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# HERBAL TABLETS CONTAINING *MOMORDICA CHARANTIA* EXTRACT FOR ANTI DIABETIC TREATMENT

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## ABSTRACT

Diabetes mellitus (DM) is a group of disorders due to rise of glucose levels in blood as consequence of impairment of lipids, carbohydrates, proteins metabolism. Plant *Momordica charantia* Linn (family Cucurbitaceae) commonly known as bitter gourd is used as an antipyretic in stomachic ailments, as a carminative tonic; and antidiabetic agent; fruit contains momordium charantin, steroidal saponin, ascorbic acid, carbohydrates, mineral matters, alkaloids, glucosides, etc. The objective of study was to formulate and assess phytochemical potential using hydroalcoholic extract and evaluate its antidiabetic potential. Herbal tablets were prepared by direct compression methods and blend was evaluated for the pre-compression parameters such as bulk density, compressibility, angle of repose etc. Formulations were evaluated for hardness, friability, weight variation, content uniformity, wetting time, water absorption ratio, disintegration time and *invitro* drug release. α- Amylase inhibition activity of herbal tablet formulation was studied. The results of the work indicate that the herbal tablet possessed considerable invitro anti diabetic activity and further these effects need to be confirmed using in vivo models for its effective utilization as therapeutic agents.

**Keywords:** Diabetes mellitus, *Momordica charantia*, α- Amylase inhibition, Herbal tablet.

## INTRODUCTION

Plants are very useful to mankind due to its medicinal properties and potential. As per World Health Organization (WHO), a medicinal plant having potential and can be used for therapeutic purposes due to the presence of phytochemicals, which are precursors for chemo-pharmaceutical semi-synthesis. Such plants are in great demand by pharmaceutical companies for their active ingredients [1,2]. Diabetes mellitus is one of the most common disorders and is one of the six major causes of death and also causing various systemic complications. Diabetes mellitus is treated by hormone therapy (insulin) or by administering glucose-lowering agents such as alpha-glucosidase inhibitors, sulfonylureas, biguanides, and thiazolidinediones [3,4]. Development of an adverse event is one of the complications in the treatment of

any systemic disorder; hence, many of the research institutes and pharmaceutical companies are involved in drug development to find the molecules with good therapeutic potential and less adverse events [5]. In the USA, 10-25% of patients experience an adverse drug reaction and these adverse drug reactions are responsible for 3.4-7.0% of hospital admissions [6]. The traditional systems of medicine, documented many plants utilized for the treatment of various systemic disorders. Many of the traditional/indigenous systems of medicine are effective than the modern system of medicine, due to lack of knowledge and resources, standardization which is one of the important challenge. *Momordica charantia* belongs to family Cucurbitaceae is cultivated throughout India, Malaya, China, Tropical Africa, and America. Earlier claims showed that its bitter fruits have carminative, aphrodisiac, and anthelmintic properties, and are used in syphilis, rheumatism, troubles of spleen, and ophthalmia. It is also useful in piles, leprosy, jaundice, and also used as a vermifuge [7]. Literature review, evident that it contains moisture (83.2%), proteins (2.9%), fat (1.0%), carbon (9.8%), fibers (1.7%), mineral matters (1.4%), calcium, phosphorus, iron, carotene, thiamine, nicotinic acid, riboflavin, ascorbic acid (88 mg/100 g), copper, and potassium[8]. Charantin, β-sitosterolglucoside, stigmast-5, 25-dien-3 β-O-glucoside, stigmast7,25-dien-3 β-ol, and stigmast-7, 22,25-trien-3 β-ol are isolated from the fruit [9]. Many pharmacological properties have been reported including antioxidant, adipogenesisreducing, antilipolytic, hypoglycemic, antidiabetic, anticancer, antifertility, antigenotoxic, anthelmintic, antimicrobial, antiviral, and hepatoprotective activity [10]. Hence, the present study was planned to formulate and evaluated a herbal tablet formulation using a plant having known antidiabetic activity and evaluate its therapeutic effects in invitro model.

## MATERIALS AND METHODS

### Plant material

Fruits of *Momordica charantia* were collected from local area of Bhopal.

