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Preparation and Evaluation of Antacid Suspension using Eggshells

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KEYWORDS

Suspension, Antacid, Eggshells,

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ABSTRACT:

Introduction: Antacids are commonly prescribed for treating gastroesophageal reflux diseases (GERD). This study aims to prepare an antacid from(eggshell) and compare its physical parameters with marketed formulation Calcium carbonate, essential for tooth and bone formation, it is used in antacid preparation. A study creates a new methodology of preparing an antacid suspension using eggshells, replacing synthetic calcium carbonate through natural biological extraction process. Previous literature indicated that no systematic scientific evaluation had been conducted on eggshell-derived antacid suspensions. Results indicated that parameters are within prescribed limits and comparable with marketed formulations.

Objectives: The objective of the study was to formulate the antacid from the natural source (eggshells) and to evaluate its physical parameters with the marketed formulation

Methods: The present study involves an attempt to extract the calcium carbonate from the eggshells through the biological extraction process. This process ensures the eggshells are safe and effective. The naturally extracted calcium carbonate that was used as an API for the preparation of the antacid suspension & it involves numerous stages like washing and the drying process for the extraction of the calcium carbonate. The eggshells are crushed and mixed with sorbitol, water, hydroxyethyl cellulose, xanthan gum, calcium carbonate, magnesium hydroxide, flavour, and sodium saccharides. The antacid suspension is then stored in a well-closed, air-tight container.

Results: The formulated suspension was compared to evaluate its physical parameters with the marketed formulation. The quantitative tests that are done to determine the presence of the calcium carbonate in the eggshells and the physical parameters that are evaluated to determine the effectiveness are within the limits for the prepared formulation are compared with that of the marketed formulation, so the prepared suspension can be proved as effectiveness as marketed one

Conclusions: The formulated suspension was found to be within the specified limit when it is compared with the marketed formulation. The formulated antacid suspension shows a better property like the marketed formulation

Introduction

Calcium carbonate is a common excipient and therapeutic substance in the pharmaceutical industry. For those with low calcium levels, calcium carbonate is a frequent supplement. Additionally, it can be used as an antacid to treat painful stomach issues. A common nutritional supplement, phosphate binder, and food ingredient is calcium carbonate, a form of naturally occurring calcium salt [1]. It may be beneficial for as Addressing specific digestive problems (acid reflux, GERD), the management of disorders involving low calcium levels, such as osteoporosis and hypothyroidism, Functioning in patients with chronic renal disease as a phosphate binder. Supplemental calcium carbonate is available as a powder, tablet, chewable, or oral suspension. Powdered calcium carbonate is the best form for your body to absorb calcium, although other forms work well too. It is

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naturally present in egg and oyster shells and is one among the most prevalent substances in the earth's crust, Crustaceans skeletons outside, kale and other dark leafy greens.

Calcium carbonate is used as the ingredients in antacid contain aluminium hydroxide, magnesium hydroxide and it's also used as the main and single ingredient in the preparation of the antacid. The overproduction of acids in the human body usually results in stomach distress. During digestion, the stomach secretes hydrochloric acid to function. An excess of hydrochloric acid results in stomach pain and irritation. Stomach ulcers may potentially result from this. In the year 1970, antacids were first used to manage acidity. The stomach secretes acids, which are neutralized by antacids. The cause of symptoms like heartburn and discomfort is the stomach's acidity [2].

Antacids serve to alleviate this feeling. Antacids used orally can reduce the symptoms of acidity. Antacids help counteract the burning sensation in the chest caused by acid reflux. Antacids are essentially alkaline ions. They can thus chemically neutralize an acid. For the majority of recipients, there are no negative consequences. One class of medications that has been available for many years is antacids. At originally, they served as the first line of defence against peptic ulcer disease. These drugs are self-prescribed, meaning they don't need a prescription. It is a mixture of several substances with different calcium, magnesium, and aluminium salts as active components. It works by neutralizing stomach acid and preventing the proteolytic enzyme pepsin from functioning [3].

Egg shells are a great supply of mineral salts, particularly calcium carbonate, which is 90% absorbable and perhaps the finest natural source of calcium [4]. The eggshells have a 98% calcium carbonate content, a 0.9% magnesium content, and a 0.9% phosphorous (phosphate) content. Recycled eggshells are useful liming sources and are frequently used as plant fertilizer. The reason for this is that the calcium in eggshells raises or balances the pH of acidic soils' top layer. The main ingredient in eggshells is calcium. Along with trace amounts of other microelements, the eggshell also contains a little amount of magnesium [5]. The best natural calcium supply is eggshell calcium, which is 90% more absorbable than calcium from coral or limestone. About 750–800 mg of calcium can be obtained from one teaspoon of powder made from a medium-

sized eggshell. An eggshell's composition is quite similar to that of our teeth and bones [6].

