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PREPARATION AND EVALUATION OF POLYHERBAL TABLETS FOR DIABETES MELLITUS AND IT'S COMPLICATIONS

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1. INTRODUCTION

Diabetes mellitus is the predominant public health concern disorder that causes substantial mortality, morbidity and long term complications. The diabetes mellitus is basically a systematic metabolic disorder characterized by hyperglycemia, insulin resistance and relative insulin deficiency with disturbances of carbohydrate, fat and protein metabolism. Diabetes mellitus also known as diabetes which was observed as disease related with "sweet urine" and muscle loss. Glucose blood levels are maintained by insulin which is a hormone released from β-cells in islets of Langerhans which are present in pancreas. Diabetes mellitus are three types, Type 1, Type 2 and gestational diabetes mellitus. Type 1 diabetes mellitus is known as Insulin Dependent diabetes which is due to total loss of β-cells of pancreas. Type 2 diabetes mellitus is known by temporary loss of β-cell mass. Gestational diabetes is a type of diabetes which present with hyperglycemia in pregnant women. The symptoms of diabetes mellitus are polydipsia, polyuria, fatigue, and nausea, vomiting, slow wound healing and blurred vision. According to International Diabetes Federation (IDF) survey in 2016 diabetes is a disorder which affects

415 million people in the world and it may increase to 642 million by the year 2040. India is also known as Diabetes mellitus capital of the world.

India has a rich cultural heritage of traditional medicines which chiefly comprised the two widely flourishing systems like Ayurveda, Siddha, Unani systems since ancient times. All the renowned classic texts of Ayurveda like Charaka Samhita (1000 BC), Sushruta Samhita (600 BC) and subsequent works refer to this disease under the term *Madhumeha* or *Ikshumeha*. In India indigenous medicines have been used in the treatment of diabetes mellitus since the time of Charaka and Sushruta (6^{th} century BC).

India is considered as the epicenter of the global diabetes epidemic and the diabetic capital in the world with the score of second highest number of diabetic people in the world. It is estimated to have over 20 million diabetic cases which are estimated to increase to 57 million by 2025. In India, diabetes is a serious disease due to irrational food habits. Most of the hypoglycemic agents used in allopathic practice to treat diabetes mellitus are reported to have side effects in long term use. Hence there is need to search for effective and safe drugs for these ailments. Pharmaceutical research across the world shows that natural products are potential sources of novel molecules for drug development.

Nature is the putative pharmacy for the prevention and treatment of Diabetes mellitus. India is considered as the "Emporium of Medicinal Plants", because in different bioclimatic zones, there are varied and diverse availability of several thousands of medicinal plants. Medicinal plants not only play a pivotal role in traditional systems of medicine but also in modern medicine. As per worldwide estimation, about 12000 plants are being used in medicinal purpose. Considering the facts, the most commercially successful and widely used branch of alternative medicine is "Phytotherapy". The Phytotherapy flourishes more, having more than one herb in the formulation to achieve the extra therapeutic effectiveness known as polyherbalism. Thus, polyherbal is expected to raise the effectiveness and potency of formulation, reduction of side effects, and increase of life span. The recent scenario of phytotherapy assures the advantages of polyherbal, and thus holds the future prospects of healthy population. The present study was conducted on the Poly Herbal Powders (PHP), to study its pharmacognostic and physiological parameters. Their constituent not only acts in maintaining the blood glucose level, but also provides with the protective effect thus preventing its long term complications.

1.1. Cinnamon verum

- **Synonyms:** Cortex cinnamoni, Ceylon cinnamon, Saigon cinnamon, Chinese cassia, *Cinnamomum aromaticum, Cinnamomum laurus.*

- **Biological source:** Cinnamon is the dried inner bark of the coppiced shoots of *Cinnamomum zeylanicum* Nees., belonging to family Lauraceae.

