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Research Article

Formulation And Evaluation of Tablets Containing Fennel and Ginger for The Treatment of Gastroesophageal Reflux Disease

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ABSTRACT

Background: For the purpose of treating gastroesophageal reflux disease, tablets containing powdered ginger and fennel were formulated using Effervescent agent/gas producing agent. Tablets enhance medication bioavailability and enable local drug distribution to the stomach when formulated using effervescent agent which prolongs their gastric residence duration. Methods: Using the direct compression method, tablets containing HPMC E50 and HPMC K4M, talc, magnesium stearate, powdered fennel and ginger, and sodium bicarbonate (gas producing agent) were prepared. Physical characteristics such as thickness, hardness, friability, weight uniformity, buoyancy time, and disintegration test were assessed for the formulations. Results: All formulations had thicknesses between 3.0-3.15 mm and bulk and tap densities of 0.575-0.590 and 0.650-0.680, respectively. The range of hardness was 3.5 to 4.0 kg/cm². Every formulation met the USP standards for weight uniformity and friability. All tablet formulations with effervescent agent had disintegration time in range of seven minutes and all tablet formulations without effervescent agent had disintegration time in range of three-to-five minutes during the investigation. Conclusion: A tablet containing powdered fennel and ginger has shown promising results in treating GERD symptoms. These natural substances, known for their anti-inflammatory, anti-spasmodic, and digestive properties, are effective, stable, and bioavailable in reducing heartburn and acid reflux. The combination may offer a safer alternative to conventional prescription treatments, but further clinical trials and research are needed.

INTRODUCTION

1.1.Gastroesophageal Reflux Disease (GERD)

Reflux of stomach contents into the oesophagus is a common gastrointestinal illness, affecting 20% of US patients. It negatively impacts quality of life and causes significant financial burdens (1).

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GERD is caused by various mechanisms, including intrinsic, structural, or both, disrupting the esophagogastric junction barrier, exposing the esophagus to acidic gastric contents (2). Common symptoms include heartburn and regurgitation, but it can also manifest with extra-esophageal symptoms like asthma, laryngitis, chronic cough, chest pain, or tooth erosions. GERD can be categorized into Barrett esophagus (BE), erosive esophagitis (EE), and non-erosive reflux disease (NERD). NERD affects 60-70% of patients, followed by EE and BE. Treatment with proton pump inhibitors and lifestyle changes has been successful, but the increasing prevalence of medically refractory GERD necessitates a customized approach.

1.1.1. Epidemiology

About 20% of adults in western culture suffer from GERD, making it one of the most prevalent gastrointestinal conditions (3). The prevalence in the US ranges from 18.1% to 27.8%. However, with more people accessing over-the-counter acid, fewer people may need to take drugs, potentially increasing the genuine prevalence of GERD (4). Males are slightly more likely to have GERD than women, with a slightly higher pooled prevalence of symptoms. Women with GERD symptoms are more likely to develop NERD compared to men. Barrett's esophagus is more common in males with chronic GERD symptoms (23%) (5,6).

1.2. Ginger

Ginger, a medicinal herb and nutritional spice, has been used for thousands of years to treat various illnesses and flavour cuisine. It contains hundreds of chemicals and metabolites, with the most investigated components being gingerols and shogaols (7). The preparation and source of the ginger rhizome affect each component's content. Ginger's anti-inflammatory, antioxidant, anticancer, and antiulcer properties have been demonstrated in scientific research. The Zingiberaceae family includes ginger, which has been used as a spice worldwide. The main components of ginger rhizomes include terpenes, lipids, carbohydrates, and phenolic chemicals. Ginger contains phenolic chemicals like gingerol, paradols, and shogaol, as well as terpene components like zingiberene, β-bisabolene, α-farnesene, β-sesquiphellandrene, and α-curcumene. Zingiberene and bisabolene give ginger its distinct smell, while the volatile oils of gingerols and shogaols give it its strong flavor. Ginger also contains amino acids, raw fiber, ash, protein, phytosterols, vitamins, and minerals. Other compounds found in ginger rhizome include 6-paradol, 1-dehydrogingerdione, 6-gingerdione and 10-gingerdione, 4-gingerdiol, 6-gingerdiol, 8-gingerdiol, and 10-gingerdiol, and diarylheptanoids (8).

