRO STUDY

In vitro∝-amylase inhibition assay of MEAV

MEAV's -amylase inhibitory activity was measured utilizing a spectrophotometric test with acarbose as the control drug. MEAV was dissolved in DMSO and concentrations of 10, 50, and 100 g/ml were obtained. 3.246 mg of amylase (EC 3.2.1.1) was mixed in 100 ml of 40 mm phosphate buffer pH 6.9 to make the enzyme amylase solution (0.5 unit/ml). 60 ml of 40 mm phosphate buffer (pH 6.9)/acarbose/MEAV, 30 ml of amylase enzyme, and 120 ml of 2-chloro-p-nitrophenyl-dmaltotrioside (CNPG3) were added, mixed, and incubated at 37°C for 8 minutes. At 405 nm, the absorbance was measured, and a control reaction was performed without the extract. Percentage inhibition was calculated by expression:

% Inhibition = AbsorbanceControl –AbsorbanceTest Absorbance Control×100

In vitro¸-amylase inhibition assay of MEAV table 5 results revealedthatMEAVshowedsignificant inhibition of -amylase enzyme. IC50 values of MEAV and acarbose are 10.19 and 0.312 g/ml respectively.

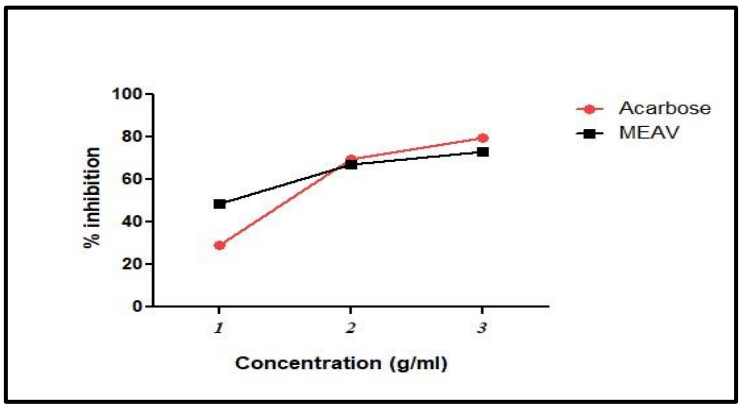

Fig. No. 1: α amylase activity of Acarbose and Amaranthus viridis extract (Graph of Conc. Vs % inhibition)

IV. FORMULATION OF HERBAL TABLETS

Formulation of Antidiabetic tablet

By using the wet granulation process, dried powder of macerated extract of *Amaranthus viridis* leaves was formed into tablet dosage form in this study. *Amaranthus viridis*, Glycine max, Starch, Sodium benzoate, Gelatin, Microcrystalline cellulose, Talc, and Magnesium stearate make up the formulation.

Table No. 01: Formulation of Herbal extract

Sr.No.	Ingredient	Quantity	Category
1.	Amaranths Viridis	700 mg	API
2.	Glycine max	15mg	Active Fraction

3.	Starch	40mg	Binder
4.	Sodium Benzoate	5 mg	Preservative
5.	Gelatine	5 mg	Coating Material
6.	Methyl Cellulose	10 mg	Diluents
7.	Magnesium Stearate	5 mg	Lubricant

Dispensing and Sifting

As per formulation table 1.correctly weighed amounts of extract were dispensed and filtered through a 40 no. sieve in a clean dispensing chamber.

Granulation process:

The wet granulation process is used to produce granules.

1. Weighing the needed amount of Starch and mixing it with water to form a granulating liquid, then adding sodium benzoate as a preservative.

2. In a water bath, the starch emulsion was completely boiled and simmered with the preservative until it formed a transparent semisolid mass.

3. The gelatine paste was made separately with the needed amount of water.

4. Weighing the excipients and thoroughly mixing them with the extract, the boiling starch and gelatine paste were carefully added until the powder became a moist mass.

5. The moist formulation was sieved using a number 20 sieve and dried for 3 hours at 60°C until the granules were totally dry.

