

Development And Evaluation of Medicated Chocolate

Mansee Bhoir*, Sanket Dharashivkar

Department of Pharmaceutics, St. Wilfred's Institute of pharmacy, Panvel

ABSTRACT

This study focused on the formulation and evaluation of oral medicated jellies incorporating natural plant extracts from *Trachyspermum ammi* (Ajwain), *Foeniculum vulgare* (Fennel), and *Cuminum cyminum* (Cumin), selected for their potential antacid properties. Bioactive compounds were extracted using maceration and decoction techniques, and the presence of phytochemicals such as alkaloids, flavonoids, phenols, and terpenoids was confirmed through preliminary screening. A total of six jelly formulations (F1–F6) were prepared using gelatin as the primary gelling agent, complemented by castor sugar, glycerin, and peppermint oil to enhance palatability and stability. Preformulation studies involved melting point analysis, calibration curve generation, and Fourier-transform infrared (FTIR) spectroscopy to evaluate component compatibility. Among the six, formulation F4 demonstrated optimal characteristics and was selected for further analysis. Comprehensive physicochemical evaluations, including assessments of pH, thickness, viscosity, weight variation, and moisture content, were conducted. In addition, microbiological stability, in vitro dissolution, and acid-neutralizing capacity (ANC) were investigated. The optimized formulation exhibited desirable physical attributes, stable pH, acceptable microbial limits, and effective ANC, indicating its suitability as a natural antacid. These findings suggest that plant-based medicated jellies represent a viable, patient-friendly approach for managing gastrointestinal conditions, combining therapeutic efficacy with ease of administration.

Keywords: Ajwain, Cumin, Fennel, oral medicated jellies, acid neutralizing capacity.

INTRODUCTION

What is Acidity?

The term acidity refers to the stomach's excessive output of hydrochloric acid. Hyperacidity is simply an elevated level of acid in the stomach. The stomach secretes hydrochloric acid, a digestive liquid that reduces food particles to their smallest form to ease digestion. Hyperacidity occurs when the cells in the stomach lining secrete more hydrochloric acid than usual [1,2].

Common Symptoms of Acid Reflux and GERD

Gastroesophageal Reflux Disease (GERD), commonly referred to as acid reflux, presents with a range of symptoms that can vary in severity and frequency. One of the most commonly reported symptoms is chest discomfort or pain, which is often mistaken for cardiac-related issues. A burning sensation in the chest or throat known as heartburn is

a hallmark feature, resulting from stomach acid rising into the esophagus [2,3].

Difficulty swallowing (dysphagia) is also frequently observed, often due to inflammation or irritation of the esophageal lining, which can create a sensation of food being stuck. Additionally, individuals may experience a sour or bitter taste in the mouth when acid reflux reaches the oral cavity. Respiratory manifestations are not uncommon and may include chronic coughing, wheezing, breathing difficulties, or asthma-like symptoms, often due to acid irritating the respiratory tract. Excessive salivation can occur as a reflex to neutralize stomach acid. Over time, repeated acid exposure may erode tooth enamel, leading to dental sensitivity and an increased risk of cavities [4,5]. Another commonly reported symptom is frequent burping or belching, typically caused by swallowed air or excess gas production in the stomach.

Prevalence of Acidity

Relevant conflicts of interest/financial disclosures: The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

Over the past few decades, the incidence of gastroesophageal reflux disease (GERD) characterized by frequent episodes of heartburn or acid regurgitation has significantly increased across Asia. In East Asian countries, its prevalence rose from 2.5%-4.8% before 2005 to 5.2%-8.5% between 2005 and 2010, while cases of endoscopic reflux esophagitis also grew, reaching 4.3%-15.7% after 2005 compared to 3.4%-5.0% before 2000. Country-specific data highlight regional differences, with GERD rates reported at 4.1%-7.3% in China, 7.7% in Japan, 3.5%-8.5% in Korea, 12.4% in Taiwan, and 10.5% in Singapore. In Iran, prevalence estimates vary from 6.3% to 18.3%, with some findings indicating rates as high as 21.86%. The increasing trend in GERD across these regions is largely attributed to lifestyle changes such as urbanization, adoption of Western dietary patterns, rising obesity rates, and socioeconomic transformation [6,7].

Factors affecting the acidity

Acidity, or gastroesophageal reflux disease (GERD), occurs when stomach acid flows back into the esophagus, causing discomfort and complications. Several factors contribute to the risk of developing acidity. A weakened lower esophageal sphincter (LES) fails to prevent acid backflow, while a hiatal hernia allows the upper stomach to push through the diaphragm, exacerbating reflux. Obesity and pregnancy increase abdominal pressure, promoting acid movement into the esophagus. Smoking reduces LES efficiency and saliva production, both vital in neutralizing stomach acid. Certain medications, including NSAIDs, calcium channel blockers, and antidepressants, may either relax the LES or irritate the esophageal lining. Dietary habits such as consuming citrus fruits, tomatoes, caffeine, chocolate, alcohol, carbonated drinks, onions, garlic, mint, and high-fat foods can trigger acid reflux. Eating large meals, lying down after eating, and delayed gastric emptying due to conditions like gastroparesis also heighten risk. Additionally, aging may weaken esophageal function and LES integrity. Common symptoms include heartburn, a sour taste in the mouth, bloating, frequent burping, nausea, vomiting, and headaches. Stomach acid, typically with a pH of 1–2, plays a crucial role in digestion, but excessive secretion can lead to GERD a condition known in

Ayurveda as Urdhva Gata Amalpitta composed mainly of hydrochloric acid, potassium chloride, and sodium chloride. Early identification of symptoms is essential for effective management and to prevent chronic complications [2,8].

Treatment of Acidity by Antacids

Sodium bicarbonate (NaHCO_3) functions as an effective antacid by neutralizing the hydrochloric acid (HCl) present in the stomach. When ingested, sodium bicarbonate reacts with gastric hydrogen ions (H^+) to produce carbonic acid (H_2CO_3), which rapidly decomposes into water (H_2O) and carbon dioxide (CO_2). This process results in a swift reduction of stomach acidity. The sodium ions (Na^+) released during this reaction are absorbed into the bloodstream, while the pancreas helps regulate bicarbonate levels through the secretion of sodium (Na^+) and bicarbonate (HCO_3^-) ions [9]. Other frequently utilized antacid agents include calcium carbonate (CaCO_3), magnesium hydroxide ($\text{Mg}(\text{OH})_2$), and aluminum hydroxide ($\text{Al}(\text{OH})_3$). These substances neutralize gastric acid through interactions between hydrogen ions and either carbonate (CO_3^{2-}) or hydroxide (OH^-) ions, depending on the compound involved. Calcium carbonate neutralizes acid via carbonate ions, whereas magnesium and aluminum hydroxides act through hydroxide ions [10].

