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FORMULATION, DEVELOPMENT AND EVALUATION OF HERBAL EFFERVESCENT TABLET

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ABSTRACT: The main advantages of effervescent tablets are quick production of solution. Thus, it is faster and better to absorb. Effervescent tablets were designed to produce solutions that release carbon dioxide simultaneously. Usually, these tablets are prepared by compressing the active ingredients. Effervescent technique can be used as alternate to develop a dosage form which can accelerate drug disintegration and dissolution, is usually applied in quick release preparations. Along with the development of new pharmaceutical technique, effervescent tablet is more and more extensively to adjust the behavior of drug release.

KEYWORDS: Beal, peptic ulcer, effervescent, herbal medicine, Aegle marmelos.

INTRODUCTION: Peptic ulcers are open sores that form in the stomach lining and upper part of the intestine. The most common symptom of peptic ulcer is stomach pain.

Peptic ulcers include:

- Gastric ulcers that occur on the inside of the stomach
- Duodenal ulcers that occur on the inside of the upper portion of your small intestine (duodenum)

The most common causes of peptic ulcers are Helicobacter pylori (H. pylori) infection and long-term use of nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen (Advil, Motrin IB, others) and naproxen sodium (Aleve).

Peptic ulcers occur when acid in the digestive tract eats away at the inner surface of the stomach or small intestine. The acid can create a painful open sore that may bleed.

Your digestive tract is coated with a mucous layer that normally protects against acid. But if the amount of acid is increased or the amount of mucus is decreased, you could develop an ulcer.

Risk factors

In addition to having risks related to taking NSAIDs, you may have an increased risk of peptic ulcers if you:

- Smoke. Smoking may increase the risk of peptic ulcers in people who are infected with H. pylori.
- Drink alcohol. Alcohol can irritate and erode the mucous lining of your stomach, and it increases the amount of stomach acid that's produced.
- Have untreated stress.

Symptoms

Burning stomach pain

Feeling of fullness, bloating or belching

Intolerance to fatty foods

Heartburn

Nausea

Pathogenesis of Peptic Ulcer:

H. Pylori Bacteria or Risk factors (NSAID, Gastric Acid, Alcohol)

⇓

Increased acidity activities H. Pylori

⇓

H. Pylori toxins damage mucosa, formation of ammonia (ammonia is a cytotoxic)

⇓

Mucosa inflammation

⇓

Peptic ulcer

Bael Fruit:

Properties of Bael:

Bael has various properties, and it might play a role to help with many diseases. It might possess the potential properties such as:

- It may act as an antidiarrheal agent
- It may be an antimicrobial (effectively kills various microorganisms)
- It may have radioprotective potential (protects the body from harmful effects of radiation)
- It might have anticancer potential
- It may act as an antipyretic (fever-reducing) agent
- It may have anti-ulcer properties
- It may be an antigenotoxic (prevents damage to DNA)
- It may be a diuretic (increases urine output)
- It may act as an anti- inflammatory agent

Possible use of Bael in treating diabetes:

According to animal studies, Bael fruit extract taken orally or injected may help reduce blood sugar and hemoglobin bound glucose. It may also help increase insulin levels in the blood and help regulate glucose levels in the liver. Some compounds (coumarins) contained in currant extract may help the liver secrete insulin and therefore help reduce blood sugar.

Possible use of bael to treat stomach disorders:

Bael may have antiinflammatory properties. Stomach ulcers are often caused by the accumulation of free radicals (oxidative stress) in stomach cells. Thanks to its antioxidant capacity, bael may have anti-inflammatory properties and can eliminate oxidative stress and damage to the stomach lining. Additionally, unripe bergamot may help relieve gastrointestinal problems caused by ethanol (alcohol) in the stomach. However, more research is needed. Please talk to your doctor and do not self-medicate.

Possible uses of Bael to inflammation:

Bael extract may help reduce swelling, pain, and fever. Alcoholic extracts of bael leaves may affect the activity of receptors responsible for swelling and inflammation (histamine receptors). The most common symptoms are allergies and asthma. However, more research is needed. Also, for health reasons, you should consult your doctor before using bael.