### Chemical reagents

The chemicals used in this study were obtained from Sigma Aldrich Chemical Co. (Milwaukee, WI, USA), and SD Fine-Chem. Ltd. (Mumbai, India) were of analytical grade.

### Defatting of plant material

Fruits of *Momordica charantia* were shade dried at room temperature. 80.46 gram of dried fruits was coarsely powdered and subjected to extraction with petroleum ether by maceration for 24 hrs.

### Extraction by maceration process

Defatted fruits of *Momordica charantia* were extracted with hydroalcoholic solvent (ethanol: water: 70:30) using maceration process (24hrs). Then extract was dried above its boiling points. Finally, the percentage yields were calculated of the dried extracts [11].

**Preliminary Phytochemical Screening of Extract**

The aqueous extract obtained after extraction studied for phytochemical screening in order to determine the presence of various phytochemical components present in the extracts. The standard procedure was adopted to perform the study [12, 13].

**Preparation of herbal tablets**

Herbal tablet of hydroalcoholic extract of *Momordica charantia* were prepared by direct compression [14] according to the formulae given in Table 1. All the ingredients were passed through # 60 meshes separately. Then the ingredients were weighed and mixed in geometrical order and compressed into tablets of 300 mg using 8 mm round flat punches on 10-station rotary tablet machine.

**Table 1: Composition of herbal tablets**

| Ingredient (mg) (For single tablet) | F1 | F2 | F3 | F4 | F5 | F6 |
|---|---|---|---|---|---|---|
| **Fruits extract** | 200 | 200 | 200 | 200 | 200 | 200 |
| **Starch** | 30 | 25 | 20 | 30 | 25 | 20 |
| **Sodium benzoate** | 5 | 5 | 5 | 5 | 5 | 5 |
| **Gelatin** | 5 | 10 | 15 | 5 | 10 | 5 |
| ***Microcrystalline cellulose*** | 20 | 20 | 20 | 20 | 20 | 20 |
| **Talc** | 15 | 15 | 15 | 15 | 15 | 15 |
| **Magnesium stearate** | 5 | 5 | 5 | 5 | 5 | 5 |
| **DCP** | 20 | 20 | 20 | 20 | 20 | 20 |
| **Total weight (mg)** | 300 | 300 | 300 | 300 | 300 | 300 |

**Preformulation studies**

Preformulation parameters such as bulk density, tap density, Carr's index, Hausner's ratio, and angle of repose were determined for the laboratory granules [15, 16].

**Bulk density**

Bulk densities were determined by pouring gently 25 gm of sample through a glass funnel into a 100 ml graduated cylinder. The volumes occupied by the sample were recorded. Bulk density was calculated by the using following formula:

**Bulk density (g/ml) = weight of sample in gms/ volume occupied by the sample**

**Tapped density**

Tapped densities were determined by pouring gently 25 gm of sample through a glass funnel into a 100 ml graduated cylinder. The cylinder was tapped from height of 2 inches till constant weight. Volume occupied by the sample after tapping were recorded and tapped density was calculated.

**Tapped density (g/ml) = weight of sample in gms/ volume occupied by the sample**

**Compressibility index**

A useful empirical guide is given by the Carr's compressibility to check the compressibility in powder .

**Carr's index= TD-BD/TDX100**

**Hausner ratio**

It provides an indication of the degree of densification which could result from vibration of the feed hopper.

**Hausner ratio = Tapped density/ Bulk density**

Lower Hausner ratio = Better flow ability, Higher Hausner ratio = Poor flow ability

**Angle of repose**

Flow properties of the physical mixtures of all the formulations were determined by calculating angle of repose by fixed height method. A glass funnel was fixed at a height of 2 cm over the platform. To this about 10 gm of sample was slowly passed along the wall of the funnel till the tip of the pile formed and touches the steam of the funnel. Marked around the pile base and the radius of the powder cone was measured. Angle of repose was calculated from the average radius using the following formula.

$$\tan \theta = h/r$$

Where, θ = Angle of repose, h = Height of the pile, r = Average radius of the powder cone

**Evaluation of herbal tablets**

**Shape and colour of tablets**

Uncoated tablets were examined under a lens for the shape of the tablet and colour

**Thickness test**

Three tablets were randomly taken from each formulation batch and thickness was measured individually.

