WORLD JOURNAL OF PHARMACY AND PHARMACEUTICAL SCIENCES
SJIF Impact Factor 7.421
Volume 8, Issue 3, 1416-1424 Research Article ISSN 2278 – 4357

FORMULATION AND EVALUATION OF CHEWABLE TABLETS CONTAINING AQUEOUS EXTRACT OF *ZINGIBER OFFICINALE*

Shrishail M. Ghurghure[1], Mahewash Sana Asadulla Pathan[1]*, Priyanka Ramesh Surwase[1], Parikshit Dhanu Shirure[1] and Prasad Mallinath Gote[1]

P.G. Department of Pharmaceutics, D.S.T.S. Mandal's College of Pharmacy, Solapur-413004 Maharashtra. India.

Article Received on
14 Jan. 2019,

Revised on 03 Feb. 2019,
Accepted on 24 Feb. 2019

DOI: 10.20959/wjpps20193-13328

***Corresponding Author**
Mahewash Sana Asadulla Pathan
P.G. Department of Pharmaceutics, D.S.T.S. Mandal's College of Pharmacy, Solapur-413004 Maharashtra. India.

ABSTRACT

Ginger, the rhizome of *Zingiber officinale*, species of the ginger family Zingiberaceae has a long history of medicinal use for more than 2000 years as one of the most versatile medicinal plants having a wide spectrum of biological activity and a common condiment for various foods and beverages. Currently, there is a renewed interest in ginger, and several scientific investigations aimed at isolation, identification of active constituents, scientific verification of its pharmacological actions for treatment of several diseases and conditions. The chemicals responsible for medicinal properties of ginger are considerably variable, main components are gingerol, paradol, shogaols and their homologous which are responsible for its pungent taste. Ginger is used as a food and medicine and as an aromatic, carminative, expectorant in cough and cold, antiemetic and digestive and as common herbal remedy. It is also useful in sore throat and other infectious diseases. Chewable tablets are among the convenient dosage forms which patients prefer due to their advantages. Chewable tablets are the tablets which are required to be chewed or broken in between the teeth before ingestion. This study was aimed at formulating the aqueous extract of ginger rhizome to chewable tablet using syrup (66.7%). In the present research work, the chewable tablets of ginger were prepared by wet granulation. Compression of chewable tablets was done by Karnavati lab scale tablet compression machine. The pre-compression parameters assessed for the granules produced include angle of repose, bulk and tapped density, Carr's index, Housner's ratio. Compressed tablets were evaluated for thickness, hardness, friability, disintegration time and dissolution time.

KEYWORDS: *Zingiber officinale*, Aqueous extract, syrup, chewable tablet.

INTRODUCTION

Ginger scientifically known as *Zingiber officinale Roscoe*, belonging to family Zingiberaceae is one of the most important plant with several medicinal, nutritional and ethnomedical values therefore, used extensively worldwide as a spice, flavoring agent and herbal remedy. Traditionally, *Z. officinale* is used in Ayurveda, Siddha, Chinese, Arabian, Africans, Caribbean and many other medicinal systems to cure a variety of diseases such as nausea, vomiting, asthma, cough, palpitation, inflammation, dyspepsia, loss of appetite, constipation, indigestion and pain.[1] The English botanist William Roscoe (1753- 1831) gave the plant the name *Zingiber officinale* in an 1807 publication.[2] At least 115 constituents in fresh and dried ginger varieties have been identified by a variety of analytical processes.[3] *Z. officinale* is reported to possess essential oils, phenolic compounds, flavonoids, carbohydrates, proteins, alkaloids, glycosides, saponins, steroids, terpenoids and tannin as the major phytochemical groups. The pungency of dry ginger mainly results from shogaols, which are dehydrated forms of gingerols. The biological activities of several volatile and non-volatile constituents of ginger through selected in vitro and in vivo models reveal that ginger has Antioxidant, Antimicrobial, Anti-diabetic, Anti-cancer, Anti-inflammatory, Analgesic, Anti-platelet aggregation, Antipyretic, Anti angiogenic, Immunomodulatory, Hepato-protective, Anti-atherosclerotic, larvicidal, Anti-obesity, Anti-emetic, renoprotective, neuroprotective, anthelmintic, gastroprotective, Cardiovascular etc activities.[1]

The most important drug delivery route is undoubtedly the oral route. Tablet is the most popular among all dosage forms existing today because of its convenience of self administration, compactness and easy manufacturing. Many patients find it difficult to swallow tablets and hard gelatin capsules and do not take their medication as prescribed. The difficulty is experienced in particular by pediatric and geriatric patients, but it also applies to people who are ill in bed and to those active working patients who are busy or traveling, especially those who have no access to water.[4]

Chewable tablets are an immediate release (IR) oral dosage form intended to be chewed and then swallowed by the patient rather than swallowed whole.[5] The advantages of chewable tablets include palatability, stability, precise dosing, portability and ease of delivery. The available literature suggests that chewable tablets provides a safe, well-tolerated alternative to

traditional pediatric drug formulations and offer significant advantages in children with two years of age and above.[5] Ginger has been found effective in multiple studies for tearing nausea caused by sea sickness, morning sickness and chemotherapy, though ginger was found superior over a place for post operative nausea.[6] The aim of this research was to study tableting properties of aqueous extract of ginger rhizomes and formulation of chewable tablets using concentrated syrup as binder.

