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# FORMULATION AND EVALUATION OF POLY-HERBAL ANTI-DIABETIC FAST-DISSOLVING TABLET FROM HOME REMEDY AND COMPARISON WITH MARKETED METFORMIN TABLET

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**Keywords:**

Direct compression, Anti-diabetic, Pre-compression studies, Poly-herbal *etc*

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**ABSTRACT:** The current study's purpose was to develop and test a multi-herbal anti-diabetic quick-dissolving tablet compared to a commercially available metformin tablet. The multi-herbal anti-diabetic tablet contains natural medicines with anti-diabetic properties, such as *Curcuma longa, Cinnamomum zeylanicum, Zingiber officinale,* and *Trigonella foenumgraecum*. This mixture contains the botanical extracts *Curcuma longa, Cinnamomum zeylanicum, Zingiber officinale,* and *Trigonella foenumgraecum*. MCC is employed as a diluent and sodium saccharin as a sweetening agent in the tablet formulation to attain this purpose. In the formulation of tablets, superdisintegrants such as crospovidone, sodium starch glycolate (SSG), and a blend of crospovidone and sodium starch glycolate were used to improve dissolve rate and disintegration. Weight variation, drug content uniformity, hardness, friability, wetting time, *in-vitro* dispersion time and *in-vitro* drug release investigations were performed on the tablets. Every parameter's evaluation results for the poly-herbal anti-diabetic pill were within acceptable boundaries. The thickness, hardness, weight fluctuation, friability and *in-vitro* drug release investigations of the poly-herbal anti-diabetic tablet were all found to be within acceptable ranges.

**INTRODUCTION:** Fast-dissolving medication delivery methods are widely utilized nowadays to promote bioavailability and patient compliance. Fast-dissolving tablets (FDTs) have earned great attention as a preferable alternative to conventional tablets and capsules during the last three decades due to enhanced patient compliance, solubility, and stability characteristics [1, 2].

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FDTs are solid dosage forms that contain medical chemicals that disintegrate quickly, usually within seconds, when placed on the tongue [3, 4]. New FDT technologies address pharmaceutical and patient demands, from improved life-cycle management to simple dosing for dysphagic paediatric, geriatric, and psychiatric patients.

This has prompted academia and industry to develop novel Fast dissolving formulations and technology techniques in this area [5, 6]. Fast-dissolving tablets dissolve or disintegrate on the patient's tongue or buccal mucosa instantly. It is suitable for tablets with high first-pass metabolism and is used to improve bioavailability while

reducing dose frequency to reduce adverse effects and make it more cost-effective. This study sought to identify materials that disintegrate or dissolve quickly once introduced in the oral cavity [7]. Herbal medicine uses plant seeds, berries, heritages, leaves, bark, or flowers for therapeutic purposes. Studies demonstrate that they are effective in the treatment and prevention of disease. Because of their natural origin and fewer adverse effects, these medications are gaining appeal in both developing and developed countries [8]. Diabetes mellitus is a metabolic condition that causes a rise in blood glucose levels due to increased hepatic glucose synthesis, decreased insulin secretion and impaired insulin action [9]. Rasayana refers to a group of medicinal herbs that have been utilized for over 1000 years and are present in herbal formulations used in Indian traditional healthcare systems [10, 11]. The current study focuses on the development and evaluation of polyherbal anti-diabetic rapid dissolving tablets and their evaluation for various criteria and comparison with commercially available preparations.

## EXPERIMENTAL DESIGN:

**MATERIALS:** The plants of *Curcuma longa*, *Cinnamomum zeylanicum*, *Zingiber officinale*, and *Trigonella foenumgraecum* was collected from a local nursery and authenticated by a taxonomist. The plant parts were extracted. Crospovidone, Sodium starch glycolate, and microcrystalline cellulose were obtained as gift samples from Loba Chemie Pvt Ltd Mumbai. All other chemicals and reagents were of analytical grade.

**Preparation of Fast Dissolving Tablet:** Herbal Fast dissolving tablets were made using a direct compression method and different amounts of formulation components. All of the materials were ground individually in a clean, dry porcelain mortar before being sieved through a # 60 mesh sieve. After complexing the extract and -cyclodextrin (kneading process), all of the additives were thoroughly mixed in an inflated polyethylene pouch in a geometric ratio of their weight. The powder mixture was then compressed into 400 mg tablets, the composition of which is shown in **Table 1** [12].

