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# FORMULATION AND TABLETING PROPERTIES OF AQUEOUS EXTRACT OF FRESH GINGER *(ZINGIBER OFFICINALE)* RHIZOME

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## ABSTRACT

*Zingiber officinale* rhizome is generally known as ginger which is perhaps one of the most commonly used spice and usually forms an integral part of our diet. In addition to its dietary use, ginger is equally reputed for its medicinal properties. This study was aimed at formulating the aqueous extract of *Zingiber officinale* rhizome to a chewable tablet using altered concentration of maize starch as binder (2.5, 5.0, 7.5 and 10.0 %w/v). The pre-compression parameters assessed for the aqueous extract and the granules produced include moisture content, angle of repose, bulk and tapped density, Carr's index, Hausner's ratio and microbial load. Compressed tablets were evaluated for non-Pharmacopoeial and Pharmacopoeial tests. The findings of these study shows that the aqueous extract of *Zingiber officinale* can be tableted using altered concentration of maize starch binder to chewable tablets.

**KEYWORDS**: *Zingiber officinale*, Formulation, Chewable tablet and Aqueous extract.

## INTRODUCTION

Chewable tablets are the tablets which are required to be broken and chewed in between the teeth before ingestion [1]. Since pediatric, geriatric and bedridden patients show inconvenience swallowing conventional tablets or capsules due to difficulties in swallowing with lesser volumes of water with the medication, unable to tolerate the taste of many drugs when formulated as liquid dosage forms, resulting in poor patient adherence[2]. The benefits of chewable tablets include palatability, stability, precise dosing, portability and ease of

delivery[1]. Hence the decisions to formulate the aqueous extract of *Zingiber officinale* into chewable tablet in order to improve patient adherence.

Ginger (*Zingiber officinale*, family Zingiberaceae) is an underground rhizome and presently considered as a common constituent of diet worldwide [3]. The herb is widely cultivated in tropical Asia and other warmer regions of whole world notably in the West Indies, India and Nigeria[4]. It is one of the important medicinal plants which naturally occur in various countries like India, China, South East Asia, West Indies, Mexico and other parts of the world[5].

Numerous studies have been performed to ratify the therapeutic potentials of Ginger; however, to the best of our knowledge, none exists to ascertain the tableting properties of ginger. Some authors reported that ginger pre-treatment inhibited the induced hyperglycaemia and hypoinsulinemia[6] as well as hypolipidemic effect[7]. Furthermore, studies on the protective effect of ginger extract against the induced nephrotoxicity and renal failure have also been reported[8]. Some works have been devoted to the anti-tumour activity of ginger[9]. It has also been reported that ethanol extract of ginger can be used alongside conventional antibiotics[10]. Hence, this study is aimed at formulating and evaluating the aqueous extract of *Zingiber officinale* rhizome as a chewable tablet using altered binder concentrations.

## MATERIALS AND METHODS

### Source of plant material, collection and proof of identity

*Zingiber officinale* rhizomes were obtained from Gomboru Market in Maiduguri, Borno State, Nigeria. The sample was subsequently identified by Professor S. S. Sanusi, a Taxonomist in the Department of Biological Sciences, University of Maiduguri.

### Preparation of Extracts

Fresh sample of *Zingiber officinale rhizomes* were peeled and washed with distilled water and subsequently size reduced with pestle and mortar. The rhizomes were air dried to a constant weight and size reduced using pestle and mortar. The weight of the sample was then noted.

The sample was then soaked in 1 L of distilled water for 24 hours at room temperature with occasional mechanical shaking. The filtrate obtained was concentrated using Rotary

evaporator (R201D, U.S.A) and the extract subsequently air dried. The weight of the aqueous extract obtained was recorded.

**Pre-compression parameters of *Zingiber officinale* powder (aqueous extract) and the granules produced**

**Moisture content**

The moisture content of *Zingiber officinale* powder and the granules produced prior to compression were determined using a moisture analyser (Sartorius, Germany). A 3 g weight of each sample was poured unto the moisture balance and evenly distributed on the tray. The machine was set at 130 ± 1 $^{o}$C. The readings were noted when the machine automatically halts[11].

**Angle of Repose**

The angle of repose of the *Zingiber officinale* powder and the granules produced were determined using a glass funnel clamped on a retort stand which is 10 cm away from the flat surface of a bench. 30 g each of the *Zingiber officinale* powder and the granules produced were poured gently into the funnel and allowed to flow freely forming a conical heap. The angle of repose was calculated from the heap of each sample using the equation;

Angle of repose, $\tan \theta = \frac{h}{r}$

Where h = height and r = radius of the circular heap.