MATERIALS AND METHODS

Materials

Ginger rhizomes were obtained from the local market of Solapur. All other ingredients used i.e. Lactose, Aspartame, Magnesium stearate, glucose were of pharmaceutical grade.

Preparation of Extracts

Fresh sample of *Zingiber officinale rhizomes* were peeled and washed with distilled water. 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 and the extract subsequently air dried. The weight of the aqueous extract obtained was recorded.

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 (lactose and aspartame) were dry-mixed thoroughly in a porcelain mortar and pestle. An appropriate quantity of freshly prepared maize glucose syrup solution of concentration 66.7% w/v was added. The damp mass was passed through a 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.

Pre-compression parameters

1. Angle of Repose

The angle of repose of the *Zingiber officinale* 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 of granules 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;

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

Where, h = height

r = radius of the circular heap.

2. Bulk and Tapped Densities

This was carried out by measuring the volume occupied by a 20 g weight of the granules into a dry measuring cylinder. The bulk density was calculated using the formula;

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

The measuring cylinder then tapped 100 times on a wooden table from a height of 2 cm and the taped volume was noted. The tapped density was calculated as;

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

3. Determination of Carr's index

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

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

4. 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;

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

Compression of granules

The granules were compressed in a rotary tableting machine (Karnavati). The tablets produced were kept in an air tight container for 24 hours prior to quality control tests in order to allow for recovery.

Quality Control Tests of Formulated Tablets

1. General appearance

The general appearance of tablets, its visual identity and overall elegance is essential for consumer acceptance. The tablets were checked for the presence of cracks, depressions, pinholes, uniformity of color, and the polish of the tablet.

2. 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.

3. Uniformity of weight test

Twenty tablets were weighed individually and all together. Average weight was calculated from the total weight of all tablets. The individual weights were compared with the average weight. The percentage difference in the weight variation should be within the permissible limits. The percent deviation was calculated using the following formula:-

Percentage deviation = [(Individual weight-Average weight) /Average weight] ×100

Any deviation in the weight of tablet leads to either under medication or over medication. So, every tablet in each batch should have a uniform weight. Corrections were made during the compression of tablets to get uniform weight. The USP has provided limits for the average weight of uncoated compressed tablets. These are applicable when the tablet contains 50mg or more of the drug substance or when the latter comprises 50% or more, by weight of the dosage form. Twenty tablets were weighed individually and the average weight was calculated. The individual tablet weights are then compared to the average weight. Not more than two of the tablets must differ from the average weight by not more than the percentages stated. No tablet must differ by more than double the relevant percentage.

4. Hardness test

Hardness is generally measured as the force needed to break the tablet in a specific plane. Tablet hardness may be used to determine the chewing difficulty index. 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.

5. Friability test

Friability is the loss of weight of tablet in the container or package, due to removal of fine particles from the surface. To ensure the ability of tablets to withstand the shocks during processing, handling, transportation, and shipment. Permitted friability limit is 1.0%. Roche friabilator was used to measure the friability of the tablets. Ten tablets were weighed collectively and placed in the chamber of the friabilator. In the friabilator the tablets were exposed to rolling, resulting free fall of tablets (6 inches) within the chamber of the friabilator. It was rotated at a rate of 25 rpm. After 100 rotations (4 min.) the tablets were taken out from the friabilator and intact tablets were again weighed collectively. The percent friability was determined using the following formula:

$$F= (1-W)/ W_0 \times 100$$

Where, W_0= Weight of the tablet before test

W= Weight of the tablets after test.

6. Disintegration test

For a drug to be absorbed from a solid dosage form after oral administration, it must first be in solution, and the first important step toward this condition is usually the break-up of the tablet; a process known as disintegration. The time required for a tablet to break up into small particles is its disintegration time. For chewable tablets, disintegration time should be short enough to prevent GI obstruction in the event a tablet is not completely chewed by the patient.

Disintegration time was determined in artificial saliva (Phosphate buffer solution pH 5.8) according to the USP method at 37 ± 0.5°C. The disintegration time of six individual tablets was recorded. Mean of six determinations was taken for each batch.

RESULTS AND 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. The granules produced however showed better flow property compared to the powered *Zingiber officinale* (aqueous extract).

Table 2 shows the results for uniformity of diameter and uniformity of thickness. These parameters are very important when using a selected packaging material and in counting tablets using filling equipment. 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.

Chewable tablets are supposed to disintegrate in not more than 30 minutes. Therefore, our findings indicate that, F2 batch fails the test whereas F1 batch passes the disintegration test.

Table No. 1: Pre-compression parameters of granules.

