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OVERVIEW ON DEVELOPMENT AND EVALUATION OF AN ANTACID SUSPENSION

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Abstract:

Antacids are among the most extensively used pharmaceutical agents for the neutralization of excess gastric acid and the relief of symptoms such as heartburn, acidity, and dyspepsia. A wide range of over-the-counter (OTC) antacid formulations are available globally, formulated either as single or combination preparations containing active ingredients effective in controlling gastric hyperacidity. Based on their absorption profile, antacids are broadly classified into systemic and non-systemic categories. Systemic antacids, including sodium bicarbonate, calcium carbonate, and magnesium carbonate, are absorbed into systemic circulation, while non-systemic antacids such as aluminium hydroxide and magnesium hydroxide act locally by neutralizing or adsorbing gastric acid. Among the various dosage forms, suspensions are preferred due to their pre-dispersed nature, larger surface area, and faster acid-neutralizing capacity compared to solid formulations. Pharmaceutical suspensions are biphasic systems consisting of finely divided insoluble particles dispersed in a liquid medium, usually stabilized by suspending agents that enhance physical stability and redispersibility. Aluminium hydroxide, a common component of antacid formulations, is effective but may exhibit toxicity upon prolonged accumulation. The pathophysiology of gastric acidity involves excessive secretion of hydrochloric acid (HCl) by parietal cells, leading to a gastric pH range of 1.5–2.5 in the fasting state and 5–6 postprandially. Due to their alkaline nature, antacid suspensions are prone to microbial contamination, emphasizing the importance of incorporating suitable preservatives. This review highlights the formulation aspects, mechanisms of action, classification, and stability considerations of antacid suspensions, providing a comprehensive overview of their therapeutic importance and formulation challenges in modern pharmaceutics.

Keyword: *Antacid, Suspension, Formulation development, Acid neutralizing capacity, Aluminium hydroxide, stability studies*

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INTRODUCTION:

Antacids are extensively used to neutralize extra acid and relieve the circumstance of heartburn or acidity in lots of patients. An extensive spectrum of antacids is now available inside the international pharmaceutical marketplace as over-the-counter (OTC) tablets. Those one or multiple aspect tablets include medical elements appropriate for treating signs which include heartburn and dyspepsia, which can be associated with hyperacidity within the stomach. They are categorized as systemic antacids or non-systemic antacids. Systemic antacids, which include sodium bicarbonate, calcium bicarbonate (caco3), and magnesium bicarbonate (mgco3), are simply dissolved and absorbed systemically. Acid neutralizing antacids are available in a number of dosage forms including suspensions, chewable drugs and powders crammed into sachets of those suspensions are the most famous because the energetic additives are pre dispersed in a liquid which provides for a large surface vicinity upon administration and doubtlessly extra speedy acid neutralization. A few medications used inside the treatment of gastric inflammation aim to reduce the acid secretion inside the belly thereby reducing the acidity in the gastric lumen and promoting gastric ulcer recovery. Gastric juice is made of water, electrolytes, hydrochloric acid (hcl), enzymes, mucus, and intrinsic thing. HCI is se-created by using the parietal cells.

Liquid preparations of antacids are generally considered to be more powerful than the stable ones (tablets) because of their already dispersed form . Antacids are divided into two classes; the first class consists of the ones antacids that work by means of chemical neutralization of gastric acid, most extensively sodium bicarbonate; and the second magnificence of antacids act via adsorption of the acid (non-absorbable antacids), together with calcium and magnesium salts.

One of the maximum common antacid additives is Aluminum Hydroxide, which may be poisonous to people while it builds up in the frame (Crisponi et al., 2013). A pharmaceutical suspension is a biphasic device composed of finely divided insoluble strong fabric suspended in a liquid medium. The common length of suspended particles tiers from zero. Five µm to five µm in maximum of the prescribed drugs suspensions. suspending agent which reduces the rate of settling and allows clean redispersion of any settled particulate be counted both via protective colloidal movement and through increasing the consistency of the suspending medium. a few pills inclusive of kaolin, magnesium carbonate and magnesium silicate are required to appear within the gastrointestinal tract in a finely divided shape. while these capsules are formulated as suspensions, the favored high surface location is produced (Okafo and Chukwu, 2017).

