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*Original Article*

# Formulation And Evaluation Of Polyherbal Orodispersible Tablets Containing Ginger (Zingiber Officinale) And Cinnamon (Cinnamomum Verum) Extracts For Primary Dysmenorrhea Management.

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## ABSTRACT

The present research work aimed to formulate herbal orodispersible tablets of ginger, cinnamon and cumin for primary dysmennorhea using various concentrations of natural superdisintegrant agents like banana powder and psyllium husk powder by wet granulation method. Three formulations were prepared with superdisintegrants at different concentration levels. The tablets were characterized for drug release, weight variation, hardness, wetting time and in-vitro disintegration time. Among the formulations, tablets of batch F3 with higher psyllium husk content exhibited better organoleptic properties, excellent in-vitro disintegration time and drug release than the other formulation batches. It was concluded that addition of natural superdisintegrants is useful in preparing herbal orodispersible tablets by reducing the side effects and for effective management of primary dysmennorhea.

**Keywords**: Orodispersible tablets(ODTs), ginger, cinnamon, primary dysmennorhea, natural superdisintegrants, banana powder, psyllium husk powder.

## INTRODUCTION

Primary dysmenorrhea is a common gynecologic problem encountered in adolescent girls and young women. It is characterized by painful menstrual cramps in the lower abdomen in the absence of any pelvic pathology; Primary dysmenorrhea adversely affects the quality of life, daily activities, academic performance and psychological well-being of the women around the globe. The conventional treatment includes mainly non-steroidal anti-inflammatory drugs (NSAIDs) and hormonal therapy. However, prolonged use of these medications may produce adverse effects such as gastric irritation, nausea, renal complications and hormonal imbalance.

In recent years, herbal medicines have attracted considerable attention due to their safety, efficacy and cost effectiveness with fewer side effects than synthetic drugs. Ginger (Zingiber officinale) has active constituents, including gingerols and shogaols, that are anti-inflammatory, analgesic, antioxidant and antispasmodic. Cinnamon (Cinnamomum verum or Cinnamomum zeylanicum) has analgesic, anti-inflammatory, antimicrobial and antispasmodic actions as well. Cinnamon contains cinnamaldehyde and eugenol, which are bioactive compounds that help in reducing menstrual pain and improve blood circulation.

Orodispersible tablets (ODTs) are solid dosage forms that disintegrate or dissolve rapidly in the mouth with little or no water and thus improve patient convenience and compliance. Rapid onset of action, ease of administration, accurate dosing, improved bioavailability and better patient acceptability particularly in pediatric, geriatric and dysphagic patients are the advantages of ODTs. Herbal ODTs have emerged as a promising approach for effective delivery of phytoconstituents with faster therapeutic response. Banana powder and psyllium husk powder are natural materials with good swelling and water absorption properties which favours fast tablet disintegration and drug release. Herbal excipients can be used in herbal formulations to improve the

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performance of the tablet with minimum use of synthetic excipients.

The present study was planned to formulate and evaluate herbal orodispersible tablets of ginger and cinnamon for management of primary dysmenorrhea using natural superdisintegrants like banana powder and psyllium husk powder. The prepared formulations were evaluated for different pre-compression and post-compression parameters such as weight variation, hardness, wetting time, in-vitro disintegration time and drug release to find an optimized formulation for better therapeutic efficacy and patient compliance.

## MATERIALS AND METHODS:

All the ingredients like ginger, cinnamon, cumin, psyllium husk, corn starch, stevia were purchased from the local market of Nashik. Banana powder used as natural superdisintegrant was prepared in-house by drying raw bananas followed by pulverization and sieving to obtain a fine powder. All the materials used in the study were of food or pharmaceutical grade.

### Preparation method:

Orodispersible tablets of ginger and cinnamon were prepared by wet granulation method according to the formula given in Table 1. Three formulations were prepared in total. Each ingredient was separately sieved through a 60-mesh sieve and collected. Small quantities of ginger powder, cinnamon powder and banana powder and psyllium husk were mixed at a time and mixed well to get uniform mixture. The other ingredients were accurately weighed and mixed in geometrical sequence. Preparation of granules, sufficient amount of granulating agent (gum acacia) was added to prepare a damp mass which was passed through the sieve to form granules. The prepared granules were dried, lubricated and compressed to get tablets of 500 mg weight using single punch tablet compression machine with the help of flat faced punches(Hardik tablet mini press). Before preparing the tablets, the powder blends of all the formulations were subjected to compatibility studies and pre-compression parameters such as bulk density, tapped density, angle of repose, percentage compressibility and Hausner's ratio.

