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# Preparation and Evaluation of Polyherbal Anti Diabetic Formulation

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**A b s t r a c t**
The aim of this study is to develop and evaluate antidiabetic polyherbal capsules containing multiple plant extracts. Utilizing plants as sources of medication has a long history, with many existing medications having originated directly or indirectly from plant-derived compounds. In this research, we focus on a solid pharmaceutical dosage form comprising a unique dry plant extract and various excipients such as starch, microcrystalline cellulose, and talc, which has shown promising statistically significant anti-diabetic activity. The evaluation of the prepared tablets includes assessing parameters such as weight variation and disintegration time to ensure the quality and efficacy of the final product.
**Keywords:** antidiabetic polyherbal, anti-diabetic activity, microcrystalline cellulose

**A r t i c l e I n f o**

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**C O N T E N T S**



## 1. Introduction

India is considered as the diabetic capital of the world. Diabetes mellitus (DM) is the systematic metabolic disorder characterized by hyperglycemia, insulin resistance and relative insulin deficiency with disturbances of carbohydrate, fat and protein metabolism. Its incidence is increasing throughout the world at an alarming pace, which is expected to cause grave secondary complications over time like neuropathy, nephropathy, retinopathy, cardiovascular disease, retinopathy and dyslipidemia. In today's scenario, about 90 % of the young population accounts for a major share in the incidence of type II diabetes mainly due to a shift to the sedentary lifestyle comprising of unhealthy diet habits and less physical activity. Various synthetic drugs such as oral hypoglycemic drugs along with insulin are available to control the level of blood sugar, but their cost, complications, limited tolerability

and various side effects hamper wider acceptance. Thus, it is notably one of the refractory diseases identified by the Indian Council of Medical Research for which there is a dire need for alternative medical treatment[1-5].

Considering the facts, the most commercially successful and widely used branch of alternate or complementary medicine is phytotherapy, which acquires to be 'synergy' that is more effective than the sum of their parts. India is considered as the emporium of medicinal plants because in different bioclimatic zones, there exists a diverse availability of several thousands of medicinal plants and thus has a rich history of using herbal plants for medicinal purposes. Traditionally, herbal medicines and their preparations are being used in various therapies owing to its natural origin and lesser side effects than synthetic drugs [6-11].

Herbal medicine has gained attention as an alternative or complementary approach to conventional treatments due to its perceived safety and potential effectiveness in managing diabetes. Many existing anti-diabetic drugs have origins in natural sources, further encouraging exploration into polyherbal formulations.

## 2. Materials and Methods

**Selection and collection of plant material:**

Polyherbal antidiabetic formulation consists of five herbs viz., *Berberis aristata (*dried Stem), *Terminalia chebula* (pericarp of matured fruit), *Emblica officinalis* (pericarp of dried matured fruit), *Terminalia belerica* (pericarp of dried ripe fruit) and *Cyperus rotundus* (dried rhizome). Lactose, Micro crystalline cellulose, Magnesium carbonate, Starch, Sodium methyl paraben, Bronopol are the other materials used for the preparation of formulation.

**Collection and Authentication**

Herbs used for formulation were procured from Tirumala hills and further authenticated by Dr. K. Madhava chetty, Dept. of Botany, S V University, Tirupati.

***Processing of Raw Materials***

The procured plant materials were cleaned thoroughly. They were then dried under shade for a week or so. Once they were completely dried, they were ground into coarse powder and stored in air tight containers and preserved for the further processing.

***Extraction by hot percolation method:***

About 200g of coarsely powdered parts of the plant was extracted with Ethanol at 60-70°C. Extract of individual plants were concentrated using rotary vacuum evaporator. The percentage yield, colour and consistency of all the extracts were noted and were taken up for further detailed phytochemical and pharmacological screening.

***Development of Formulation***

The ethanolic extracts of *Berberis aristata, Terminalia chebula*, *Emblica officinalis*, *Terminalia belerica* and *Cyperus rotundus* were subjected to freeze drying process .The extracts were dried for a period of time according to their rate of drying. The lyophiliser was made utilized in the Pharmaceutics Laboratory, of our college. Diluents like, Microcrystalline cellulose, Magnesium stearate, Lactose, starch were dried. All active ingredients were weighed according to the formula, mixed with adsorbent magnesium carbonate followed by diluents and preservatives like Sodium methyl paraben and bronopol as specified in formula were mixed well. The mixture was blended thoroughly for 30 minutes. Then the powder was transferred to the polythene bags and labelled for further studies.

