

Development and Evaluation of Carminative Herbal Chewable Tablets Based on Turmeric, Fennel Seed, and Mango Ginger

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ABSTRACT

The present study aimed at the formulation of carminative herbal chewable tablets using herbal constituents. *Curcuma longa* (turmeric), *Foeniculum vulgare* (fennel), and *Curcuma amada* (mango ginger) are the most celebrated herbs in Indian system of traditional medicine. In the present research work, oral chewable tablets were prepared by direct compression and wet granulation method incorporating these three herbs. In both the methods, the powder of turmeric, fennel seed, and ginger mango was prepared initially and it was mixed with additives and preservatives. Physicochemical analysis of the individual drugs, pre-formulation studies, and post-formulation standardization was done to evaluate the quality and purity of the conformation. In the pre-formulation study, it was observed that all the parameters checked for the ingredients were within standard range. Thus, the ingredients were processed for preparing tablets following IP. During the evaluation of tablets, it was found that all the prepared batches of tablets were within the standard range of chewable tablet parameters. Thus, considering these values and following the IP, we found that the chewable tablet that was prepared without altering its therapeutic property was satisfactory with general characteristics of tablet, namely, hardness, disintegration time, friability, and weight variation. The formulation was tested for common people with respect to taste; odor and time required for complete chewing and showed that it can be accepted for the present trends of newer drug delivery dosage forms. The present study provides an approach to come up with a modern outlook to traditional folklore formulations without altering its therapeutic property which is highly essential in industrial applications and to meet consumer preferences and demands. Therefore, it is concluded that the developed chewable tablets may be better alternative to the conventional uses of the herbs.

Keywords: Chewable tablet, *Curcuma amada*, *Curcuma longa*, *Foeniculum vulgare*, Herbal
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INTRODUCTION

Herbal medicines are becoming increasingly popular and reliable in the global market as pharmaceutical scientists acquire a better understanding of the physicochemical and biochemical parameters and their evaluation by modern techniques.^[1] The demand for plant-based therapeutics is increasing in both developed and developing countries due to the growing recognition that these are natural products, easily biodegradable, non-narcotic, have no adverse side effects, and easily available at affordable prices. The World Health Organization estimates that 80% of the population of Asian and African countries presently uses herbal medicine for primary health care.^[2] One investigation of targeting preparation of formulations having digestive activity by focusing on these plants – *Curcuma longa* is commonly known as turmeric. Species of *Curcuma* are perennial rhizomatous herbs belonging to the family Zingiberaceae. *Curcuma* species have great importance for their medicinal value, *Curcuma* species plants also play a major role in the socioeconomic and culture. In the indigenous system of medicine, turmeric enjoys the reputation as a stomachic, blood purifier, useful in common cold, leprosy, intermittent fevers, dropsy, purulent ophthalmia, indolent ulcers, pyogenic infection,^[3] anti-inflammatory, antitumor, aromatic, stimulant, and carminative properties in native medicine. It is used as an external applicant in bruises, leech bites and is said to be anti-helminthic and anti-protozoan. *Foeniculum vulgare* is commonly called a fennel seed. *F. vulgare* has been enormously used in indigenous medicine for a large range of ailments. Its stem, fruit, leaves, seeds, and the whole plant itself are medicinally used in different forms in the treatment of a variety of diseased conditions. The composition procedure uses and application of

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F. vulgare are well documented in the common ethnobotanical literature.^[4] It also has a wide range of veterinary uses.^[5] *F. vulgare* is used in many parts of the world for the treatment of several diseases, for example, abdominal pains, antiemetic, aperitif, arthritis, cancer, colic in children, conjunctivitis, constipation, depurative, diarrhea, fever, gastritis, kidney ailments, laxative, liver pain, mouth ulcer, and stomachache. In the Ayurveda system of medicine, mango ginger (*Curcuma amada*), also known as Amra Haridra or Karpura Haridra, is famous for its medicinal values. It is used as a spice and also for pickling. Therapeutic value is remarkably shown in all or similar other members of genus *Curcuma* which are also in different digestive complaints. Its use gives relief in abdominal gas. It promotes appetite and improves digestive strength. Similar to ginger, it is expectorant and gives relief to cold and cough. Its use is also recommended for liver inflammation, joint pain, rheumatism, and inflammation due to injuries. The rhizomes are made into a paste and applied to sprains, bruises, and skin

diseases.^[6] Chewable tablets are a widely used pediatric dosage form.^[7] Successful tablet formulation development involves the careful selection of ingredients to manufacture a robust solid dosage form. Chewable tablets are made in such a way that can easily be broken and chewed easily in between the teeth before ingestion. These tablets are given to children who have difficulty in swallowing and to adults who dislike swallowing.^[8] The main aim of these tablets is to disintegrate smoothly in our mouth at an average period or we can also consume by without chewing chewable tablet characteristics mainly focus on having a smooth texture on disintegration, having pleasant taste no bitterness or unpleasant taste.^[9] Following all data and knowledge, the present work is designed to develop one digestive herbal formulation using *C. longa*, *C. amada*, and *F. vulgare*. Here, an attempt is made to convert this formulation into a carminative chewable tablet containing these three main ingredients in powder form in varying conditions.