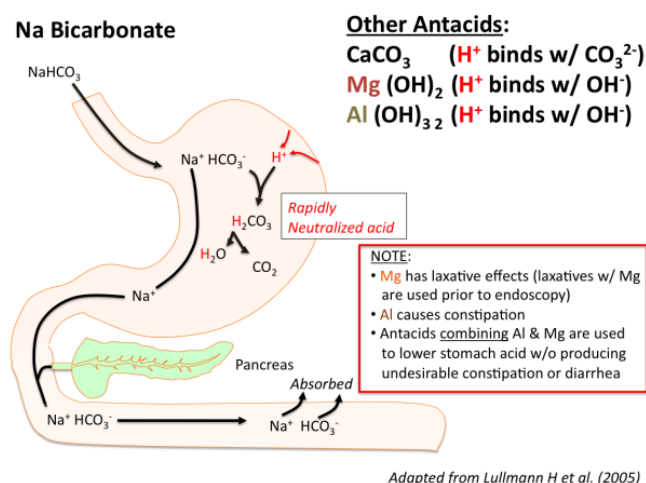


Figure no 1 Action of antacid on acidity

Each antacid exhibits distinct gastrointestinal side effects. Magnesium-based antacids often induce a laxative effect and are occasionally used for bowel



cleansing prior to endoscopic examinations. Conversely, aluminum-containing antacids tend to cause constipation. To mitigate these opposing effects, combination formulations of magnesium and aluminum are commonly employed, effectively reducing stomach acidity while minimizing adverse gastrointestinal symptoms such as diarrhea or constipation ^[11].

HERBAL AND TRADITIONAL MEDICINE FOR ACIDITY

Herbal remedies, especially those incorporating probiotics, play a crucial role in supporting digestive health. These treatments are commonly derived from natural plant parts such as leaves, roots, seeds, and flowers ^[12]. Traditional healing systems have long relied on polyherbal formulations combinations of multiple herbs to enhance therapeutic effects. This approach is a hallmark of ancient medical traditions, including Ayurveda and Traditional Chinese Medicine.

Polyherbal formulations aim to leverage the synergistic interaction of different herbs, which can increase overall efficacy while reducing the required dosage and limiting adverse effects. This strategy not only optimizes therapeutic benefits but also enhances patient safety. Although these formulations have a rich history of use, ongoing scientific research is essential to better understand the complex interactions among the constituent plant compounds, which can yield both synergistic and antagonistic effects ^[13].

The use of herbal medicine traces back to ancient civilizations, with documented practices in Greece between 468 and 377 B.C. This knowledge was preserved and expanded by the Romans and further developed by Islamic scholars after the Roman Empire's decline. By the 10th century, herbal medicine was widespread across Europe, often regulated by religious institutions. Despite the rise of formal medical schools in the late Middle Ages, the influence of the church on herbal practices remained significant ^[14].

The benefits of polyherbal formulations include enhanced therapeutic synergy, reduced drug dosage requirements, improved patient compliance through

simplified regimens, and potentiation of active phytochemicals when combined ^[15].

Ajwain (*Trachyspermum ammi* L.) is a herbaceous plant from the Apiaceae family, growing 60–90 cm tall with feathery foliage and small red-white flowers. Its seeds are oval, brown to grey, and known for a strong, thyme-like aroma with a mildly bitter taste.

Thymol, the main bioactive compound in ajwain, underpins its therapeutic effects, particularly for gastrointestinal issues such as indigestion, bloating, and cramps. It also plays a role in managing acid-related conditions like *Urdhva Gata Amalpittha* in Ayurvedic medicine.

Nutritionally, ajwain is rich in carbohydrates (24.6%), proteins (17.1%), fats (21.1%), and dietary fiber (11.9%). It provides essential minerals including calcium, iron, magnesium, and phosphorus. Its essential oil content (2.5%–5%) primarily consists of thymol and carvacrol, along with other volatile compounds like γ -terpinene, p -cymene, and limonene, which contribute to its distinctive flavor and medicinal value ^[16].

Fennel (*Foeniculum vulgare*), a perennial herb from the Apiaceae family, is native to the Mediterranean and widely naturalized globally. Growing up to 2.5 meters, it features feathery leaves and yellow flower clusters. It is classified into bitter and sweet varieties and flourishes in dry coastal or riverine areas.

Widely valued for both culinary and medicinal purposes, fennel aids in managing digestive issues, fever, insomnia, liver ailments, and hypertension. It is rich in bioactive compounds, including essential oils (anethole, estragole, fenchone), flavonoids, saponins, and vitamins. Pharmacologically, it exhibits antimicrobial, antidiabetic, antioxidant, anti-inflammatory, and potential anticancer activities, supporting cardiovascular and gastrointestinal health. Its roots, leaves, and seeds are most commonly used for therapeutic applications ^[17].

Cummin (*Cuminum cyminum*), a member of the Apiaceae family, is widely cultivated in the Mediterranean, Indian subcontinent, and Middle East. Its medicinal value stems from bioactive compounds such as cuminaldehyde, γ -terpinene, and β -pinene,



known for their anti-inflammatory and carminative properties. Rich in antioxidants like caffeic and ferulic acids, as well as flavonoids (apigenin, luteolin, quercetin), cumin supports gastrointestinal health and aids in acid neutralization.

Alkaloids such as pyrazines stimulate digestive enzyme secretion, while saponins like diosgenin protect the gastric lining and help regulate stomach pH. Essential minerals including calcium, magnesium, zinc, and potassium support enzymatic activity and buffer gastric acid.

Cumin's antacid effects are attributed to acid neutralization, digestive stimulation, and mucosal protection. Additionally, its constituents help relieve bloating and support gut microbiota balance. Traditionally, it is consumed as cumin water, tea, roasted powder in buttermilk, or raw seeds after meals to aid digestion.

In summary, cumin promotes digestive wellness by reducing acidity, enhancing enzyme activity, protecting the gastric lining, alleviating gas, and maintaining gut health ^[18].