**Weight variation test**

Twenty tablets were selected randomly from each formulation and average weight was determined, individually weighed and average find out.

**Hardness test**

The hardness of tablet was measured by Pfizer hardness tester and results were expressed in $Kg/cm^2$

**Friability test**

20 tablets were taken from each formulation batch and the friability was determined using Roche friabilator. The equipment was run for 4min at 25 revolutions per minute, then removed dedusted and reweighted and % friability was calculated. The friability was determined as the mass loss in percent according to Equation:-

$$\%\text{Friability} = (\text{Loss in weight}/\text{Initial weight}) \times 100$$

The test complies if tablets not loose more than 1% of their weight

**Uniformity of drug content**

The test is mandatory for tablets with 10mg or less weight of active ingredient. Ten randomly selected tablets from each formulation (F1 to F6) were finely powdered and 10 mg of drug dissolved in 10 ml 0.1 N HCl (Simulated gastric fluid of pH 1.2 without enzymes) sonicate it for 20 minutes, till the entire drug leached out from complex, then the solution was filtered through whatman filter paper No. 41. From this Solution take 1 ml and Diluted up to 100 ml with 0.1 N HCl and the drug content was determined spectrophotometrically at 318 nm for *Momordica charantia* extract.

***In-vitro* Anti-diabetic activity**

**α- Amylase Inhibition Activity**

A total of 500 µl of test samples and standard drug (100-500µg/ml) were added to 500 µl of 0.20 mM phosphate buffer (pH 6.9) containing α-amylase (0.5mg/ml) solution and were incubated at 25°C for 10 min. After these, 500 µl of a 1% starch solution in 0.02 M sodium phosphate buffer (pH 6.9) was added to each tube. The reaction mixtures were then incubated at 25°C for 10 min. The reaction was stopped with 1.0 ml of 3, 5 dinitrosalicylic acid colour reagent. The test tubes were then incubated in a boiling water bath for 5 min, cooled to room temperature. The reaction mixture was then diluted after adding 10 ml distilled water and absorbance was measured at 540 nm. Control represent 100% enzyme activity and were conducted in similar way by replacing extract with vehicle [17].

**Results and Discussions**

The crude extracts so obtained after each of the maceration extraction process were concentrated on water bath by evaporation the solvents completely to obtain the actual yield of extraction. The yield of extracts obtained from the fruits of the plants was founds to be 4.85% w/w. The results of qualitative phytochemical analysis of the crude powder fruits of *Momordica charantia* were shown in Table 2. Hydroalcoholic extracts of fruits sample of *Momordica charantia* showed the presence of alkaloids, phenol, proteins and tannins. The $\lambda_{max}$ of *Momordica charantia* was found to be 318 nm by using U.V. spectrophotometer (Systronics 1700 UV-Vis) in linearity range 5-25µg/ml Figure 1. Tablet powder blend was subjected to various pre-compression parameters Table 3. The angle of repose values indicates that the powder blend has good flow properties. The bulk density, tapped density, compressibility index and hauser's ratio of all the formulations was found to be within the range and showing that the powder has well flow properties. The results of post-compression parameters such as the uniformity of weight, hardness, thickness, friability and drug content of the tablets are given in Table 4. All the tablets of

different batches complied with the official requirements of uniformity of weight. The hardness of the tablets ranged from 3.1±0.1 to 3.5±0.2 kg/cm$^2$ and the friability values were less than 0.742±0.036 % indicating that the tablets were compact and hard. All the formulations satisfied the content of the drug as they contained 98.12±0.47 to 99.45±0.14 % of herbal tablet and good uniformity in drug content was observed. Thus all the physical attributes of the prepared tablets were found be practically within control. The result in vitro disintegration were within the prescribe limit and comply with the criteria for orally disintegrating tablets Table 5. Under α- amylase inhibition activity the inhibitory concentration 50% ($IC_{50}$) value of herbal tablet was found to be 265.82µg/ml as compared to that of acarbose (73.05µg/ml). A dose dependent activity with respect to concentration was observed Table 6.