To supplement dietary calcium, individuals with osteoporosis are advised to take 400–500 mg daily [7]. The majority of shell quality studies focused on the fact that eggshell is constituted of around 97% calcium carbonate, according to chemical examinations [8]. However, eggshell is a valuable raw material or ingredient for several industries, including the production of paper and fertilizer, among others. The separated eggshell membrane is a very useful material since it may be used to extract and purify a variety of collagens, hyaluronic acid, or amino acids of interest for a wide range of applications (such as dietary supplements and cosmetics). The method of extraction of the calcium carbonate from the eggshells that relates to the technical field of biological extraction process [9]. In this research paper, instead of calcium carbonate we use eggshells because it contains "major content of proteins'' and it is used as a calcium supplement. The synthetic to the natural process and they low acidic quality makes them a good option against heartburn.

1. Objectives

The main objective of this study is to the extract the calcium carbonate from the eggshells using biological extraction process. This study proves that the synthetic calcium carbonate can be replaced by the natural sources. The eggshells is the main ingredient that are combined with the excipients for the complete antacid formulation. The antacid that is prepared without the preservative, which is the one of the advantages of this suspension. The formulated antacid that was compared to evaluate its effectiveness and the antacid neutralizing capacity are compared with that marketed formulation. Important physical parameters that are evaluated are pH, sedimentation volume which used to determine the physical stability which is used to decide the consistency and the quality. Viscosity which is done with the help of Brookfield viscometer, the rate of the separation was done for the specified period to determine the stability, the release of the drug *invitro* was done using frank cell diffusion. The activity shows that the formulated antacid is within the specified limit and showed the good

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stability and shelf life similarly like marketed one.

2. Methods

Materials required: Eggshell debris was gathered from eateries, homes, and chicken farms (damaged eggs). The eggshells were then ground into a powder using a mortar and pestle and a strainer. No fully grown egg was wasted or harmed during the eggshell collection process [10].

Chemicals and Equipment required: Chemicals: Eggshells, Sorbitol solution, Xanthan gum, Hydro ethyl cellulose, Peppermint oil, Sodium saccharin, pH adjusting agent Mg (OH)2, Purified water Equipment: pH meter, electronic balance, Brook field viscometer, Frank cell diffusion, Water bath.

Extraction of calcium carbonate from the eggshells:

The research provides a method of extracting calcium carbonate from eggshells using biological process. The eggshells that contain the more amount of the calcium carbonate. The boiled eggshells are washed with the distilled water and soaked in the water for the specified period of time and these are again subject to the boiling again and then to drying. Eggshells are dried for 2 to 3 days after that the eggshells are crushed with the help of mortar and pestle. Calcium carbonate is extracted from the eggshells and then they are collected and these are used for the preparation [11].

Figure 1: Eggshells overview

Figure 2: Colour change of assay

mL of diluted hydrochloric acid (1 in 10), and let the carbon dioxide out by boiling. Cool, neutralize with ammonia TS, add 60 mL of a solution of ammonium oxalate monohydrate (1 in 25), and heat on a water bath for 1 hour. After cooling, add water to make 100 mL, and stir thoroughly. Centrifuge it, and takes the supernatant. Measure 50 mL of the filtrate, add 0.5 mL of sulfuric acid, evaporate to dryness, ignite to constant weight at 600°C and weigh [13].

LOD: Loss on Drying refers to the process of measuring the percentage of moisture content present in a substance, typically a solid or semi-solid material. It involves subjecting a sample to controlled heating, causing the moisture within the sample to evaporate, and then calculating the difference in weight before and after heating. The result is expressed as a percentage of the initial weight presents the moisture content [14].

Assay: Weigh accurately about 2.0g of calcium carbonate, and add gradually about 50 mL of 1 mol/L hydrochloric acid. Heat the container containing the solution in a water bath for about 10 minutes. After cooling, titrate the excess hydrochloric acid with 1mol/L sodium hydroxide (using methyl red indicator). The endpoint is the color of the solution changes from red to yellow [15].