LIST OF MATERIALS

The formulation comprises a range of carefully selected ingredients, each fulfilling a distinct functional role. Ajwain, cumin, and fennel serve as the active pharmaceutical ingredients (APIs) and were procured from the local market. Glycerin, supplied by Chemdyes Corporation, functions as a gelling agent, while gelatin, sourced from Chefzaa, acts as a lubricant. Castor sugar, obtained from Organic and Pure, is incorporated as a sweetening agent. Peppermint oil, utilized for flavoring, and methyl paraben, serving as a preservative, were both acquired from Sisco Research Lab. Distilled water is employed as the solvent throughout the formulation process.

LIST OF INSTRUMENTS

Various instruments were employed throughout the formulation development and evaluation process. The concentration of unknown substances was determined using a UV-Visible spectrophotometer (Lab India). Precise weighing of materials was conducted with an electronic balance (Wensar). The formulation's pH

was measured using a digital pH meter (Swastika Scientific Instruments). Solution mixing was facilitated by a magnetic stirrer manufactured by Gupta, an ISO 9001-2008 certified company. Formulation thickness was assessed using a vernier caliper (Swastika Scientific Instruments). Drug dissolution and release profiles were evaluated with a Dissolution Test Apparatus (Model TDT 08L, USP) from Electro Lab. Stability studies utilized a desiccator (Swastika Scientific Instruments). The flow properties of the formulation were analyzed using a Brookfield Viscometer. Finally, compatibility assessments were performed employing Fourier Transform Infrared (FTIR) spectroscopy with the Miracle 10 Single Reflection ATR Accessory from Shimadzu.

EXPERIMENTAL WORK

1) Extraction process (Maceration process)

The process began with the selection and preparation of the plant material. A total of 100 grams of dried plant material was accurately weighed and then coarsely powdered using either a grinder or a mortar and pestle. For the extraction, the powdered material was transferred into a clean, dry glass container equipped with a tight-fitting lid. Subsequently, 1000 mL of solvent was added to the container, which was then sealed and shaken thoroughly to ensure complete wetting of the plant material. The mixture was left to macerate at room temperature ($25 \pm 2^\circ\text{C}$) for 72 hours, during which it was shaken three to four times daily to enhance the extraction process. After the soaking period, the mixture was subjected to filtration using either muslin cloth or Whatman No. 1 filter paper, and the resulting filtrate was collected in a clean, dry beaker. To concentrate the extract, the filtrate was transferred to a rotary evaporator and evaporated under reduced pressure at a controlled temperature of $40\text{--}50^\circ\text{C}$ until a semi-solid mass was obtained. In the absence of a rotary evaporator, a water bath was used as an alternative method for slow solvent evaporation. Finally, the concentrated extract was weighed and stored in a sealed amber vial under refrigeration at $4\text{--}8^\circ\text{C}$ for future use.

2) Phytochemical Screening



Extract of drugs was subjected to qualitative analysis of various active constituents, such as alkaloids, saponins, glycosides, tannins, terpenoids, phenol, flavonoids etc.

3) Calibration curve of standard drug

To prepare a calibration curve, you'll need to dissolve a known weight of the active ingredient in a solvent and then create a series of dilutions to establish a range of concentrations. These dilutions will be analyzed using a spectrophotometer to measure absorbance at a specific wavelength, and then a graph will be plotted with absorbance on the y-axis and concentration on the x-axis

4) Determination of melting point

Melting point determination equipment was used to ascertain the drug's melting point as given in fig A thermometer was used to determine the drug's melting point after it had been put into a capillary tube.

5) Compatibility study

FTIR (Fourier Transform Infrared) study, or FTIR spectroscopy, is an analytical technique that identifies the chemical composition of materials by analyzing

how they interact with infrared light. It works by measuring the infrared radiation absorbed by a sample, creating a unique spectrum or "fingerprint" that reveals the presence of specific chemical bonds and functional groups.

FORMULATION OF ORAL MEDICATED JELLIES

Oral medicated jellies can be prepared by using gelling agent gelatin. Castor Sugar is used as a sweetening agent. Methyl paraben (0.18%) is used as preservatives. Peppermint oil is used as flavouring agent. API (i.e. Decoction of Ajwain, Fennel, Cumin) decoction. Purified water up to 100% as vehicle can be used. Firstly, decoction was prepared by heating all accurately weighed ingredients in 1000 ml distilled water up to reduction of volume by 500 ml. Extract so obtained was then filtered. Then, 20 gm of gelatine and 37.5 ml of distilled water were heated separately on water bath and 10 ml of glycerine was added to it and heated. Further, 6 gm castor sugar was added. To clear solution, about 10 ml of each extract was added and heating stopped. Lastly, peppermint oil was added as flavouring agent. Then, mixture was poured into moulds and allowed to cool at room temperature ^[20].

Table no 1 Formula table of medicated jellies

Sr. No.	F1	F2	F3	F4	F5	F6
Gelatin	20gm	20gm	20gm	20gm	20gm	20gm
Glycerine	5ml	4ml	5.5ml	10ml	6.5ml	6.5ml
Castor Sugar	15gm	10gm	8gm	6gm	3gm	0gm
Ajwain decoction	10ml	10ml	10ml	10ml	10ml	10ml
Fennel Decoction	10ml	10ml	10ml	10ml	10ml	10ml
Cumin Decoction	10ml	10ml	10ml	10ml	10ml	10ml
Methyl Paraben	0.1mg	0.1mg	0.1mg	0.1mg	0.1mg	0.1mg
Peppermint oil	0.1ml	0.1ml	0.1ml	0.1ml	0.1ml	0.1ml
Distilled Water	q.s. 100ml	q.s. 100ml	q.s. 100ml	q.s. 100ml	q.s. 100ml	q.s. 100ml

EVALUATION OF ORAL MEDICATED JELLIES

- 1) **Physical Appearance:** Colour, Uniformity, texture, surface smoothness, flexibility
- 2) **Thickness:** The thickness of the jellies was measured using digital vernier calliper. For each

formulation three randomly selected jellies were used and average thickness was recorded.

- 3) **Weight variation:** Six jellies from each batch were weighed individually and the average weight was calculated.
- 4) **Stickiness and Grittiness:** The texture of the medicated jelly in terms of stickiness and



grittiness was examined by visually inspecting the product after gently rubbing a sample between two fingers.

- 5) **pH:** The pH of the final jelly influences both its stability and taste. It was measured using a digital pH meter at room temperature. A 1% solution was prepared by dispersing 0.5 gm of jelly in 50 ml of distilled water, and the pH was recorded.

