

FORMULATION, DEVELOPMENT, AND EVALUATION OF AN ANTACID MADE USING LABORATORY CHEMICALS AND COMMON HERBAL INGREDIENTS BLENDED INTO A SUITABLE DESIRED LIQUID FORMULATION/PREPARATION FOR INTERNAL ADMINISTRATION TO THE PATIENT WITH HYPERACIDITY

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ABSTRACT

Developing an antacid that determines the high or fast rate of relief from the symptoms of hyperacidity is a major concern in the development of this formulation. A mixture of herbal and pure chemical methods resulted in the development of this effective formulation that cures the symptoms of hyperacidity. Majorly sodium-bi-carbonate, a soda, is usually taken to neutralise the acid or the condition of hyperacidity as a traditional way of dealing the hyperacidity condition; apart from soda, a pharmaceutical preparation will also benefit the patient by relieving other symptoms, such as: hyperacidity-related symptoms like gastric acid ulcers and peptic ulcers. Along with laboratory chemical agents, simple herbal ingredients have been shown to be beneficial in relieving acidity and curing peptic ulcers; therefore, these simple herbal ingredients were used in the preparation of this formulation to provide an effective therapy regimen for doctors to prescribe as well as a broad range of peptic ulcer healing or curing herbal antacid.

KEYWORDS: Antacid, Herbal antacid, Herbal sugar free antacid, Peptic ulcer healing antacid, Soothing and sleep promoting antacid, Wound healing antacid.

1. INTRODUCTION

Antacids are a type of medication that can be used to relieve symptoms of acid reflux, heartburn, and indigestion. They work by neutralising stomach acid, which can help to reduce discomfort and pain in the oesophagus (The esophagus is sometimes called the gullet. Humans and other vertebrates have an esophagus. The word comes from the Greek word oisophagos, which means gullet, from the roots oisein, meaning to carry, and phagein, meaning to eat.)^[39] and, stomach.

Common active ingredients in antacids include magnesium hydroxide, aluminium hydroxide, calcium carbonate, and sodium bicarbonate. These compounds work by reacting with stomach acid to form neutral salts, which do not cause irritation or inflammation of the lining of the stomach or oesophagus.

Antacids are available over-the-counter and can be found in various forms, including tablets, liquids, and chewable tablets. They are generally safe and effective for short-term use, but should not be used for more than a few weeks without consulting a healthcare provider.

It's important to note that antacids may interact with other medications, so it's important to talk to a healthcare provider before using them if you are taking other medications. Additionally, long-term use of antacids can lead to certain side effects, such as: diarrhoea, constipation, and changes in the levels of minerals in the body.

Antacids are primarily used to relieve symptoms of acid reflux, heartburn, and indigestion. These symptoms are caused by stomach acid moving back up into the oesophagus, which can cause pain, discomfort, and irritation. Antacids work by neutralising stomach acid, which can help to alleviate these symptoms.

Developing an antacid involves several steps, including identifying the active ingredients, determining the optimal formulation and dosage form, and testing the safety and efficacy of the product.

1.a. Here are some general steps to develop an antacid

1.a.i. Identify the active ingredients: Antacids typically contain one or more alkaline compounds, such as: calcium carbonate, magnesium hydroxide, or aluminium

hydroxide, that neutralise stomach acid. Other ingredients, such as simethicone, may be added to relieve gas and bloating.

1.a.ii. Determine the optimal formulation and dosage form: The active ingredients must be formulated into a dosage form that is stable, easy to administer, and effective at neutralising stomach acid. Antacids are commonly available as tablets, liquids, or chewable tablets.

1.a.iii. Conduct preclinical studies: Preclinical studies are performed to evaluate the safety and efficacy of the antacid in animal models. These studies help to determine the appropriate dosage and identify any potential side effects or toxicities.

1.a.iv. Conduct clinical trials: Clinical trials are conducted to test the safety and efficacy of the antacid in humans. These studies are typically conducted in three phases and involve testing the product in a progressively larger group of people.

Obtain regulatory approval: Once the clinical trials are completed, the antacid must be approved by regulatory agencies, such as the Food and Drug Administration (FDA), before it can be marketed to the public.

1.a.v. Manufacture and distribute the product: After the product is approved, it can be manufactured and distributed to pharmacies and retailers.

It's worth noting that developing an antacid can be a complex and lengthy process that requires expertise in chemistry, pharmacology, and regulatory affairs. It is important to follow strict guidelines and regulations to ensure the safety and efficacy of the product.

1.a.1. Some common uses of antacids include

1. Heartburn relief: Antacids can quickly relieve the burning sensation and pain associated with heartburn.

2. Acid reflux relief: Antacids can also help to relieve symptoms of acid reflux, such as: regurgitation and a sour taste in the mouth.

3. Indigestion relief: Antacids can be used to relieve symptoms of indigestion, such as: bloating, belching, and abdominal discomfort.

Treatment of peptic ulcers: Antacids can be used in combination with other medications to help heal and prevent peptic ulcers.

4. Prevention of gastritis: Antacids may be used to prevent gastritis, a condition in which the lining of the stomach becomes inflamed and irritated.

It's important to note that antacids are not a long-term solution for these conditions and should not be used for more than a few weeks without consulting a healthcare provider. If symptoms persist or worsen, it's important to seek medical attention to rule out any underlying conditions.

1.b. Popular herbal antacids

There are several herbal remedies that can act as natural antacids and may help to alleviate symptoms of acid reflux, heartburn, and indigestion. Some popular herbal antacids include:

1. Ginger: Ginger is a natural anti-inflammatory and can help to reduce inflammation in the stomach and oesophagus. It may also help to improve digestion and reduce nausea.

2. Licorice root: Licorice root has been used for centuries to treat digestive issues, including acid reflux and heartburn. It contains compounds that help to reduce inflammation and protect the lining of the stomach and oesophagus.

3. Peppermint: Peppermint has a calming effect on the digestive system and can help to relieve symptoms of indigestion and heartburn. It may also help to reduce inflammation and soothe the lining of the stomach.

Peppermint has been used for centuries due to its potential benefits for the digestive system. It contains several compounds, such as menthol and menthone, that contribute to its unique aroma and potential therapeutic effects. Here's how peppermint can impact the digestive system:

1.a. Relieving Digestive Discomfort: Peppermint is commonly used to alleviate symptoms of indigestion, including bloating, gas, and stomach cramps. It may help relax the muscles in the gastrointestinal tract, promoting smoother digestion and reducing discomfort.

2.b. Irritable Bowel Syndrome (IBS): Peppermint oil has shown promising results in managing symptoms of IBS. It can help reduce abdominal pain, bloating, and changes in bowel habits. However, it's important to note that some individuals with IBS may be sensitive to peppermint and experience worsening symptoms, so it's best to consult a healthcare professional for personalized advice.

3.c. Gallbladder and Bile Flow: Peppermint may support the flow of bile, a substance produced by the liver and stored in the gallbladder that aids in digestion. Improved bile flow can help with the breakdown of fats and promote better digestion.

4.d. Nausea and Vomiting: Peppermint has been traditionally used to alleviate nausea and vomiting. The aroma of peppermint or the consumption of peppermint tea may help soothe an upset stomach.

5.e. Acid Reflux and Heartburn: Some individuals find that peppermint can worsen symptoms of acid reflux or heartburn. This is because peppermint may relax the lower esophageal sphincter, allowing stomach acid to flow back up into the esophagus. If you have acid reflux, it's generally advisable to avoid peppermint.

6.f. Appetite Stimulation: Peppermint's scent is known to stimulate the appetite. It can be helpful for individuals who have a reduced appetite or difficulty eating.

It's important to note that while peppermint is generally considered safe for most people, it can cause side effects in some individuals, including allergic reactions,

heartburn, and interactions with certain medications. If you have any specific concerns or pre-existing medical conditions, it's always best to consult with a healthcare professional before using peppermint or any herbal remedies.

4. Chamomile: Chamomile has anti-inflammatory properties and may help to reduce inflammation in the stomach and oesophagus. It can also help to soothe the digestive tract and reduce symptoms of indigestion.

Chamomile is another herb that has been traditionally used for its potential benefits on the digestive system. It is derived from the flowers of the chamomile plant and contains various compounds that contribute to its medicinal properties. Here's how chamomile can impact the digestive system:

1.a. Soothing Digestive Discomfort: Chamomile is known for its calming and anti-inflammatory properties. It can help soothe and relax the muscles in the gastrointestinal tract, which may alleviate symptoms of indigestion, such as bloating, gas, and stomach cramps.

2.b. Digestive Upset: Chamomile tea is often consumed to ease digestive upset, including nausea, vomiting, and diarrhea. It can have a calming effect on the stomach and help reduce inflammation in the gut.

3.c. Acid Reflux and Heartburn: Chamomile tea may help relieve symptoms of acid reflux and heartburn. It can help neutralize stomach acid and reduce inflammation in the esophagus, providing relief from discomfort.

4.d. Irritable Bowel Syndrome (IBS): Chamomile has been used as a natural remedy for managing symptoms of IBS. It may help reduce abdominal pain, cramping, and diarrhea. However, it's important to note that individual responses to chamomile can vary, and some people with IBS may be sensitive to its effects.

5.e. Anti-inflammatory Effects: Chamomile contains compounds, such as chamazulene, that have anti-inflammatory properties. This can be beneficial for individuals with inflammatory conditions of the digestive system, such as inflammatory bowel disease (IBD).

6.f. Relaxation and Stress Reduction: Stress and anxiety can negatively impact the digestive system. Chamomile has mild sedative properties and can help promote relaxation and reduce stress levels, which may indirectly benefit the digestive system.

It's worth mentioning that chamomile is generally considered safe for most people when consumed in moderation. However, some individuals may experience allergic reactions, especially if they are sensitive to other plants in the daisy family, such as ragweed. If you have any concerns or pre-existing medical conditions, it's always a good idea to consult with a healthcare professional before using chamomile or any herbal remedies.