- **Cinnamomum verum:** (Family Lauraceae) commonly known as Dalchini has been shown to exhibit insulin potentiating effect in glucose metabolism. It is reported to enhance the glucose uptake by activating insulin receptor kinase activity, and autophosphorylation of the insulin receptor and glycogen synthase activity.

- **Chemical constituents:** Cinnamon contains about 10% of volatile oil, tannin, mucilage, calcium oxalate and sugar. Volatile oil contains 50 to 65% cinnamic aldehyde, along with 5 to 10% eugenol, terpene hydrocarbons and small quantities of ketones and alcohols.

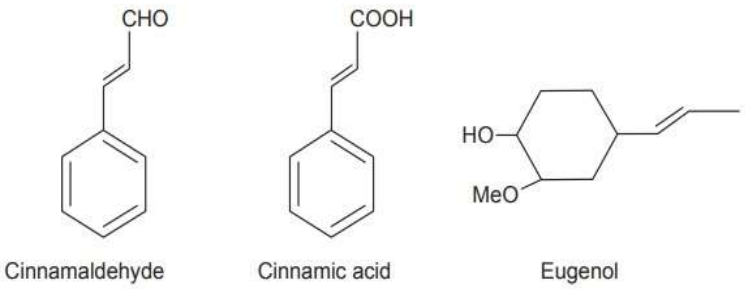


Fig. 1: Chemical constituents of cinnamomum verum.

- **Chemical tests**

- A drop of volatile oil is dissolved in 5 ml of alcohol and to it a drop of ferric chloride is added, A pale green colour is produced. Cinnamic aldehyde gives brown colour with ferric chloride, whereas eugenol gives blue colour.

- The alcoholic extract is treated with phenylhydrazine hydrochloride, it produces red colour due to the formation of phenylhydrazone of cinnamic aldehyde.

- **Uses:** It is used as an alterative, aromatic, carminative, flavouring agent, analgesic, antiseptic, antirheumatic, antispasmodic, demulcent, digestive, expectorant, stomachic, diaphoretic, antibacterial, antifungal, etc. It stops vomiting, relieves flatulence and is given with chalk and as astringents for diarrhoea and haemorrhage of the womb. It is also

used in the treatment of bronchitis, colds, palpitations, nausea, congestion, and liver problems.

- **Other species:** *Cinnamon cassia* is often used as a substituent. *C. culiawan* is native of Amboyna and the bark has the flavour of clove, *C. iners, Cassia burmarin, Saigon cinnamon*, and *C. nitidum* are also used.

- **Marketed products:** It is one of the ingredients of the preparations known as Rumalaya gel, Koflet lozenges, Chyavanprash (Himalaya Drug Company), Garbhapal ras, Sutsekhar ras (Dabur), and Sage Staminex capsules (Sage Herbals).

Fig. 1.1: Bark of cinnamomum verum.

1.2. Coriandrum sativum

- **Synonyms:** Fructus coriandri, Coriander fruits, Cilantro, Chinese parsley.

- **Biological source:** Coriander consists of dried ripe fruits of *Coriandrum sativum* Linn., belonging to family Umbelliferae.

- **Chemical constituents:** Coriander consist of about 1% of volatile oil the chief volatile components are D-(+)-linalool (Coriandrol), along with other constituents like, borneol, p-cymene, camphor, geraniol, limonene, and alpha-pinenes. The fruits also contain fatty oil and hydroxycoumarins. The fatty oils include acids of petroselic acid, oleic acid, linolenic acid, whereas the hydroxycoumarins include the umbelliferone and scopoletine.