6) **Viscosity Measurement**

A Brookfield viscometer is frequently used to measure the viscosity of medicinal jelly. This entails using a spindle to carefully measure the jelly's resistance to flowing at a certain temperature and speed, then interpreting the results. Make that there are no air bubbles or other contaminants in the jelly and that it is at the proper temperature, which is typically $25^{\circ}\text{C} \pm 5^{\circ}\text{C}$. Choose the proper spindle: Select a spindle (such as spindle number 63) that is appropriate for the jelly's anticipated viscosity range. Get the viscometer set up: Decide on the desired measurement period (e.g., 2 minutes) and speed (e.g., 50 rpm). Start the viscometer after inserting the spindle completely into the jelly sample. At the conclusion of the measuring period, note the viscosity reading. To ensure accuracy and determine the average viscosity, repeat the measurement multiple times. The viscosity measurement, which is commonly expressed in millipascal seconds (mPa.s) or centipoises (cP), shows how difficult it is for the jelly to flow [21].

7) **Microbiological Studies**

Prepare nutrient agar and sterilise by auto clave at 121°C , 15. lbs from 15 minutes. Pour the medium (about is to 20m) into Petriplates carefully. Rotate the petriplate to allow for uniform distribution of the medium and solidity it. Follow all aseptic conditions to avoid contamination. Take a small amount of bacterial to inoculum by nichrome wire loop from agar slants or agar plates. Carefully lift the lid and streak the culture on the agars medium. Streak the culture as a first zone by using inoculum and then flame the wire loop to destroy the culture present on wire loop. By using first. Zone, prepare a second zone of inoculum, and again flame the wire loop. Prepare third zone of

inoculum the wire by using second zone and again flame loop. Spread the culture in fourth cone by using third zone and finally sterilize the wire loop. Different techniques of streaking may be performed on different Petri plates using the same inoculum. Incubate the Petri plates at 30 to 37°C for 24 to 48 hours.

8) **Dissolution Studies of Medicated Jelly**

In-vitro dissolution studies for antacid jellies are essential for evaluating the release rate and pattern of active ingredients, such as antacid agents, from the jelly formulation. These studies simulate how the drug behaves in the body after administration, ensuring its efficacy and safety. The study typically involves the use of a dissolution apparatus, such as USP Apparatus II (paddle method) or USP Apparatus I (basket method), where the jelly sample is placed in a dissolution medium (simulated gastric or intestinal fluid) at 37°C , with the paddle or basket rotating at 75 rpm. The dissolution medium is generally a buffer solution mimicking the stomach or intestinal environment, with a pH of 1.2 for gastric fluid or 6.8 for intestinal fluid. During the study, the jelly sample is agitated in the medium, and at predefined time intervals (e.g., 5, 10, 15, 30, 60, and 120 minutes), samples are withdrawn for analysis. The drug release is analysed using UV spectrophotometry to measure the concentration of the active ingredient [19].

9) **Determine Acid-Neutralizing Capacity (ACN)**

The experiment was carried out at a temperature of $37^{\circ}\text{C} \pm 3$ and three determinations were performed for every brand. A volume of 30 ml of 1 N HCl accurately measured was added to the preparation and the stirring was continued for 15 min accurately timed at a rate of 300 rpm. At the end of the 15 min, the excess HCl was titrated in less than 5 minutes with a 0.5 N solution of NaOH to attain a stable pH of 3.5. When the pH obtained at the end of the 15 min before beginning the titration was superior to 3.5, the procedure was started all over again using 60 ml of HCl instead of 30 ml and the appropriate modification was made in the formula. The number of milliequivalents (mEq) of acid consumed was calculated by the formula:



$$\text{ANC (mEq)} = (30 \times \text{NHCl}) - (\text{VNaOH} \times \text{NNaOH})$$

10) Stability

The jelly formulations kind of were packed in aluminium foils and stored in polyethylene containers at 0 °C, 25 °C/60% RH for 90 days. A typical procedure for a stability study of an antacid jelly involves assessing its physical, chemical, and microbiological characteristics

studies

over time under controlled conditions. This helps determine shelf life and potential degradation pathways.

RESULTS & DISCUSSION

1. Phytochemical Analysis of API

The phytochemical screening of the ajwain, fennel and cummin is revealed the presence and absence of various phytoconstituents, as summarized in table no 2.

Table no 2 Results of Phytochemical screening

Sr No	Phytoconstituents	Ajwain	Fennel	Cummin
1	Alkaloids	+	+	+
2	Flavonoids	+	+	+
3	Tannins	-	+	+
4	Saponins	+	+	-
5	Terpenoids	+	+	+
6	Phenols	+	+	+
7	Glycosides	-	-	+
8	Cardiac Glycosides	-	-	+

1) Determination of maximum wavelength

Table no 3 Absorbances of ajwain

AJWAIN			
Stock Solution taken (ml)	Distilled Water (ml)	Concentration (ppm)	Absorbance
0	10	0	0
0.2	9.8	2	0.102
0.4	9.6	4	0.198
0.6	9.4	6	0.298
0.8	9.2	8	0.403
1	9	10	0.502
1.2	8.8	12	0.599
1.4	8.6	14	0.698
1.6	8.4	16	0.804
1.8	8.2	18	0.856
2	8	20	0.998