MATERIALS AND METHODS

Collection and Drying of the Plant Material

The rhizome of *C. long* and *C. amada*, and seeds of *F. vulgare* were collected from Nagaon district, Assam, in the winter season in February 2019. Usually, the plant part (rhizome) of turmeric and mango ginger and seeds of fennel were collected as a whole and dried in shade. In fresh condition, it is then oven-dried at reduced temperature (40°C) to make suitable for grinding purpose. The seeds were crushed in the mixed grinder to a coarse powder. The coarse powder is then stored in an airtight container or polybags and kept in a cool, dark, and dry place for further. All other ingredients used were procured from Merck Ltd.

Determination of Physicochemical Parameters

In physicochemical evaluation, moisture content, determination of pH, and physical characteristics of crude powder help in understanding the pharmacopoeial standards of the drug. Physical constants were determined following Shah and Quadry (1996) and Kokate (1994).^[10,11]

Determination of Moisture Content

About 10 g of fresh crude powder was weight into a flat porcelain dish and subjected to hot air oven at 105°C for 1 h. The sample was then stand for cool and weight was taken by electric balance. This was repeated till constant weight was obtained and percentage of loss on drying was calculated with reference to the air-dried drug.^[10,11]

Determination of pH

The powder sample prepared from the able formulation was weighed about 5 g immersed in 100 ml of water in a beaker. The beaker was closed with aluminum foil and left behind for 24 h at room temperature. Later, the supernatant solution was decanted into another beaker and the pH of the formulations was determined using a calibrated pH meter.^[10,11]

Formulation of Chewable Tablet

Direct compression method

In this method of compression, all the ingredients were weighed separately. Turmeric powder, fennel seeds powder, mango ginger, sucrose, mannitol, black salt, citric acid, MCC, and methyl paraben were blended for 10 min in a mortar pestle. The above blend was then lubricated with magnesium stearate and talc for 2 min. The powder blend was evaluated for the flowing properties and was found to be good. The evaluated blend was compressed into tablets of 642.7 mg weight each. A minimum of 50 tablets was prepared for each batch. The manufacturing formula for the tablets is given in Table 1.

Wet Granulation Method

In this method, all the ingredients were separately weighed. Turmeric powder, fennel seeds powder, and mango ginger were blended for 10 min in mortar pestle. Then, a small amount of sucrose with distilled water was prepared separately in a test tube. The above blend was granulated with the sucrose solution and sifted using sieve no.16 and dried in a drier at the temperature of 40°C until the moisture of the mixture gets reduced. After drying, the dried granules were passed through sieve no. 30, and mannitol, MCC, methyl paraben, black salt, and citric acid required quantities were added and blended for 10 min in mortar pestle. A uniform paste of starch with water was prepared in a beaker. Then, the above dry mixture was granulated with binder solution (starch paste) and sieved using sieve no. 16 and dried in a drier at the temperature of 40°C until the moisture reduce down. Again, the dried granules were passed through sieve no. 30. All these granules were lubricated with magnesium stearate and talc for 2 min. The evaluated blend was compressed into tablets of 646.4 mg weigh each. A minimum of 50 tablets were prepared for each batch. The manufacturing formula for the tablets is given in Table 1.

Pre-Formulation Study of the Prepared Tablet

In the development of new dosage forms, the pre-formulation study is the prior step in the potential drug development. Following pre-formulation parameters were studied such as angle of repose, bulk density, tapped density, and compressibility indices.

Determination of Angle of Repose

The crude powder/granules were passed through a funnel fixed to a burette at a height of 4 cm. A graph paper was placed below the funnel on the table Leon *et al.*, 2009.^[11]

Table 1: Composition of the prepared chewable tablet

Ingredients (mg)	Wet granulation (mg)	Direct compression (mg)
Turmeric	12.5	12.5
Fennel	25	25
Mango ginger	50	50
Sucrose	50	50
Mannitol	300	300
MCC	100	100
Black salt	50	50
Citric acid	25	25
Starch (paste)	3.5	–
Methyl paraben	1.3	1.3
Mg. stearate	12.9	12.9
Talc	16.2	16
Total weight	646.4 g	642.7 g