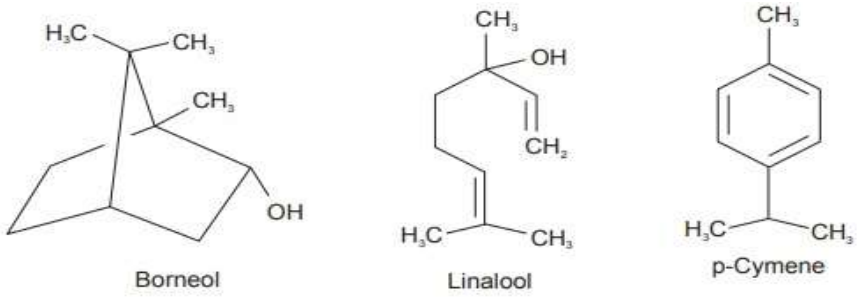


Fig. 2: Chemical constituents of coriandrum sativum.

- **Chemical tests**

- 5 ml of extract was mixed with 2ml of chloroform and carefully add 3 ml of concentrated sulphuric acid to form a layer, a reddish brown coloration of the inter face was formed.
- 1 ml of drug extract was treated with chloroform, acetic anhydride and few drops of sulphuric acid was added, then dark green color formed.

- **Uses:** Aromatic, carminative, stimulant, alterative, antispasmodic, diaphoretic and flavouring agent. It is also used as refriger-ant, tonic, appetizer, diuretic, aphrodisiac, and stomachic. Coriander can be applied externally for rheumatism and painful joints. The infusion of decoction of dried fruit of cardamom is useful for the treatment of sore-throat, indigestion, vomiting, flatulence, and other intestinal dis-orders.

- **Other species:** Coriander tordylium (Used as anti inflammatory agent), Coriandru abyssinicum also known as Ethopian coriander used as medicinal aromatic agent.

- **Marketed products:** It is one of the ingredients of the preparations known as Cystone, Bilwadi churna and Sage massage oil (Sage Herbals).

1.3. Moringa oleifera

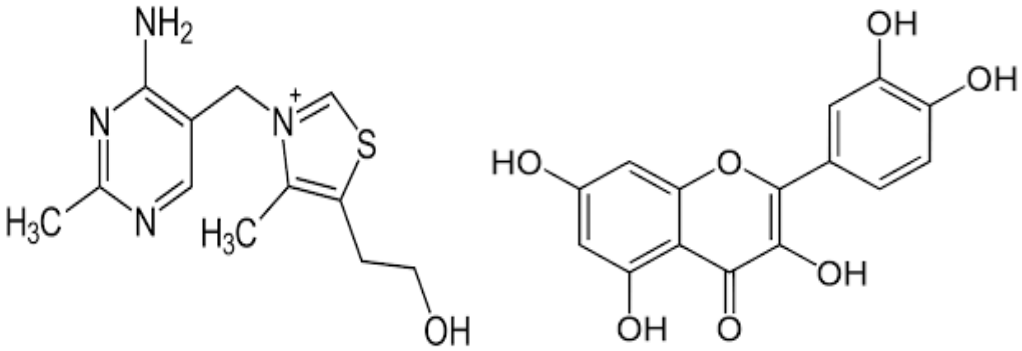
- **Synonym:** Drum stick tree, horse radish tree, Ben oil tree, Miracle tree, Sahijan (In India)

- **Biological source:** Moringa species contain various phytoconstituents such as alkaloids, saponins, tannins, steroids, phenolic acids, glucosinolates, flavonoids, and terpenes. The diversity of these phytochemicals in the genus contributes to its numerous pharmacological uses.

- **Moringa oleifera:** (Family Moringaceae) leaves have shown to reduce glycemia, without causing any adverse effects. The mechanism for reducing glycemia include inhibition of

α- amylase and α-glucosidase activities, increased glucose uptake from the intestine, decreased gluconeogenesis in liver, and increased insulin secretion and sensitivity.

- **Chemical constituents:** Moringa is also known as the drumstick and is renowned for its medicinal properties. Some of the constituents are vitamins like folate, thiamine, riboflavin, and niacin. Then minerals, fatty acids like oleic acid, linoleic acid, and palmetic acid. The Proteins, anti oxidants like quercetin, beta carotene.