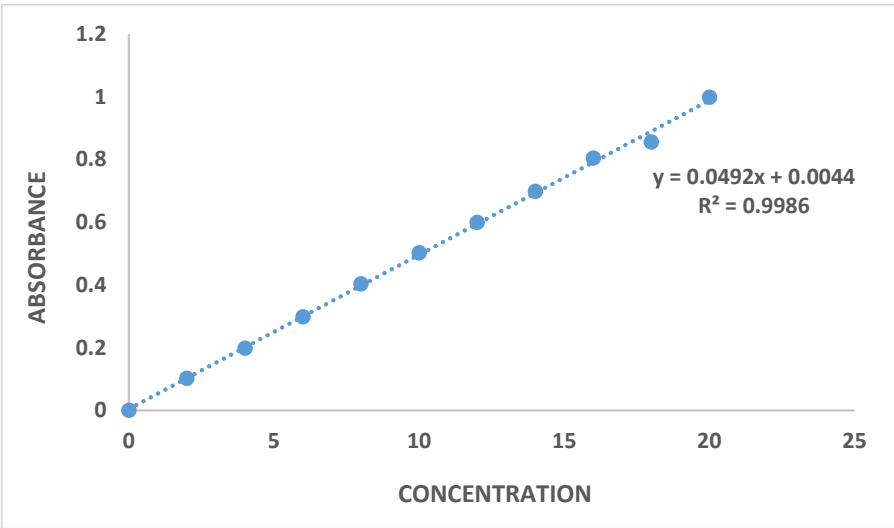


Figure no 2 Graph of linearity of ajwain

Table no 4 Absorbances of cummin

CUMMIN			
Stock Solution taken (ml)	Distilled Water (ml)	Concentration (ppm)	Absorbance
0	10	0	0
0.2	9.8	2	0.189
0.4	9.6	4	0.215
0.6	9.4	6	0.305
0.8	9.2	8	0.395
1	9	10	0.451
1.2	8.8	12	0.504
1.4	8.6	14	0.586
1.6	8.4	16	0.642
1.8	8.2	18	0.745
2	8	20	0.894

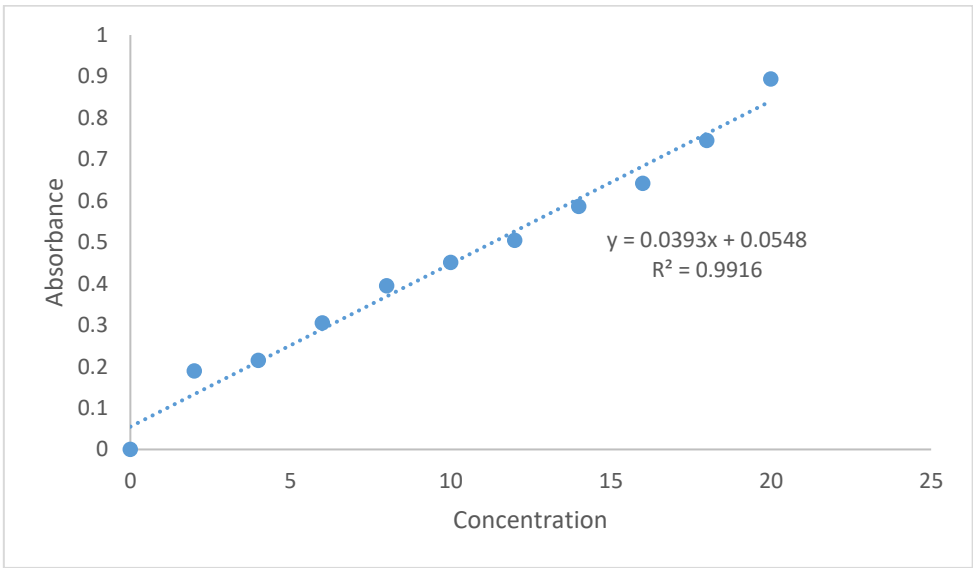


Figure no 3 Graph of linearity of cummin

Table no 5 Absorbances of funnel

FUNNEL			
Stock Solution taken (ml)	Distilled Water (ml)	Concentration (ppm)	Absorbance
0	10	0	0
0.2	9.8	2	0.095
0.4	9.6	4	0.249
0.6	9.4	6	0.306
0.8	9.2	8	0.365
1	9	10	0.463
1.2	8.8	12	0.573
1.4	8.6	14	0.624
1.6	8.4	16	0.732
1.8	8.2	18	0.817
2	8	20	0.934

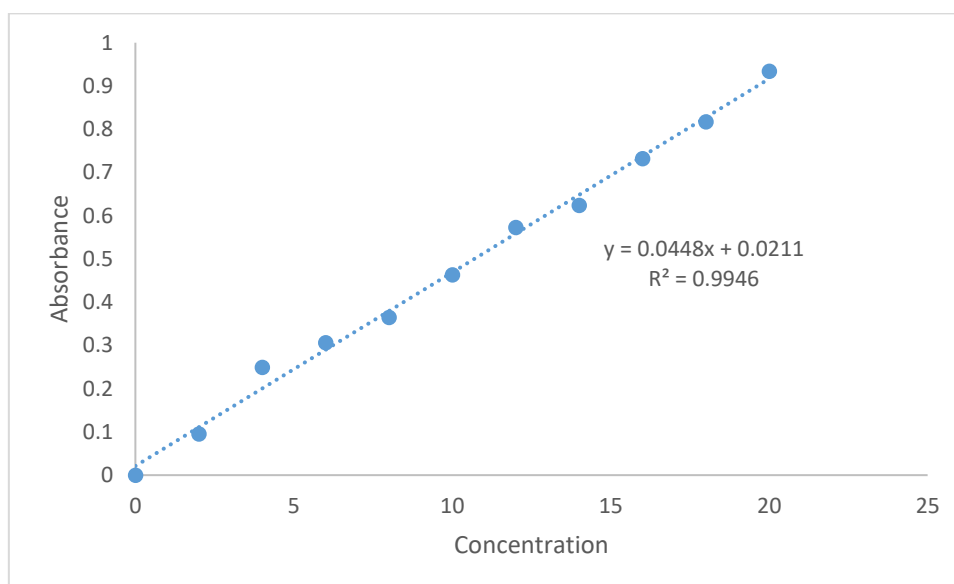


Figure no 4 Graph of linearity of Funnel

2) Determination of melting point

The melting point of ajwain, funnel and cummin was found to be 50 °C, 200 °C, 95 °C

3) Compatibility studies by FTIR

FTIR (Fourier Transform Infrared Spectroscopy) can be used to analyze the chemical composition of

antacid jelly made from fennel, Cummin, Ajwain and Gelatin. FTIR analysis can identify the presence of functional groups like OH stretching, CH₂, carboxyl/carbonyl, C=C, and other vibrational modes present in components. These functional groups can provide insights into the chemical nature of the antacid jelly and its compatibility with other ingredients. Shown in following Figure