These are one or a couple of issue drugs that comprise scientific components match in a position for treating such signs and symptoms as heartburn and dyspepsia, which might be historically related to hyperacidity in the stomach. Gastric acidity happens due to immoderate secretion of hcl in stomach due to numerous motives. The ph of the belly is 1. five- 2.5 while empty and increases to five- 6 whilst food is ingested. amongst oral liquid formulations antacids suspensions are one in all the extreme instances due to the fact that their susceptibility to bacteria and fungi is greater because of their alkalinity and fundamental ph. (Udeze et al 2012; Urmi et al 2014).

Antacids can be classified into essential types; systemic antacids and non-systemic antacids. Systemic antacids are those who undergo entire systemic absorption following oral ingestion. The non-systemic antacids are the ones that don't go through systemic absorption following the oral ingestion. The systemic antacids have a rapid onset with a brief duration of movement. The systemic antacids, on lengthen use reasons systemic alkalosis for example sodium bicarbonate. Non-systemic antacids have slow onset but a protracted duration of action along with magnesium carbonate, magnesium hydroxide and aluminum . The crucial functions of antacid education are rapid onset of action and powerful neutralization of acid. Antacids are available in one-of-a-kind formulations like tablets, effervescent, powders, and suspensions. The suspension formulations are extra favored as they have got the quickest onset of motion. some research reported that some antacids may be thoroughly used at some point of pregnancy because of their local motion in place of systemic outcomes.

Advantages

- Good oral antacid with prompt and sustained neutralizing action
- Effective even without absorption by the body
- Increases the gastric pH (basic)
- Raises the pH of the gastric juice, Adsorbs pepsin
- Non-absorbable antacid
- Slow but prolonged action laxative

Disadvantages

- Low systemic absorption
- GI distress Nausea/vomiting Hypercalcemia Hypo-phosphatemia milk alkali syndrome
- Efficient, low systemic absorption, Decreases phosphate excretion via kidney
- Gas production in the GI tract is not reduced
- Diarrhoea Constipation Intestinal pain
- Metabolic alkalosis with urine alkalinisation, Intake of large doses

Properties

Organoleptic properties:

- The colour was visually identified and the odour was inspected by nasal inhalation by healthy human volunteers and the average qualitative values were noted.
- The organoleptic tests were explained about the products before the test procedure.

Particle size:

- The microscope was calibrated using the objective micro meter, Tokyo.

Specific gravity:

- Specific gravity was determined by using specific gravity bottle

Suspension

A pharmaceutical suspension is a biphasic system composed of finely divided insoluble solid material suspended in a liquid medium. The average size of suspended particles ranges from 0.5 µm to 5 µm in most of the pharmaceutical's suspensions [1]. At rest, the suspension should be sufficiently viscous to prevent sedimentation and thus aggregation or caking of the particles. Suspension essentially facilitates the administration of insoluble and often distasteful substances which is pleasant in taste. They also provide a suitable from for the application of dermatological materials to the skin and mucous membrane. Insoluble particles must be uniformly dispersed in ideal suspensions. The solid particles are isolated from the liquid as sediments in a standing state.

Types of suspension:

- According to route of administration

1. Oral suspensions: These suspensions are given through oral route therefore they contain f flavouring and sweetening compounds for masking of bitter taste of drug [5].
2. Topical suspensions: These are applied on external surface of body, and must be free from any type of gritty particles so that they can't cause irritation on skin [6]
3. Parenteral suspensions: These suspensions are administered through parenteral routes like intravenously or intramuscularly that's why they should be sterile and free from foreign particles [7]
4. Ophthalmic suspensions: Ophthalmic suspensions are used to treat eyes disorder that's why these should also be sterile and should be free from foreign particles [8]