Identification of calcium carbonate in eggshells: Compositional Specifications Substance Name: calcium carbonate

Molecular formula: CaCO3 Molecular weight: 100.0

Description: It is odourless and colourless. Identification test:

To 1 g of calcium carbonate (eggshells), add 10 mL of water and 7 mL of diluted acetic acid (1 in 4). Effervescences ceases and dissolves. When boiled and neutralized with ammonia, it is responded to all qualitative test

Purity test:

Free alkali: Weigh 3.0 g of calcium carbonate (from eggshells), add 30 mL of freshly boiled and cooled water, shake for 3 minutes and filter the solution. To 20 mL of the filtrate add 2 drops of phenolphthalein. A pink colour develops, and it disappears when 0.20 mL of 0.1 mol/L hydrochloric acid is added [12].

Alkali metals and magnesium: Weigh 1.0 g of Calcium

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Carbonate (from egg shells) dissolve it by gradually adding 30

Preparation of antacid suspension from egg shells:

Calcium carbonate from the eggshells is prepared with the suitable excipients and the sorbitol, hydroxyethyl cellulose, xanthan gum are added in the suitable vessel and mixed well for about thirty minutes.

Calcium carbonate (From the eggshells), magnesium hydroxide Mg (OH)2, Flavor and sodium saccharide are added and mixed well at regular intervals and stored in the well closed air tight container.

Figure 3: Formulation

Table 1: Preparation of antacid suspension using eggshells

Ingredients	mg/5ml	gms/100ml
Calcium carbonate (Eggshells)	1500	8
Purified water	3165	79.5
Sorbitol solution	1000	20
Xanthan gum	13.0	0.26
Hydroxyethyl cellulose	5.0	0.1
PH adjusting agent, Mg (OH)2	30.0	6.0
Peppermint flavor	25	0.50
Sodium saccharin	1.425	0.0285

EVALUATION OF ANTACID SUSPENSION:

Evaluation parameters:

- pH determination
- Sedimentation volume
- Degree of flocculation
- Rheology study
- Rate of separation
- Redispersibility
- Frank cell diffusion

pH DETERMINATION: The pH meter is used to measure the pH in order to calculate the isoelectric point of suspension and prevent coagulation and instability.

Procedure:

pH of the sample was determined using the calibrated pH meter

Physical stability: A state of physical stability is one in which there are no indications of sedimentation and the particles are evenly dispersed throughout the dispersion. It can be characterized practically as a state where modest shaking should quickly re-suspend the particles. If suspensions are resolved when set aside. Because larger particles are pulled by gravity, the solids have a tendency to settle near the bottom of the container. The standard evaluation approach for determining the physical stability is to consider the sedimentation volume, which cannot be prevented, in the event of re-dispersion.

The two sedimentation parameters are employed such as

1. Sedimentation volume
2. Degree of flocculation

Sedimentation volume: Sedimentation volume, or F, is a dimensionless number that may be easily quantified using the term volume, which is included when a suspension is taken in a measuring cylinder. Height and volume are proportionate. The F value of the majority of pharmacological suspensions is less than one. The product is in perfect condition if f=1 and contains neither sediment nor clear supernatant upon standing. The F value typically ranges from 0 to 1. There are moments when the

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ultimate volume of material rises and the flow network is loose and frothy. The F value will be bigger than one in this case. The ratio of the final height (Vu) of the sediment to the beginning height (Vo) of the entire suspension as it settles in a cylinder under typical circumstances is known as the sedimentation volume. The sedimentation volume, or F (%), was computed using the following equation after a measured volume of the suspension was left in a graduated cylinder in an undisturbed state for a predetermined amount of time.

where Vo is the suspension's initial volume and Vu is the sediment's final volume.

Figure 4: Sedimentation volume

Degree of flocculation: The degree of flocculation was determined following the equation β= F/Fα, where F is the ultimate sedimentation volume in the flocculated suspension and Fα is the ultimate sedimentation volume in the deflocculated suspension [16].