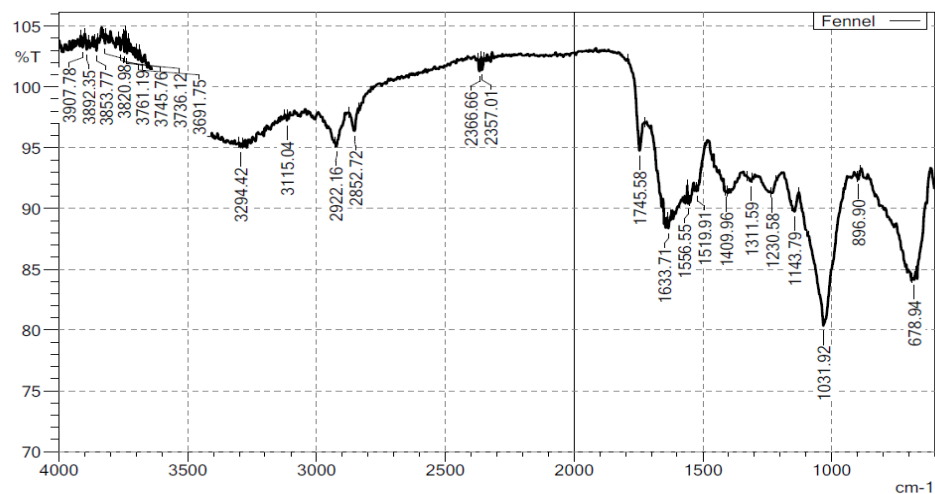


Figure no 5 FTIR of Fennel

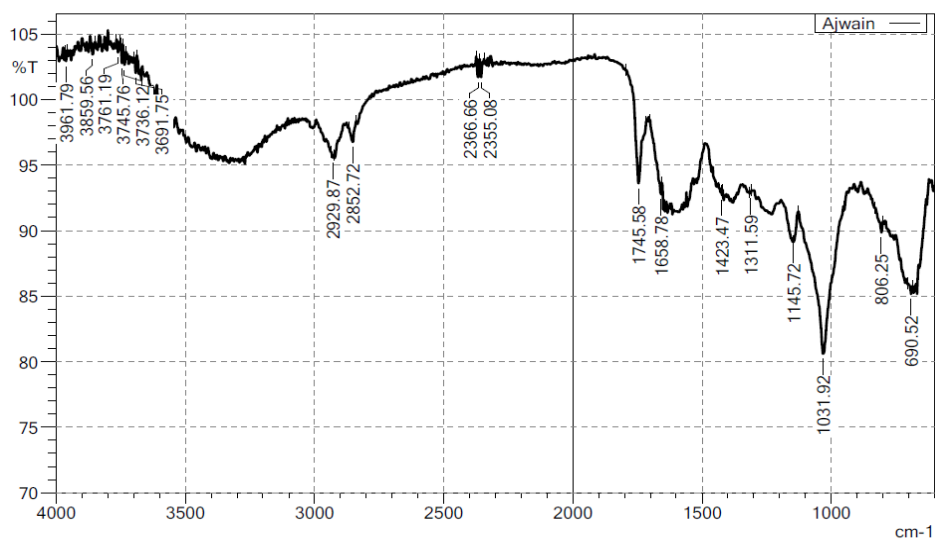


Figure no 6 FTIR of ajwain

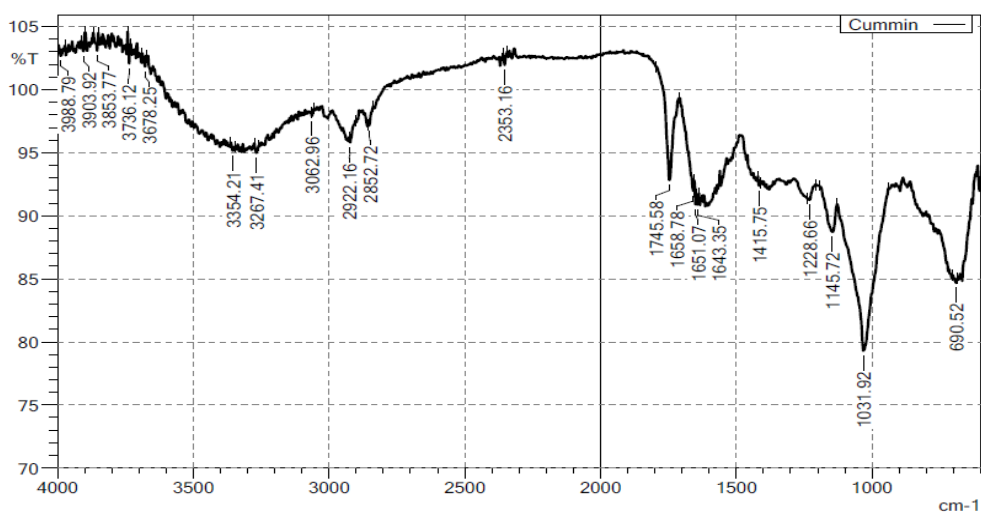


Figure no 7 FTIR of cummin



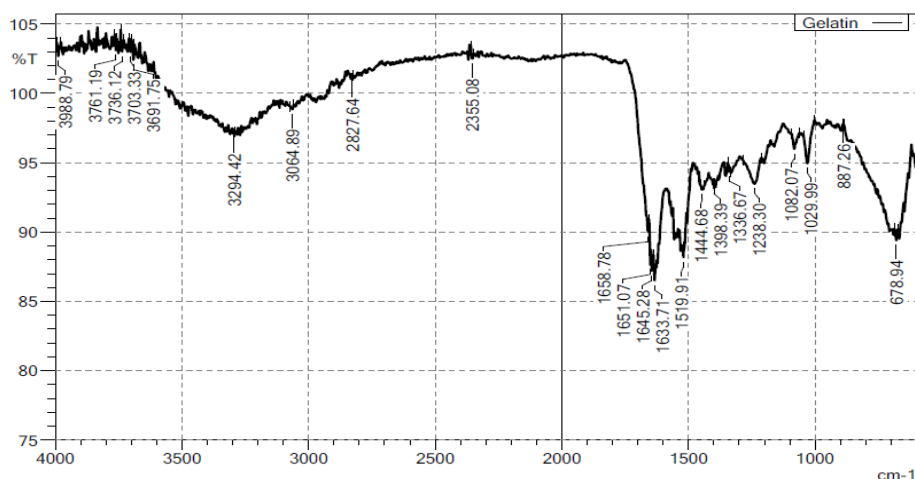


Figure no 8 FTIR of gelatin

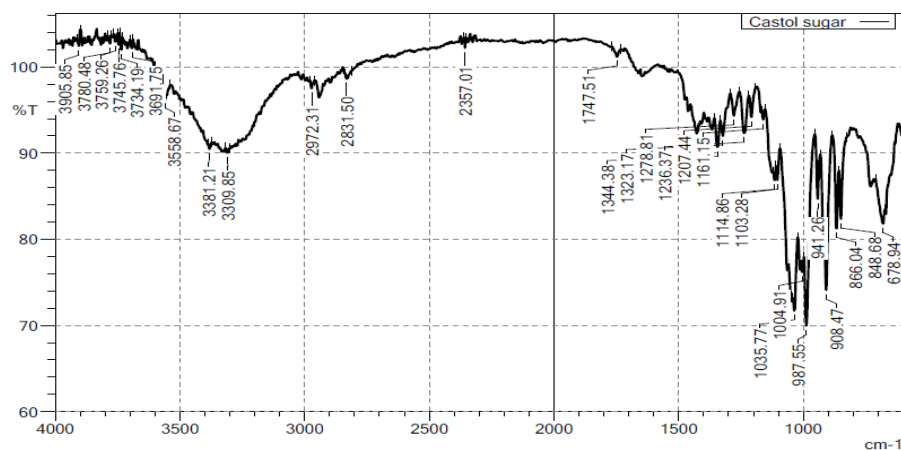


Figure no 9 FTIR of Castor sugar

Table no 6 FTIR peaks of drug + excipients

Peak (cm-1)	Assignment	Functional group
682.8	C-H Bending	Aromatic ring
896.9	C-H wagging	Aromatic / Alkene
1029.9	C-O stretch	Alcohols, ethers
1153.4	C-N stretch/ C-O	Amines or esters
1234.4	C-N/ C-O	Amine or ether groups
1392.6	O-N Bend	Phenols or alcohols
1444.7	CH2 bending	Alkanes
1519.9, 1556.6	C=C stretch	Aromatic rings
1633.7, 1658.8	C=O/ C=C	Amide or alkene
1745.6	C=O stretch	Ester/ carboxylic acid
2862.4-2937.6	C-H stretching	Alkanes
3290.6	N-H/ O-H stretch	Amide (Gelatin), hydroxyl
3691-3886.6	O-H stretch	Alcohol, phenols

The FTIR analysis of the formulation reveals distinct functional groups corresponding to its herbal and

soothing components. Cummin (cumin), which contains cuminaldehyde, terpenes, and flavonoids,

shows characteristic peaks at approximately 1029, 1444, and 1519 cm^{-1} , indicating the presence of aromatic and aldehyde structures. Fennel, rich in anethole, estragole, and fenchone, exhibits peaks at around 896, 1234, and 1519 cm^{-1} , suggesting methoxy and aromatic functionalities. Ajwain, known for thymol and carvacrol content, demonstrates peaks at 682, 1392, and 1519 cm^{-1} , which align with phenolic and aromatic groups. Castor sugar (sucrose), a polyhydroxy compound, shows peaks at 1029, 1153, 1234, and 3290 cm^{-1} , corresponding to C–O and O–H stretching, typical of sugars. Gelatin, a protein with amide bonds, displays peaks at 1633 cm^{-1} (amide I), 3290 cm^{-1} (N–H), and 1444 cm^{-1} , consistent with protein structures.

These chemical characteristics have implications for the antacid properties of the formulation. Phenolic compounds from ajwain, cumin, and fennel exhibit antioxidant and anti-inflammatory effects, which may help reduce gastric irritation. The presence of sugars and gelatin suggests a potential soothing and protective coating effect on the stomach lining. Additionally, hydroxyl-rich groups from essential oils and sugars may aid in acid neutralization due to their weak basicity. Aromatic terpenes such as thymol and anethole are also known to modulate gastric motility and acidity.