**Preformulation Studies**

Prior to formulation, it is essential that fundamental physical and chemical properties of the drug molecule and other derived properties of the drug powder are determined. This information decides many of the subsequent events and approaches in formulation development. This first learning is known as Preformulation. It aims to optimize the process of turning a drug into a drug product. During preformulation the physiochemical properties of the drug candidate are determined.

**Development of Formulation -Trial Batches**

Four trial batches of capsules were formulated by varying the composition of the excipients proportions for excellent flow property.

**Formulation of Capsules**

Capsule is the most versatile of all dosage forms. Capsules are solid dosage form in which one or more medicinal and inert ingredients are enclosed in a small shell usually made of gelatin. There are two types of capsules, "hard" and "soft". The hard capsule is also called "two piece" as it consists of two pieces in the form of small cylinders closed at one end, the shorter piece is called the "cap" which fits over the open end of the longer piece, called the "body". The soft gelatin capsule is also called as "one piece". Capsules are available in many sizes to provide dosing flexibility.

**Selection of Capsule Size**

The volume of material to be filled into the capsule should be determined. Generally, capsules of sizes "0" to "4" were readily available in the market and the relationship between the capsule size and related body volume to be known at the development stage. For pharmaceutical products it is unusual to use a size larger than "0" because of the difficulty in swallowing larger size capsules, whilst size "5" is rarely used due to difficulties in the automatic filling process. Capsule of size "0" were selected to fill the polyherbal formulation.

***Capsule Filling***

The formulated granules were filled in"0" size capsules to an average net content weight 520mg per capsule by manual filling method. The capsules were then dedusted, transferred into polythene bags, labelled and the samples were evaluated as per testing requirements.

**Standardization of Polyherbal Capsules**

The developed polyherbal capsules were standardised for its Description, uniformity of weight, disintegration time, moisture content, pH, physicochemical parameters, phytochemical studies, fluorescence analysis, heavy metal analysis and microbial load analysis. Determination of uniformity of weight, disintegration time and moisture content of capsules were carried out as per Indian pharmacopoeial procedures.

***In Vitro* Anti – Diabetic Activity**

**α-amylase inhibition assay**

*α-amylase was dissolved in phosphate buffer saline (PBS, 0.02 mol/L, pH 6.8) at a concentration of 0.1 mg/mL. Various concentrations of sample solutions (0.25 mL) were mixed with α-amylase solution (0.010 mL) and incubated at 37 °C for 5 min. Then the reaction was initiated by adding 0.1 mL 1.0% (w/v) starch substrate solution to the incubation medium. After incubation at 37 °C for 3 min, the reaction was stopped by adding 1 mL DNS reagent (1% Dinitrosalicylic acid, 0.05% $Na_2SO_3$ and 1% NaOH solution) to the reaction mixture and boiling at 100 °C for 5 min. After cooling to room temperature, the absorbance (Abs) at 540 nm was recorded by a spectrophotometer. The inhibition percentage was calculated by the following equation:*

**Inhibition (%) = [(Abs1 − Abs2)/Abs1] × 100**

Where, Abs1=sample and Abs2 = control.

## 3. Results and Discussion

**Preparation of Extracts**

The shade dried crude dried drugs of *Berberis aristata (*dried Stem), *Terminalia chebula* (pericarp of matured fruit), *Emblica officinalis* (pericarp of dried matured fruit), *Terminalia belerica* (pericarp of dried ripe fruit) and *Cyperus rotundus* (dried rhizome) weres extracted in soxhlet extractor with ethanol. All the extracts were concentrated using rotary vacuum evaporator. The percentage yield was calculated for every extract in terms of dried weight of plant material. The colour and consistency of the concentrated extracts are given in table.