- Advantages of Suspension
  a. Duration of drug and onset of drug can be controlled.
  b. It masks the bitter taste of drugs example chloramphenicol.
  c. Chemical stability of some drugs can improve by making suspension E.g., penicillin
  d. Efficient in intramuscular depot therapy.
  e. Use of co-solvents can be avoided.
  f. In the comparison of other doses form suspension have higher rate of bioavailability. Order of bioavailability is as follow: solution >suspension >capsule >compressed tablets >coated tablet.
- Disadvantages of Suspension
  a. Difficulties in formulating the formulation
  b. During handling and transportation sufficient care is required.
  c. Sedimentation and stability can cause problems.
  d. Chances of non-uniformity and non-accuracy of dose.

METHODS AND MATERIALS:

1. Acid neutralizing capacity (ANC)
2. Buffering capacity (BC)
3. Sample preparation
4. Preliminary antacid test (PAT)
5. Evaluation of pH and density
6. Determination of flow time and viscosity
7. Antacid samples and reagents

1. Acid neutralizing capacity (ANC)

The ANC was determined for all the brands since each had a pH of 3.5 or greater from the PAT. According to Ayensu et al. (2020), antacid efficacy can be determined according to neutralizing capacity. Hydrochloric acid in gastric secretions when it is dissolved in the stomach, which is why the preferred formulation of Calcium Carbonate is in a compressed powder tablet.

The ANC was calculated using equation 1:

The ANC (mEq) = (Volume HCI ml) × (Normality HCI) - Volume NaOH ml × Normality Na0H

Official methods for measuring the acid neutralizing capacity of antacid in vitro at 37 °C include a United States Pharmacopoeia (USP) test, British Pharmacopoeia (BP) Test (European Pharmacopoeia [pH Eur] Test), pH Stat or Sjogren Test, Acid Consuming Capacity (ACC) and Rossett Rice Test. The acid neutralization capacity (ANC) was analysed in triplicate determinations as per the USP method [4]. ANC was determined as described in the United States Pharmacopeia and National Formulary

2. Buffering capacity (BC)

An accurate volume of 5 mL each of the antacid samples were measured and transferred into a 250 mL beaker and 50 mL of distilled water added and heated to 37 °C ±3 °C

3. Sample preparation

A formulation containing only the active ingredients without a suspending agent was considered as the control.

4. Preliminary antacid test (PAT)

An accurate amount of a well-mixed antacid product equivalent to the minimum labelled dosage; (5 mL) was weighed into a 100 ml beaker.

For oral suspensions, the bottles were shaken well and a volume of MLD was put in a 100 mL conical flask. Distilled water was then added to provide a final volume of 40 mL. The solution was stirred on a hotplate magnetic stirrer at 300±30 rpm for one minute

5. Evaluation of pH and density

The pH of each antacid was determined using a calibrated digital pH meter (model ST3100-F; OHAUS Corporation, Par-sippany, NJ, USA). Each antacid was well shaken, after which 10 mL of the suspension was transferred into a 25 mL beaker for pH measurement. The relative density of each mixture was determined using a pycnometer. All measurements were performed at room temperature. Triplicate determinations were performed for each sample.

6. Determination of flow time and viscosity

The time taken for 10 mL of each suspension to flow through a 10 mL pipette was determined. The viscosities of the samples were determined using a digital rotary viscometer. The test was performed on 100 mL of adequately agitated suspension. Triplicate determinations were performed for each sample in each test at room temperature

7. Antacid samples and reagents

A comprehensive list of liquid antacids available in retail community pharmacies in the Ho Municipality of the Volta Region of Ghana was compiled, from which 14 different brands were randomly sampled. All the products were purchased on the same day and labelled A −N

Evaluation parameter

1. Rheology

The time required for each suspension sample to flow through a 10 ml pipette was determined and the apparent viscosity (ηα in ml) was calculated using the equation.

$$\text{Shear rate} = \dot{\gamma} = \frac{\text{velocity difference}}{\text{distance}} = \frac{dv}{dy}$$

$$\text{Shear stress} = \sigma = \frac{F}{A} = \frac{\text{Force}}{\text{Area}}$$

$$\text{Viscosity} = \eta = \frac{\sigma}{\dot{\gamma}} = \frac{\text{Shear stress}}{\text{Shear rate}}$$

2. Sedimentation parameter

The sedimentation volume is ratio of the ultimate height (Vu) of the sediment to the initial height (Vo) of the total suspension as the suspension settles in a cylinder under standard conditions.