5. Slippery elm: Slippery elm contains a mucilage that can help to coat and soothe the lining of the digestive

tract. It may also help to reduce inflammation and relieve symptoms of acid reflux and heartburn.

It's important to note that herbal remedies can have side effects and may interact with other medications. It's important to talk to a healthcare provider before using any herbal remedies as a natural antacid.

Antacids can contain a variety of different active ingredients that work to neutralise stomach acid and alleviate symptoms of acid reflux, heartburn, and indigestion.

1.c. There are several brand names of herbal antacids available on the market. Some popular examples include

1. Ginger Rescue by The Ginger People: This product contains ginger and helps to relieve symptoms of acid reflux, heartburn, and indigestion.

2. DGL Chewable Tablets by Enzymatic Therapy: This product contains liquorice root and helps to soothe the digestive tract and reduce symptoms of acid reflux and heartburn.

3. Peppermint Oil Capsules by Heather's Tummy Care: This product contains peppermint oil and helps to reduce symptoms of indigestion and bloating.

4. Chamomile Tea by Traditional Medicinals: This product contains chamomile and helps to reduce inflammation in the digestive tract and alleviate symptoms of acid reflux and heartburn.

5. Slippery Elm Lozenges by Thayers: This product contains slippery elm and helps to coat and soothe the lining of the digestive tract, reducing symptoms of acid reflux and heartburn.

It's important to note that these brand names are just a few examples and there are many other herbal antacids available on the market. It's important to talk to a healthcare provider before using any herbal remedies as a natural antacid to ensure they are safe and appropriate for your individual needs.

6. Sea grapes, scientifically known as *Caulerpa lentillifera*,^{[37][38]} are a type of edible seaweed commonly found in coastal regions. While they are primarily enjoyed as a culinary ingredient, they may also offer potential benefits to the digestive system. Here's how sea grapes may impact digestion:

1.a. Fibre Content: Sea grapes are a good source of dietary fibre, which plays a crucial role in maintaining a healthy digestive system. fibre adds bulk to the stool, promotes regular bowel movements, and helps prevent constipation.

2.b. Gut Health: Sea grapes contain certain types of dietary fibre, such as: soluble fibre and resistant starch. These fibres can serve as prebiotics, which are substances that nourish beneficial bacteria in the gut. Promoting a healthy balance of gut bacteria is important for overall digestive health.

3.c. Nutrient Absorption: The fibre content in sea grapes can help slow down the digestion process, which may enhance nutrient absorption in the intestines. This

can ensure that essential nutrients are effectively absorbed and utilized by the body.

4.d. Anti-inflammatory Properties: Sea grapes contain antioxidants, such as: phenolic compounds, which have anti-inflammatory properties. Inflammation in the digestive system can lead to various digestive disorders, and consuming foods with anti-inflammatory properties may help alleviate symptoms.

5.e. Digestive Enzymes: Sea grapes are known to contain certain digestive enzymes, such as amylase and lipase. These enzymes can aid in the breakdown of carbohydrates and fats, facilitating digestion and nutrient absorption.

6.f. Alleviating Gastric Distress: Some anecdotal evidence suggests that sea grapes may help alleviate symptoms of gastric distress, including stomach discomfort and bloating. However, more scientific research is needed to confirm these potential benefits.

It's important to note that individual responses to sea grapes may vary, and some people may be allergic to seaweed. If you have any concerns or pre-existing medical conditions, it's advisable to consult with a healthcare professional before incorporating sea grapes or any new food into your diet.

1.d. Some common components of antacids include

1. Aluminium hydroxide: Aluminium hydroxide is a common antacid ingredient that works by neutralising stomach acid and reducing symptoms of heartburn and acid reflux.

2. Magnesium hydroxide: Magnesium hydroxide is another common antacid ingredient that works by neutralising stomach acid and relieving symptoms of heartburn and indigestion.

3. Calcium carbonate: Calcium carbonate is an antacid ingredient that works by neutralising stomach acid and reducing symptoms of heartburn and acid reflux. It may also help to strengthen bones and prevent osteoporosis.

4. Sodium bicarbonate: Sodium bicarbonate is an antacid ingredient that works by neutralising stomach acid and reducing symptoms of heartburn and acid reflux. It may also help to alleviate symptoms of indigestion and bloating.

5. Simethicone: Simethicone is an antacid ingredient that works by reducing gas and bloating in the digestive tract. It may be added to antacids to help relieve symptoms of indigestion and flatulence.

It's important to note that different antacids may contain different combinations of these ingredients, and some may also contain other active ingredients. It's important to read the label carefully and talk to a healthcare provider before using antacids if you are taking other medications or have any underlying medical conditions. Antacids are medications that work to neutralise stomach acid and relieve symptoms of acid reflux, heartburn, and indigestion.

1.e. There are several types of antacids available on the market, including

1. Calcium Carbonate Antacids: These antacids contain calcium carbonate as the active ingredient, and work by neutralising stomach acid. They are often available as chewable tablets or liquid suspensions.

2. Magnesium Hydroxide Antacids: These antacids contain magnesium hydroxide as the active ingredient, and work by neutralising stomach acid. They are often combined with aluminium hydroxide to balance the potential side effects of each component.

3. Aluminium Hydroxide Antacids: These antacids contain aluminium hydroxide as the active ingredient, and work by neutralising stomach acid. They are often combined with magnesium hydroxide to balance the potential side effects of each component.

4. Sodium Bicarbonate Antacids: These antacids contain sodium bicarbonate as the active ingredient, and work by neutralising stomach acid. They are often available as effervescent tablets that dissolve in water.

5. Combination Antacids: These antacids contain a combination of active ingredients, such as: calcium carbonate, magnesium hydroxide, and aluminium hydroxide. They are often used to provide a more comprehensive approach to acid reflux, heartburn, and indigestion.

It's important to note that different antacids may have different active ingredients and may have different potential side effects or interactions with other medications. It's important to read the label carefully and talk to a healthcare provider before using antacids if you are taking other medications or have any underlying medical conditions.

1.f. The mechanism of action of antacids involves neutralising excess stomach acid to alleviate symptoms of acid reflux, heartburn, and indigestion. Stomach acid is produced by cells in the lining of the stomach and is necessary for the digestion of food. However, excessive acid production or a weakened lower oesophageal sphincter (LES) can lead to the reflux of stomach acid into the oesophagus, causing discomfort and irritation.

Antacids work by neutralising stomach acid through a chemical reaction that occurs when the active ingredients of the antacid interact with the acid in the stomach. The active ingredients in antacids can vary, but many antacids contain alkaline substances such as: calcium carbonate, magnesium hydroxide, or aluminium hydroxide, which react with the acidic gastric contents and form neutral salts.

The neutralisation of stomach acid by antacids helps to alleviate symptoms of acid reflux, heartburn, and indigestion by reducing the acidity of the gastric contents and preventing the reflux of acid into the oesophagus. Additionally, some antacids may also form a protective coating over the stomach lining, which can help to reduce irritation and inflammation.

It's important to note that while antacids can provide temporary relief from symptoms of acid reflux, heartburn, and indigestion, they do not treat the underlying cause of these conditions. If you experience frequent or severe symptoms, it's important to talk to a healthcare provider to determine the cause and develop an appropriate treatment plan.

1.g. Proton pump inhibitors (PPIs) are a type of medication that are commonly used to treat conditions related to excess stomach acid, such as: gastroesophageal reflux disease (GERD), peptic ulcers, and Zollinger-Ellison syndrome.

PPIs work by blocking the proton pump, an enzyme located in the stomach lining that is responsible for producing stomach acid. By inhibiting the proton pump, PPIs reduce the amount of acid that is produced in the stomach, which can help to alleviate symptoms of acid reflux, heartburn, and indigestion.

PPIs are available by prescription and over-the-counter and are typically taken orally as a pill or capsule. Common examples of PPIs include omeprazole, esomeprazole, lansoprazole, pantoprazole, and rabeprazole.

While PPIs can be effective in reducing symptoms related to excess stomach acid, they are not without potential side effects. Prolonged use of PPIs has been associated with an increased risk of bone fractures, vitamin and mineral deficiencies, kidney disease, and infections such as: pneumonia and *C. difficile*. It's important to talk to a healthcare provider before taking PPIs, especially for an extended period, and to follow their recommended dosages and instructions.

1.1. Antacid and their uses

Antacids are a kind of drug that alleviates heartburn and indigestion by reducing the amount of acid in a patient's stomach. Antacids prevent an enzyme that produces acid to break down food for digestion, which neutralises the acid in the stomach (pepsin). Antacids are available **over-the-counter (OTC)** without a prescription.

Antacids are weak bases that chemically neutralise stomach gastric acid, reducing damage to the stomach lining and oesophagus, thereby relieving pain. Antacids are available in different dosage formulations like tablets, effervescent, powders, and suspensions as over the counter drugs. The suspension formulations are more preferred as they have the fastest onset of action. They are over the counter medications used as quick relief methods that work by directly counteracting the acidity inside the stomach. An antacid is one pharmaceutical medication^[20] that can be prescribed by a doctor or can be taken over the counter. "As per Charak Sāāheeta; Ghee, Indian Goose-beery, sugarcane juice, Hirda, and

proportionate quantity of the alcohol is useful in the treatment of such condition."^[34, Ibid 35]

1.2. Related signs and symptoms that an antacid treat

1.2.1. Heartburn and indigestion symptoms that are relieved by antacids include

- i. An experience of the burning sensation, especially after eating or at night, in patient's chest or stomach.
- ii. A sour or acidic aftertaste in mouth.
- iii. Feeling bloated or full.
- iv. Stomach and chest ache that isn't very bad.

Antacids are licenced by the Food and Drug Administration to treat mild episodes of indigestion and heartburn. Heartburn that occurs infrequently or sporadically rather than daily is referred to as a mild case.

1.2.2. Antacids can also help with the following symptoms: i. (GERD^[31] or gastroesophageal reflux disease). ii. Intestinal inflammation (gastritis). iii. Abdominal ulcers.

For a few hours, antacids swiftly ease symptoms. The physiology that causes symptoms are not treated by antacids.