Determination of Bulk Density

It is determined by transferring an accurately weighed amount of powder sample to the graduated cylinder with the aid of a funnel. The initial volume was noted. The ratio of weight of the volume it occupied was calculated.^[11]

Determination of Tapped Density

It is measured by transferring a known quantity 10 g of powder into a graduated cylinder and tapping it for a specific number of times. The initial volume was noted. The graduated cylinder was tapped continuously for a period of 10–15 min. The density can be determined as the ratio of mass of the powder to the tapped volume.^[11]

Determination of Carr's Index

It is the property of the powder to be compressed. Based on the apparent bulk density and tapped density, the percentage compressibility of the powder can be determined Pal *et al.*, 2014.^[11] A Carr's index >25 is considered to be an indication of poor flowability and below 15 of good flowability.

Determination of Hausner's Ratio

The ratio of tapped density to the bulk density of the powder is called Hausner's ratio.

Evaluation of Prepared Tablets

Physical characterization

The general appearance of tablets, its visual identity, and overall elegance are essential for consumer acceptance. The formulated chewable tablets were evaluated for size, shape, and organoleptic characters such as color, odor, and taste. The diameter and thickness of the tablets were measured using Vernier caliper scale.^[12]

Weight variation

Twenty tablets of each batch were selected at random and weighed individually and collectively on a digital weighing balance. Average weight was calculated from the total weight of all tablets. The weight of individual tablets was compared with the average weight. The difference in weight variation will show in percentage followed by permissible limits.^[13]

Hardness test

The hardness of the tablets was measured using Monsanto hardness tester. The values were expressed in kg/cm² Chauhan *et al.*, 2013.^[14]

Friability test

The friability of tablets was determined using Roche's friabilator. Six tablets were weighed and placed in friabilator and rotated at 25 rpm for 4 min. Then, the tablets were taken out, dusted, and reweighed. The percentage friability of the tablets was calculated.^[13]

Disintegration test

The disintegration test is a measure of the time required under a given set of conditions for a group of tablets to disintegrate into particles which will pass through a 10 mesh screen. The disintegration test is carried out using the disintegration tester which consists of a basket rack holding six plastic tubes, open at the top and bottom, the bottom of the tube is covered by a 10 mesh screen. The basket was immersed in a bath of suitable liquid held at 37°C, preferably in a 1 L beaker. For compressed uncoated tablets, the testing fluid was usually water at 37°C. If one or two tablets fail to disintegrate, the test was repeated using 12 tablets. The individual drug monographs specify the time disintegration must occur to meet the pharmacopoeial standards.^[12,15]

RESULTS AND DISCUSSION

This study was an attempt to develop a formulation of chewable tablets by direct compression method and wet granulation method using *C. longa* powder, *C. amada* powder, and *F. vulgare* powder. In both the methods, the formulated tablets were prepared by adding additives and preservatives to improve the stability of the tablets. The physicochemical analysis, pre-compression and post-compression studies were tested and compared with the studies performed on chewable tablets and it showed within normal limits which are discussed below.

Physicochemical analysis of the individual drugs and formulation has been done to evaluate the quality and purity of the conformation (Tables 2 and 3). The pH of *C. longa* powder and *F. vulgare* powder was found to be 6.46 and 5.69, respectively. The result of moisture content for *C. longa* powder and *F. vulgare* powder was found to be 11.53 % and 2.9%, respectively (Tables 2 and 3). These findings resemble with the studies of pH and moisture content studied by Lee *et al.*, 2013,^[16] Dosoky *et al.*, 2018,^[17] and Badrul *et al.*, 2011,^[18] Santhosh *et al.*, 2012^[19] and it showed that the values were within the normal limits.

Table 2: Physicochemical parameters of *C. longa*

Parameter	Result
pH	6.46
Moisture content (w/w)	11.53
Foreign matter	Nil

C. longa: *Curcuma longa*

Table 3: Physicochemical parameters of *F. vulgare*

Parameter	Result
pH	5.69
Moisture content (w/w)	2.9
Foreign matter	Nil

F. vulgare: *Foeniculum vulgare*

Table 4: Pre-compression studies of the powder blend (Mean±SD, n=3)

Parameter	Powder
Angle of repose (°)	32.56±3.56
Bulk density (gm/cm ³)	0.57±0.03
Tapped density (gm/ml)	0.68±0.05
Carr's index (%)	15.5±2.8
Hausner's ratio	1.18±0.5
Type of flow	Good

Table 5: Pre-compression study of granules (Mean±SD, n=3)

Parameter	Granules
Angle of repose (°)	28.065±0.46
Bulk density (gm/cm ³)	0.39±0.1
Tapped density	0.46±0.3
Carr's index (%)	14.98±3.46
Hausner's ratio	1.17±0.04
Type of flow	Excellent

