FORMULATION AND EVALUATION OF POLY HERBAL ANTI DIABETIC TABLETS

1*Himaja N., 2Ashok Kumar Appapurapu and 3Bharat Kumar B.

1*Research Assistant, Darwin Research and Ayur Pharma, Surampalli, Gannavaram (M), Vijayawada. Andhra Pradesh, India-521212.
2,3Formulation Research Assistant, Darwin Research and Ayur Pharma, Surampalli, Gannavaram (M), Vijayawada. Andhra Pradesh, India-521212.

ABSTRACT

**Objective:** The main objective of the work is to formulate and evaluate poly herbal anti diabetic tablet for medicinal purpose.

**Materials and methods:** Azadirachta indica, Mangifera indica, Ocimum sanctum leaves were collected from the local area, dried, powdered and extracted with ethanol separately and stored for further use. Tablets were prepared after preformulation studies and tablets were evaluated by using Weight variation, Hardness, Friability, Thickness and Disintegration Time. **Results:** Prepared granules by wet granulation method were performed preformulation studies based on the preformulation studies powder flow properties are good and 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. **Discussion and Conclusion:** Now a day’s Herbal medicines plays major role in the treatment than allopathic medicines because of less toxicity. Azadirachta indica, Mangifera indica, Ocimum sanctum ethanolic extracts were used to formulate tablets. Based on the results it is clearly concluded that the prepared formulation of poly herbal antidiabetic tablets and evaluations are good.

**KEYWORDS:** poly herbal, anti diabetic tablet, Azadirachta indica, Mangifera indica, Ocimum sanctum, Disintegration time.
INTRODUCTION

The traditional knowledge on medicinal plants is by the main basis of biocultural and ecosystem conservation as well as further Pharmacological, Phytochemical, Toxicological and Ecological studies.\(^1\) Traditional medicinal plants widely used and accounts for around 40% of all health care delivered.\(^2\)

From the past few years there has been an exponential growth in the field of herbal medicine and these herbs are increasing popularity in all over world because of their natural origin and less side effects.

Herbal medicines have good values in treatment in many countries, scientific investigation of Medicinal plants have been initiated because of their potential.\(^3\) Traditional medicine and ethnobotanical information play an important role in scientific research.\(^4,5\) In India indigenous medicines have been used in the treatment of Diabetes mellitus since the time of Charaka and Sushruta (6th century BC).\(^6\)

According to WHO estimations, more than 80% of the world population depends on traditional medicinal practise for primary health care needs.\(^7\) Over 75% of the world population is depending on local health practioners and traditional medicines for their primary needs.\(^8\) Traditional ethonobotanical studies have received much attention in recent years due to their wide acceptability and clues for new or lesser – known medicinal plants.\(^9\) A number of reviews have been published in the last three decades on plants pharmacological activities. Very recently, two exhaustive reviews have been published based on the global literature survey on 150 plants and 343 plants in different part of the world.\(^10-25\)

Diabetes mellitus is the common endocrine disorder that affects more than 100 million People worldwide (6% of the population) and in the next 10 years it may affect about five times more people than it does now.\(^26,27\) In India, the prevalence rate of diabetes is estimated to be 1-15%.\(^28,30\) The disease was well known to the ancient Indian medical experts. All the renowned classic texts of Ayurveda like Charaka Samhita (1000 B.C.), Sushruta Samhita (600 B.C.) and subsequent works refer to this disease under the term Madhumeha or Ikshumeha.

The main objective of the present study was to focus on the formulation and evaluation of poly herbal anti diabetic tablet by using Azadirachta indica, Mangifera indica, Ocimum
sanctum leaves extracts based on the literatures these plants were selected for the formulation of conventional dosage of herbal tablets used for the treatment of Diabetes mellitus.\textsuperscript{31-35}

**MATERIALS AND METHODS**

**Plant Materials collection and Extraction**

The materials Azadirachta indica, Mangifera indica, Ocimum sanctum leaves 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.\textsuperscript{36-38}

**Excipients used to formulate tablets**

In this formulation Lactose, Starch, Di calcium phosphate, Acacia, Aerosil, Magnesium stearate, Methyl paraben, 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.\textsuperscript{39-41}

**FORMULATION OF POLY HERBAL ANTI DIABETIC TABLETS**

In the present study dried ethanolic extract of Azadirachta indica, Mangifera indica and Ocimum sanctum was formulated into tablet dosage form by wet granulation method.\textsuperscript{42}

Formulation has the following composition as depicted in the following Table 1.