1.2.3. Forms of antacids for R_x

1.2.3.i. There are four types of antacids

1. Liquid. (Flavoured.). 2. Tablet you can chew. (Flavoured.). 3. Effervescent powder of Soda, or sodium bi-carbonate. (Flavoured.). 4. Effervescent tablet of Soda, or the sodium bi-carbonate. (Flavoured.). In comparison to chewable tablets, liquid antacids work faster to relieve heartburn and indigestion symptoms.

1.3. Dosage strengths available for antacids

Depending on the age and the intended use, different antacid dosages are recommended. By manufacturer, dosage also varies by the prescriber's knowledge.

1.3.1. Antacids as addictive

No, antacids aren't addictive.^[2]

1.3.1.i. Components of the antacids

Aluminium, calcium, magnesium, and salts (particularly sodium) are other typical constituents.

- A. Alginate.
- B. Alkyl aluminosilicate. (Aluminium hydroxide.).
- C. Carbonate of calcium. (Calcium carbonate.).
- D. carbonate of magnesium. (Magnesium carbonate.).
- E. Magnesium oxychloride. (Magnesium hydroxide.).
- F. Calcium magnesium silicate. (Magnesium trisilicate.).
- G. Bicarbonate of sodium. (Sodium bicarbonate.).
- H. Ranitidine is a medicine that reduces the amount of acid the stomach.^[21]

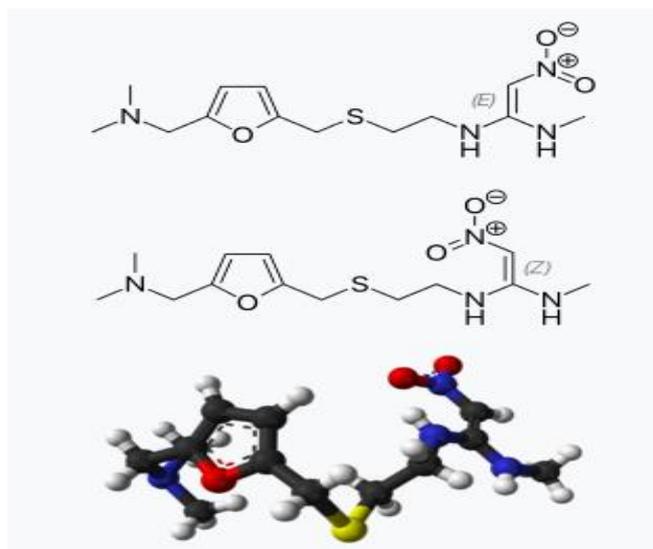


Figure 1: Ranitidine.^[27]

1.4. Negative effects that might an antacid cause

Infants and those over the age of 65 are most commonly affected by complications after taking an antacid. The negative consequences include diarrhoea or constipation.

1. Gas (flatulence).
2. Headache.
3. Vomiting and nauseous.
4. Abdominal ache or cramps in the stomach. (Pain).
5. Possible severe adverse effects include: (Serious side effects):

1.4.1. Acid rebound: With intake of an antacids, body produces extra acid, which exacerbates or worsen patient's symptoms.

Antiacids are neurotoxic because they alter how nervous system works.

Iron deficiency causes microcytic anaemia.

Osteopenia: Bones that are weak. (Weakened bones.).

1.4.2. Hypercalcemia: An excessive level of the calcium in the blood.

Avoid using antacids all the time. Reach out to a healthcare professional to discuss the reason of symptoms if regularly experience heartburn or indigestion.

1.4.3. Harmful interactions of an antacids

To avoid interactions, take other medications at least four hours before or after taking an antacid.

1.4.4. Do antacids pass into the breast milk? Highlights^[2]

Some components in antacids, like as calcium, can enter breastmilk. It is safe to take antacids if you are breastfeeding (chest feeding).

1.4.5. Drugs misidentified/mistaken as an antacid

Many medications that treat heartburn or indigestion are not antacids because the chemicals function in ways that are distinct from those of antacids.

1.4.6. Non-antacid medications that are frequently used include

Esomeprazole (trade name: Nexium®³²): Treats ulcers and acid reflux.

Treats GERD, esophagitis, and stomach ulcers with famotidine (Pepcid®³²).

Omeprazole (Prilosec®³²): Treats issues with the stomach and oesophagus.

Pantoprazole (Protonix®³²): Treats GERD^[31, 32] as well as issues with the stomach and oesophagus.

Simethicone (Gas-X®): Treats bloating and gas.^[31,32]

1.5. Peptic ulcers

Peptic ulcers, or stomach ulcers, are breaks or holes in the lining of the stomach. An ulcer in the first part of the intestines is known as a duodenal ulcer. An ulcer in the stomach is known as a gastric ulcer.^[6]

An ulcer on that is developed on the lining of a patients' stomach, or the small intestine, or oesophagus is referred to or is scientifically termed as a peptic ulcer. A peptic ulcer in the stomach refers to the gastric ulcers. Peptic ulcer develops/appears in the small intestines' first section which is called a duodenal ulcer (duodenum). The lower portion of the oesophagus is the site/location where oesophageal ulcer develops.

1.5.1. Signs or symptoms indicating a stomach ulcer

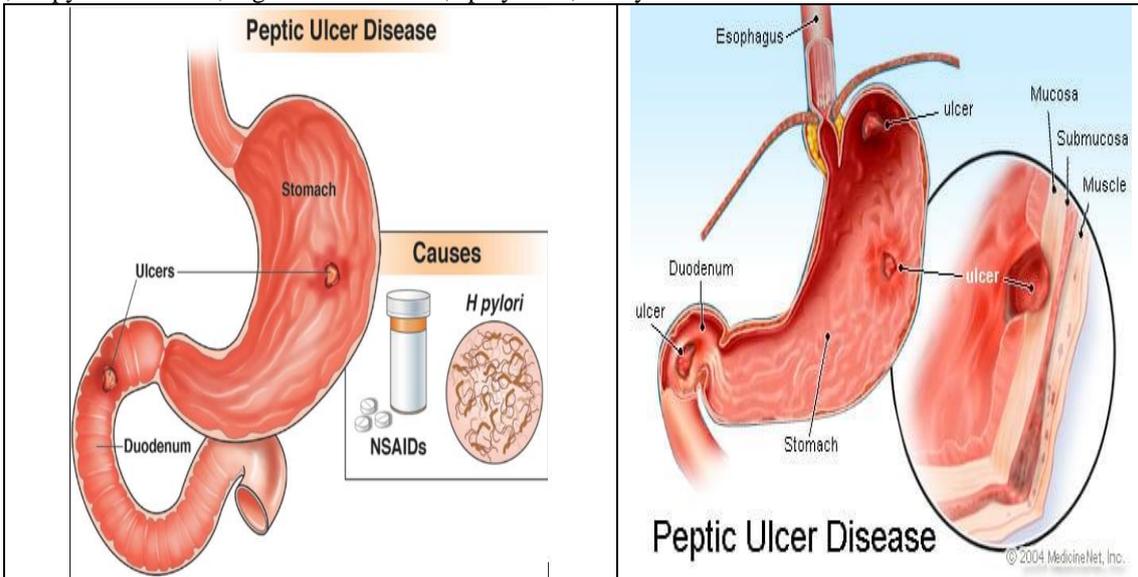
1.5.1.i. Symptoms and signs

Stomach discomfort that includes burning or gnawing, is the most typical sign of a stomach ulcer in (abdomen).^[ibid 33]

1.5.2. Reasons for ulcers include

1.5.2.1. Risk elements

Smoke, H. pylori infection, ingestion of alcohol, spicy food, heavy NSAIDs.



Gastric ulcers.



Endoscopic image obtained; showing a single pyloric channel.



An esophagogastroduodenoscopy revealed a double pylorus. A clean-based ulcer is also visible.

Figure 2: Gastric ulcer. [1, 3, 4, 22, 12]

1.5.2.2. Symptoms

A sharp stomach ache,

Belching, bloating or bloating intolerance to fatty foods,

Heartburn,

Nausea,

Burning stomach discomfort is the most typical sign of stomach ulcers. Both stomach acid and an empty stomach make the agony worse. One can have habit of eating some meals that will sufficiently buffer the stomach acid or use an acid-reducing medication to reduce the alleviated pain; nevertheless, the pain may return. The pain may be worse between meals and at night. Many people with peptic ulcer disease show no signs or symptoms at all.

Less frequently, severe signs or symptoms such vomiting blood that may seem red or black are caused by ulcers.

Stools that are dark, tarry, or contain blood.

Breathing difficulties, feeling lightheaded, nausea or vomiting,

Unexpected weight reduction, altered appetite,

1.5.2.3. Causes

Development of peptic ulcers happens when the stomach or small intestine's inner surface is attacked by digestive tract acid. It results in peptic ulcers. The acid can cause a painful open wound that may bleed. A layer of mucus covers the digestive tract, which often protects it from acid. An ulcer is also developed if the amount of acid is increased or the amount of mucus is decreased or reduced.

1.5.2.3. Typical causes include

A microbe. The mucus layer that covers and protects the stomach and small intestine tissues is a favourite habitat for *Helicobacter pylori* bacteria. The *H. pylori* bacterium often doesn't cause any problems, but it can also lead to ulcers by inflaming the inner lining of the stomach. Regular use of specific painkillers. Aspirin and other nonsteroidal anti-inflammatory drugs (NSAIDs), which include several over-the-counter and prescription pain relievers, can irritate or inflame the lining of the stomach and small intestine. These include ibuprofen (Advil, Motrin IB etc), naproxen sodium (Aleve, Anaprox DS etc), ketoprofen, and other medications etc. They are free of paracetamol (Tylenol, others). Various drugs. Combining certain additional medications with NSAIDs can significantly increase the risk of developing ulcers. The list includes anticoagulants, steroids, high-dose of aspirin, alendronate (Fosamax), selective serotonin reuptake inhibitors (SSRIs), and risedronate (Actonel).^[31, 32]

1.5.2.4. Complications

Internal bleeding can occur as a result of untreated gastric ulcers. Blood loss can be gradual and cause anaemia, or it can be severe and necessitate hospitalisation or blood transfusions. Black or bloody faeces or vomit might result from significant blood loss.

a perforation in the wall of stomach. If stomach or small intestine is perforated by stomach ulcers, you are at risk of developing severe inflammation of the abdominal cavity (peritonitis). Obstruction. Peptic ulcers stop food from passing through the digestive tract, making patient feel bloated, throw up, and lose weight either via swelling from inflammation or by the scarring.

