Formulation and Evaluation of Herbal Floating Tablet for the Treatment of Gastric Ulcer

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Abstract:

Introduction: The goal of the current study was to create and assess herbal floating tablet that would treat stomach ulcers. Many of the medications that are currently on the market have either been directly or indirectly produced from plants, which have long been considered an experimental source of medication. Different diseases are treated with plant extracts. There are so many chemically active components in plants that can be used to cure so many different diseases. Herbal floating tablet increase bioavailability, extend the period that pharmaceuticals stay in the stomach, and make it easier to administer medications locally to the stomach. For the treatment of gastric ulcers, floating tablets with alcoholic extract of amla as the primary active ingredient were created in this study.

Method: The herbal floating tablet was made using the direct compression method and contains alcoholic extracts of amla, aqueous extracts of ginger and fenugreek, psyllium husk, HPMC K100M, sodium bicarbonate, talc, and magnesium stearate. Additional evaluation tests for the herbal floating tablet include those for hardness, thickness, diameter, weight uniformity, and buoyancy duration. The use of buoyancy time improved the formulation. The tablet were made using the direct compression process and contained alcoholic extract of amla, aqueous extract of ginger and fenugreek, psyllium husk, HPMC K100M, sodium bicarbonate, talc, and magnesium stearate. For gastro retentive drug delivery systems, a combination of psyllium husk, sodium bicarbonate, and HPMC K100M can prove promising.

Keyword: Herbal floating tablet, amla, fenugreek, buoyancy time, HPMC K100M, Psyllium husk, ginger, Gastric ulcer.

1.Introduction:

Due to factors including patient compliance, convenience of administration, and formulation flexibility, oral medication delivery is by far the preferred method of drug delivery. Oral dosage formulations have advanced significantly, going from instant release to site-specific delivery. Gastro retentive dosage forms dramatically lengthen the time that a medicine may be released, extending the time between doses and improving patient compliance. Due to the significant therapeutic benefits of oral controlled release dosage forms, including their simplicity of administration, patient compliance, and formulation flexibility, they have been developed throughout the past three decades. This method, however, has a number of physiological challenges, including the inability to contain and identify the controlled drug delivery system within the appropriate region of the gastrointestinal tract (GIT) because of fluctuating stomach emptying and motility. Drugs' gastric residence times can be greatly extended by gastro retentive dose forms, which can stay in the gastric region for several hours. Long-term stomach retention
increases bioavailability, lowers drug waste, and boosts the solubility of medications that are less soluble in high pH environments. Effervescent and non effervescent floating drug delivery systems are examples of gastro retentive dosage forms. Having peptic ulcer disease is a major medical issue.

Each year, there are over 500,000 new cases recorded, affecting 5 million people in the United States alone. Interestingly, people who were born in the middle of the 20th century have the highest risk of developing peptic ulcer illness. With the peak incidence happening between the ages of 55 and 65, ulcer disease has evolved into a condition that primarily affects the elderly population. Gastro retentive dosage forms significantly extend the period of time, over which drug may be released and thus prolong dosing intervals and increase patient compliance. Such retention systems are important for those drug that are degraded in the intestine like antacids or certain antibiotics, enzymes that act locally in the stomach. This system can be retained in the stomach and assist in improving the oral sustained delivery of drugs that have an absorption window in a particular region of the gastrointestinal tract, thus ensuring optimal bioavailability. In addition to increasing bioavailability and reducing drug waste, prolonged stomach retention also increases the solubility of drugs that are less soluble in high PH environments. Floating medication system dosage forms are examples of gastro-retentive dose forms.

Amla (Emblica officinalis) is revered in the ancient Indian medical system known as Ayurveda. Amla fruit is frequently used in Ayurvedic medicine, and it is said to strengthen the body's defences against illness. It plays a positive function in the treatment of degenerative conditions like cancer, diabetes, ulcers, anaemia, and heart problems, and it is a key ingredient in hepatoprotective formulations. One of the richest sources of vitamin C, amino acids, and minerals is amla, which is very nutrient-dense. It has many different chemical components, including tannins, alkaloids, and phenols. Among all hydrolyzable tannins, Emblicanin A and B, gallic acid, and ellagic acid are found to have biological action. Names used informally: English: Emblic myrobalan, Sanskrit: Aamalaki, Hindi: Amla, Kannada: Nelli Kayi.
herbs. Ginger, also known as sunthi in Ayurveda, is an essential component of the Indian system of medicine known as Ayurveda (Hrdayam of Srimadvaagbhatt, 1999). As well as lowering cholesterol and treating arthritis, it was used to prevent excessive blood clotting in arteries and veins. Ginger is a spicy, dry, and warming herb that is used to treat illnesses brought on by cold and wet weather in Traditional Chinese Medicine (TCM). It was also used to cure respiratory problems, rheumatism, baldness, toothaches, and nausea as well as blood disorders, gastrointestinal problems and snakebite.