**Bulk and Tapped Densities**

This was carried out by measuring the volume occupied by a 30 g weight of the *Zingiber officinale* powder and the granules produced into a dry measuring cylinder. The bulk density was calculated using the formula;

$$\text{Bulk density} = \frac{\text{Weight of the sample}}{\text{Volume of the sample}}$$

The measuring cylinder then tapped 50 times on a wooden table from a height of 2 cm and the taped volume was noted. The tapped density was calculated as;

$$\text{Tapped density} = \frac{\text{Weight of sample}}{\text{Tapped volume of sample}}$$

**Determination of Carr's index**

Carr's index was calculated using results obtained for both bulk density and tapped densities by the relation;

$$\text{Carr's index (\%)} = \frac{\text{Tapped density - Bulk density}}{\text{Tapped density}} \times 100$$

**Determination of Hausner's ratio**

Hausner's ratio was determined using the result obtained for both bulk densities and tapped densities. It was calculated using the formula;

$$\text{Hausner's ratio} = \frac{\text{Tapped density}}{\text{Bulk density}}$$

**Enumeration of microbial count**

The method used by Emejuru *et al.*[12] was adopted with some modifications. Inoculation by pour plate method was carried out after 1 in 1000 serial dilutions of 1 g weight of the aqueous extract *Zingiber officinale* powder. One milliliter of the diluted sample was then aseptically aspirated into the media (Nutrient Agar). The media was poured aseptically into a sterile petri dish at 40-45 $^{o}$C then swirled and allowed to solidify for incubation at 37 °C for 24 hr.

Typical colonies of microbial growth on plates were counted at the end of incubation and the total numbers of counts were multiplied by dilution factor ($1 \times 10^3$) to get the total viable count for all samples.

**Preparation of granules for aqueous extract of *Zingiber officinale***

Wet granulation method of massing and screening was employed in preparing all the batches of granules. The aqueous extract of *Zingiber officinale* powder and the intra-granular excipients (Maize starch, lactose and aspartame) were dry-mixed thoroughly in a porcelain pestle and mortar. An appropriate quantity of freshly prepared maize starch mucilage of concentration between 2.5 and 10% w/v was added depending on the batch to be produced. The damp mass in each case was passed through a stainless steel sieve number 5 to form granules. The wet granules were air dried for 24 hours and passed through number 8 stainless steel sieve in order to produce uniformly sized granules. Extra-granular adjuncts (magnesium stearate and talc) were then added and mixed thoroughly prior to granule characterization.

**Compression of granules**

The granules were compressed in a single punch tableting machine (Manesty type F3, England) at a compression pressure of 7.5 metric tones. The tablets produced were kept in an air tight container for 24 hours prior to quality control tests in order to allow for recovery. [13]

Evaluation of the tablets produced by *Zingiber Officinale*

**Quality Control Tests of Formulated Tablets**

**Uniformity of thickness and diameter**

Vernier caliper was used to measure the thickness and diameter of the tablets. The mean value of five determinations was recorded in each case.

**Uniformity of weight test**

Twenty tablets were randomly selected from each batch and weighed individually. The mean weight of the tablets was then calculated and the standard deviation determined.

**Hardness test**

Six tablets prepared using aqueous extract of *Zingiber officinale* were randomly selected and tested for hardness strength using the official Erweka hardness tester (Erweka TBH 100, Germany). Each tablet was placed between the jaws of the tester and subjected to increasing pressure by turning the knurled knob until the tablet was crushed. The mean of the six determinations was taken for each batch.

**Friability test**

Erweka friabilator (Erweka D-63150, Germany) was used for the test. Twenty (20) tablets randomly selected and weighed were positioned inside the drum of the friabilator and set to spin at 25 rpm for four (4) minutes, the intact tablets were removed from the drum, dusted and reweighed and percentage weight loss calculated.

**Disintegration test**

Six tablets were randomly selected and placed individually in the six tubes of the disintegration test apparatus (Erweka, Germany) filled to the assigned level with distilled water whose temperature was thermostatically maintained at 37 ± 1 °C. The time taken for the complete disappearance of the tablet or its fragment through the 2mm mesh into the disintegrating medium was recorded for each batch[14].