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

<table>
<thead>
<tr>
<th>S.No</th>
<th>Ingredients</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Azadirachta indica</td>
<td>40 mg</td>
</tr>
<tr>
<td>2</td>
<td>Mangifera indica</td>
<td>30 mg</td>
</tr>
<tr>
<td>3</td>
<td>Ocimum sanctum</td>
<td>30 mg</td>
</tr>
<tr>
<td>4</td>
<td>Lactose</td>
<td>100 mg</td>
</tr>
<tr>
<td>5</td>
<td>Starch</td>
<td>100 mg</td>
</tr>
<tr>
<td>6</td>
<td>Di calcium phosphate</td>
<td>150 mg</td>
</tr>
<tr>
<td>7</td>
<td>Acacia</td>
<td>10%</td>
</tr>
<tr>
<td>8</td>
<td>Aerosil</td>
<td>5 mg</td>
</tr>
<tr>
<td>9</td>
<td>Magnesium stearate</td>
<td>5 mg</td>
</tr>
<tr>
<td>10</td>
<td>Methyl paraben</td>
<td>0.1 %</td>
</tr>
<tr>
<td>11</td>
<td>Propyl paraben</td>
<td>0.1 %</td>
</tr>
</tbody>
</table>
Preparation of granules 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.
- 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 20 and subjected to lubrication.
- Aerosil and Megnesium stearate were mixed thoroughly and sieved through Sieve number 40 and mixed with the dried granules. Finally the tablets were compressed with 17mm punches by using single punch machine. (CM D3-16, S.No- A/1882/94, Cadmac machinery co. pvt. ltd, Ahmadabad-8, India)

EVALUATION\textsuperscript{[43]}

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 -

$$\tan \theta = \frac{h}{r}$$ Where h = height of powder cone formed r = radius of the powder cone formed.

<table>
<thead>
<tr>
<th>Angle of Repose ((\theta))</th>
<th>Type of flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>25</td>
<td>Excellent</td>
</tr>
<tr>
<td>25-30</td>
<td>Good</td>
</tr>
<tr>
<td>30-40</td>
<td>Passable</td>
</tr>
<tr>
<td>&gt;40</td>
<td>Very poor</td>
</tr>
</tbody>
</table>
**Bulk density**

By pouring the weighed quantity of blend into graduated cylinder and measuring the volume.

\[
\text{Bulk Density} = \frac{\text{Weight of the powder}}{\text{Volume of the packing}}
\]

**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”.

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

**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.

\[
\text{Compressibility index (\%)} = \frac{(\text{Tapped Bulk Density} - \text{Loose Bulk Density})}{\text{Tapped Bulk Density}} \times 100
\]

**Table 3 - Grading of powders for their flow properties.**

<table>
<thead>
<tr>
<th>Consolidation Flow index (Carr’s index)</th>
<th>Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>5-15</td>
<td>Excellent</td>
</tr>
<tr>
<td>12-16</td>
<td>Good</td>
</tr>
<tr>
<td>18-21</td>
<td>Fair to Passable</td>
</tr>
<tr>
<td>23-35</td>
<td>Poor</td>
</tr>
<tr>
<td>33-38</td>
<td>Very poor</td>
</tr>
<tr>
<td>&lt;40</td>
<td>Very Very poor</td>
</tr>
</tbody>
</table>

**Physical evaluation of Tablets**

Tablets were subjected to following evaluation parameters.

**Colour and appearance**

For the colour and appearance the tablets were visually examined.
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 tablets thicknesses was 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 mesh (10 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.

<table>
<thead>
<tr>
<th>S.No</th>
<th>Parameters</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Angle of repose</td>
<td>27.15°</td>
</tr>
<tr>
<td>2</td>
<td>Bulk density</td>
<td>0.26 g/cm³</td>
</tr>
<tr>
<td>3</td>
<td>Tapped bulk density</td>
<td>0.33 g/cm³</td>
</tr>
<tr>
<td>4</td>
<td>Compressibility index</td>
<td>23.33 %</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>S.No</th>
<th>Parameters</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Colour</td>
<td>Greenish White</td>
</tr>
<tr>
<td>2</td>
<td>Weight variation Test</td>
<td>±5%</td>
</tr>
<tr>
<td>3</td>
<td>Hardness (kg/cm²)</td>
<td>3.5 ± 0.43</td>
</tr>
<tr>
<td>4</td>
<td>Friability (%)</td>
<td>0.58 ± 0.05</td>
</tr>
<tr>
<td>5</td>
<td>Thickness (mm)</td>
<td>3 ± 0.02</td>
</tr>
<tr>
<td>6</td>
<td>Disintegration time (min)</td>
<td>6 ± 0.32</td>
</tr>
</tbody>
</table>

DISCUSSION AND CONCLUSION

Herbs plays major role in the treatment 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 antidiabetic purpose.

All the three plants used in the work was Azadirachta indica, Mangifera indica, Ocimum sanctum leaves was extracted by using ethanol and the extracts were used to formulate tablets Tablet and evaluated for physical parameters and standardize as per pharmacopoeial standards. Preformulation study and Physical Parameter revealed that all the values were within acceptable limit. The polyherbal formulation showed significant antidiabetic activity and the tablet standardize as 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.

ACKNOWLEDGEMENT

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