Possible use of Bael to treat cancer:

One study has shown that application of Bael can inhibit tumor growth. The exact mechanism has not been determined, but Bael's alcoholic liquid may help inhibit the growth of cancer cells. A bioactive compound found in bael leaf extract may interfere with the growth of breast cancer. However, more research is needed. Moreover, cancer is a serious disease that must be diagnosed and treated by a doctor.

Bael can be used to treat diarrhoea:

The root extract and immature pulp of Bael will help treat diarrhoea, and this may have even been mentioned in ancient Indian books. This may be because it can affect many diseases that cause stomach pain. However, more research is needed. Please do not self-medicate.

Potential uses of Bael for infections:

Bael might be effective for various infections caused by bacteria, indicating that it might act as a potent antibacterial agent.

LITERATURE REVIEW:

According to a survey (1993) of World Health Organization, the practitioners of traditional system of medicine treat about 80% of patients in India, 85% in Burma and 90% in Bangladesh.

Nature has provided a complete storehouse of remedies to cure ailment of mankind. About 80% of the world's population depends wholly or partially on traditional medicine for its primary health care needs.

In 2004, Jagetia et al. showed that intraperitoneally used hydroalcoholic leaf extract of A. marmelos in mice increases its survival rate when the mice are exposed to lethal dose of 10 Gyof g-radiation.

Balasubramanian et al. showed that A. marmelos extracts against white spot syndrome virusin shrimp at the concentration of 150 mg/kg of animal body weight.

Abdulla Kasim et al.: The fruit is also reported to have potent free-radical scavenging and antioxidant effects. Recently, Abdullakasim et al. have observed that A. marmelos fruit drink had high quantities of total phenolic compounds and was a good antioxidant.

Gupta et al. showed that A. marmelos fruit extracts have chemopreventive role against DMBA induced skin carcinogenesis in mice.

Kaur et al.: Antigenotoxic activity of A. marmelos fruit extracts were tested by Kaur et al. using E. coli PQ37 (SOS chromotest) and the peripheral human blood lymphocytes (Comet assay).

Shukla et al. evaluated the antipyretic property of A. marmelos on Brewer's yeast induced pyrexia in albino rats. They reveal that the ethanolic extract, at dose of 200 mg/kg body weight and 400 mg/kg body weight, produced significant reduction in elevated body temperature in adose dependent manner. This antipyretic effect of extracts was comparable to that of paracetamol (100 mg/kg body weight).

EXPERIMENTAL WORK:

- **Ingredients:**

Sr no.	Ingredients	Role
1	Bael fruit pulp powder (Luvangetin, Marmin)	API
2	Anhydrous lactose	Diluent
3	Aromatic oil (paper mint and orange oil)	Flavoring agent
4	Sodium bicarbonate	Alkali compound
5	Citric acid	Acid compound
6	Talc	Lubricant

DRUG PROFILE:

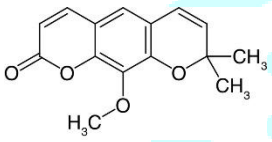
1. **BAEL FRUIT PULP**

Scientific Classification

- ➢ Kingdom- Plantae.
- ➢ Order- Sapindales.
- ➢ Family- Rutaceae.
- ➢ Subfamily-Aurantioideae.
- ➢ Genus- Aegle.
- ➢ Species- Aegle Marmelos.
- ➢ Botanical name- Aegle marmelos

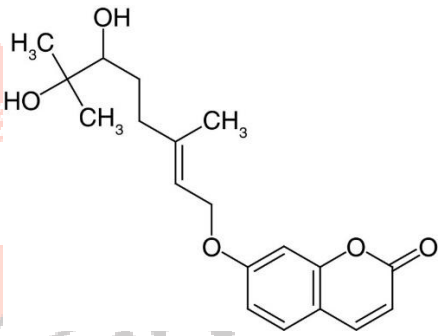
A) Luvangetin:

$C_{15}H_{14}O_4$



B) Marmin

$C_{19}H_{24}O_5$



PLAN OF WORK:

1) Literature survey.

2) Selection of drug and excipient.

3) Procurement of drug and excipient.