**Dissolution time test**

**Calibration curve**

The calibration curve was constructed using the aqueous *Zingiber officinale* extract. 0.1 M NaOH was used as the dissolution medium. A 50 mg weight of the extract was weighed and diluted in 10 ml of 0.1M NaOH (5 mg/ml). The stock (5 mg/ml) was then serially diluted to a concentration of 2.5, 5.0, 7.5, 10.5 12.5 µg/ml respectively. The absorbance of the different concentrations were determined at 195 nm wavelength using a ultra violet (UV) spectrophotometer (Barlowond Scientific, 6405 UK) and a graph of absorbance against concentration plotted.

**Procedure for the dissolution**

The dissolution test apparatus (Erweka DT 700, Germany) was used to determine the dissolution rate of the aqueous *Zingiber officinale* tablets produced. Each jar was filled with 900ml of the dissolution medium (0.1 M NaOH) thermostatically maintained at 37 ± 0.5 $^{o}$C. One tablet was placed into each glass jar and the paddle set to rotate at 50rpm. Samples of the dissolution medium were withdrawn at specific time interval of 5, 15, 30, 45, and 60 minutes respectively and analysed at 195nm using UV spectrophotometer. After each withdrawal of the sample, equal volume of the dissolution medium was introduced/replaced.

**RESULTS**

**Table 1: Pre-compression parameters of *Zingiber officinale* powder (aqueous extract)**

| **Parameters** | ***Zingiber officinale* powder** |
|---|---|
| Moisture content (%) ± SD | 13.61 ± 0.48 |
| Angle of repose (°) ± SD | 43.69 ± 2.38 |
| Bulk density (g/ml) ± SD | 0.49 ± 0.00 |
| Tapped density (g/ml) ± SD | 0.76 ± 0.0091 |
| Carr's index (%) ± SD | 35.33 ± 0.01 |
| Hausner's ratio ± SD | 1.55 ± 0.03 |
| Microbial load (cfu/ml) | 234.50 |

Key: All values are expressed as mean ± Standard deviation

**Table 2: Pre-compression parameters of the granules produced using various binder concentrations**

| **Parameters** | **$F_1$** | **$F_2$** | **$F_3$** | **$F_4$** |
|---|---|---|---|---|
| Moisture content (%) ± SD | 6.51± 2.13 | 6.26± 0.59 | 5.17±2.12 | 5.87±0.39 |
| Angle of repose (°) ± SD | 22.75±1.49 | 21.16±1.67 | 20.55±1.31 | 24.57±1.77 |
| Bulk density (g/ml) ± SD | 0.82±0.01 | 1.11 ±0.05 | 1.16±0.03 | 0.83±0.01 |
| Tapped density (g/ml) ± SD | 0.89±0.02 | 1.15±0.01 | 1.24±0.02 | 0.95±00.3 |
| Carr's index (%) ± SD | 11.94±6.39 | 6.18±1.62 | 6.19±1.24 | 12.6±3.22 |
| Hausner's ratio ± SD | 1.09± 0.02 | 1.09± 0.02 | 1.07±0.02 | 1.15±0.05 |

Key: All values are expressed as mean ± Standard deviation. $F_1$, $F_2$, $F_3$ and $F_4$ are 2.5, 5.0, 7.5 and 10.0 %w/v of binder concentration respectively.

**Table 3: Evaluation of the tablets produced by the aqueous extract of *Zingiber Officinale***

| Parameter | $F_1$ | $F_2$ | $F_3$ | $F_4$ |
|---|---|---|---|---|
| Uniformity of Diameter (mm) | 3.27±0.17 | 3.21±0.03 | 3.26±0.04 | 3.20±0.13 |
| Uniformity of Thickness (mm) | 0.88±0.04 | 0.90±0.06 | 0.89±0.03 | 0.87±0.0067 |
| Uniformity of Weight (g) ± SD | 0.17±0.02 | 0.17±0.0092 | 0.17±0.0051 | 0.16±0.0060 |
| Crushing strength (kg/F) ± SD | 1.38±0.47 | 2.18±0.66 | 3.39±0.14 | 4.25±0.11 |
| Friability (%) ± SD | 17.03 ±1.33 | 32.54 ±3.14 | 1.30 ±0.21 | 0.79 ±0.04 |
| Disintegration time (min) ± SD | 19.21 ±0.98 | 25.10 ± 2.03 | 34.04 ±1.27 | 51.03±2.11 |

Key: All values are expressed as mean ± Standard deviation. $F_1$, $F_2$, $F_3$ and $F_4$ are 2.5, 5.0, 7.5 and 10.0 %w/v of binder concentration respectively.