**TABLE 1: COMPOSITION OF HERBAL FAST DISSOLVING TABLETS**

| Ingredients (mg/ tab) | F1 | F2 | F3 | F4 | F5 | F6 | F7 | F8 | F9 |
|---|---|---|---|---|---|---|---|---|---|
| Extract | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 |
| β-cyclo dextrin | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 | 150 |
| Crospovidone | 20 | - | - | 20 | - | - | 20 | - | - |
| SSG | - | 25 | - | - | 25 | - | - | 25 | - |
| Mixture of Crospovidone+ Sodium starch glycolate | - | - | 30 | - | - | 30 | - | - | 30 |
| MCC | 60 | 55 | 50 | 60 | 55 | 50 | 60 | 55 | 50 |
| Sodium saccharin | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Mg.sterate | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Talc | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| TOTAL | 400 | 400 | 400 | 400 | 400 | 400 | 400 | 400 | 400 |

## Evaluation of Tablets:

**Post-compressional Studies of Prepared Tablets:** To overcome faults during formulation preparation, the poly-herbal quick-dissolving anti-diabetic tablets were examined for several parameters. These include characteristics such as appearance, thickness, weight variation, hardness, friability, Disintegration Time, Drug Content and Wetting Time. All of the formulation evaluation parameters are given in **Table 2** [12].

**Physical Appearance:** The overall look of the tablet was visually examined in terms of shape, colour, texture and odour. Vernier callipers were used to determine the thickness of the tablet. The tablet was placed vertically between two jaws, and the thickness was measured in millimetres. Six tablets were utilised for this test [12].

**Weight Variation:** The weight variation test is run by weighing 20 tablets individually, calculating the average weight and comparing individual tablet weight to the average. The weight variation test would be a satisfactory method of determining the drug content uniformity of tablets. Hardness is also termed tablet-crushing strength.

The tablet hardness was determined by Monsanto hardness tester. The tablet was placed lengthwise between upper and lower plunger and force was

applied by turning a threaded bolt until the tablet fractures and; measured the hardness of the tablet in Kg/cm [13].

**Friability:** It is decided by the Roche friabilator, which treats a number of tablets to the combined effects of abrasion and shock by utilising a plastic chamber that revolves at 25 rpm, dropping tablet from inches distance for 100 revolutions. Pre-weighed tablets were dusted and reweighed, and friability should be less than 1% according to established limits [14].

It is calculated using a formula-

% friability = Initial weight – Final weight / Initial weight

**Dispersion Time:** Two tablets were carefully mixed in 100 cc of water until completely distributed. The result is a smooth dispersion that passes through a sieve screen with a nominal mesh aperture of 710 m [15].

**Wetting Time:** A folded sheet of tissue paper (12cmx10.75cm) was placed in a Petri dish with 10 ml of water. A Petri plate containing Eosin, a water-soluble dye, was introduced. A tablet was placed carefully on the surface of the tissue paper and allowed to completely soak. The time it took for water to reach the tablet's upper surface was recorded as a wetting time [16].

**Drug Content:** The drug content of each batch was determined. In a tiny glass mortar, six tablets were weighed and crushed with a pestle. The fine powder was weighed to obtain 500 mg and transferred to a 250 ml conical flask containing 100 ml of distilled water, which was agitated in an ultrasonicator for 45 minutes. The solution was filtered and the filtrates were UV spectrophotometrically examined to determine the drug content [17].

**Disintegration Time:** The tablet disintegration time was determined in water (37°C) using the USP Disintegration test device [18].

***In-vitro* Dissolution:** The *in-vitro* dissolution investigation was carried out in the USP apparatus type II. An aliquot of 5 ml of dissolving media was taken at regular intervals and replenished with fresh medium to maintain the sink condition. UV spectroscopy was used to determine the absorbance of filtered liquids. All formulations' dissolution rates were investigated [19].

**Stability Studies:** The ability of a certain medicine or dosage form in a specific container to maintain its physical, chemical, therapeutic, and toxicological requirements is referred to as stability. The stability of the active component must be a major criterion in determining their approval or rejection in any reasonable design and evaluation of medication dosage forms. The product is exposed to regular temperature and humidity during the stability tests.

However, the studies will take longer; thus, it would be more convenient to conduct expedited stability experiments where the product is stored in harsh temperature and humidity conditions. In the current investigation, stability studies on optimized formulations were conducted for one month under the following conditions, as stipulated by ICH guidelines for accelerated studies: 40°C±2°C and RH 75%± 5%. After 30 days, the tablets were extracted and analyzed for physical characterization, dissolution, and drug content [20].