1.2.1. Phytochemical composition of Ginger

Ginger, a medicinal herb and nutritional spice, has been used for thousands of years to treat various illnesses and flavor cuisine. It contains hundreds of chemicals and metabolites, with the most investigated components being gingerols and shogaols. The preparation and source of the ginger rhizome affect each component's content. Ginger's anti-inflammatory, antioxidant, anticancer, and antiulcer properties have been demonstrated in scientific research (9).

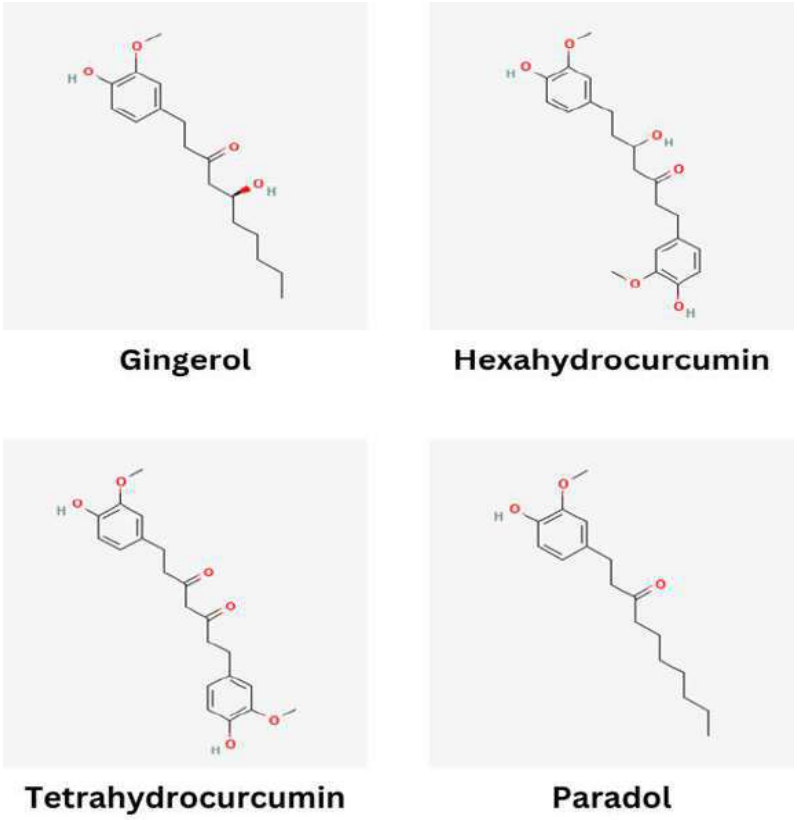

Fig.1. Bioactive components of ginger obtained from PubChem

The Zingiberaceae family includes ginger, which has been used as a spice worldwide. The main components of ginger rhizomes include terpenes, lipids, carbohydrates, and phenolic chemicals. Ginger contains phenolic chemicals like gingerol, paradols, and shogaol, as well as terpene components like zingiberene, β-bisabolene, α-farnesene, β-sesquiphellandrene, and α-curcumene. Zingiberene and bisabolene give ginger its distinct smell, while the volatile oils of gingerols and shogaols give it its strong flavor. Ginger also contains amino acids, raw fiber, ash, protein, phytosterols, vitamins, and minerals (10). Other compounds found in ginger rhizome include 6-paradol, 1-dehydrogingerdione, 6-gingerdione and 10-gingerdione, 4-gingerdiol, 6-gingerdiol, 8-gingerdiol, and 10-gingerdiol, and diarylheptanoids.

1.3. Fennel

Fennel is a medicinal and aromatic herbaceous plant native to the Mediterranean region. Its fruits, leaves, and bulbs are used in various dishes and medicine worldwide. The essential oil (EO) of fennel fruits, including seeds, is known for its various health benefits. The phytochemicals found in fennel fruit have been shown to be effective in various fields, including insecticide, memory enhancer, anti-aging, anti-cancer, antibacterial, antifungal, antithrombotic, anti-inflammatory, chemo-preventive, hepatoprotective , and anti-aging. The quality of fennel essential oil depends on factors such as cultivar, fruit age, environment, and farming methods (11). Fennel has been used in medicine and cooking for centuries, with its larger base used as a vegetable, leaves used in cooking, and seeds used to extract essential oils and as a spice. It is also used in dyes, with pollen being the most powerful form. Fennel is believed to have been cultivated in India since 2000 BC and

is mentioned in the pagan Anglo-Saxon Nine Herbs Charm. It is native to southern Europe and the Mediterranean region but has spread to northern Europe, Cyprus, the United States, southern Canada, Asia, the Far East, and Australia (12,13).