Table 6: Post-compression studies of the prepared tablet (evaluation of tablets) (Mean±SD, n=3)

Parameter	Observation
Color	Light yellow
Odor	Odorless
Taste	Salty-sour-sweet
Shape	Round flat plain both sides
Thickness (mm)	7
Diameter (mm)	10
Weight variation (mg)	644±8.5
Friability (%)	3.98±0.32
Hardness test (kg)	2.75±0.76
Disintegration test (s)	150.33±11

Table 7: Post-compression studies of the prepared tablet (evaluation of tablets) (Mean±SD, n=3)

Parameter	Observation
Color	Light yellow
Odor	Odorless
Taste	Salty-sour-sweet
Shape	Round flat plain both sides
Thickness (mm)	7
Diameter (mm)	10
Weight variation (mg)	648.3±9.49
Friability (%)	0.32±0.06
Hardness test (kg)	4.83±0.98
Disintegration test (min)	72.83±19.45

In the pre-compression studies, the granules and powder thus prepared were evaluated which were shown in Tables 4 and 5 respectively. Angle of repose of powder and granules was found to be 32.56 ± 3.56 and 28.065 ± 0.46 , respectively. Angle of repose ≤ 30 indicates excellent flow property so it was concluded that the granules prepared by wet granulation had excellent flow property. The bulk density value for powder and granules was found to be 0.57 ± 0.03 and 0.39 ± 0.01 , respectively. The tapped density value was found to be 0.68 ± 0.05 in powdered form and 0.46 ± 0.3 in granulated form. The Hausner's ratio for powder and granules was found to be 1.18 ± 0.05 and 1.17 ± 0.04 , respectively, which represents good flowability because Hausner's ratio < 1.25 represents good flowability.

The value of % compressibility for powder was found to be $15.5 \pm 2.8\%$ while for granules which was found to be $14.98 \pm 3.46\%$ and it indicates excellent flowability than powder. These values were compared with the study performed by Nagaich *et al.*, 2014, and it was observed that granules formulation of tablet has advantage over its counterpart, that is, powder formulation of tablets. In the pre-formulation study, it was observed that all the parameters checked for the ingredients were within standard range. Thus, the ingredients were processed for preparing tablets following IP.

In post-compression studies, the organoleptic properties such as color, odor, taste, and shape were observed. The general

appearance of the tablet for both powder (Table 6) and granules (Table 7) were found to be round in shape, light yellow in color, smooth texture, and odorless. The thickness and diameter were found to be 7 mm and 10 mm.

During the evaluation of tablets, it was found that all the prepared batches of tablets were within the standard range of chewable tablet parameters. Using Monsanto hardness tester, the strength of the tablets was tested. All the tablets showed good hardness. Direct compression had a minimum hardness (2.75 ± 0.76 kg) while wet granulation had a maximum hardness (4.8 ± 0.98 kg). Tablet showed different weight variation within the given limits. The percentage of weight variation for direct compression and wet granulation method was found to be 644.3 ± 8.5 and 648 ± 9.49 , respectively. Friability was found to be for direct compression and wet granulation method $3.98 \pm 0.32\%$ and $0.32 \pm 0.06\%$, respectively. The disintegration time required for complete chewing ranges from direct compression and wet granulation 150.33 ± 11 s and 72.82 ± 19.45 min, respectively. After evaluation of all the tablets and comparing with the values obtained by Achhra and Pawar, 2017,^[20] and Pal *et al.*, 2013,^[11] it was observed that the values evaluated by wet granulation method in terms of hardness, disintegration ability, friability, and uniformity are within the acceptable ranges in comparison to direct compression method and meeting all official limits.

Thus, considering these values and following the IP, we found that the chewable tablet that was prepared without altering its therapeutic property was satisfactory with general characteristics of tablet, namely, hardness, disintegration time, and friability and weight variation. The formulation was tested for common people with respect to taste; odor and time required for complete chewing and showed that it can be accepted for the present trends of newer drug delivery dosage forms.

CONCLUSION

Compressed tablets are the most widely used solid dosage form so they must satisfy a number of physical requirements in terms of hardness, friability, and uniformity. Both wet granulation and direct compression method could be used successfully for developing tablet formulation by incorporating turmeric, fennel seeds, and mango ginger. Hence, the present study recommends the current needs to generate similar data for different herbal drugs or Ayurvedic formulations, which is highly essential in industrial applications and to meet consumer preferences and demands. Therefore, it is concluded that the developed chewable tablets may be better alternative to the conventional uses of the herbs. Moreover, this work may enlighten the field of herbal technology in future.

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