Thiamine **Quercetin**

Fig. 3: Chemical constituents of moringa oliefera.

- **Chemical tests**

- A few drops of a 2% solution of aluminium chloride (AlCI3) to a solution containing quercetin forms a yellow coloration, which intensified upon addition of dilute sodium hydroxide (NaOH) solution.
- This test involves the addition of a few drops of concentrated hydrochloric acid (HCl) to a solution containing quecetin, a pink to red color formed.

- **Uses:** Moringa oleifera plays an important role in protecting the liver from damage, oxidation and toxicity due to the high concentrations of polyphenols in its leaves and flowers. Moringaoleifera oil can also restore liver enzymes to normal levels, reducing oxidative stress and increasing protein content in the liver.

- **Other species:** Moringa arborea, Moringa borziana, Moringa concanensis (Indigenous to northen India), Moringa longituba, Moringa drouhardii (Anti oxidant).

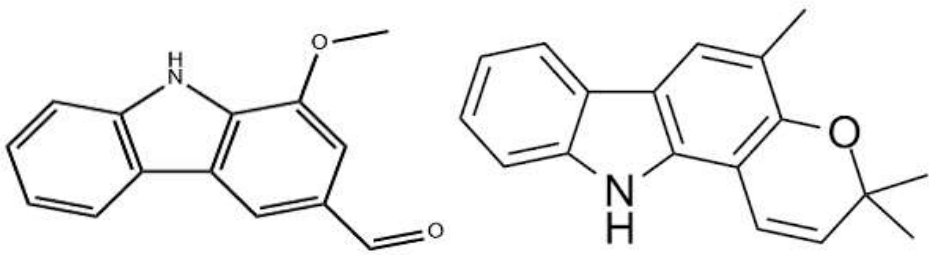
- **Marketed products:** The leaf powder, tea, oil, and seeds are the several product categories that make up the market. In 2021, leaf powder held more than 30 % of the market share, making it the most popular product in this category.

1.4. Murraya koenigi

- **Synonym:** Bergera koenigi, Chalcas koenigi, Karuvepilai, Karivepaku, Bishahari curry leaf and tree curry leaf.

- **Biological source:** Murraya koenigi, commonly known as curry leaf, is a plant native to the Indian subcontinent. It is primarly cultivated for it's aromatic leaves, which are used as a seasoning in Indoan cooking. The biological sources pf cirry leaves is the Murraya koenigi plant itself, speciall its leaves. These leaves contain essential oils and compounds that give them their distinctive flavor and aroma.

- **Chemical constituents:** Murraya koenigii, contains various chemical constituents that contribute to its flavor, aroma, etc., Some of them are Carbazole Alkaloids like murrayanine, isomurrayanine, girinimbine, and mahanine. The Essential Oils like beta-caryophyllene, beta-pinene, beta-phellandrene, and terpinolene. The Flavonoids like quercetin, kaempferol, rutin, and myricetin. Triterpenoids like koenigin, koenigine, and koenine are triterpenoids. Beta-carotene (provitamin A) and vitamin C.



Murrayanine **Girinimbine**

Fig. 4: Chemical constituents of murraya koenigi.

- **Chemical tests**

- It involves addition of magnesium metal to the extract, and also added concentrated hydrochloric acid. A pink, red, or orange coloration indicates the presence of flavonoids.
- It has performed to detect essential oils by heating a small quantity of crushed curry leaves and observed the aroma.

- **Uses:** In preventing oxidative stress-related diseases such as cardiovascular diseases, cancer, and neurodegenerative disorders. Conditions like arthritis, asthma, and inflammatory bowel disease will be treat. The hepatoprotective activity could be beneficial in preventing liver diseases and promoting liver health, which may enhance insulin sensitivity and regulate blood sugar levels.

- **Other species:** Murraya paniculata, Murraya exotica, Murraya microphylla, Murraya sumatrana, also cultivated as an ornamental plant, Murraya euchrestifolia.