1.3.1. Phytochemical composition of Fennel

Fennel is a plant with various components, including seeds, roots, leaves, and fruit. It contains 42.3% carbohydrates, 9.5% protein, 10% fat, 13.4% mineral, 18.5% fiber, and 6.3% water. Fennel leaves contain vitamins and minerals like calcium, potassium, salt, iron, phosphorus, thiamine, riboflavin, niacin, and vitamin C (14). Fennel fruit oil, stored in the seeds, makes up 10–12% of fruits. The fragrant quality of fennel comes from its essence. Fennel essential oil contains over 30 distinct terpene compounds, with 50–80% trans-anethole and 5% limonene being the most important. Fennel also contains phenolic compounds, such as flavonoids, hydroxycinnamic acids, tannin, and coumarin (15,16). Fennel's phenolic component helps reduce the impacts of conditions like cancer, inflammation, and cardiovascular diseases linked to oxidative stress. The main naturally occurring plant-based phytoconstituents are tocopherols, carotenoids, terpenoids, polyphenolics, and ascorbates, which have been investigated and used as effective chemotherapeutic medications to treat oxidative stress conditions.

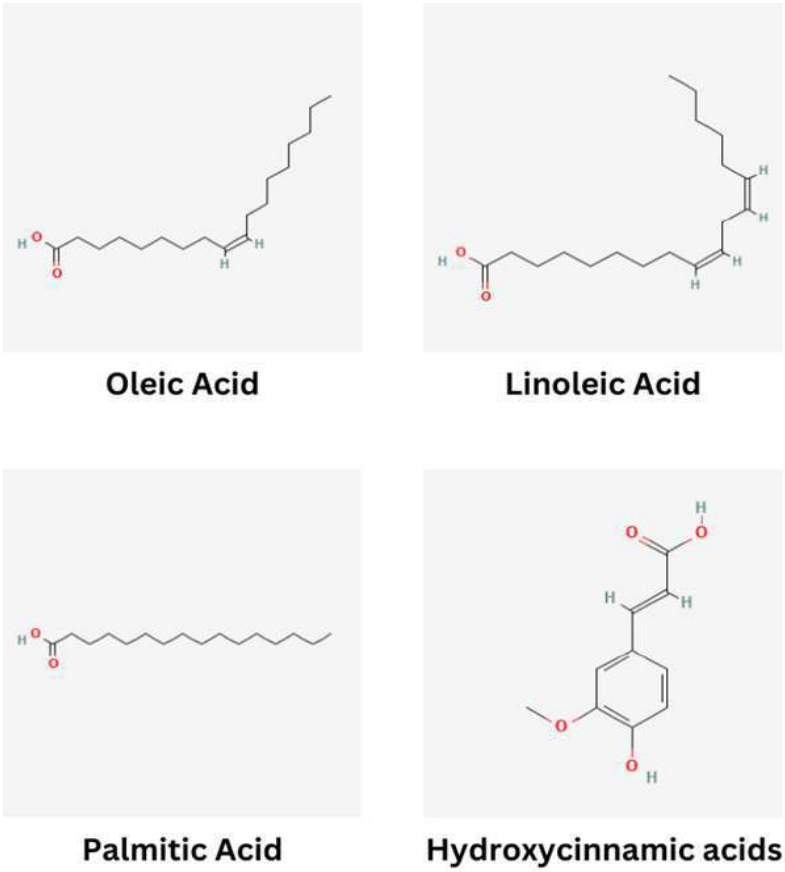

Fig.2. Bioactive components of fennel obtained from PubChem

2. MATERIAL AND METHODS

2.1. MATERIAL

Ginger (*Zingiber officinale*) and Fennel (*Foeniculum vulgare Mill.*) was Obtained from the local market. Collected from the local area of Akurdi.