**Table 2 Phytochemical screening of extract *of Momordica charantia***

| S. No. | Constituents | Hydroalcoholic extract | Observation |
|---|---|---|---|
| 1. | **Alkaloids** | | |
| | Wagner's test | +ve | Reddish precipitated |
| | Hager's test | +ve | Yellow precipitated |
| 2. | **Glycosides** | | |
| | Legal's test | -ve | Green coloured |
| 3. | **Flavonoids** | | |
| | Lead acetate | -ve | White coloured |
| | Alkaline test | -ve | Green colour |
| 4. | **Phenol** | | |
| | Ferric chloride test | +ve | Blue coloured |
| 5. | **Proteins** | | |
| | Xanthoproteic test | +ve | Yellow coloured |
| 6. | **Carbohydrates** | | |
| | Fehling's test | -ve | Green coloured |
| 7. | **Saponins** | | |
| | Foam test | -ve | No foam |
| 8. | **Diterpenes** | | |
| | Copper acetate test | -ve | Green coloured |
| 9. | **Tannins** | | |
| | Gelatin Test | +ve | White colour precipitate |

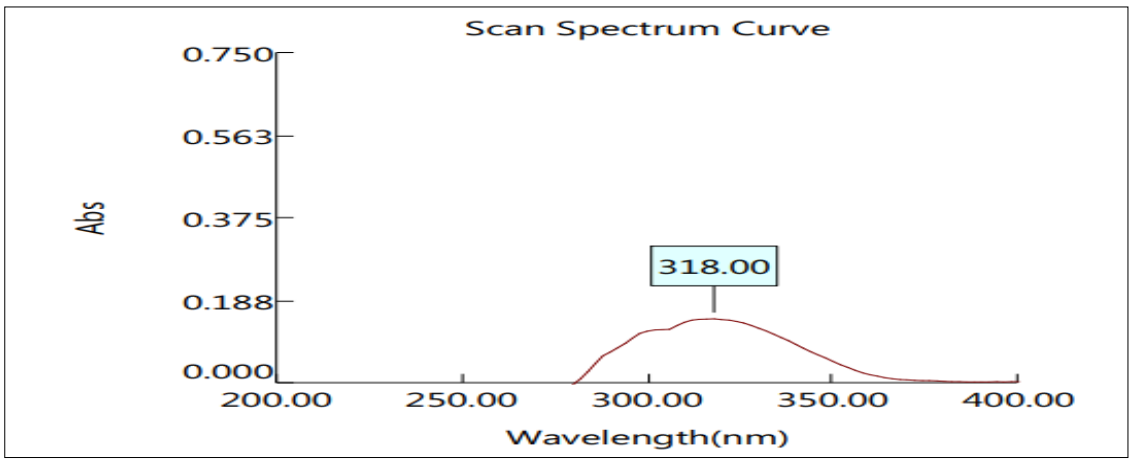


**Figure 1 Graph of determination of wavelength of *Momordica charantia* extract in 0.1 N HCl**

**Table 3 Results of pre-compressional parameters of herbal tablets**

| Formulation code | Parameters | | | |
|---|---|---|---|---|
| | Loose Bulk density(gm/ml) | Tapped bulk density(gm/ml) | Carr's Index (%) | Hausner's Ratio |
| F1 | 0.315 | 0.425 | 25.882 | 1.349 |
| F2 | 0.325 | 0.432 | 24.769 | 1.329 |
| F3 | 0.332 | 0.441 | 24.717 | 1.328 |
| F4 | 0.326 | 0.436 | 25.229 | 1.337 |
| F5 | 0.334 | 0.452 | 26.106 | 1.353 |
| F6 | 0.337 | 0.442 | 23.756 | 1.312 |