Stomach cancer *H. pylori* infection has been linked to an increased risk of gastric cancer, according to studies.

1.5.2.5. Case study^[5]

A 61-year-old man went to the hospital for a check-up because he had been experiencing postprandial pain and continuous epigastric pain for four months. He underwent an upper endoscopy at another facility three months prior, where a stomach ulcer was discovered. The symptoms remained despite drug treatment. The results of a complete blood count (CBC) at our hospital showed that the patient's haemoglobin was 6.2 g/dL, his hematocrit was 21.4%, his white blood cell (WBC) count was 5750 103/L, and his platelet count was 223 103/L. Aspartate transaminase (AST), 62 U/L; alanine transaminase (ALT), 32 U/L; alkaline phosphatase (ALP), 152 U/L; and lactate dehydrogenase (LDH), 563 U/L were the results of the serum laboratory tests. Several gastric ulcers without active bleeding in the antrum were discovered during an upper endoscopy.

Ulcers are elevated round margins and varied in the diameter from 3 to 6 mm; their base are covered with exudate.

1.5.2.6. Case study in gastroenterology & hepatology: an uncommon complication of peptic ulcer disease

A 54-year-old African American woman presented with a 1-month history of intermittent, burning epigastric abdominal pain that was moderately severe in intensity. Her pain radiated toward her back in a band-like fashion. She also noted nausea and vomited once, with the vomit consisting of food particles. The patient denied having signs and symptoms of melena, hematochezia, or hematemesis. Her medical history was significant for peptic ulcer disease, and the patient had had multiple endoscopies in the past 6 years. It was learned that she had 2 clean-based antral ulcers 5 years prior (Figure 2) and was started on lansoprazole, which she could not afford and so was switched to omeprazole, which she used intermittently. She also admitted to past use of an over-the-counter analgesic consisting of acetaminophen, aspirin, and caffeine.

The patient's abdomen was soft and undistended upon examination. All four quadrants contained bowel noises. There was a slight soreness over the epigastrium. Her basic laboratory results were normal, and her hematocrit was 39.3%. An upper GI series from imaging scans revealed an auxiliary tract inside the pylorus.

Esophagogastroduodenoscopy (EGD) results revealed clean-based gastric and duodenal bulb ulcers, as well as 2 distinct pylorus openings into the small intestine. Helicobacter pylori biopsies were also performed, although the results were unfavourable. Figure 2.

Double pylorus, a rare complication of peptic ulcer disease, was identified in the patient. Proton pump inhibitor (PPI), effective for patients. Patient to avoid nonsteroidal anti-inflammatory medicines (NSAIDs).

Congenital or acquired double pylori are both possible. Congenital double pylori are very uncommon. Peptic ulcer illness can lead to complications such as acquired double pylorus. According to Roki-tansky and colleagues, the new channel is thought to be the outcome of two independent ulcers that erode towards one another, one in the lower curvature of the stomach and the other in the duodenum.^[13, 14]

2. Research methodology

2.1. Materials

2.1.1. Aegle murelos: Bael fruits (*Aegle murelos*) are an important Ayurvedic medicine, they contain coumarins, flavonoids (rutin and muremesin) and a glucosylated propelargonidin containing up to five units of pelargonidin with immunomodulatory activity.^[7]

2.1.2. Nutraceutical: GSPE, Antioxidants: present, source: Grapes.^[7]

2.1.3. Proanthocyanidins and grape seeds

2.1.3.i. Vitis vinifera, known as the grapevine, is indigenous to southern Europe and western Asia, and is today cultivated worldwide. Grape seeds are byproducts of grapes separated during the industrial production of grape juice and wine. They are a potent source of proanthocyanidins, which are also found in almonds, cashews, hazelnuts, pecans, pistachios, peanuts, and walnuts. The *in vitro* and *in vivo* experimental data support the concept that proanthocyanidins exert chemoprotective properties against free radicals and oxidative stress, anti-inflammatory activity, and anticarcinogenic properties. Potential cancer chemopreventive activities include cell proliferation inhibition, apoptosis induction, and cell-cycle arrest in tumour cells. They also modulate the expression and activity of NF- κ B and its targeted genes, including the invasion and metastasis-specific molecular targets.^[24]

2.1.3.ii. Resveratrol is found in the leaves, skins and petals of *Vitis Vinifera*, and also wines and grapes juice, and levels are elevated when the vine is infected with the fungus, Botrytis cinerea. Red wines contain increased levels due to extended time in contact with the skins, a number of other stilbene derivatives are also found in grape products. Resveratrol is also present in other plant product, such as peanut butter, wide-ranging levels of resveratrol have been found in wines from different varieties. Of grapes and different geographical sources: 0.3-47 mg/l (French Barolo, French chateaufneuf) concomitant levels of catechin 23-136 mg/l (French Barolo, French Burgundy) and epicatechin, 17-64 mg/l (French Barolo, French Beaujolais) are also present.^[7]

Resveratrol is a natural compound found in certain plants, including grapes, peanuts, and berries. It belongs to a group of compounds known as polyphenols, which are known for their antioxidant properties.

2.1.3.ii.a. Resveratrol has been the subject of numerous studies due to its potential health benefits.

Some of the reported benefits of resveratrol include

i. Anti-inflammatory properties: Resveratrol has been shown to have anti-inflammatory effects, which may help to reduce the risk of chronic diseases such as cancer, heart disease, and Alzheimer's disease.

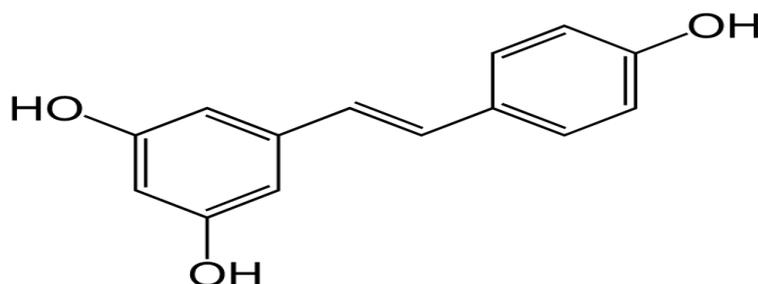
ii. Cardiovascular benefits: Resveratrol may help to lower blood pressure and reduce the risk of heart disease by improving the function of blood vessels and reducing the build-up of plaque in the arteries.

iii. Anti-cancer properties: Resveratrol has been shown to have anti-cancer properties in laboratory studies, and some studies have suggested that it may help to prevent the development of certain types of cancer.

iv. Neuroprotective effects: Resveratrol may help to protect the brain from damage and reduce the risk of age-related cognitive decline.

v. Anti-aging effects: Resveratrol has been shown to activate certain genes that are involved in the regulation of aging, and may help to slow the aging process.

Resveratrol supplements are available in capsule and tablet form, and are often marketed as a way to promote overall health and well-being. However, it is important to note that the research on the health benefits of resveratrol is still in its early stages, and further studies are needed to fully understand its effects on human health.



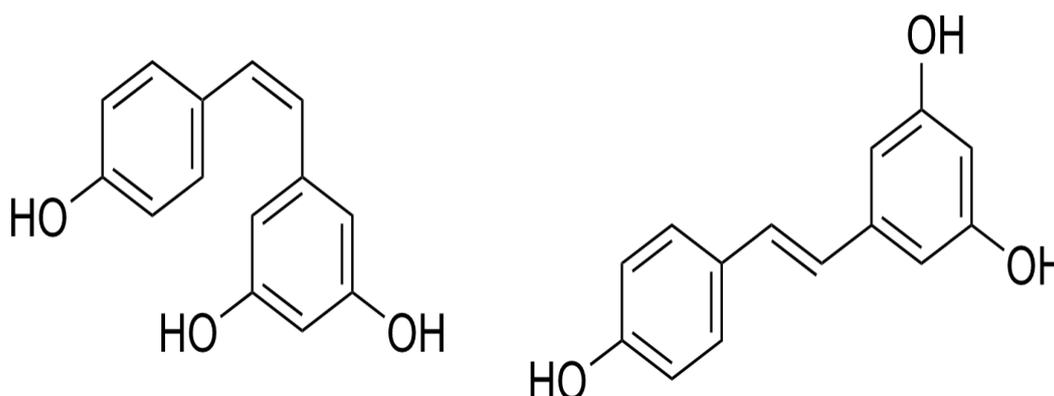


Figure 3: Resveratrol, Chemical structures of *cis*- ((*Z*)-resveratrol, left) and *trans*-resveratrol ((*E*)-resveratrol, right). 5-[(*E*)-2-(4-Hydroxyphenyl)ethen-1-yl]benzene-1,3-diol.^[28, 29, 30]

Research in animals and humans has demonstrated a range of biological activities, including antioxidant activity, inhibition of platelet aggregation and modulation of hepatic apolipoprotein and lipid synthesis. Red wine is the major dietary source of resveratrol, and it is implicated in risk reduction for 9 number of cancers including upper digestive tract, lung and colon cancers, Resveratrol inhibits metabolic activation of carcinogens, induces apoptosis and is anti-inflammatory.⁷ The term nutraceutical, a syncretic neologism of the words nutrient and pharmaceutical, was originally coined by Stephen DeFelice, who defined nutraceuticals as “food or part of a food that provides medical or health benefits, including the prevention and/or treatment of a disease.”^[11]

I. Nutraceutical– Resveratrol, Antioxidant-present.

ii. Plant source – Grapes, (*Vitis Vinifera*), wine cranberry juice.