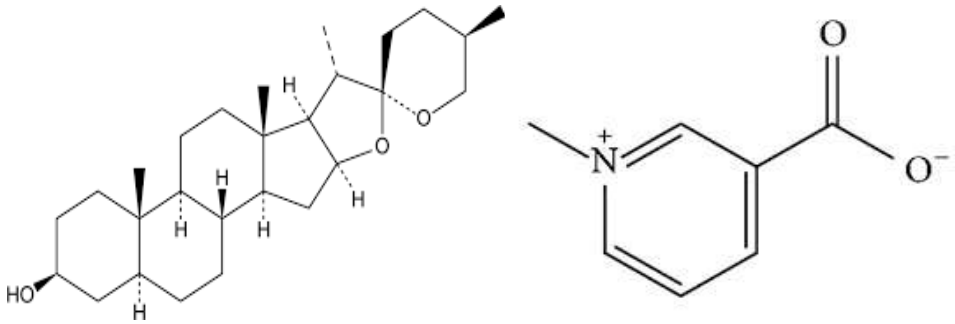
- **Marketed products:** Curry leaf-infused hair oils are popular, Digestive Tonics, Skin Care Products like Ayurvedic skincare products such as creams, lotions, Ayurvedic Teas.

1.5. Trigonella foenum greacum

- **Synonyms:** Fenugreek, Methika, Chandrika, Hulba, Greek clover.

- **Biological source:** The biological source of fenugreek is the seeds of the Trigonella foenum-graecum plant. These seeds are small, yellowish-brown, and have a distinctive bitter taste and aroma. Fenugreek seeds are commonly used as a culinary spice and also have various medicinal uses in traditional medicine systems such as Ayurveda and traditional Chinese medicine.

- **Chemical constituents:** Fenugreek seeds contain several types of saponins, including diosgenin, yamogenin, and tigogenin. Also contain alkaloids such as trigonelline, gentianine, and carpaine. Trigonelline. Flavonoids such as vitexin, quercetin, and luteolin. Steroidal saponins, including gitogenin and yuccagenin. Good source of protein, making up about 20-30% of their composition vitamin C, vitamin A, calcium, iron, and magnesium, which contribute to their nutritional value.



Tigogenin **Trigonelline**

Fig. 5: Chemical constituents of fenugreek.

- **Chemical tests**

- Add a few drops of copper sulfate (CuSO4) solution followed by sodium hydroxide (NaOH) solution to the seed extract. The formation of a violet color indicates the presence of proteins.

- Mix the seed extract with vanillin reagent and concentrated sulfuric acid (H2SO4). The formation of a blue-green color indicates the presence of cellulose and hemicellulose.

➢ **Uses:** It reduces the risk of diabetes, improve milk production, promote weight loss. It increases the testosterone level and boost sperm count. As also help to reduce the inflammation and risk of heart problems.

➢ **Other species:** Trigonella caerulea, Trigonella balansae, Trigonella monspeliaca, Trigonella ornithopodioides.

➢ **Marketed products:** Fenugreek Capsules or Tablets, Fenugreek Powder and pastes for skin and hair care. Fenugreek Herbal Teas for detoxifying properties. Fenugreek Hair Oil for promoting hair growth, preventing hair loss, and improving hair texture and shine. Fenugreek Herbal Formulations like Fenugreek Skin Care Products, Fenugreek Massage Oils.

2. MATERIALS AND METHODS

2.1. Plant Materials Collection and Extraction

The material leaves Cinnamomum verum, Coriandrum sativum, Moringa oleifera, Murraya koenigi, and Trigonella foenum greacum are used in the present study were collected from the local area, dried, powdered and extracted with ethanol. The powdered plant materials are separately extracted by using Soxhlet extractor with ethanol using as a solvent, collected solvent from Soxhlet extractor dried and the extracts were stored for further use.