**Preformulation Studies**

Totally four trials of formulation were carried out using different choices of excipients considering different facts of manufacturing problems as well as quality defects in mind. All the resultant formulations were evaluated for their flow property, uniformity of filling, uniformity of weight, moisture content and disintegration time.

**Standardization of the Finished Product**

The final formulation was analyzed for its quality control parameters in three trials. The mean value was obtained and Standard deviation was calculated. Wherever there were no official standard, limits for each parameter was established based on trial and error analysis of Trial IV batch capsules.

***Table 1. Proposed Strength of Formulation***

| S.NO. | Active Ingredients | Strength (in mg) |
|---|---|---|
| 1 | *Berberis aristata* | 50 |
| 2 | *Terminalia chebula* | 100 |
| 3 | *Emblica officinalis* | 120 |
| 4 | *Terminalia belerica* | 120 |
| 5 | *Cyperus rotundus* | 80 |

**Table 2. Development of Formulation**

| S.NO | Materials | TRIAL-1(mg) | TRIAL-2(mg) | TRIAL-3(mg) | TRIAL-4 (mg) |
|---|---|---|---|---|---|
| 1 | *Berberis aristata* | 50 | 50 | 50 | 50 |
| 2 | *Terminalia chebula* | 100 | 100 | 100 | 100 |
| 3 | *Emblica officinalis* | 120 | 120 | 120 | 120 |
| 4 | *Terminalia belerica* | 120 | 120 | 120 | 120 |
| 5 | *Cyperus rotundus* | 80 | 80 | 80 | 80 |
| 6 | Lactose | 35 | 40 | 55 | 35 |
| 7 | Micro crystalline cellulos | 18 | 20 | 25 | 10 |
| 8 | Magnesium carbonate | 1.2 | 3 | 4.5 | 5 |
| 9 | Starch paste | Aq | Aq | Aq | Aq |
| 10 | Sodium methyl paraber | 0.5 | 0.5 | 0.5 | 0.5 |
| 11 | Bronopol | 0.5 | 0.5 | 0.5 | 0.5 |

**Table: 3 Final Batch**

| S.NO | Materials | Trailiv (mg) |
|---|---|---|
| 1. | *Berberis aristata* | 50 |
| 2. | *Terminalia chebula* | 100 |
| 3. | *Emblica officinalis* | 120 |

| | | |
|---|---|---|
| 4. | *Terminalia belerica* | 120 |
| 5. | *Cyperus rotundus* | 80 |
| 6. | Lactose | 35 |
| 7. | Micro crystalline cellulose | 10 |
| 8. | Magnesium Carbonate | 5 |
| 9. | Starch paste | Aq |
| 10 | Sodium methyl paraben | 0.5 |
| 11 | Bronopol | 0.5 |

***Table 4. Percentage yield of various extracts***

| S. No. | Plant name | Method of extraction | Physical nature | Colour | Yield %w/w |
|---|---|---|---|---|---|
| 1 | *Berberis aristata* | Continuous hot percolation | Semi solid | Dark brown | **5.29** |
| 2 | *Terminalia chebula* | | | | **22.05** |
| 3 | *Emblica officinalis* | | | | **16.9** |
| 4 | *Terminalia belerica* | | | | **16.16** |
| 5 | *Cyperus rotundus* | | | | **8.75** |

***Table 5. Evaluation of trial batches***

| Parameters | Trial 1 | Trial 2 | Trial 3 | Trial 4 |
|---|---|---|---|---|
| Bulk density ($g/cm^{2)}$ | 0.50±0.04 | 0.60±0.05 | 0.55±0.01 | 0.54±0.04 |
| Tapped density($g/cm^{2)}$ | 0.61±0.02 | 0.53±0.03 | 0.54±0.03 | 0.57±0.04 |
| Compressibility index (%w/w) | 09.99±0.03 | 09.09±0.63 | 5.55±0.91 | 4.71±0.04 |
| Hausner's Ratio | 1.35±0.02 | 1.43±0.02 | 1.13±0.12 | 1.03±0.12 |
| Angle of repose (degrees) | 35.05±1.0 | 34.66±0.02 | 43.03±3.78 | 33.03±3.78 |