**Table 4 Results of post-compression parameters of all formulations**

| F. Code | Hardness test ($kg/cm^2$) | Friability (%) | Weight variation (%) | Thickness (mm) | Drug content (%) |
|---|---|---|---|---|---|
| F1 | 3.3±0.2 | 0.568±0.045 | 298±5 | 2.2±0.2 | 98.85±0.45 |
| F2 | 3.4±0.3 | 0.652±0.023 | 302±4 | 2.3±0.3 | 98.87±0.23 |
| F3 | 3.5±0.2 | 0.478±0.032 | 300±3 | 2.2±0.2 | 98.85±0.25 |
| F4 | 3.2±0.2 | 0.621±0.041 | 308±5 | 2.2±0.1 | 99.45±0.14 |
| F5 | 3.1±0.1 | 0.742±0.036 | 303±4 | 2.4±0.2 | 99.12±0.36 |
| F6 | 3.3±0.2 | 0.558±0.032 | 296±2 | 2.3±0.2 | 98.12±0.47 |

**Table 5 Results of Disintegration time of prepared herbal tablets**

| Formulation code | Disintegration time (Min.) |
|---|---|
| F1 | 22±3 |
| F2 | 25±2 |
| F3 | 33±5 |
| F4 | 19±2 |
| F5 | 25±1 |
| F6 | 29±4 |