6. After passing through sieve number 20, the dry granules were lubricated.

7. For 600mg strength tablets, the lubricated mix was crushed using amultiple compression machine with a 12.50 mm round standard punch. The processing space was kept at a temperature of 25°C to 30°C, with a relative humidity of 30 to 32 percent. Wet granulation technology was used to generate several batches of formulations F1 to F12, according to the composition shown in table 2.

V. EVALUATION OF HERBAL FORMULATION

Evaluation of Powder Blends

To estimate bulk density, tapped density, angle of repose, Carr's index, and Hausner's ratio, the lubricated blends were examined for different precompression parameters before compression.

Angle of repose

The funnel technique was used to determine the angle of repose. A funnel was used to collect the precisely weighed mixture. The funnel's height was modified such that the tip of the funnel just touches the peak of the heap or blend head. The medication excipients mixture was allowed to run freely down the funnel and onto the surface. The powder cone's diameter was measured, and the angle of repose was computed using the equation:

$$\mathbf{Tan(\theta) = h/r}$$

Where, h = height of powder cone formed

r = radius of the powder cone formed

Bulk Density- A powder sample weighing 10 gm was correctly weighed and placed into a graduated cylinder with a capacity of 50 ml. The powder was leveled, and the volume of the unsettled volume, V0, was recorded. The bulk density in g/cm3 was derived using the formula,

Bulk density (ρ0) = M/V0

Where, M = Mass of powder taken,

V0= Apparent unsettled volume

Tapped Density

A 10 g powder sample was placed in a graduated cylinder with a 50 ml capacity. The cylinder was mechanically tapped with the use of tapped density instrument.

Compressibility index

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

Compressibility index (%) = (Tapped Density- Bulk density) x 100 / Tapped Density

Hausner's ratio

It is the measurement of the drug's frictional resistance. The optimal range is between 1.2 and 1.5. The following formula is used to calculate it:

Hausner's ratio= Tapped density / Bulk density

Loss on drying

1g of well-mixed granules was placed in a dry, glass stopper shallow weighing container. The contents were equally dispersed and then placed in the drying chamber (Sartorius moisture balance). The bottle's cork was removed, and the contents were dried for a certain amount of time to create a consistent weight.

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

Evaluation of Tablets

Physical factors such as description, hardness, thickness, weight fluctuation, friability, and disintegration tests were tested on the prepared tablets.

Description

The colour and overall look of the crushed tablets were assessed.

Hardness

A calibrated Monsanto hardness tester was used to test ten tablets. Hardness is measured in Kg/cm2 and indicates tablet crushing strength.

Weight variation test

The average weight was calculated by choosing and weighing 20 pills at random. Each pill was weighed separately as well. In each example, the weight variation from the average was determined and reported as a percentage. A maximum of two pills from the sample size should differ.

Friability Test

Friability determines combined effect of shock and abrasion. Friability was tested as per pharmacopoeia for the tablets by using Roche friabilitor (100 revolutions at 25 rpm). For acceptance friability, should not be more than 1.0%. The friability was calculated by the equation, % Friability = [W0 – Wt. / W0] × 100 Where, W0 = Initial weight of tablets, Wt. = Final weight of tablets

Disintegration Test for Tablets

The basket was disintegrated in the disintegration test, and the apparatus was kept at 37.50°C in the immersion liquid. The time it took for the tablet to completely disintegrate was recorded. When no particles remain above the gauge after passing through a 10# mesh screen, the tablets are destroyed.

Stability Study

For the stability tests, the improved formulation F9 was chosen. Because to chemical changes in the active components or product instability, drug composition or degradation occurs during stability, reducing the concentration of the medication in the dosage form. The samples were stored at 40 °C and 75.5% RH for the accelerated stability investigations, which were carried out

according to ICH recommendations. The tablets were compared to tablets that were examined immediately in terms of description, percent friability, and disintegration tests.