4) Experimental work Phytochemical analysis of drug. Pre-compression study of drug and excipient. a. Particle size analysis b. Flow ability c. Angle of repose d. Tapped density e. Bulk density f. Hauser's ratio g. Compress-ibility Index/ Car's Index

5) Evaluation post-compression tests a. Measurement of tablet hardness b. Measurment of tablet thickness c. Friability d. Evaluation of weight variation e. Measurement of effervescent time f. Determination of effervescent solution pH

EVALUATION PARAMETERES:

Precompression Tests:

1.Particle Size Analysis:

The average particle size of powder mixture was determined by sieve analysis method. 100 grams of powder mixtures and granules poured on the upper sieve.

Series of sieve were placed on ERWEKA shaking apparatus for 10 minutes after this period; the amount remaining on each sieve was measured.13

The mean diameter of the powders was calculated by equation (1).

D = £ Xidex/100. EQ (1)

Xi = The average size of both upper and lower sieve

Di = The percentage of the amount of in limited area by two sieves.

2.Flowability:

For evaluation of powder flow, the angle of repose, compressibility index and Hauser's ratio can be used.

3.Angle of Repose (α):

The powder or granule mass was passed from the funnel. Angle of repose was determined by

equation 2.

Tan (α) = Height / r Eel (2)

The average of three measurements was interpreted according to USP NF. 2008.

Height: The height of the formed cone

Base: radius of the formed cone

Serono.	Angle of repose (θ)	Flowability
1	<20	Excellent
2	20-30	Good
3	30-35	Passable
4	>40	Very poor

Angle of repose & flowability

4.Compressibility Index and Hauser's Ratio:

For measurement of bulk density, 100 grams of powders and granules was poured into the graduated cylinder (250 ml) using a glass funnel and its volume is recorded.

P bulk = M / V. Eq. (3)
M: weight
V: volume of powder
Tapping to cylinder containing the powder continued until no further volume changes occur.
Tapped density is obtained from the following equation.

A = M / vs. Eel (4)

Were,
M: weight
Vt: minimum volume after tapping

Compressibility Index and Hauser's ratio parameters obtained by using the mean of three measurements from bulk and tapped and were compared according to the USP NF.2008.

Compressibility index/ Care's index = 100 * (p tapped – p bulk / p tapped) Eq. (5)

HR = tapped density / bulk density. Eq. (6)

Car's Index	Flow property	Hauser's ratio
≤10	Excellent	1.00-1.11
11-15	Good	1.12-1.18
16-20	Fair	1.19-1.25
21-25	Passable	1.26-1.34
26-31	Poor	1.35-1.45
32-37	Very poor	1.46-1.59
>38	Very very poor	>1.60

Carr's index, Hausner's ratio & flow property

➢ **Post compression Tests:**

1.Measurement of Tablet Hardness:
Hardness of tablets was determined according to the USP for 10 tablets of each formulation by using a hardness tester.
Hardness of effervescent tablets is usually lower than conventional tablets and minimum of acceptable hardness of uncoated tablets is 40 N approximately.

Monsanto meter (tablet hardness tester)

2.Measurement of Tablet Thickness:
The thickness of 10 tablets from each formulation was determined by using calibrated collies. Average fluctuations of thickness, should not exceed more than 5 % of its normal limits.

3.Friability:
20 tablets of each formulation were taken randomly and after weighting altogether, were placed in the friabilator chamber for 4 minutes at 25 rpm. If weight loss is greater than 1% is unacceptable.

4.Evaluation of Weight Variation:
20 tablets of each formulation were weighed individually and the mean of weight were determined. According to the USP for tablets with weight more than 324 mg, among 20 tablets; just two tablets can be out of the 5% of the average weight and none deviated by more than twice that percentage.

5. Measurement of Effervescence Time:
A single tablet was placed in a beaker containing 200 ml of purified water at 20 °C ± 1 °C. Whenever a clear solution without particles was obtained effervescence time has finished.15
The mean of three measurements of each formulation was reported.

6. Determination of Effervescent Solution pH:
pH solution was determined with one tablet in 200 ml of purified water at 20 ± 1 °C by using pH meter (Met Rohm, 632, Switzerland), immediately after completing the dissolution time.15 This experiment was repeated 3 times for each formulation.

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