Figure 5: Degree of flocculation

Rheology:

Brookfield viscometer: The rotational viscometer idea is used by Brookfield viscometers; the torque needed to rotate an item, like a spindle, shows the fluid's viscosity. A disk or bob spindle submerged in test fluid receives torque from a calibrated spring; the spring deflection indicates the fluid's viscous drag against the spindle. The viscosity of a Newtonian fluid and the torque needed to rotate the spindle are directly correlated with the quantity of viscous drag. Brookfield viscosities measured under identical conditions (model, spindle, speed, temperature, test time, container, and any other sample preparation processes that may alter the fluid's behaviour) can be compared in the case of non-Newtonian fluids. To find the right spindle and speeds while creating a new test procedure, trial and error is frequently required. When test procedures are successful, a torque percentage reading between 10 and 100 will be obtained. A proper rheometer cannot be used with this setup because the fluid's geometry around a rotating bob or disk spindle in a large container does not allow for the assignment of a single shear rate. However, the same spindle can be used to observe the test fluid's rheological behaviour at different speeds. The Brookfield viscometer calculates the viscosity of a fluid at specific shear rates. The viscosity of a fluid indicates how resistant it is to flow. A viscometer measures the torque required to overcome the viscous resistance to the produced movement by rotating a sensor element in a fluid. The submerged element, known as a spindle, is driven through a beryllium copper spring to achieve this. The viscosity of the fluid determines how much the spring is wound, as shown by the red pointer. Since the real viscosity for a particular spring deflection is proportional to the spindle speed and is influenced by the size and form of the spindle, the viscometer can measure throughout a variety of ranges.

Procedure:

The equation was used to compute the apparent viscosity (ηα in ml) and the amount of time needed for the suspension sample to pass through a 10 ml pipette. At 25°C, the viscosity (in poise) of the suspensions was measured using a Brookfield viscometer at 50 rpm with spindle number 3[17].

Redispersibility: It can be measured manually or by shaking the suspension with the aid of a mechanical instrument. They were kept at room temperature for different periods of time (5, 15, 25 days) in a fixed volume (50 ml). To redistribute the sediment and record the presence of any deposits, the container was taken out and aggressively shook at regular intervals starting on the fifth day [18].

Rate of separation: The rate of separation of the suspensions were determined by keeping 50 ml portion of each suspension in stoppered measuring cylinder and stored undisturbed at room temperature. The separation of clear liquid was noted at intervals of 5, 10 and 15

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days [19].

Frank cell diffusion (*Invitro test):* Franz Cells are a popular technique for assessing in vitro drug penetration because of its benefits, which include little tissue handling, no ongoing sample collection, and a small amount of medication needed for examination. The development of many pharmacological dosage forms for the same active chemical is required due to the rise of personalized treatment, which permits dosage and administration variations [20].

3. Results

Table 2 Frank cell Diffusion study

Time (mins)	Absorption (Prepared formulation)	Absorption (Marketed formulation)
0	0	0
15	0.0042	0.0064
30	0.0096	0.0120
45	0.0125	0.0145
60	0.0183	0.0196
90	0.0389	0.0401
120	0.0442	0.0496
150	0.0567	0.0589
180	0.0597	0.6210

Table 3 Evaluation parameters of both formulation (Antacid suspension)

Evaluation parameters	Prepared formulation	Marketed formulation
Identification test	Positive	Positive
Alkali test	Pink color	Pink color
Alkali metals and magnesium test	0.94%	0.98%
LOD (Loss on drying)	1.90%	1.70%
Assay	Color changes from red to yellow	Color changes from red to yellow
pH determination	7.62	8.54
Sedimentation volume	10	9
Degree of flocculation	2	2
Rheology studies (Brookfield viscometer)	195.2cp	188.7 cp
Rate of separation 5^{th} day 10^{th} day 15^{th} day	4ml of clear liquid 4 ml of clear liquid 4.1 ml of clear liquid	4.1 ml of clear liquid 4.1 ml of clear liquid 4.2 ml of clear liquid

4. Discussion

The antacid suspension using the eggshells are formulated and compared with the marketed formulation (Peppermint oral antacid suspension) and are reported. Quantitative test was done to determine the presence of Calcium carbonate, LOD was determined as 1.9% for the prepared formulation & marketed formulation that have 1.7% Endpoint of assay produces color changes from red to yellow for both prepared and marketed formulation. pH of the preparation was found to be 7.62 and for the marketed one it was found to be 8.54. Sedimentation volume of the preparation was found to be 10 & marketed one it was found to be 9. Degree

of flocculation was found to be 2 for both the formulation Viscosity of the suspension are also determined by using Brookfield viscometer and it was found to be 195.2 cp and the market product was found to be 188.7 cp. Rate of separation was done for both the formulation. Redispersibility number are also calculated and compare with the marketed formulation. Frank cell diffusion was determined and compare with the marketed formulation up to 3 hours. All the evaluation parameters comply with the marketed formulation and found to be within the standard limit.

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Conflict of interest: None

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