**TABLE 2: POST-COMPRESSION STUDIES OF TABLET**

| Formulations | Thickness (mm) | Hardness ($kg/cm^2$) | % Weight Variation | % Friability | Disintegration time | Wetting Time | Drug Content |
|---|---|---|---|---|---|---|---|
| F1 | 1.2±0.16 | 5.5±0.2 | 0.399±0.021 | 0.23±0.023 | 19 sec | 48 sec | 103.25 |
| F2 | 1.2±0.24 | 4.8±0.11 | 0.399±0.034 | 0.31±0.0.12 | 52 sec | 1min 10 sec | 100.75 |
| F3 | 1.2±0.24 | 4.31±0.21 | 0.397±0.012 | 0.14±0.045 | 1 min 8 sec | 1 min 4 sec | 99.27 |
| F4 | 1.2±0.24 | 5.21±0.033 | 0.398±0.019 | 0.22±0.011 | 1 min 28 sec | 2 min 9 sec | 98.54 |
| F5 | 1.2±0.17 | 4.8±0.11 | 0.397±0.012 | 0.22±0.011 | 1 min 57 sec | 2 min 9 sec | 98.91 |
| F6 | 1.3±0.16 | 4.8±0.11 | 0.399±0.034 | 0.31±0.0.12 | 2 min 10 sec | 3 min 6 sec | 100.30 |
| F7 | 1.2±0.41 | 4.31±0.21 | 0.397±0.012 | 0.14±0.045 | 1 min 22 sec | 1 min 5 sec | 100.96 |
| F8 | 1.2±0.31 | 5.21±0.033 | 0.398±0.019 | 0.22±0.011 | 1 min 33 sec | 3 min | 101.51 |
| F9 | 1.2±0.13 | 4.8±0.11 | 0.397±0.012 | 0.22±0.011 | 1 min 6 sec | 2 min 50sec | 99.71 |
| Marketed | 1.3±0.11 | 4.8±0.11 | 0.399±0.034 | 0.31±0.0.12 | 58 sec | 1 min 40 sec | 100.10 |

**TABLE 3: *IN-VITRO* DRUG RELEASE STUDIES OF TABLET**

| Time in min | F1 %CDR | F2 %CDR | F3 %CDR | F4 %CDR | F5 %CDR | F6 %CDR | F7 %CDR | F8 %CDR | F9 %CDR | MARKETED %CDR |
|---|---|---|---|---|---|---|---|---|---|---|
| 2 | 3.85 | 1.85 | 3.71 | 0.92 | 0.94 | 2.78 | 4.64 | 0.92 | 1.85 | 2.10 |
| 4 | 22.86 | 22.97 | 12.07 | 10.90 | 21.35 | 10.00 | 17.64 | 11.04 | 22.97 | 23.06 |
| 6 | 30.33 | 30.33 | 32.98 | 29.90 | 33.33 | 30.21 | 28.00 | 32.88 | 27.99 | 31.22 |
| 8 | 39.06 | 38.33 | 39.63 | 43.37 | 44.62 | 38.26 | 39.26 | 38.26 | 38.35 | 41.33 |
| 10 | 47.98 | 56.32 | 56.37 | 53.37 | 51.21 | 50.26 | 53.25 | 53.26 | 54.77 | 55.89 |
| 15 | 67.47 | 71.41 | 67.37 | 65.17 | 66.16 | 64.62 | 65.62 | 64.36 | 67.84 | 69.67 |
| 20 | 75.98 | 77.14 | 73.15 | 72.15 | 78.15 | 81.15 | 78.52 | 77.73 | 73.26 | 80.36 |
| 25 | 83.87 | 82.15 | 78.17 | 77.15 | 81.16 | 83.15 | 83.15 | 81.36 | 86.78 | 87.16 |
| 30 | 88.20 | 86.34 | 84.49 | 82.63 | 83.57 | 83.76 | 88.16 | 91.00 | 92.78 | 89.12 |
| 45 | 91.00 | 88.26 | 87.26 | 87.36 | 88.61 | 89.15 | 89.25 | 89.26 | 91.37 | 91.37 |
| 60 | 97.48 | 91.90 | 91.10 | 94.71 | 94.79 | 91.98 | 93.78 | 94.70 | 94.75 | 96.98 |