VI. RESULTSAND DISCUSSION

The findings of the pharmacological investigation indicated that an extract of *Amaranthus viridis* leaves had substantial anti-diabetic effect. Following a thorough examination of crude drug, extracts, and solvent evaporated powder of *Amaranthus viridis* extract, a single drug formulation based on the plant extract was created, and the formulation was reviewed and standardized according to pharmacopoeia standards. Preformulation experiments were used to create and analyse dried granules of powder from *Amaranthus viridis* seeds, which included metrics such as angle of repose, loose bulk density, tapped bulk density, loss on drying, compressibility index, and Hausner's ratio, among others. All of the parameters examined in the Preformulation research of granules generated by the wet granulation technique were within the permissible range.Moisture content, and in-vitro disintegration time was all assessed. With the use of a Monsanto tester, the hardness of the formulation was tested in kg/cm. The formulation exhibited noticeable hardness characteristics (5.40), which aided in its rapid disintegration. The formulation's friability (0.32) revealed that the tablets were mechanically stable. Because the average weight of the tablets was 700 mg, a weight fluctuation range of 5% is permitted. As a result, the weight variation test was passed on the full formed tablet. The formulation took more than 5 minutes to disintegrate.

Fig. No. 2: Herbal Antidiabetic tablets from *Amaranthus viridis* extract

Table No. 02:Preformulation studies of dried granules

Sr. No	Parameter	Result
1	Angle of repose	28^0
2	Bulk density	0.28 gm/cm^3
3	Tapped density	0.37 gm/cm^3
4	Compressibility index	29.72%
5	Hausner’s ratio	1.32
7	Loss on drying	0.98%

Table No. 03: Evaluation study of tablets

Parameter	Colour	Average Wt. (Gm.)	Hardness N/mm^2	Thickness	Friability	Disintegration Time(min)
F1	Green	0.701	3.20	5.30	0.84	6.15
F2	Green	0.700	3.60	5.28	0.55	7.02
F3	Green	0.702	4.10	5.27	0.49	7.10
F4	Green	0.701	5.40	5.25	0.32	7.23

Table No. 04: Stability study of Herbal tablets.

Physical Parameter	Results			
	Initial	1 Month	2 Month	3 Month
Appearance	Smooth	Smooth	Smooth	Smooth
Green	Green	Green	Green	Green
Hardness	5.40	5.31	5.27	5.24
Thickness	5.25	5.23	5.20	5.18
Friability	0.32	0.31	0.30	0.30
Disintegration Time(min)	7.23	7.21	7.18	7.17

Table No. 05- In vitro∝- -amylase inhibition activity of extract of *Amaranths viridis*

Sample	Concentration (ug/ml)	% inhibition	IC50 (ug/ml)
Acarbose	0.1	29.23 ± 0.11	0.298
	0.5	69.56 ± 0.07	
	1.0	79.39 ± 0.13	
MEAV	10	48.44 ± 0.26	09.98
	50	67.12 ± 0.16	
	100	73.17 ± 0.14	

The data are expressed in mean ± S.E.M. n = 3 in each group.

All of the parameters tested in the granule Optimized formulation research and the standardisation parameter of the produced tablet were found to be within acceptable ranges. The hardness, friability, disintegration rateand stability results of the formulation were all found being within acceptable limits during physical testing.

VII. Conclusion

Physical testing revealed that the formulation's hardness, friability, and disintegration time were all within acceptable limits. The disintegration time for Formulation F9 was 10.10 minutes. As a result, it was chosen as an optimum formulation and tested for stability. As a result, it may be concluded that the prepared tablet of extract of *Amaranths Viridis* leaves need more research to completely understand the underlying mechanism of action. The findings of the stability investigation demonstrated that formulation F4 was a stable formulation with a faster disintegration time and higher percent friability, and that it could be utilized to treat diabetes mellitus effectively.

VIII. ACKNOWLEDGEMENT

The authors are thankful to Samarth Institute of Pharmacy, Belhe, Pune, (India) for providing facilities to carry out this work. Also the Parul Institute of Pharmacy, Vadodara, Gujarat (India) for providing facilities to carry out the research work.

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