2.2. Excipients used to formulate tablets

In this formulation Lactose, Starch, Di calcium phosphate, Acacia, Aerosil, Magnesium stearate, Methyl paraben, and Propyl paraben used to compose tablets. Di calcium phosphate and Lactose used as Bulking agents, Acacia and Starch used as granulating agents, Aerosil and Magnesium stearate use for lubrication and Methyl paraben, Propyl paraben used as preservatives.

2.3. Formulation of poly herbal anti diabetic tablets

In the present study dried ethanolic extracts of Cinnamomum verum, Coriandrum sativum, Moringa oliefera, Murraya koenigi and Trigonella foenum greacum was formulated into tablet dosage form by wet granulation method.

- Starch was weighed and made into an emulsion along with preservatives and cooked well on a water bath until translucent semisolid mass was formed.
- The Acacia binding solution was prepared by using required quantity of water separately.
- The weighed quantities of excipients were mixed thoroughly with extract, the cooked starch and acacia solution were added slowly till the powder became a damp mass.

Table 1: Composition on formulation ingredients for poly herbal anti diabetic tablets.

S. No.	Ingredients	Composition
1	Cinnamomum verum	100 mg
2	Coriandrum sativum	100 mg
3	Moringa oleifera	100 mg
4	Murraya koenigi	100 mg
5	Trigonella foenum graecum	100 mg
6	Lactose	20 mg
7	Starch	20 mg
8	Di Calcium Phosphate	40 mg
9	Acacia	10 %
10	Aerosil	10 mg
11	Magnesium stearate	10 mg
12	Methyl paraben	0.1%
13	Propyl paraben	0.1%

- This damp mass was passed through sieve number 16 and dried in an oven at a temperature of 105°C, until granules were dried properly.
- Then the dried granules were passed through sieve number 60 and subjected to lubrication.
- Aerosil and Magnesium stearate were mixed thoroughly and sieved through Sieve number 40 and mixed with the dried granules. Finally the tablets were compressed with 18 mm punches by using single punch machine.

Evaluation

Preformulation studies

Preformulation studies were performed before formulating the tablets powders were subjected to following evaluation parameters.

- **Angle of repose:** Angle of repose was determined by using funnel method, in a funnel the accurately weighed blend was taken. The funnel height was arranged in a manner that the funnel tip just touches the “apex of the heap” or “head of blend”. Through the funnel “the drug excipient blend” was allowed to flow freely on to the surface. Table 2 shows the

relationship between Angle of Repose and Powder Flow. The diameter of the powder cone and angle of repose were calculated by using the following equation.

Tan θ = h/r

Where, **h** = height of powder cone formed,

r = radius of the powder cone formed.

Table 2: 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

Angle of Repose of prepared powder was found to be 26.15 C

- **Bulk density:** By pouring the weighed quantity of blend into graduated cylinder and measuring the volume.

$$\text{Bulk Density} = \frac{\text{Weight of powder}}{\text{Volume of packing}}$$

Bulk density of formulated tablets was found to be 0.263 mg/ml

- **Tapped bulk density:** A known mass of drug excipient blend was placed in a graduated cylinder. The cylinder was tapped on to a hard surface from the height of 10 cm at two second interval. Tapping was continued, "Until no further change in volume was noted".

$$\text{Tapped Bulk Density} = \frac{\text{Weight of the powder}}{\text{Volume of the tapped packing}}$$

Tapped density of prepared powder was found to be 0.417 gm/ml

- **Hausnars Ratio:** The hausner predict the the flow properties of powder by using interparticle friction and it is a simple index that can be determined on small quantities of powder.

Hausner ratio = Tapped density / Poured density

Haunser ratio	Type of flow
<1.25	Good Flow
>1.25	Poor Flow

- **Compressibility index:** The Compressibility index of the blends was determined by Carr's compressibility index. Table 3 shows grading of powders for their flow properties.

$$\text{Compressibility index (\%)} = \frac{\text{Tapped bulk density-Loose bulk density}}{\text{Tapped bulk density}} \times 100$$

Table 3: Grading of powders for their flow properties.