Figure no.2. Ginger or Zingiber officinale Roscoe

The seeds and leaves of fenugreek have been found to have antioxidant qualities, making it one of the earliest therapeutic herbs to have been used in written history. One of the main plant species consumed by humans is fenugreek. It supplies the body with natural dietary fibre and other essential nutrients. Both cuisine and the Ayurvedic medical system use its leaves and seeds. Popular spice fenugreek is aromatic and tasty, and it has both culinary and medical uses. Fenugreek has a potent spicy flavour and a sweet flavour like to seasoning. "Kasuri methi" is well known for its incredible scent and is often utilised in food preparations.

Figure no.3. fenugreek
2. Material and Method:

Plant components were obtained from Plant nursery and local market of Yawatmal including Amla fruits, ginger rhizomes, fenugreek seeds, and psyllium husk. Other ingredients like magnesium stearate, talc, HPMC K 100M, sodium bicarbonate.

2.1. Preparation of extracts:

Preparation of Amla extract:

The fresh fruit of amla had been collected from the plant nursery. Fruits were cleaned with deionized water after the seeds were removed, and then dried in an oven at 40-45°C for 3-4 days until weight became stable. The 15 g of dried amla pulp was ground, soaked in 50 ml of 100% ethanol, and then placed in a 250 ml sterile conical flask for 24 hours at 37 °C with 120 rpm of shaking. Whatman filter paper No. 1 was used to filter the material, and a 0.22 member was used to sterilize it. The obtained filtrates were kept in separate storage.

Preparation of Ginger extract:

Ginger was collected from the local market. Rhizomes of ginger were cleansed, rinsed, dried by air drying, and grounded to a coarse powder. 10 gm of powder was defatted using hexane in Soxhlet apparatus, 1 gram of the defatted powder was added to 10 ml of distilled water, heated for 5 minutes, cooled, then centrifuged at 1000 rpm for 10 minutes to separate the clear solution, which is known as the ginger aqueous extract.

Preparation of Fenugreek extract:

The fenugreek seed was collected from the local market and ground into coarse powder and then boiled with water, and mucilage was separated out.

2.2. Formulation of tablet:

According to the recipe found in Table No. 1, all items were put through Sieve No. 80 and precisely weighed using an electronic balance. Talc and magnesium stearate were then included with the mixture after all the ingredients had been well blended in a mortar and pestle to create a consistent tablet blend. Next, the tablet mixture was individually weighed in accordance with a formula and crushed into tablets using a single punch tablet machine in accordance with a different formula.

<table>
<thead>
<tr>
<th>Sr. no.</th>
<th>Ingredients</th>
<th>F1 (mg)</th>
<th>F2 (mg)</th>
<th>F3 (mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Amla extract</td>
<td>200</td>
<td>200</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>Ginger extract</td>
<td>30</td>
<td>30</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>Fenugreek extract</td>
<td>20</td>
<td>20</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>Total active ingredients</td>
<td>250</td>
<td>250</td>
<td>250</td>
</tr>
<tr>
<td>2</td>
<td>Isabgol husk</td>
<td>75</td>
<td>100</td>
<td>125</td>
</tr>
</tbody>
</table>
2.3. Evaluation of Floating Tablet:

Vernier calipers were used to measure the diameter and thickness of the prepared floating tablets. Monsanto's hardness tester was used to gauge the tablets' hardness. In a Roche friabilitor, the friability was evaluated. The average weight of 20 tablet from each formulation was calculated.

**Diameter and Thickness** - Using Vernier Calipers diameter and thickness of each tablet were measured and noted.

**Hardness** - The tablets were evaluated using a Monsanto hardness tester. The hardness of 6 tablets were checked of each formulation and noted.

**Friability**: Friability was determined by using a Roche friabilitor.

**Weight variation test**: Twenty tablets from each formulation were weighed and their average weight was determined.

**Buoyancy time**: Measurements were made of the period of time between the introduction of the dose form and the time at which it becomes buoyant on a simulated stomach fluid. The total amount of time a pill stayed on the surface was calculated (TFT), together with the time it took for the dosage form to emerge on the medium's surface (also known as the floating lag time or buoyancy lag time).

3. DISCUSSION:

Three different batches, designated as F1, F2, and F3, were created as gastro-retentive herbal floating tablets. These formulations' physical evaluations are shown in Table No. 2. Additional measurements of diameter, thickness, hardness, weight uniformity, and buoyancy time were made, and the results are displayed in Tables Nos. 3, 4, 5, and 7 in the appropriate order. The polymer's swelling ability, density, and gas-generating agent all play a role in the floating medication delivery system (8). Table (7) displays the formulation's buoyancy time. All of the formulations' floating lag times (FLTs) were discovered to be under 2 minutes.

4. CONCLUSION:

Amla extract herbal floating tablet were created utilising talc, sodium bicarbonate, magnesium stearate, HPMC K100M, and isabgol husk. For several physiochemical assessments of tablets, such as tablet dimensions, hardness, uniformity of weight, friability, and buoyancy duration, the range of the prepared tablets was within acceptable bounds. Conclusion: Isabgol husk, sodium bicarbonate, and HPMC K100M can work together to create a promising polymer for gastrointestinal drug delivery systems. It is possible to create floating amla extract tablet to extend the time the medication spends in the stomach.
and boost its absorption. The findings point to a promising potential for floating tablets containing an alcoholic extract of amla as a substitute for the traditional dose form.

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