In conclusion, the FTIR spectrum confirms the presence of aromatic and phenolic compounds, hydroxyl and ether groups, and protein-related amide groups. These chemical constituents collectively support the antacid, soothing, and protective roles of the combination of cummin, fennel, ajwain, castor sugar, and gelatin in the formulation.

4) Physical Appearance

The physical appearance of the formulations ranged from light yellow to dark yellow. Batches F1, F4, and F5 displayed a desirable light-yellow color, indicating good visual acceptability, while F2 and F3 were darker, potentially due to ingredient concentration or interaction.

Table no 7 Results of physical appearance

Batch no	Physical Appearance
F1	Light Yellow
F2	Dark Yellow
F3	Dark yellow
F4	Light Yellow
F5	Light Yellow

5) Weight variation

Weight variation across batches was consistent and within acceptable limits for F1, F2, F4, and F5, demonstrating uniformity. Batch F3 lacked data and cannot be assessed. Uniform weight is critical for dosage consistency.

Table no 8 Results of Weight variation

Batch no	Weight variation (grams)
F1	1.4 $\pm$ 0.005
F2	1.6 $\pm$ 0.002
F3	-
F4	1.08 $\pm$ 0.001
F5	1.25 $\pm$ 0.010

6) Stickiness and Grittiness

Stickiness evaluation showed that F4 and F5 were non-sticky and ideal for patient compliance. F1 was moderately sticky, while F2 and F3 were super sticky, which may reduce consumer acceptability and ease of administration.

Table no 9 Results of stickiness

Batch no	Stickiness/Grittiness
F1	Moderate Sticky
F2	Super sticky
F3	Super sticky
F4	Non-Sticky
F5	Non sticky

7) pH of Formulation

The pH values ranged from 3.2 to 6.8, with batch F4 exhibiting the most desirable pH (6.8), closer to the neutral range and hence safer for oral mucosa. F2 had a low pH (3.2), which could cause irritation or reduce patient comfort.



Table no 10 Results of pH test

Batch no	pH variations
F1	5.4
F2	3.2
F3	4.3
F4	6.8
F5	5.7

8) Viscosity Measurement

The viscosity of Jelly was determined by using Brookfield viscometer and it was found to be 1.89-1.94 centipoises i.e. within limit of 1.5-3.0 centipoises for Antacid Jelly formulation using gelatine.

9) Microbiological Studies

No any microbial growth was observed in storage.