Formula,

F = Vu\Vo

Where,

Vu = ultimate volume of the sediment

Vo = original volume of the suspension.

3. Sedimentation volume

Sedimentation means settling of particle (or) floccules occur under gravitational force in liquid dosage form. Sedimentation velocity in cm / sec. Velocity of sedimentation expressed by Stroke's equation expressed.

$$\text{Sedimentation rate} = \frac{d^2(\rho_s - \rho_l)g}{18\eta}$$

Where d is the particle diameter

ρ_s, ρ_l are densities of a particle and liquid respectively.

g is the acceleration of gravity.

η is the viscosity of the medium.

4. Particle size analysis

Particle size of any suspension is critical and must be reduced within the range. Too large or too small particles should be avoided. Larger particles will settle faster at the bottom of the container and impart a gritty texture to the product and also cause irritation if injected or instilled to the eye particles may block the needle.

5. pH

The pH of the suspensions was determined at intervals of one week for 14 days using pH meter (Neo Chemiphar company)

6. Rate of separation

The rate of separation of the suspensions was 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 d up to 45 d.

7. Degree of Flocculation

The degree of flocculation was determined following the equation

Formula,

β= F/Fα

where ,

F = ultimate sedimentation volume in the flocculated suspension

F = ultimate sedimentation volume in the deflocculated suspension

8. Redispersibility

Redispersibility can be estimated by shaking the suspension with the help of a mechanical device, which simulates motion of human arm during shaking. Fixed volume (50 ml) of each suspension was kept in calibrated tubes which were then stored at room temperature for various time intervals (5, 15, 25 days).

9. Flow Rate

The flow rate was determined by assessing the time required for a 10 ml sample of suspension to flow through a 10 ml pipette. The flow rate was

determined by dividing the volume of suspension by the time of flow.

10. Statistical Analysis

Where applicable, test results were subjected to statistical analysis using analysis of variance (ANOVA) or the Kruskal-Wallis's test (non-parametric data) with a p-value of 0.05.

11. Ease of Redispersion

Suspension samples of 100 ml were allowed to settle in measuring cylinders for 7 days. After the 7 days, the opening of the measuring cylinder was sealed and inverted through 180°. The redispersibility number (the number of inversions required to uniformly disperse any sedimented materials completely) was recorded.

Formulation table:

Table no 1: Composition of an antacid suspension

Sr .no	Ingredients	Quantity	Function /Uses
1	Aluminium hydroxide gel	18 g	Antacid (neutralizes stomach acid)
2	Magnesium oxide	9 g	Antacid, laxative (balances constipation effect of aluminium hydroxide)
3	Calcium carbonate	9 g	Antacid, provides calcium supplement
4	Simethicone	0.5 g	Antiflatulent agent – reduces gas and bloating
5	Sorbitol /mannitol	7 g	Sweetening agent and viscosity enhancer
6	Sodium saccharin	0.02 g	Artificial sweetener (Improve palatability)
7	Methyl paraben	0.05 g	Preservatives (prevents microbial growth)
8	Propyl paraben	0.005 g	Preservatives (enhances preservative effect)
9	Peppermint oil	0.02 ml	Flavouring and cooling agent
10	Alcohol	1 ml	Co-solvent and preservative enhancer
11	Purified water	q.s to 100 ml	Solvent /vehicle

RESULTS AND DISCUSSION:

1. Acid Neutralizing Capacity (ANC)

The Acid Neutralizing Capacity (ANC) is one of the most important pharmacological parameters that determines the effectiveness of an antacid formulation. In this study, it was observed that all the antacids with high and intermediate ANC values contained at least two active ingredients, typically magnesium hydroxide and aluminium hydroxide. These combinations enhanced the overall acid-neutralizing efficiency while balancing each other's side effects.