## EVALUATION:

The prepared tablets were evaluated for various official and non-official specifications.

### Pre-compression evaluation parameters:

### 1. Bulk Density:

Bulk density is the ratio of the mass of powder to its bulk volume before tapping. It indicates the packing ability and flow characteristics of the powder blend.

Bulk density = Mass of powder / Bulk volume

### 2. Tapped Density:

Tapped density is the ratio of the mass of powder to the volume occupied after mechanical tapping. It helps in assessing powder consolidation behavior.

Tapped density = Mass of powder / Tapped volume

### 3. Compressibility Index (Carr's Index):

Compressibility index is calculated from bulk and tapped density values and is used to evaluate flowability of powder blends. Lower values indicate better flow properties.

Compressibility index(%) = Tapped density – Bulk density / Tapped density x 100

| | |
|---|---|
| 5 – 15% | Excellent |
| 16 – 20% | Good |
| 21 – 25% | Fair |
| 26– 31% | Poor |
| >32% | Very poor |

### 4. Hausner Ratio:

Hausner ratio is the ratio of tapped density to bulk density. It provides information regarding interparticle friction and flowability of the powder mixture.

Hausner ratio = Tapped density / Bulk density

| | |
|---|---|
| 1.00-1.11 | Excellent |
| 1.12-1.18 | Good |
| 1.19-1.25 | Fair |
| 1.26-1.34 | Poor |
| >1.35 | Very Poor |

**5. Angle of Repose:**

Angle of repose is the maximum angle formed between the surface of a pile of powder and the horizontal plane. It is used to determine the flow characteristics of powder blends.

$$\Theta = \tan^{-1}( h / r )$$

| | |
|---|---|
| 25-30° | Excellent |
| 31-35° | Good |
| 36-40° | Fair |
| 41-45° | Passable |
| >45° | Poor |

**Post-compression evaluation parameters:**

**1.Weight variation:**

Twenty tablets were randomly selected and weighed individually. The average weight of the tablets was calculated, and each individual tablet weight was compared with the average weight.

**2.Hardness:**

The hardness test was performed to determine the mechanical strength of the tablets. The hardness of randomly selected tablets was measured using a Monsanto hardness tester, and the results were expressed in kg/cm². This test ensures that the tablets possess sufficient strength to withstand handling and transportation.

**3.Wetting time:**

The wetting time is closely related to the inner structure of the tablets and the hydrophilicity of the excipient. Obviously, the size of the pores is reduced and the wetting time is extended with the increase of compression force or with the reduction of porosity. 6 ml of water was added to a petri plate in which a double folded tissue paper was placed. The tablet was placed on the paper and the time to complete wetting of the tablet was measured in seconds.

**4.In-vitro disintegration time:**

The in-vitro disintegration time was determined using disintegration test apparatus. The apparatus consisted of 6 tubes. A tablet was placed in each tube and a disc was placed in each tube . The time in seconds was noted for complete disintegration of the tablet with no palatable mass remaining in the apparatus.

**5.In-vitro drug release study:**

In vitro drug release study was performed by USP dissolution apparatus II (paddle method). The dissolution medium was 900 ml of phosphate buffer (pH 6.8) maintained at 37 ± 0.5°C stirred at 50 rpm. One tablet was added to the dissolution medium and samples were withdrawn at fixed time intervals (5,10,15,20,25). The withdrawn samples(5ml) were filtered and then analyzed by a UV-visible spectrophotometer (Labindia analyticals) at the selected wavelength(285nm). After each sampling an equal volume of fresh dissolution medium was replaced to maintain the sink conditions.

## RESULTS AND DISCUSSION:

Herbal orodispersible tablets containing ginger, cinnamon and cumin powder were successfully prepared by wet granulation method and were evaluated for various pre-compression and post-compression parameters. All formulations exhibited acceptable characteristics and satisfactory performance of tablets.

The pre-compression test revealed that the granules had good flow properties. Bulk density values of 0.45 g/ml, 0.33 g/ml and 0.55 g/ml were obtained for F1, F2 and F3 respectively while tapped density values of 0.52 g/ml, 0.41 g/ml and 0.58 g/ml were obtained for F1, F2 and F3 respectively. The compressibility index values ranged between 13.36% and 19.51% indicating fair to good flowability. The Hausner's ratio values were found to be in the range of 1.05-1.24 indicating acceptable flow properties of granules for

compression. The angle of repose was in the range of 32.2° to 40.6° indicating good flow behavior.