Parameters	F1	F2
Moisture content (%)	5.41	4.32
Angle of repose (°)	23.85	19.34
Bulk density (g/ml)	0.92	1.18
Tapped density (g/ml)	1.09	1.23
Carr's index (%)	9.85	7.21
Hausner's ratio	1.10	1.12

Table No. 2: Post compression parameters.

Parameter	F1	F2
Uniformity of Diameter (mm)	3.27	3.26
Uniformity of Thickness (mm)	0.88	0.89
Uniformity of Weight (g)	0.17	0.17
Crushing strength (kg/F)	1.38	3.39
Friability (%)	17.03	1.30
Disintegration time (min)	21	32

CONCLUSION

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

ACKNOWLEDGEMENT

Authors are very much thankful to Mr. K. A. Kamlapurkar, Assistant professor, D.S.T.S. Mandal's Collage of Pharmacy, Solapur, Maharashtra, India for his continuous support, guidance and encouragement.

REFERENCES

1. Dhanik J, Arya N, Nand V. A Review on Zingiber officinale. J Pharmacog Phytochem, 2017; 6(3): 174-184.
2. Banerjee S, Mullick HI, Banerjee J. Zingiber officinale: A Natural Gold. Int J Pharm Bio Sci., 2011; 2(1): 283-294.

3. Bode AM, Dong Z. The Amazing and Mighty Ginger. Herbal Medicine: Biomolecular and Clinical Aspects. 2nd edition.
4. Bharawaj S, Jain V, Sharma S, Jat RC, Jain S. Orally Disintegrating Tablets: A Review. Drug Invention Today, 2010; 2(1): 81-88.
5. Khokra SL, Parashar B, Dhamija HK, Purohit R, Chandel A. Formulation Development and Evaluation of Chewable Tablet of Albendazole by different Techniques. Int Journal Pharm. Pharm Sci., 2012; 4(1): 461-464.
6. Sebiomo A, Awofodu AD, Awosanya AO, Awotona FE, Ajayi AJ. Comparative Studies of Antibacterial Effect of some Antibiotics and Ginger (*Zingiber officinale*) on two pathogenic bacteria. J Microbiol. Anti M., 2011; 3(1): 18-22.
7. Muazu J, Lame S, Mohammed GT, Madu SJ. Formulation and tableting properties of aqueous extract of fresh ginger *(Zingiber officinale*) rhizome. W J Pharm Res., 2015; 4(9): 9-18.
8. Prasad BSG, Das P, Kiran CVSR. Formulation and Evaluation of Chewable Tablets of Montelukast. Ind J Res Pharm Biotech. ISSN: 2320–3471.
9. Tajuddin SS, Afaq SH. Spices and Medicine: *Zingiber officinale*. Int J Appl Bio Pharm Tech., 2010; 1(3): 968-973.
10. Sharma M, Shukla S. Hypoglycaemic Effect of Ginger. The J. Res India Yoga Homoeopathy, 1996; 12: 127-130.
11. Abdullahi S. Ginger Extract (*Zingiber officinale*) Triggers Apoptosis and G0/G1 Cells Arrest in HCT 116and HT 29 Colon Cancer Cell Lines. AJBR, 2010; 4(4): 134-142.
12. Marshall KI, Lachman L, Liberman H, Kanig JL. The Theory and Practice of Industrial Pharmacy. 3rd ed. India Varghese publishing house, 1987.
13. Kandi M, Sivasai G, Rathnanand M, Reddy MSK. Formulation and Evaluation of Chewable Tablet of Metformin HCl using Stevia by Different Techniques. Int J PharmTech Res., 2013; 5(3): 1364-1372.
14. Rajashree R, Gangolli D, Panigrahy S, Sarkar S, Kundalwal S. Mouth Dissolving Tablets and Candies prepared from popularly Known Spices. Res J Chem. Sci., 2013; 3(5): 57-62.
15. Jamel MS, Arkan BM, Maad AA. Effect of Aqueous extract of ginger (Zingiber officinale) on blood biochemistry parameters of Broiler. Int J Poul Sci., 2010; 9(10): 1682-8356.
16. Kasar HA, Dev A, Dhal S. Formulation and Evaluation of Lidocaine Hydrochloride Chewable Tablet. Asian J Pharm Clinical Res., 2018; 11(11): 190-194.

17. Renu, Dahiya J, Jalwal P, Singh B. Chewable Tablets: A Comprehensive Review. The Pharma Innovation J., 2015; 4(5): 100-105.
18. Achhra CV, Pawar HA. Development and Evaluation of Sucrose Free Herbal Orally Disintegrating Tablets of Ginger. J. Bioana Biomed, 2017; 9(6): 288-293.
19. Ratnaparkhi MP, Dr. Mohanta GP, Dr. Upadhyay L. Review On: Fast Dissolving Tablet. J Pharm Res.., 2009; 2(1): 5-12.
20. Prashar D, Saklani S. Formulation and evaluation of anthelmintic chewable tablets, 2012; IPS 2: 13-16.
21. Khandelwal KR (2007) Practical Pharmacognosy Techniques & Experiments. 18th edn. Nirali Prakashan, Pune, India.