Fig.3. Ginger And Fennel from The Local Market

- The Excipients (Table 1) were collected from the laboratory of Dr. D.Y Patil College of Pharmacy, Akurdi, Pune.

Table No. 1. List Of Material Used

Sr No.	Material Used
1	Ginger Powder
2	Fennel Powder
3	HPMC E50
4	HPMC K4M
5	Carbopol 940
6	Sodium bicarbonate
7	Magnesium sterate

2.2. Instruments used

The Instruments used for the formulation and evaluation are given in Table 2.

Table No. 2. List Of Instruments Used

Sr No.	Instruments Used
1	Electronic Weighing balance
2	Sieve shaker
3	Mortar Pestle
4	Hot air oven
5	Tablet Punching Machine
6	Disintegration Apparatus
7	Friabilator

2.3. Formulation of Tablets

Formulations for fennel and ginger were made through direct compression. HPMC E50, HPMC K4M, and Carbopol 940 were chosen as excipients, and the dosage of ginger and fennel was set at 250 mg (125 mg of ginger and 125 mg of fennel, respectively). Magnesium stearate served as the lubricant and sodium bicarbonate (NaHCO3) as the effervescent agent. A tablet-punching machine was used to compress the formulation mix into a tablet. The hardness of the tablet was maintained at 4 kg.

Table no. 3. Formulation Table

Sr No	Ingredients	F1 (mg)	F2 (mg)	Role
1	Ginger Powder	125	125	API
2	Fennel Powder	125	125	API
3	HPMC E50	120	90	Swelling agent
4	HPMC K4M	60	90	Rate controlling polymer
5	Carbapol 940	60	60	Thickening and Suspending agent
6	Sodium bicarbonate	60	60	Effervescent agent

7	Magnesium sterate	5.5	5.5	Lubricant

Fig.4. Prepared tablets containing both Fennel and Ginger

3. Evaluation of the Tablets

3.1. Pre-Compression Studies

3.1.1. Angle of Repose:

The fixed funnel method, which involved measuring the powder pile's dimensions after letting 30 g of powder mass pass, was used to calculate the angle of repose. via a funnel. By applying the following formula and basing it on the diameter of the created powder pile, we could calculate the angle of repose.

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

Excellent	<25
Good	25-30
Moderate	30-40
Poor flow	>40

3.1.2. Bulk Density:

The mass (M) of the powder filling a known volume (Vo) is known as the bulk density, which is often stated in g/ml. Using a funnel, the granules are transferred into a 50 ml measuring cylinder. The unsettled apparent volume is the volume that the granules occupy. After that, bulk density is computed using a certain formula

Bulk Density = Weight of powder / Bulk Volume

3.1.3. Tapped Density:

Measured by employing a tester to record volume changes after 500 taps on a powder-filled cylinder.

$$\rho t = m/Vt$$

3.1.4. Carr's Index:

Shows the propensity for arch creation and ease of failure.

CI is equal to ρt - ρbulk / ρt × 100.

Carr's Index= [(Tapped Density - Bulk Density) /Tapped Density] x 100

Excellent	5 - 15
Good	12 – 16
Fair	18 – 21
Slightly Poor	23 – 28
Poor	28 – 35
Very poor	35 – 38
Extremely poor	> 40

3.1.5. Hausner Ratio:

Hausner's ratio (ρt / ρbulk) uses interparticle friction to forecast flow. Higher ratios for cohesive powders and lower ratios for free-flowing powders.

Hausner's Ratio is equal to ρt + ρbulk.

Hausner Ratio = Tapped Density / Bulk Density

Excellent	1.00 – 1.11
Good	1.12 – 1.18
Fair	1.19 – 1.25
Passable	1.26 – 1.34
Poor	1.35 – 1.45

Very poor	1.46 – 1.59
Extremely poor	> 1.60

3.2. Post-compression parameters

3.2.1 Thickness of tablet:

A digital screw gauge micrometer was used to measure the thickness of ten randomly selected tablets from each formulation. They computed the mean SD values.

3.2.2. Hardness test:

The force was applied when the tablet was sandwiched between two Monsanto hardness tester anvils. The pressure at which breakdown occurred was measured and recorded using the indicated scale of the tablet takes place.