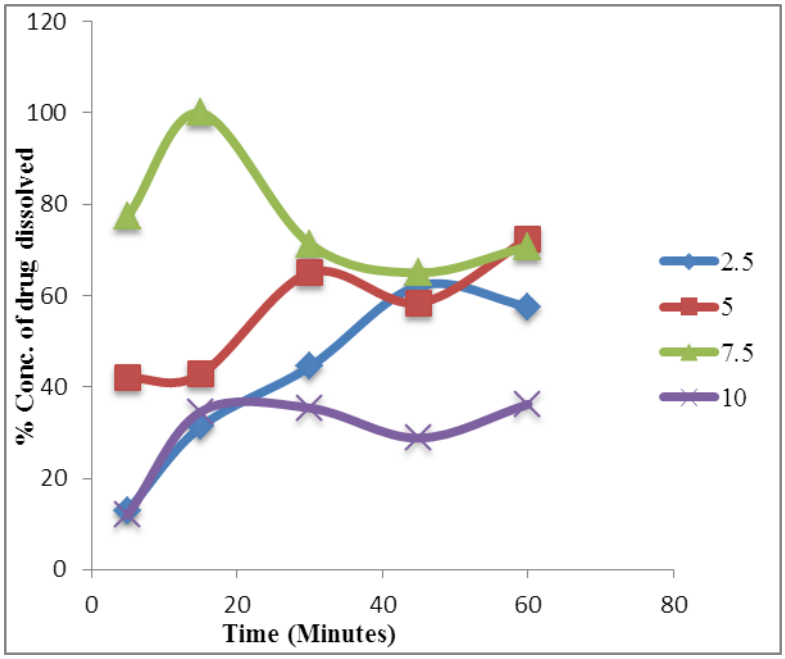


**Figure 1: Dissolution profile of various binder concentration used in formulation of *Zingiber officinale* tablets.**

## DISCUSSION

The powdered aqueous extract of *Zingiber officinale* and the granules produced (moist granulation prior to compression) were evaluated for pre-compression parameters and the values were found to be within prescribed units for tablet formulation[15]. The granules produced however showed better flow property compared to the powered *Zingiber officinale* (aqueous extract) since according to Hickey *et al.*[16] free-flow occurs with particles greater than 250 µm, reduced flow with particles smaller than 100 µm, and poor flow with particles

smaller than 10 μm (except as large agglomerates). Also, values of angle of repose between 54°-59° have very poor flow properties. These results were presented in (Tables 1 and 2)[17]. Table 3 shows the results for uniformity of diameter and uniformity of thickness. The values for the deviation are very low indicating that the tablets are identical in diameter and thickness. These parameters are very important when using a selected packaging material and in counting tablets using filling equipment[17]. Also, the uniformity of weight for the tablets produced falls within the prescribed units for tablets with average weight more than 80 mg but less than 250 mg with the percentage deviations for all the tablet batches less than 7.5[18]. The findings as shown in Table 3 demonstrate an increase in crushing strength with increasing binder concentration. Only tablets with 7.5 %w/v and 10 %w/v had a crushing strength within the acceptable range 3 – 6 KgF for tablets[11]. Similarly, with increasing binder concentration, the tablets produced become less friable. Tablets with 10 %w/v of binder concentration had less than 1% friability value as stipulated by the USP, 2008[19] for conventional tablets. However, values of friability up to 4 % are acceptable for chewable tablets[20].

The disintegration time for the tablets produced increases as the binder concentration is increased (Table 3). According to Anusha *et al.*[15] chewable tablets are supposed to disintegrate in not more than 30 minutes. Therefore, our findings indicate that batches of tablets with higher binder concentration (7.5 %w/v and 10 %w/v) have failed the test (Disintegration time 34.04 ± 1.27 and 51.03 ± 2.11 minutes respectively). However, Kandi *et al.*[21] in their report stated that disintegration may not appear appropriate for chewable tablets as these are to be chewed before being swallowed. Conversely, patients especially paediatric and geriatric have been known to swallow these chewable dosage forms. This test would thus indicate the ability of the tablet to disintegrate and still provide the benefit of the drug if it is accidentally swallowed. Similarly, with increasing binder concentration, the time taken for drugs to be in solution also increases (Table 3).

The study as shown in figure two indicates that the concentration of the drug (at dissolution time 30 minutes) in solution is less than 80% of the labelled amount as specified for chewable tablets[15].

## CONCLUSION

Finally, the study demonstrated that aqueous extract *Zingiber officinale* can be suitably tableted into chewable tablet using altered binder concentration. The tablets produced showed satisfactory results with respect to most of the parameters evaluated.

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