The value are expressed as mean ± SD, (n=5); NMT-Not more than

**Table 6. Organoleptic Characters**

| S.NO | Parameter | Observation |
|---|---|---|
| 1. | Description | Light brown granule in blue cap and body "0" size capsule |
| 2. | Colour | Light brown granule |
| 3. | Odour | Characteristic odour |
| 4. | Taste | Bitter tate |

**Table 7. Physical Parameters**

| S.NO | Parameter | Observation |
|---|---|---|
| 1. | pH (1% aqueous solution) | 7.33 ± 0.21 |
| 2. | Moisture content | 3.98 ± 0.5%w/w |
| 3. | Uniformity of weight | 519.3 ±3.4mg |
| 4. | Disintegration time | 2’ 32secs ± 0.34 |

Results are reported as Mean ± Standard deviation

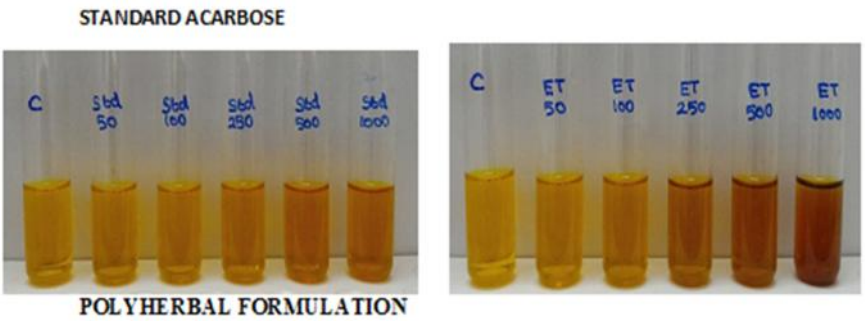


Fig 1: Graphical representation of the α-amylase inhibition assay

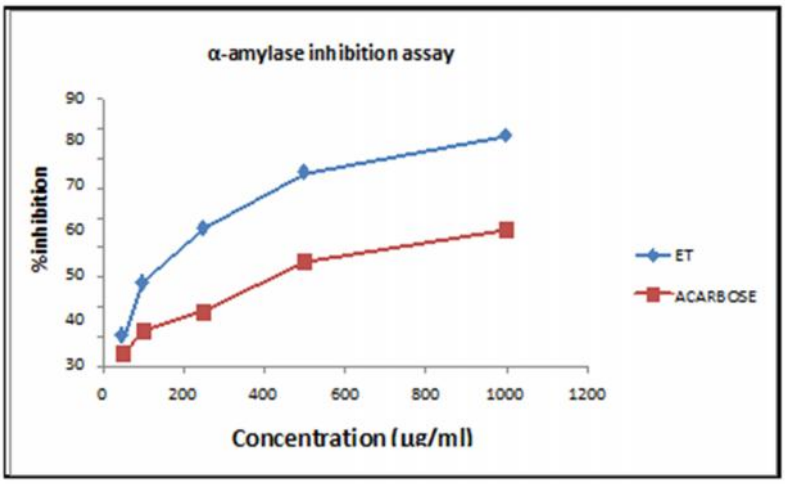


Fig 2: ET- Polyherbal Formulation

**4. Conclusion**

The coarse powders of the selected plants were extracted by using ethanol as solvent. The ethanolic extracts were dried by freeze drying and used for the formulation. The dried polyherbal extract was optimized for its quality measures and its batch consistency by making four different trial batches (Trial I, II, III, IV). The trials were subjected to preformulation parameters to confirm the uniformity and quality. The result concludes that the trial IV was excellent in all parameters and the values were found within the standard limits and it was used for formulate Polyherbal Capsule. The developed polyherbal capsules were standardized for its Description, uniformity of weight, disintegration time, moisture content, pH, Physiochemical parameters. The heavy metal analysis and the microbial load was carried out in polyherbal formulation as per the WHO Guidelines and found within the limits. In vitro anti-diabetic activity was done by using α-amylase inhibition assay method. It possesses significant antidiabetic activity as compared to standard Acarbose. Further studies are recommended for stability studies in the formulated polyherbal capsules and also clinical trials have to perform in future in Human Volunteers.

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