All the prepared tablets were light brown in colour, round in shape and had a characteristic aromatic odour of cinnamon with slightly rough surface. The weight variation test was same for all the formulations. The average weight variation values obtained for F1, F2 and F3 were 0.511 ± 0.038 g, 0.495 ± 0.011 g and 0.502 ± 0.021 g respectively, which were within the acceptable limits of pharmacopoeia. The wetting time and in-vitro disintegration time decreased gradually from F1 to F3. F1 showed maximum wetting time of 120 sec and disintegration time of 36.0 sec, while F3 showed minimum wetting time of 45.3 sec and disintegration time of 17.24 sec. The decreased wetting and disintegration time may be attributed to the increased banana powder concentration and psyllium husk powder as natural superdisintegrants and increased water absorption and breakup of tablet.

The in-vitro dissolution studies showed satisfactory release of drug from all the formulations. The percentage drug release was found to be 78.78 ± 0.85% for F1, 77.68 ± 1.12% for F2 and 79.58 ± 0.94% for F3. Amongst all the formulations, F3 showed maximum drug release and disintegrated fast which resulted in improved performance of the tablet.

In conclusion, the present study proved that natural excipients like banana powder and psyllium husk powder can be successfully used for improving the disintegration and dissolution properties of herbal orodispersible tablets. Formulation **F3** was selected as optimized formulation based on evaluation parameters viz. rapid disintegration, lower wetting time and maximum drug release.

| **Ingredients** | **F1(mg)** | **F2(mg)** | **F3(mg)** |
|---|---|---|---|
| Ginger powder | 100 | 100 | 100 |
| Cinnamon powder | 75 | 75 | 75 |
| Cumin powder | 50 | 50 | 50 |
| Banana powder | 80 | 100 | 120 |
| Psyllium husk powder | 40 | 60 | 80 |
| Corn starch | 120 | 80 | 40 |
| Stevia | 25 | 25 | 25 |
| Gum acacia | 8 | 8 | 8 |
| Cardamon powder | 2 | 2 | 2 |

**Table no.1-Formulation design:**

| **Sr.no.** | **Parameters** | **F1** | **F2** | **F3** |
|---|---|---|---|---|
| 1. | Bulk density(gm/ml) | 0.45gm/ml | 0.33gm/ml | 0.55gm/ml |
| 2. | Tapped density(gm/ml) | 0.52gm/ml | 0.41gm/ml | 0.58gm/ml |
| 3. | Car's index(%) | 13.36% | 19.51% | 5.17% |
| 4. | Hausner's ratio | 1.15 | 1.24 | 1.05 |
| 5. | Angle of repose(°) | 35.7° | 32.2° | 40.6° |

**Table no.2-Pre-compression evaluation:**

| Sr.no. | Parameters | F1 | F2 | F3 |
|---|---|---|---|---|
| 1. | Weight variation | 0.511±0.038 | 0.495±0.011 | 0.502±0.021 |
| 2. | Hardness(kg/cm$^2$) | 2.5 | 2.6 | 2.5 |
| 3. | Wetting time (sec) | 120sec | 49.2sec | 45.3sec |
| 4. | In-vitro disintegration time (sec) | 36.0sec | 18.46sec | 17.24sec |
| 5. | In-vitro dissolution study (% drug release) | 78.78±0.85% | 77.68±1.12% | 79.58±0.94% |

**Table no.3- Post-compression evaluation of tablets:**

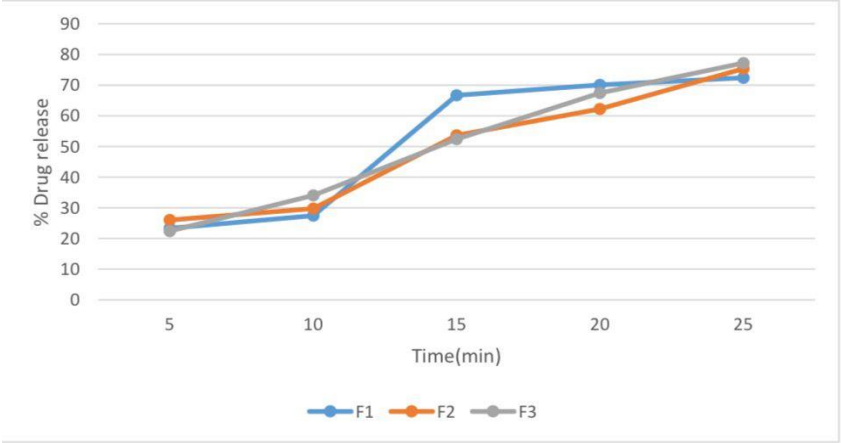


**Fig no.1 % Drug release**

**Fig no.2 Prepared Polyherbal orodispersible tablets**

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