**Average of three determinations (n=3)**

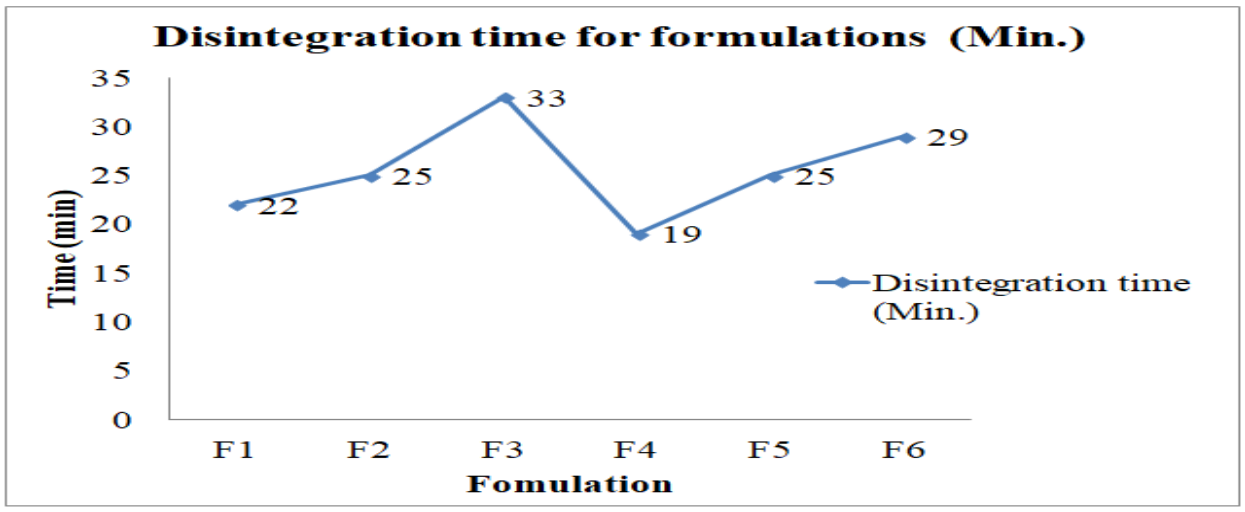


**Figure. 2. Disintegration time for formulated tablets**

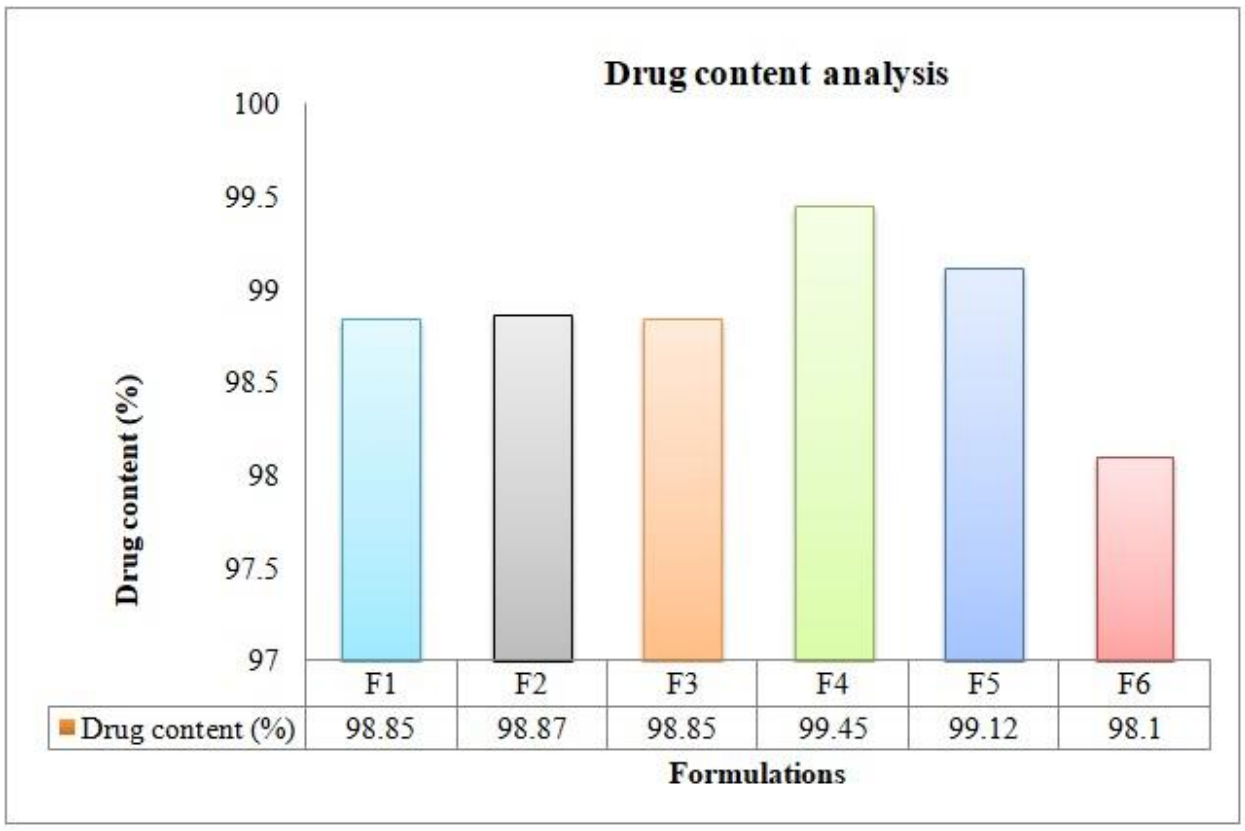


**Figure 3: Drug content analysis**

**Table 6 % Inhibition of acarbose and herbal tablet**

| S. No. | Concentration (µg/ml) | % Inhibition | |
|---|---|---|---|
| | | Acarbose | Herbal tablet |
| 1 | 100 | 50.53 | 26.85 |
| 2 | 200 | 67.82 | 39.75 |
| 3 | 300 | 72.42 | 50.63 |
| 4 | 400 | 86.74 | 76.25 |
| 5 | 500 | 95.08 | 81.65 |
| **$IC_{50}$ (µg/ml)** | | **73.05** | **265.82** |

## Conclusion

From the results of preliminary phytochemical screening it was concluded that the hydroalcoholic extracts of *Momordica charantia* contained various phytochemicals such as alkaloids, phenol, proteins and tannins. Preformulation parameters such as bulk density, tap density, carr's index, hausner's ratio and angle of repose were studied and was found within the limit. The herbal tablets were formulated and evaluated for their description, uniformity of dosage units, weight variation, disintegration time and moisture content. The results for various formulation i.e., F1 to F6 were presented. From the detailed result it was found that the formulation code, F4 is showing better results as compared to other formulation codes. Hence, formulation F4 was chosen for *In-vitro* antidiabetic activity. From the result obtained it was found that the F4 containing herbal tablet having the α-amylase inhibition activity when compared to standard drug. Further in vivo investigations should be done for confirming the anti-diabetic activity of these plants. The plant extracts understudy can serve as therapeutic agents and can be used as potential sources of novel bioactive compounds for treating Diabetes mellitus type 2.

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