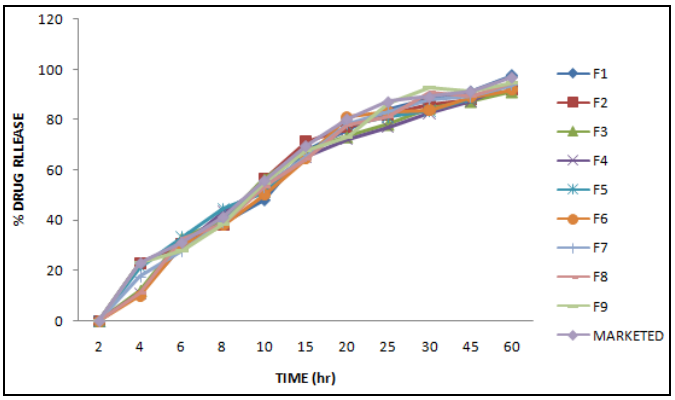


**FIG. 1: *IN-VITRO* RELEASE**

**RESULTS AND DISCUSSION:** The tablet was discovered to be spherical in shape, brown in colour, smooth in texture, and odourless. The thicknesses of poly-herbal fast dissolving anti-diabetic tablet F1-F9 and marketed metformin tablet were discovered to be 1.2±0.16, 1.2±0.24, 1.2±0.24, 1.2±0.24, 1.2±0.17, 1.3±0.16, 1.2±0.41, 1.2±0.31, 1.2±0.13, 1.3±0.11mm respectively. The hardness of conventional poly-herbal anti-diabetic tablets was determined to be 5.5±0.2, 4.8±0.11, 4.31±0.21, 5.21±0.033, 4.8±0.11, 4.8±0.11, 4.31±0.21, 5.21±0.033, 4.8±0.11, 4.8±0.11kg/cm$^2$ for F1-F9 and commercialized formulations, respectively.

Tablets demonstrated sufficient hardness to withstand breakage during packaging, shipment, and regular handling. The weight of 20 tablets was determined to be 0.399±0.021, 0.399±0.034, 0.397±0.012, 0.398±0.019, 0.397±0.012, 0.399±0.034, 0.397±0.012, 0.398±0.019, 0.397±0.012, 0.399±0.034 for all formulations individually. The the poly-herbal quick dissolving anti-diabetic tablet passed the weight variation test since the average percentage weight variation was less than 5%, which was within the USP limitations. The friability of all formulations was discovered to equal 0.14±0.045 to 0.31±0.0.12%. The friability of the tablet was found to be in the acceptable limit *i.e.*, less than 1%. No capping problem occurs in the tablets, so it could be considered for commercial use. It produced no loss during the shipping process. The drug content was found to be 98.18-102.50%, within acceptable limits. The disintegration time is shorter with quick wetting properties at the core of the tablets. The wetting time/dispersion time decreases with an increase in the concentration of superdisintegrants. *In-vitro* release study for Formulations No. F1, F4 and F7 contain 5% superdisintegrants which has better drug release.

Rapid drug dissolving could be attributed to particle disintegration and drug absorption into the dissolution medium. For a month, selected tablets were subjected to stability tests at 40°C ±2°C / 75% RH ±5%. The drug content, wetting time, water absorption ratio, dispersion time, disintegration time, and *in-vitro* drug release of the polyherbal quick-dissolving tablet were studied. According to the studies, there were no substantial changes in the tablet's qualities.

**CONCLUSION:** The developed poly-herbal rapid dissolving tablets exhibit excellent disintegration and dissolve rates. Comparative research of numerous superdisintegrants revealed that Crospovidone at 3% concentration is appropriate for the creation of Herbal fast dissolving tablets that meet all standards and official restrictions. Based on the findings of this investigation, we can infer that the poly-herbal fast-dissolving anti-diabetic tablet was made using the direct compression method and produced satisfactory and

acceptable results. Because of the presence of *Curcuma longa*, *Cinnamomum zeylanicum*, *Zingiber officinale*, and *Trigonella foenumgraecum* in the formulation, it may be more useful as an anti-diabetic. According to the above research findings, a poly-herbal rapid dissolving anti-diabetic tablet formulated in the form of a cost-efficient tablet to reduce patient's compliance in suppressing adverse effects and promoting good effects on the body.

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**CONFLICTS OF INTEREST:** The authors declare no conflict of interest exists.

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