2.1.3.iii. Grape seed extract

Vitis vinifera L. seed extract, has a high content of polyphenols, including up to 25% OPC (*oligomeric proanthocyanidins*). OPCs are polyphenols which consist of monomers and dimers of bioflavonoids, with enhanced bioavailability due to a smaller molecule size, and which are powerful antioxidants.^[23]

2.1.3.iv. Major application - cardiovascular, health and Cancer prevention.

A. *Vulgaris Lam.: Aloe vera Linn.:* South America, the species *Aloe vera* Linn. (= *A. vulgaris Lam.*) is cultivated. Young offsets are planted in rows about 50 cm. apart, just after the rains break. The first cutting of leaves is made in the second year and a plantation will continue to yield aloes for twelve years, after which the plants are dug up, the ground well worked and manured and replanted. The

vascular bundles in the leaf are isolated and form a line parallel with epidermis at a short distance within the mesophyll. Each bundle has a pericycle formed of very large thin-walled cells filled with a viscous, yellow fluid, known as the aloetic juice. These aloetic cells are somewhat elongated in the direction of the axis of the leaf and they have thin cell-walls. When the leaf-base is cut transversely, the juice flows from those cells actually cut open by the knife and, owing to the pressure of the surrounding tissues, the transverse walls between the aloetic cells in each row break down and the juice is drained from the entire system of pericyclic cells. The aloetic juice is allowed to flow away without assistance by pressure or other means. In the West

Indies, especially on the islands of Aruba and Bonaire, the workmen collecting the leaves have their hands and feet well protected against injury by the thorny plants and they put the leaves into kerosene tins in which they are carried to the draining troughs. The cut leaves are arranged along the sides of wooden troughs which are V-shaped and 1 to 11 metres long, and are tilted so that the juice runs to one end and is received in a tin. The juice is boiled in large copper pans until sufficiently thickened; it is then poured into gourds or boxes and allowed to harden, thus producing the kind of aloes known commercially as **Curaçao** or *Barbados aloes*.^[8]

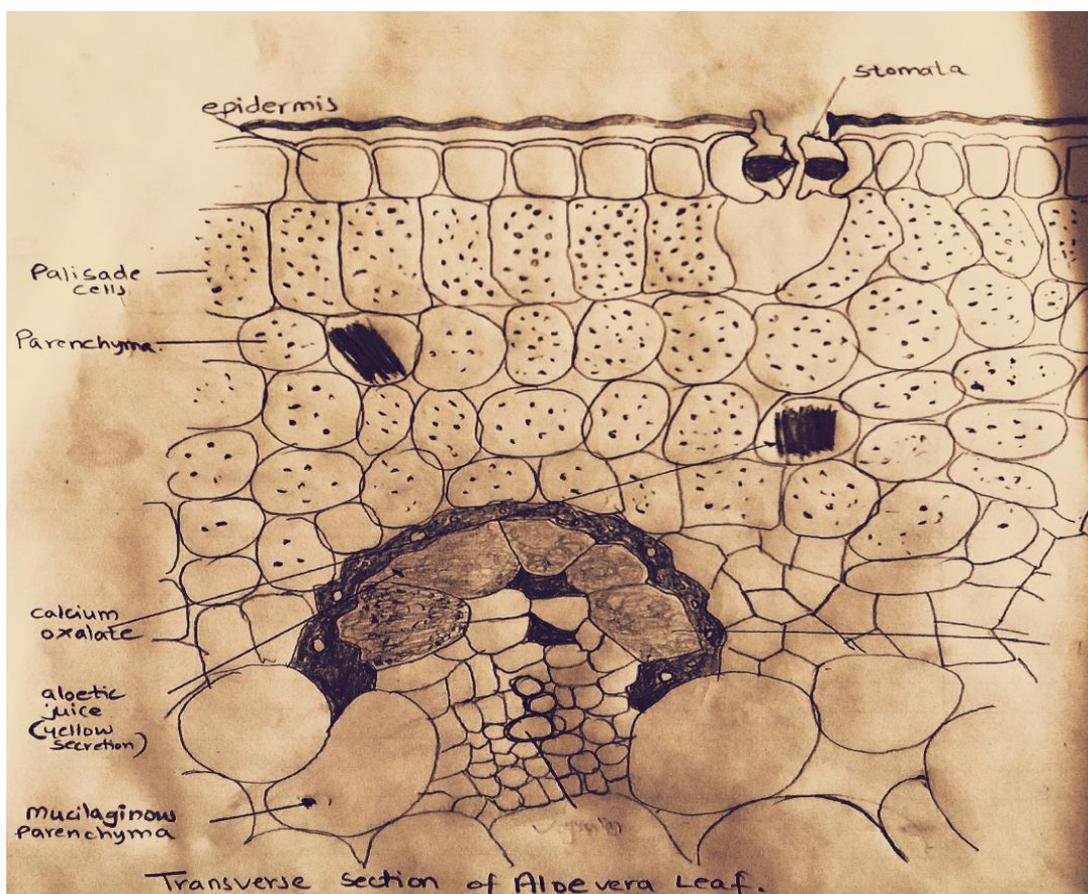


Figure 4: Transverse section of the Aloe vera leaf.

2.2. Chemicals and reagents

2.2.1. Reagents: Hydrochloric Acid, x M: Solutions of any molarity xM may be prepared by diluting 85x ml of hydrochloric acid to 1000 ml with water.

Store in containers of polyethylene or other non-reacting material at a temperature not exceeding 30 degrees.^[9]

2.2.2. Aluminium Hydroxide Gel: Aluminium Hydroxide Suspension; Aluminium Hydroxide Mixture. Aluminium Hydroxide Gel is an aqueous suspension of hydrated aluminium oxide together with varying quantities of basic aluminium carbonate and bicarbonate.

It may contain Glycerin, Sorbitol, Sucrose or Saccharin as sweetening agents and Peppermint Oil or other suitable flavours. It may also contain suitable antimicrobial agents. Aluminium Hydroxide Gel contains not less than 3.5 per cent and not more than 4.4 per cent w/w of Al_2O_3 .

By using potentiometric titration, chemical analysis, and the ratio of bound hydroxide to aluminium, it is possible to determine the initial aluminium hydroxide gel precipitate that forms when aluminium chloride or aluminium sulphate reacts with ammonium hydroxide and fit it into the previously described polymer model. It

is thought that the formation of polynuclear hydroxyaluminium particles occurs in stages and involves a deprotonation-dehydration mechanism that leads to the formation of six-membered rings, which may then coalesce using the same mechanism.^[15]

This species most likely consists of three joined, six-membered ring polymers.

The aluminium hydroxide gel precipitated from aluminium chloride can be represented by the formula $\text{Al}(\text{OH})_{2.55}(\text{Cl})_{0.45}$ and probably exists as a polymer of 10 fused six-membered rings. The aluminium hydroxide gel precipitated from aluminium sulfate can be represented by the formula $\text{Al}(\text{OH})_{2.30}(\text{SO}_4)_{0.35}$.^[15]

2.2.2. a. Category: Antacid. **Dose:** 7.5 to 15 ml. **pH:** 5.5 to 8.0.

2.2.2. b. Storage: Store at a temperature not exceeding 30°. Do not freeze.^[10]

2.2.2. c. $\text{C}_7\text{H}_4\text{NNaOS}$

2.2.2. d. Mol. Wt. 205.2

Saccharin Sodium is the sodium salt of 1,2-benzisothiazol-3(2H)-one 1,1-dioxide.

Saccharin Sodium contains not less than 99.0 per cent and not more than 101.0 per cent of $\text{C}_7\text{H}_4\text{NNaO}_3\text{S}$, calculated on the anhydrous basis.

2.2.2. e. Category: Pharmaceutical aid (sweetening agent).

2.2.2. f. Description: A white, crystalline powder or colourless crystals; efflorescent in dry air.^[10]

2.2.3. Aluminium hydroxide gel—aging mechanism studied

By measuring the pH, acid-consuming ability, hydroxide to aluminium ratio, chloride activity, and X-ray line broadening of an aluminium hydroxide gel made by the interaction of aluminium chloride and ammonium hydroxide, the ageing of the gel was investigated. The outcomes agreed with a polymer model that predicted particle development via a deprotonation-dehydration mechanism by attaching to the positively charged edges of the hydroxy aluminium polymers, anions block this process.^[16]

2.2.3. 1. Aluminiumhydroxide gel—aging mechanism studied, effect of sorbitol

By using potentiometric titration, acid-consuming capacity, pH, hydroxide to aluminum ratio, chloride activity, X-ray diffraction, and IR spectroscopy, researchers investigated the impact of sorbitol on the ageing of aluminum hydroxide gel, which was made by reacting aluminum chloride solution with strong ammonia solution to a final pH of 7.0. During a six-month ageing period, sorbitol-containing gels lost less than 10% of their ability to neutralise acids compared to a similar gel lacking sorbitol, which lost more than 60%. The secondary polymerisation reaction that occurs with

ageing appears to be inhibited, and this is thought to be how sorbitol stabilises the gel. Quercetin, another polyhydroxy component, also helps to keep aluminum hydroxide gel stable.^[17, 18]

2.3. Formula: For each preparation of 1000 mL Table.1.

Content Actual quantity category.

Quantity taken

Aluminium hydroxide: Antacid. 360 gm 36 gm

Sorbitol Sweetener. 70 mL 7 mL

Methyl paraben Preservative. 2.0 g 0.20 g

Propylparaben Preservative. 2.0 g 0.20g

Saccharine Sweetener. 2.0 g 0.20g

Peppermint oil Aromatic agent, 5 mL 0.5 mL

flavouring agent.

Alcohol 10 mL 1 mL Solubiliser.

Purified water+ vehicle. 1000 mL 100 mL

Extracts of: Aegle Marmelos, Wound healing agent,

Anit-ulcer, carminative, prevents gastric damage.

Cinnamon, Aromatic agent.

Alovera juice, Wound healing agent. **Anti-ulcer.**

Grape's extract + Basil seed. Flavouring agent +

claming/soothing agent. Soothing agent and promotes

good sleep.

2.3.a. CATEGORY: Antacid.