However, Brand A, which contained only magnesium hydroxide, showed the lowest ANC value among the samples. This indicates that formulations containing a single active ingredient are generally less effective in neutralizing gastric acid.

Since no standard dose of antacid exists due to patient variability, manufacturers determine dosage based on the ANC of the brand. Patients consuming low-ANC products, such as Brand A, may require frequent doses to relieve gastric discomfort, potentially leading to overdose and resulting side effects like diarrhoea, constipation, alkalosis, or acidosis, depending on the formulation composition.

2. Sedimentation and Redispersibility

Sedimentation and redispersibility are crucial parameters that ensure dose uniformity in suspensions. While some sedimentation is acceptable during storage, the formulation must be easily redispersible upon gentle shaking. In this study, the redispersibility was evaluated by counting the number of container inversions required to uniformly resuspend the sedimented material.

The results were expressed as whole numbers and analysed using non-parametric methods, since not all patients apply the same shaking force before use. Formulations that required fewer inversions for redispersion are considered pharmaceutically stable and convenient for patient use.

3. Systemic Absorption Studies

In this study, systemic absorption of aluminium and magnesium was not quantified in healthy volunteers. This aligns with previous findings reporting low or negligible absorption of aluminium hydroxide through the oral route. Hence, aluminium-containing antacids remain safe for use in healthy, non-pregnant adults.

Due to ethical considerations, the study did not include pregnant women. Only healthy non-pregnant women and a control group were considered to avoid confounding factors, as both aluminium and magnesium may be present in the environment and dietary sources

4. Sampling and Preliminary Tests

Antacid suspensions are widely used as over-the-counter (OTC) medications, with many being dispensed outside regulated pharmacies. Samples from multiple commercial batches were analysed for ANC and Buffering Capacity (BC) using titration with pH recording, following the method of Chidananda et al.

All tested brands recorded a pH above 3.5, confirming their classification as antacid preparations. Among individual ingredients, Calcium Carbonate exhibited the highest ANC, while Aluminium Hydroxide and Alginate followed closely

5. Role of Different Ingredients

Calcium Carbonate: Showed the highest ANC, effectively neutralizing gastric hydrochloric acid. It is commonly used in tablet formulations due to its solid-state stability and fast neutralization rate.

Aluminium Hydroxide: Offers high ANC but may cause constipation when used alone.

Magnesium Hydroxide: Acts quickly and can offset the constipating effects of aluminium hydroxide, though excessive use may lead to diarrhoea.

6. Microbiological Quality

Antacid suspensions are particularly susceptible to microbial contamination because of their neutral pH. Microbiological testing revealed that several commercial antacid suspensions failed to meet USP limits for total microbial count ($\leq 10^2$ CFU/mL).

In studies from Sudan and Nigeria, nine out of twelve and five out of six samples, respectively, exceeded the permissible microbial load and showed contamination with Staphylococcus aureus and Candida albicans.

This emphasizes the need for strict quality control during production and preservative optimization to ensure microbiological safety of oral suspensions.

7. Rheological and Physical Characteristics

Rheological studies of Calcium Carbonate suspensions showed that the flow rate decreased with increasing concentration of suspending agents, confirming pseudoplastic behaviour typical of pharmaceutical suspensions.

All formulations exhibited pleasant organoleptic properties—most being pink-coloured, mint-flavoured, and sweet-tasting—except for the Medicine® suspension, which was white but also mint-flavoured and sweet. Such properties improve patient acceptability and compliance.

8. Cost-Effectiveness and Patient Compliance

Antacids with higher ANC values are more cost-effective, as smaller doses provide equivalent or better relief compared to low-ANC products. Thus, the balance between ANC and unit cost determines the overall economic value and therapeutic efficiency of an antacid brand.

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