3.2.3. Weight Variation:

The force was applied when the tablet was sandwiched between two Monsanto hardness tester anvils. The pressure at which breakdown occurred was measured and recorded using the indicated scale of the tablet takes place.

3.2.4. Friability:

The Roche friabilator was filled with twenty weighted pills, and the device was rotated for four minutes at 25 rpm. The pills were dedusted and weighed once more following revolutions. The formula was used to calculate the % friability

3.2.5. Disintegration test:

The Disintegration Test involves immersing pills in intestinal or stomach fluid at 37±2°C in glass tubes with mesh screens. Tablets must completely dissolve and pass through a 10-mesh screen within a predetermined amount of time. They also move up and down to prevent floating with plastic disks. When the water bath reaches the proper temperature, tablets are added to the device.

4. RESULT

4.1. Pre-compression

4.1.1. Angle of repose

The angle of repose of both formulations F1 and F2 was found to be 28.34 ± 0.12 and 29.56 ± 0.17.

4.1.2. Bulk Density

The Bulk density of both formulations F1 and F2 was found to be 0.576 ± 0.13 and 0.584 ± 0.14.

4.1.3. Tapped Density

The tapped density of both formulations F1and F2 was found to be 0.652 ± 0.16 and 0.662 ± 0.17.

4.1.4. Carr's Index

The Carr's Index of both the formulations F1 and F2 was found to be 11.656 ± 0.11 and 12.670 ± 0.13.

4.1.5. Hausner Ratio

The Hausner Ratio of both the formulations F1 and F2 and F3 was found to be 1.131 and 1.141.

Formulations	Angle of repose (θ)	Bulk Density	Tapped Density	Carr's Index	Hausner Ratio
F1	28.34 ± 0.12	0.576 ± 0.13	0.652 ± 0.16	11.656 ± 0.11	1.131
F2	29.56 ± 0.16	0.584 ± 0.14	0.662 ± 0.17	12.670 ± 0.13	1.141

4.2. Post-Compression

4.2.1. Thickness of Tablet

The thickness of the tablets was found to be 3 ± 0.11 and 3 ± 0.13 for F1 and F2, the thickness of the tablet depends upon the size of the die punch.

4.2.2. Hardness

The hardness of the tablets was found to be 4 ± 0.3 and 4 ± 0.5 for F1 and F2, In which hardness of the tablet depends upon the punching force of the machine.

4.2.3. Weight Variation

The weight variation of the tablets was found to be 0.311 ± 0.009 and 0.314 ± 0.012, for F1 and F2, which is done by taking the weight of 20 tablets.

4.2.4. Friability

The Friability of the tablets was found to be 0.150 ± 0.04 to 0.165 ± 0.03, which is in an acceptable limit that is less than 1%.

4.2.5. Disintegration time

The disintegration of the tablets was found to be 420 ± 3.11 to 435± 2.28.

Formulations	Thickness (mm)	Hardness (kg/cm^2)	Weight Variation (g)	Friability (% wt. Loss)	Disintegration Time (sec)
F1	3 ± 0.11	4 ± 0.3	0.311 ± 0.009	0.154 ± 0.04	423 ± 3.11
F2	3 ± 0.13	4 ± 0.5	0.314 ± 0.012	0.162 ± 0.03	431 ± 2.28

5. CONCLUSION

In terms of efficacy, the development and testing of a tablet comprising powdered fennel and ginger for the treatment of GERD produced positive results. Fennel and ginger have long been used for their anti-inflammatory, anti-spasmodic, and digestive properties, which may help reduce GERD symptoms. When combined in the right dosage form, these natural substances may offer a comprehensive strategy to managing GERD. The results of the formulation and evaluation demonstrate that the combination of fennel and ginger powders in the chosen dosage form is effective, stable, and bioavailable in reducing the symptoms of heartburn and acid reflux associated with GERD. With potential benefits like improved digestion, less inflammation, and esophageal muscle relaxation, the combination of these natural components may also provide a safer alternative to conventional prescription treatments. In conclusion, further clinical trials and long-term research are needed to fully evaluate the formulation's therapeutic advantages and optimal dosage, which may prove to be a helpful supplement to the treatment of GERD

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