2.3.b. DOSE: 7.5 to 15 ml.

2.3.c. STORAGE: Store in the well-closed container below 30 °C. Avoid freezing.

2.3.d. LABEL: To be Labelled as directed by the guide.

2.3.e. Routes of administration of the dosage forms: Oral.

2.4. Procedure

1) In the alcohol and with enough water, preservatives, saccharine, and peppermint oil were dissolved.

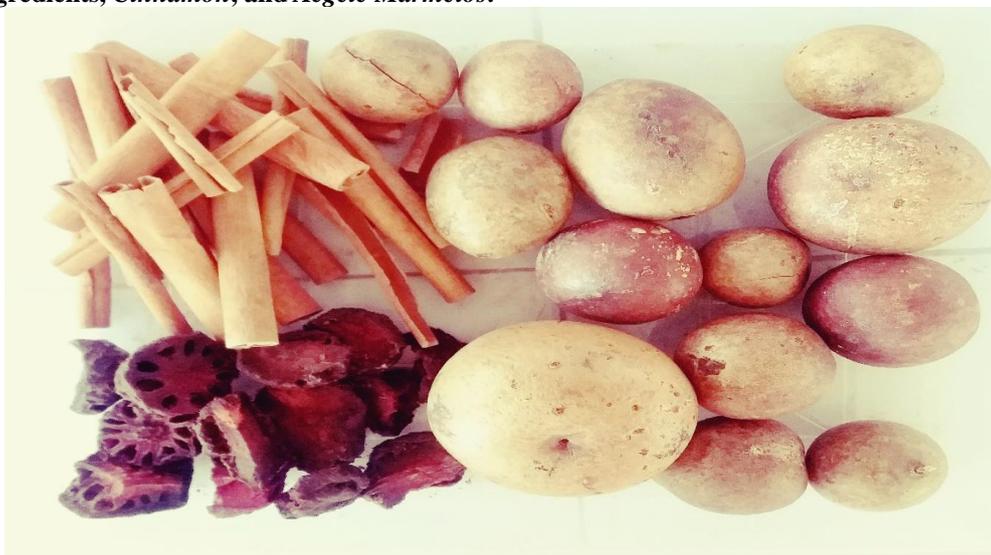
2) Aluminium hydroxide gel was added to the mortar and pestle, mixed evenly, and distributed with the other ingredients to create a homogeneous mixture.^[15]

3) The extracts and filtered purified water were used to fill the remaining capacity of the volume required and homogenised with a laboratory auto rotating blender/homogeniser to obtain smooth gel. Blending/homogenisation.

a. Basil seed extract. Grinded and pulverised. b. Chemical ingredients of the antacid.



c. Herbal ingredients, Cinnamon, and *Aegele Marmelos*.



d. Grape's *Vitis Vinifera*, collected or produced and grown from the farms in Nashik.



e. Bottle washing machine and bottle filling machine.



f. Stability studies.



Figure 5: Preparation of the Aluminium hydroxide gel.

2.5. Evaluation of the prepared formulation

2.5.i. Specific gravity

Specific gravity is a measure of the density of a substance in relation to the density of a reference substance, usually water. It is a dimensionless quantity that represents the ratio of the mass of a substance to the mass of an equal volume of water at a specific temperature and pressure.

The specific gravity of a substance is typically determined by measuring its density and comparing it to the density of water. Water has a specific gravity of 1, so substances with a specific gravity greater than 1 are denser than water, while those with a specific gravity less than 1 are less dense than water.

Specific gravity is an important physical property that can be used to identify and characterise materials. It can be used in various industries, such as: pharmaceuticals, construction, and mining, to determine the purity, concentration, and quality of materials. In addition, specific gravity is used in many scientific and engineering calculations, such as: the determination of buoyancy and the design of pipelines and storage tanks. Specific gravity of the formulation was measured using appropriate method for calculating specific gravity.

2.5.ii. Viscosity

Viscosity is a measure of a fluid's resistance to flow or its internal friction. In other words, it describes how

easily or difficultly a fluid flows. It is a physical property of liquids, gases, and even some solids, and is determined by the interaction of the molecules or particles within the fluid.

Viscosity is typically measured using the unit of measurement called poise, named after the French physician and physiologist Jean Louis Marie Poiseuille. One poise is defined as the viscosity of a fluid in which a tangential force of one dyne per square centimetre is required to maintain a difference in velocity of one centimetre per second between two parallel planes one centimetre apart.

Viscosity is an important property for many industrial and scientific applications. For example, it can affect the efficiency of oil flow through pipelines, the mixing of liquids, and the diffusion of gases. In medicine, viscosity is an important property of blood, and abnormal levels can affect circulation and contribute to cardiovascular disease.

The viscosity of the antacid was measured using Brookfield viscometer.

2.5.ii. Flowability and spreadability

The flowability and spreadability was measured using the two different designed laboratory developed techniques.

2.5.iii. Antacid acting capacity of the formulation

The antacid acting capacity of the formulation was evaluated by measuring the capacity of the prepared formulation to digest the excess secreted amount of stomach acid.

This was done using an acid base titration method that help to check the capacity of the stomach acid to be dissolved in the formation and give the hyper-acidity relief. The evaluation was done mathematically, by including the 0.5 M of the diluted HCl been released from the burette to the conical flask containing the desire amount of the antacid formulation prepared and required to be evaluated. A significant dosing of the prepared formulation could be determined by the *in-vitro* method. This includes the acid-base titration method. The end point was analysed with about a one gram of the sample weight and titrated with the 0.5 M HCL with a suitable indicator. A significant colour change produced on the titration with acid-base indicator resulted as a end point that was sufficiently identified or determined with the Methyl-orange in the complete titration, also can be performed using phenolphthalein for the end point determination. The recording was noted and document as the amount of excess HCL that is digested additionally.

In-vitro testing of antacids involves the use of laboratory techniques to evaluate the effectiveness of antacids in neutralising acid in simulated gastric environments.

2.5.iii.a. There are several methods that can be used for *in-vitro* testing of antacids, including

1. Acid-Base Titration: This method involves the addition of a known amount of antacid to an acidic solution, followed by titration with a base solution to determine the amount of acid neutralised. The endpoint of the titration is reached when the pH of the solution reaches a neutral value.

2. pH Adjustment Method: This method involves the addition of a known amount of antacid to an acidic solution, followed by the measurement of the pH of the solution. The pH is then adjusted to a neutral value by the addition of a base solution, and the amount of base required is used to calculate the amount of acid neutralised.

3. Dissolution Method: This method involves the use of a simulated gastric fluid, which is mixed with a known amount of antacid. The mixture is then stirred, and the amount of time required for the antacid to dissolve is measured. This method can provide information on the rate of antacid dissolution, as well as the amount of acid neutralised over time.

4. Gel Formation Method: This method involves the addition of an antacid to a simulated gastric fluid, followed by the measurement of the viscosity of the mixture. Antacids that form a gel in the stomach can help to protect the stomach lining from acid damage, and this

method can be used to evaluate the gel-forming properties of antacids.

In-vitro testing of antacids can provide valuable information on the effectiveness of antacids in neutralising acid in the stomach. However, it is important to note that *in-vitro* testing may not accurately reflect the conditions present in the human body, and further testing in animal models and clinical trials may be necessary to fully evaluate the safety and efficacy of antacids.

2.5.iv. Acid-Base volumetric analysis titrations: (*in-vitro* analysis)

Volumetric analysis has maintained its significance in quantitative chemical analysis despite significant advancements in the development of contemporary instrumental methods of analysis. Since reference solutions are required for calibration in instrumental methods of analysis, and one can get such standard solutions by doing either a gravimetric analysis or a volumetric analysis. In reality, provided suitable metallochromic indicators are available, some volumetric procedures, such as complexometric titration, can frequently compete with instrumental approaches. By using Winkler's approach, which involves redox titration, many industrial analyses, such as the determination of dissolved oxygen from water, can be completed. By using Karl Fischer's titration method for measuring moisture or Volhard's approach utilising precipitation titrations, it is simple to analyse the dissolved chloride from polluted water.

Analytical chemistry places a special emphasis on acid-base titrations. One can determine the pH of the solution at the equivalency point from such titrations. Moreover, K or K 's magnitude can be determined. K , the ionic product of water, or the acid dissociation constant of an acid or base, respectively. The strength of K_a , or K_b , in a titration relies on the type of acid or base, namely whether it is a strong acid, strong base, weak base, or any such combination. The hydronium (H_3O^+) ion concentration and pH are connected because:

pH or $pH = -\log [H_3O]^+$ similarly $[OH^-]$ is related to pH .

as $pOH = \log [OH^-] -\log [OH^-]$ assuming in all cases the ionic product is K , $1.0 \cdot 10^{14}$ or $pH + pOH = 14 = pK$

Since $pK_w = \log K_w$ or $-\log K$. In above expression if A is acid $B =$ base.

$[HAH_2O]$ and $K B^* [OH^-] [HOH] HB [B-H_2O]$ also $K =$ as reaction is:

$HA + H_2O = H_2O + A$ (conjugate base) HA is acid or $B + H_2O = BH + OH$ (conjugate acid BH is base).

Normally it is very easy combination of acids and bases in titrations to evaluate magnitude of (H^+) and hence pH of solution in different combination of acid, base titration.

A considered different equations for $[H]^+$ in combinations of acid and base. (a) For instance, for

titration of strong acid and strong base (e.g., in NaOH and H₂SO₄).

Assuming K₂ [OH], (H) X (a) For a powerful base and a feeble acid (e.g., CH₃COOH and NaOH).

(H)= KK (assuming [HA] [OH]) (assuming [HA] [OH]).

(e) For a powerful acid and a feeble base, it is (e.g. HSO₄ against weak base like K₂CO₃).

KK.

Finally, for (d) Weak acid and weak base, we have (for example, formic acid against sodium formate) K K. (H) = and (assuming [B] [H]).

Considering [B] [HA], (H)= As a result, the connection is used to evaluate the indicator pH.

pH range of the indicator is pK, 1. The following equations include additional formulas in addition to the one above that are used to calculate pH and titration curves precisely. VM-VM_y.