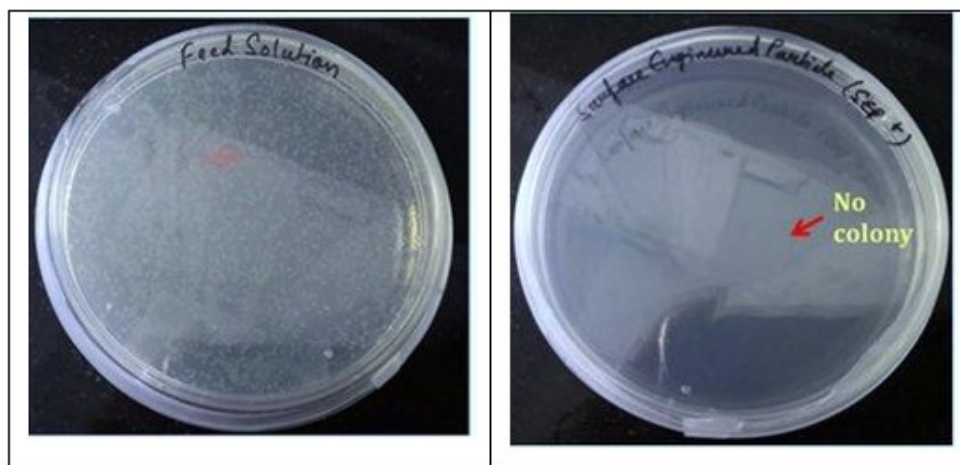


Figure no 10 Microbiological studies

10) Dissolution Studies of Medicated Jelly

The release of active ingredient from prepared formulation shown in Table.... and Figure. The drug release profile revealed a consistent increase in drug release over time, reaching 100.31% at 120 minutes. This demonstrates effective drug availability and controlled release, essential for therapeutic action in antacid formulations.

Table no 11 Results of Dissolution studies

Sr No	Time (min)	Drug Release (%)
1.	5	6.97
2.	10	15.91
3.	15	29.81
4.	30	47.44
5.	60	76.19
6.	120	100.31

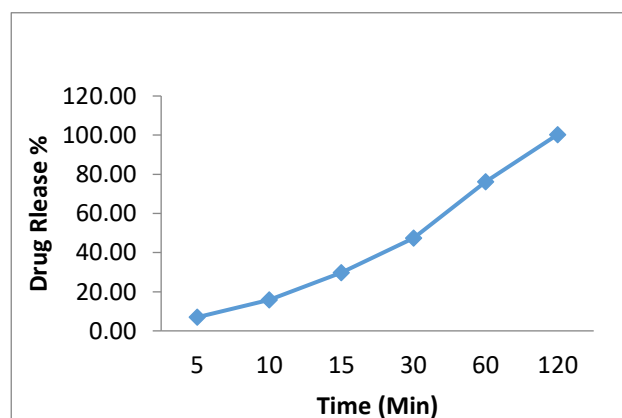


Figure no 11 Graph of Dissolution studies

11) Determine Acid-Neutralizing Capacity (ACN)

The ANC for the antacids analysed were determined and expressed as milliequivalent (mEq) of the antacid as specified by the USP 32 NF 27 (Table 12). The USA-FDA specifies that the ANC for an antacid should not be less than 5 mEq per dose of the antacid. Table ANC per minimum labelled dosage (MLD) of tested samples (Density = 0.96gm/ml).

Table no 12 Results of acid neutralizing capacity

Label	0.1N HCl 10 min	1.0 N NaOH 10 min	ANC mEq/gm
J1	4.38±0.21	1.25	19.53±0.37
J2	6.43±0.06	1.12	16.88±0.58
J3	5.15±0.02	1.17	17.19±0.37
J4	5.64±0.01	1.31	20.49±0.18
J5	4.51±0.14	1.27	20.70±0.18
J6	4.78±0.18	1.25	19.83±0.24

Sample calculation using J1. Total mEq = $(30 \times \text{NHCl}) - (\text{VNaOH} \times \text{NNaOH})$. NHCl = 1.0 M NNaOH = 0.5 M VNaOH = 22.5 mL. Total mEq = $(30 \times 1.0) - (22.5 \times 0.5) = 18.75$ mEq. ANC per gram of antacid = total mEq/density of antacid = $18.75/0.96 = 19.53$ mEq/g of antacid.

Stability investigations of produced jelly at room temperature ($25^\circ\text{C} \pm 5^\circ\text{C}$, -35°C). The stability investigations were conducted for three weeks, and the formulations were examined for changes in physical parameters such as appearance, Weight, Syneresis, pH, and Drug Content shown in Table 13.

12) Stability studies

Table no 13 Results of stability studies

Sr No	Days	Appearance	Wt (gm)	Syneresis	pH	Drug Content (%)
1.	Initial	No Change	1.08	No Water Separation	6.8	100.97
2.	7	No Change	1.08	No Water Separation	6.7	99.87
3.	14	No Change	1.08	No Water Separation	5.9	99.37
4.	21	No Change	1.08	No Water Separation	6.1	98.56
5.	28	No Change	1.08	No Water Separation	6.2	98.27
6.	35	No Change	1.08	No Water Separation	6.3	97.81

SUMMARY

The study focused on the formulation and evaluation of an herbal-based antacid jelly using ajwain, fennel, and cumin as active pharmaceutical ingredients (APIs). Phytochemical screening revealed the presence of beneficial constituents such as flavonoids, phenols, terpenoids, and alkaloids, known for their therapeutic effects.

Preformulation studies included UV-vis spectroscopy to determine the maximum wavelength and confirm linearity in absorbance-concentration relationships. Melting points were identified for all APIs, and FTIR analysis confirmed the presence of functional groups

consistent with their chemical composition, indicating compatibility among ingredients.

Organoleptic properties such as physical appearance, stickiness, and grittiness varied among formulations, with batch F4 demonstrating the most acceptable characteristics. pH values ranged from 3.2 to 6.8, with F4 again being ideal at 6.8-close to neutral and safe for oral mucosa. Viscosity was within acceptable limits (1.89–1.94 cP).

Drug release studies revealed a sustained release profile, achieving 100.31% release at 120 minutes. Acid-neutralizing capacity (ANC) of all formulations met or exceeded the USP standard of 5 mEq/g, with



batch J5 achieving the highest ANC (20.70 mEq/g). Stability studies over 35 days showed no change in appearance, no syneresis, and only minor fluctuations in pH and drug content, confirming formulation stability

CONCLUSION

The formulated herbal antacid jelly, particularly batch F4, demonstrated excellent physicochemical characteristics, sustained drug release, strong acid-neutralizing capacity, and good stability. Phytochemical and FTIR analyses confirmed the presence and compatibility of key bioactive constituents, supporting the therapeutic potential of ajwain, fennel, and cumin in a gelatin-based jelly formulation. These findings suggest that the developed formulation is a promising, effective, and patient-friendly alternative to conventional antacids.

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