Consolidation Flow 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

Compressibility index of prepared material was found to be 22.45 %

Physical evaluation of tablets

Tablets were subjected to following evaluation parameters.

- **Colour and Appearance: -** For the colour and appearance the tablets were visually examined.

Table 4: Physical evaluation by appearance.

S. No.	Sample Material	Colour and Appearance
1	Cinnamomum verum	Brownish Red
2	Coriandrum sativum	Yellowish Green
3	Moringa oliefera	Light Green
4	Murraya koenigi	Green
5	Trigonella foenum greacum	Yellow

- **Weight variation test:** For variation 20 tablets average weight was determined. Individually each tablet weight was examined. In each case deviation from the average weight was calculated and expressed as percentage. Not more than two of the tablets from the sample size deviate from the average weight by a greater percentage and none of the tablets deviate by more than double that percentage.

- **Hardness and Friability test:** Hardness test and friability tests were performed for the tablets using calibrated Monsanto hardness tester and Roche friabilitor 4 min at 25 rpm tests respectively.

- **Thickness:** By using Vernier calipers was used to evaluate thickness of tablets. Thicknesses were evaluated.

- **Disintegration test for tablets:** Glass of plastic tube 80-100 mm long with an internal diameter 28 mm and external diameter 30-31 mm fitted at the lower end with a disc of rust proof wire gauge. Six tablets were placed in the tube; the tube was raised and lowered in such a manner that the complete up and down movement was repeated 28 to 32 per min. The tablets were disintegrated when no particle remains above the gauge, which readily pass through 60 mesh screen.

RESULTS

Formulations prepared by wet granulation method were tested for the preformulation studies for potential evaluation to tablet compression. All the evaluated Preformulation parameters are shown in table 4.

Based on the preformulation studies powder flow properties are good. Then the process is continued with compression of tablet by wet granulation method, after compression tablets were evaluated by Physical parameters observed were displayed on below table 5.

The finished tablets colour was Greenish White; Weight variation was ± 5%, Hardness, Friability are respectively 3.5 ± 0.43 kg/cm2, 0.58 ± 0.05 %. Thickness was measured as 3 ± 0.02 mm and Disintegration time 6 ± 0.32 min are good for stability to consume for human use.

Table 4: Preformulation parameters for poly herbal anti diabetic tablets.

S. No.	Parameter	Results
1	Angle of Repose	26.15 C
2	Bulk density	0.263 gm/ml
3	Tapped density	0.417 gm/ml
4	Compressibility Index	22.45 %

Table 5: Physical parameters for poly herbal anti diabetic tablets.

S. No	Parameters	Results
1	Color	Light green
2	Weight variation test	±5%
3	Hardness (kg/cm2)	4
4	Friability (%)	0.28 %
5	Thickness (mm)	3±0.02
6	Disintegration (min)	4- 4.5

CONCLUSION

Herbs plays major role in the treatment of Diabetes Mellitus than the allopathic medicines because of less side effects, low cost and easy availability. The research work done on that basis and the selected plants for the formulation was literally proved for the therapeutic use of Anti Diabetic purpose. All the five plants used in the work was Cinnamomum verum, Coriandrum sativum, Moringa oliefera, Murraya koenigi and Trigonella foenum greacum were extracted by using ethanol and the extracts were used to formulate tablets. Then the tablet was evaluated for physical parameters and standardize as per pharmacopoeia standards.

Preformulation study and Physical Parameter revealed that all the values were within acceptable limit. The polyherbal anti diabetic tablets are formulated per Pharmacopoeial standards. Based on results it is concluded that the formulation and evaluations are good. Moreover, further study is required for pharmacological evaluation for the treatment of diabetes mellitus.

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