[R] = (H₂O) = (VR+VT) = [IO] Volumes of the reactant and titrant, respectively, are V if VR FT.

(Prior to equivalency).

M-M (OH) = assuming pH = -log(H₃O*) and MR MT is the molar ratio of the reactant and titrant.

(VR+V+) = [RT], where [R] = [OH] and [RT] = [H₃O⁺] are the same notations.

These two equations are frequently used in titrations to determine (H₃O) and (OH). Therefore, one can determine pH = -log (H₃O) or pOH i.e., from these equations – log (OH). The normalcy is now stated as gms equivalent per litre. For straightforward computations, we use **MV = N₂V₂**, where N₁ and N₂ are the soln's normalities. While V₁ or 1/2, are the volumes of solutions one and two, **No.1** and **No.2** is. There are numerous types of indicators utilised. The triphenyl basic dyes are typically employed as derivatives, such as: Methylorange.

The primary standards chosen keep a constant weight on exposure to the environment. Hence, it is not preferred to use compounds with water of crystallisation. Instead of detecting the end point in titration, the mixed indicators are typically utilised to determine the pH of the solution.

In the context of acid-base balance, one of the fundamental equations used is the Henderson-Hasselbalch equation. This equation relates the pH of a solution to the concentration of acid and its conjugate base. The Henderson-Hasselbalch equation is as follows: $pH = pK_a + \log([A^-]/[HA])$

In this equation:

- pH represents the negative logarithm of the hydrogen ion concentration in a solution, indicating its acidity or alkalinity.
- pK_a is the negative logarithm of the acid dissociation constant, which is a measure of the strength of an acid.
- [A⁻] represents the concentration of the conjugate base of the acid.
- [HA] represents the concentration of the acid.

The Henderson-Hasselbalch equation is commonly used to describe the relationship between the pH and the ratio of acid to its conjugate base. It is particularly useful in understanding and predicting the behavior of buffer systems in maintaining the pH of a solution.

Buffers play a vital role in maintaining the acid-base balance in biological systems, including the human body. They help resist changes in pH by accepting or donating protons (H⁺ ions) as needed. The Henderson-Hasselbalch equation is a valuable tool in studying and understanding the dynamics of acid-base balance in physiological and biochemical processes.

The Henderson-Hasselbalch equation is an equation used to relate the pH of a solution to the ratio of the concentrations of a weak acid and its conjugate base. It is commonly used in the field of chemistry, biochemistry, and physiology to understand and calculate acid-base properties and reactions. The equation is as follows: $pH = pK_a + \log([A^-]/[HA])$

In this equation:

- pH represents the negative logarithm (base 10) of the hydrogen ion concentration [H⁺] in a solution. It is a measure of the acidity or alkalinity of the solution.
- pK_a is the negative logarithm (base 10) of the acid dissociation constant (K_a) of the weak acid. The pK_a value reflects the acid's tendency to donate a proton (H⁺).
- [A⁻] represents the concentration of the conjugate base of the weak acid.
- [HA] represents the concentration of the weak acid itself.

The Henderson-Hasselbalch equation allows you to calculate the pH of a solution when the concentrations of the weak acid and its conjugate base are known, along with the pK_a value. It is particularly useful in understanding buffer systems, which are solutions that resist changes in pH. Buffer systems consist of a weak acid and its conjugate base, and their concentrations can be adjusted to maintain a relatively constant pH.

The Henderson-Hasselbalch equation can also be rearranged to solve for other variables. For example, by rearranging the equation, you can calculate the ratio of the conjugate base to the weak acid, given the pH and pK_a values.

It's important to note that the Henderson-Hasselbalch equation is applicable for weak acids and their conjugate bases, and may not accurately describe strong acids or bases. Additionally, it assumes ideal behavior and neglects the influence of ionic strength and other factors.

2.5.v. pH

pH stands for "power of hydrogen" and is a measure of the acidity or alkalinity of a solution. It is a logarithmic

scale that ranges from 0 to 14, with 7 being neutral. A pH value of less than 7 indicates acidity, while a pH value greater than 7 indicates alkalinity or basicity.

The pH of a solution is determined by the concentration of hydrogen ions (H^+) and hydroxide ions (OH^-) present in the solution. The higher the concentration of hydrogen ions, the lower the pH, and the higher the concentration of hydroxide ions, the higher the pH.

pH is an important property of solutions in many scientific, medical, and industrial applications. In chemistry, it is used to control and monitor the acidity or basicity of reactions and solutions. In biology and medicine, pH is an important factor in many physiological processes and can affect the activity of enzymes and the uptake of nutrients. In environmental science, pH can affect the quality of water and soil and the survival of aquatic organisms. In industrial processes, pH can be used to optimize the performance of chemical reactions and to control the corrosion of equipment. The pH was measured using chem.tech. Chem-line pH meter.

2.5.vi. Particle size

Particle size refers to the size of individual particles that make up a material. It is an important physical characteristic of materials, especially powders and particles, as it can have a significant impact on their properties and behavior.

Particle size is typically measured in terms of diameter, which can range from nanometers to millimeters, depending on the material and the application. Particle size distribution refers to the range of sizes present in a material and can be measured using various techniques, such as: microscopy, sedimentation, and laser diffraction.

Particle size can affect the physical and chemical properties of a material in many ways. For example, smaller particle sizes can increase the surface area of a material, which can affect its reactivity, solubility, and bioavailability. Particle size can also affect the behavior of a material in terms of flowability, compressibility, and packing density.

In many industries, particle size is an important factor in the design and optimisation of products and processes. For example, in pharmaceuticals, particle size can affect the dissolution rate and bioavailability of drugs, while in food production, particle size can affect the texture and taste of products. Particle size is also important in environmental and health studies, as it can affect the transport, deposition, and toxicity of particulate matter in the atmosphere.

Determination of particle size, particle size distribution using microscopic method was done using a calibrated eyepiece micrometer. Eye piece micrometer are scaled, which were first calibrated using a stage micrometer.

The scale was 1 mm of length that was divided into 100 parts. The smallest division on the stage micrometer is 0.01 mm or 10 μm in the length. Magnification: 10x, 45x.

2.5.vii. Sedimentation volume

Sedimentation volume is a measure of the volume of sediment that is produced when a suspension or solution is allowed to settle. It is typically used in laboratory settings to determine the concentration of particles or cells in a liquid sample.

To measure sedimentation volume, a known volume of the sample is allowed to settle for a specific period of time, typically one hour. After the settling period, the volume of the sediment at the bottom of the container is measured and compared to the original volume of the sample. The ratio of the volume of the sediment to the original volume of the sample is the sedimentation volume.

Sedimentation volume is affected by many factors, such as: particle size, density, shape, and concentration, as well as the viscosity of the liquid. It can be influenced by external factors, such as: temperature and the presence of other substances in the sample.

Sedimentation volume is commonly used in clinical settings to determine the concentration of blood cells in a blood sample, as well as in microbiology to determine the concentration of bacteria or other microorganisms in a liquid culture. It can also be used in industrial settings to monitor the concentration of particles in suspensions or to assess the efficacy of filtration processes. Sedimentation volume was performed and measured using the standard scientific method for testing the sedimentation volume.

2.5.viii. Stability studies: Stability studies were performed.

3. RESULTS AND DISCUSSIONS

3.1. Viscosity

The viscosity of the antacid was measured using Brookfield viscometer.

3.2. Flowability and spreadability

The flowability and spreadability was measured using the two different designed laboratory developed techniques.

3.3. Antacid acting capacity of the formulation: (*in-vitro* analysis)

The antacid acting capacity of the formulation was evaluated by measuring the capacity of the prepared formulation to digest the excess secreted amount of stomach acid.

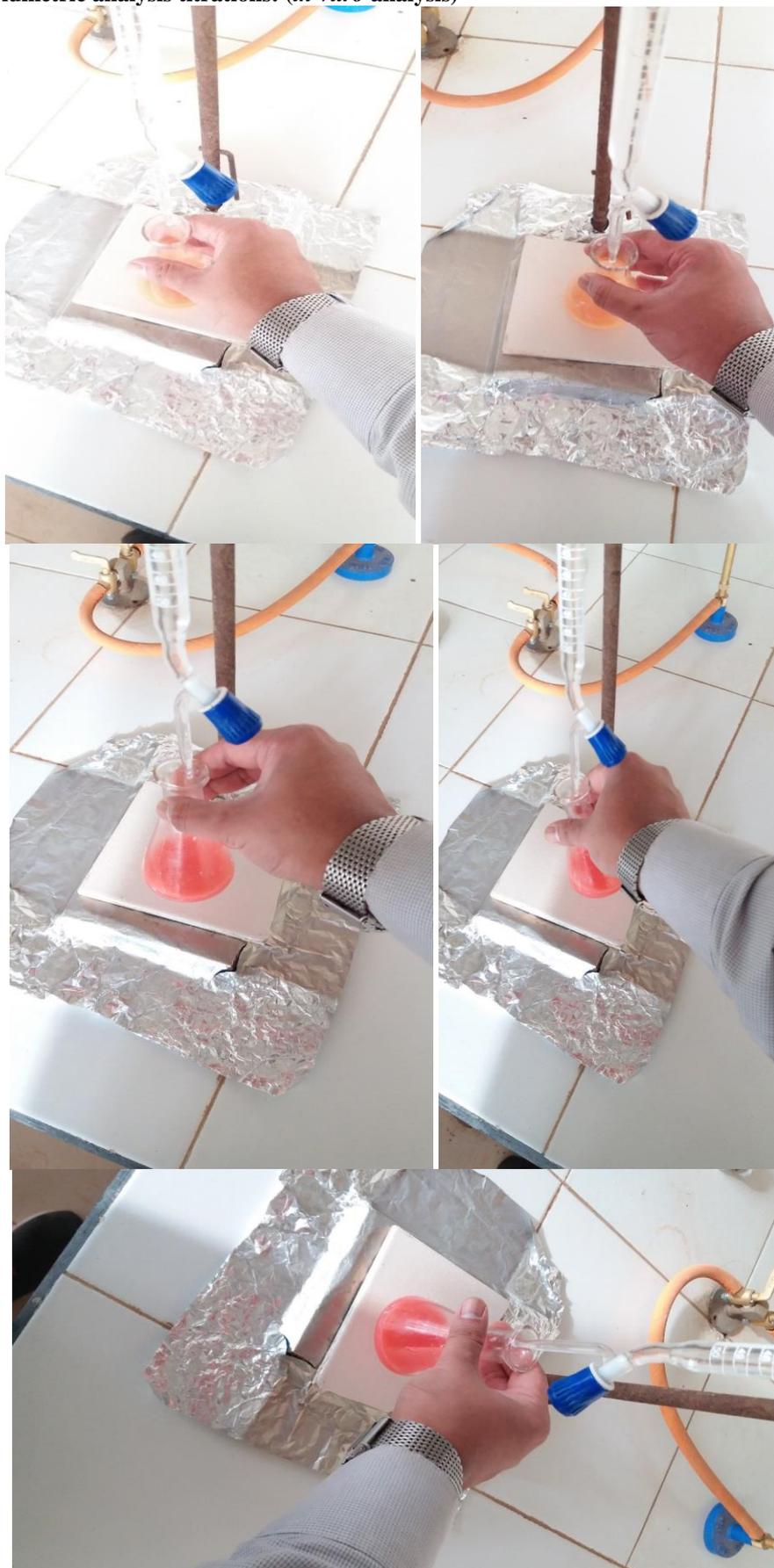
3.4. Acid-Base volumetric analysis titrations: (*in-vitro* analysis)

Figure 6: Evaluation of the formulation by chemical method of titration in the laboratory.

Table 2: Result and discussion.

Sr. no.	Parameter.	Observation.	Inference/documentated result.
1.	Specific gravity.	High or dense.	1.53 g/mL
2.	Viscosity.	Highly viscous to produce the effect. Smooth.	cP 35.
3.	Flowability and spreadability.	Super flowable, easily spreads.	Good flowability.
4.	Antacid acting capacity of the formulation. (<i>in-vitro</i> analysis)	Good/Excellent.	The antacid digesting capacity of the prepared formulation was found to be good or excellent. The formulation could digest sufficient acid that stomach produces when test <i>in-vitro</i> . Thus will 100% benefit the patient. The exact quantity of the acid that the formulated antacid can digest or neutralised, studied, and tested in the <i>in-vitro</i> method of study was recorded to be 22 mL with a sufficient dosing or the required or prescribed quantity of the dose.
5.	pH.	Basic pH was observed between 7.8 to 8.5 pH	Basic.
6.	Particle size.	Particle size was observed in microns under microscope.	420 microns.
7.	Sedimentation volume.	Sedimentation volume was measured at standard intervals between 10 minutes, 20 minutes, 30 minutes, 40 minutes, 50 minutes, 60 minutes.	Sedimentation volume was found to be less than or up to 1. Therefore, it is good.
8.	Stability studies.	Excellent and stable.	Formulation remained stable and was found suitable for the administration upon its stability checked-up was performed.

4. CONCLUSION

a. Conclusion summary: An effective method to develop the herbal preparation of an allopathic significance was achieved as an antacid developed to treat excess acid secretion, for cure of peptic and gastric ulcers. All the herbs included in the formulation are safe and sufficient to help the cure of any gastric condition in the humans or the affected person or the patient. The formula can be replaced with other such herbal or synthetic agents such as: ranitidine, famotidine, Sausage tree, (*Kigelia Africana*^[25, 26]); traditionally treat illnesses; psoriasis, wound healing, skin care, and as an aphrodisiac. Resveratrol was major focus of present work.

b. Main conclusion: An effective method to develop the herbal preparation was utilised and the formulation was prepared to effectively develop the antacid that can digest the excess acid in the stomach including the cure of the peptic ulcers and gastric troubles. All the herbal included in the formulation are safe and sufficient to help the cure of any gastric condition in the humans or the affected person or the patient. The significant role of the antacid is to neutralise the stomach acid that is found in excess. The basic fundamental to include the Alovera

was to treat the affected gastric or the stomach lining that is porm with or affected with stomach ulcers. The *Aegle marellos* add to its flavour and also helps cure the stomach problems that are associated with peptic ulcers and acidity. It revitalises the upset stomach, relieves the stomach conditions and hyperacidity easily. Cinnamon acts as a flavouring agent along with the mint oil. The formulation can be replaced with other such wound healing, ulcer curing herbal or synthetic agents to cure the peptic ulcers and hyperacidity. Such as the medication ranitidine helps to lessen the quantity of acid your stomach produces. It was employed to treat and prevent stomach ulcers, indigestion, heartburn, acid reflux, gastro-oesophageal reflux disease (GORD), and heartburn. Over-the-counter **Famotidine** is used to treat and prevent heartburn brought on by acid indigestion and sour stomach brought on by consuming particular foods and beverages. Famotidine belongs to a group of drugs known as H₂ blockers. It functions by reducing the production of stomach acid. Other similar herbal ingredients that can effectively be utilised as an antacid or antiulcer preparations include the Sausage tree, (*Kigelia Africana*^[25,26]), the herb has been used traditionally to treat a wide range of illnesses, including diarrhoea, stomach problems, rheumatism, psoriasis, and

wound healing. Moreover, it is used for skin care and as an aphrodisiac. Effective use of Resveratrol has been a major focus of this work. Resveratrol belongs to a class of substances known as polyphenols. They are believed to function similarly to antioxidants, shielding the body from harm that could increase your risk of developing diseases like cancer and heart disease.

4.1. Digital media

4.1.a. Digital e-media file.

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9. Appendix: Herbarium of Basil: Basil: (*Ocimum basilicum*).

9.1. *Ocimum basilicum*: Digital media

Ocimum basilicum, commonly known as basil or sweet basil, is a culinary herb belonging to the family *Lamiaceae*. It is native to tropical regions of central Africa and southeast Asia, India. It is now widely cultivated throughout the world for its aromatic leaves, which are commonly used as a flavouring in Italian, Thai, and other cuisines.

Basil plants are annuals that typically grow to a height of 30-60 cm. They have green, fragrant leaves that are ovate or elliptical in shape and grow in opposite pairs. The leaves are rich in essential oils, which give them their characteristic aroma and flavour.

Basil is used in a variety of culinary applications, including as a fresh herb in salads, as a seasoning in sauces and marinades, and as a topping on pizza and pasta dishes. It is also used to make pesto, a popular Italian sauce made from basil, garlic, pine nuts, and olive oil.

In addition to its culinary uses, basil has also been used in traditional medicine for its anti-inflammatory and anti-microbial properties. It is believed to have a variety of health benefits, including improving digestion, reducing stress, and lowering blood sugar levels.

Genovese basil is a variety of *Ocimum basilicum*, or sweet basil, that is known for its large, tender, and aromatic leaves. It is a popular cultivar of basil that is widely used in Italian cuisine, particularly in the region of Liguria, where it is a key ingredient in the famous pesto sauce.

Genovese basil plants grow to a height of 45-60 cm and have bright green leaves that are larger and softer than other basil varieties. The leaves have a sweet, slightly spicy flavour and a strong aroma that is often described as a combination of mint and cloves.

Genovese basil is typically grown in warm, sunny locations with well-drained soil. It is a fast-growing plant that requires regular pruning to encourage bushy growth and prevent it from flowering too early.

In addition to its culinary uses, Genovese basil is also believed to have a variety of health benefits. It is rich in vitamins A and C, as well as minerals such as calcium, iron, and potassium. It is also believed to have anti-inflammatory and antioxidant properties, and may help to improve digestion and reduce stress levels.

Purple basil, also known as dark opal basil, is a variety of sweet basil (*Ocimum basilicum*) that is characterised by its dark purple or burgundy leaves. It is often grown for its ornamental value in addition to its culinary uses.

Like other varieties of sweet basil, purple basil is an annual herb that grows to a height of 30-60 cm. It produces small, white flowers in the summer months, but these are typically removed to encourage the plant to focus its energy on producing leaves.

The leaves of purple basil are similar in shape and size to those of other sweet basil varieties, but they have a distinctive purple colour that makes them stand out in the garden. The leaves have a slightly milder flavour than green basil, but they can be used in the same way in cooking.

In addition to its culinary uses, purple basil is believed to have a number of health benefits. It is rich in antioxidants, which help to protect the body against damage from free radicals. It is also believed to have anti-inflammatory and anti-microbial properties, and may help to lower blood sugar levels.

Overall, purple basil is a flavourful and attractive addition to any herb garden or kitchen, and can be used in a variety of culinary applications, from salads and sauces to pizzas and pasta dishes.

Common Name(s): Basil, Genovese, Basil Purple Basil, Saint Joseph's Wort, Sweet Basil, Thai Basil.



9.2. Label of formulation: Digital media

Content	Actual	quantity
Quantity taken: Mfg dt.: 2023		
Exp. Date: 3 years from mfg.		
Aluminium hydroxide:	category: Antacid. 360 gm	36 gm
Sorbitol	Sweetener. 70 mL	7 mL
Methyl paraben	Preservative. 2.0 g	0.20 g
Propylparaben	Preservative. 2.0 g	0.20g
Saccharine	Sweetener. 2.0 g	0.20g
Peppermint oil	Aromatic agent, 5 mL flavouring agent.	0.5 mL
Alcohol		10 mL
Solubiliser.		
Purified water+	vehicle. 1000 mL	100 mL
Extracts of:		
Aegele Marmelos,		
Wound healing agent,		
prevents gastric damage.		
Cinnamon,		
Aromatic agent.		
Alovera juice,		
Wound healing agent.		
Anti-ulcer.		
Grape's extract + Basil seed.	Flavouring agent + claming/soothing agent.	Soothing agent and promotes good sleep.



Anti-ulcer, carminative,

Flavouring agent + claming/soothing agent. Soothing agent and