A Comparative Evaluation of Antacid Suspensions in The Ananthapuramu Market

Dr. Mohanvamsi Nuli, Dr. Hindustan Abdul Ahad*, Dr. Haranath Chinthaginjala, Dr. Padmanabha Reddy Yiragamreddy, Raji Reddy Beduduri, Indravath Rajyalakshmi

Department of Industrial Pharmacy, Raghavendra Institute of Pharmaceutical Education and Research (RIPER)-Autonomous, Ananthapuramu-515001, AP, India

*Corresponding Author- Email: drabdulriperatp@gmail.com

Abstract

Both over-the-counter and prescription antacids are offered. They block pepsin activity and neutralize gastric acid. It is vital to compare dosage amounts, efficacy levels, and prices of the many antacids available in Ananthapuramu. This study looked into the characteristics of antacid suspensions sold in Ananthapuramu, India. Four antacid suspensions with the names AS-1, AS-2, AS-3, and AS-4 were randomly selected from neighbourhood pharmacies in Ananthapuramu, Andhra Pradesh, India. The parameters viz., pH level, flow time, viscosity, and sedimentation rate etc. The studies revealed that these products' pH values ranged from 7.0±0.2 to 8.5±0.2, their flow times from 2.07±0.01 to 4.20±0.03 mL/s in and their acid-neutralizing capacities (ANC) ranged from 8.00±0.02 to 15.13±0.09 mEq. After seven days, the samples' flow rate and re-dispersibility were quite low. These suspensions commonly contain magnesium/aluminium/calcium in the form of carbonates/hydroxides/silicates. Additionally, they have active chemicals like simethicone or dimethicone in varying amounts. For 200 mL, they ranged in price from 92 to 165 INR. The product's price has no impact on ANC. Expensive products didn't always perform better in tests. Therefore, there is no justification for choosing expensive, imported liquid antacids over more affordable, generic ones.

Keywords: Antacid, Evaluation, Flow, Neutralization, Suspension, Viscosity.

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INTRODUCTION

Drugs that control stomach acid are used to treat the symptoms of heartburn, gastroesophageal reflux disease (GERD), and gastrointestinal problems. Low pH of stomach acid production makes ulcers and other conditions worse[1]. These products can be characterized as either antacids, which directly neutralizes excess acid, or drugs, such as proton pump inhibitors and H_2 (histamine receptor) antagonists, which reduce the production of stomach

acid[2]. In contrast to conventional antacid medications, acid-neutralizing compounds have advantaged such immediate action for light and are rare in terms of cost and therapeutics[3]. Aluminium, calcium, and magnesium salts, either singly or in combination, are the main ingredients of neutralizing acids[4]. These antacids work by inhibiting the proteolytic enzyme pepsin while only partially neutralizing stomach acid[5]. Neutralizing antacids come in a variety of pharmaceutical forms, including solutions, chewable pills, and powders[6]. Most of these suspensions have a large surface area after administration and may neutralize acids more quickly since the active components are already dispersed in a liquid before usage[7]. The current study aims to describe the physical characteristics of the antacid suspensions available on the Ananthapuramu market, namely their product sedimentation, re-dispersibility, etc., and liquid flow characteristics. Additionally, to evaluate their capacity to neutralize the acid, this is done.

MATERIAL AND METHODS

Antacid samples and reagents

From a full list of liquid antacids available at retail pharmacies in Anantapur, Andhra Pradesh, India, four different brands were randomly selected. The products, designated as "AS-1," "AS-2," "AS-3," and "AS-4," were all bought on the same day. Throughout the investigation time, the outside temperature was 30±1°C.

Visual inspection of the samples

All antacid suspensions were compared using a modified, objective checklist based on standards published by the World Health Organization[8]. Components from the solid dosage form evaluation tools were dropped from the final checklist to make it suitable for the goods in question. Antacids were visually inspected as part of the assessment to look for inadequate packaging and labelling as well as a lack of details about, among other things, active ingredient concentrations, dosage, and expiration dates (Table 1).

Table 1. Visual Inspection of the products

Condition of the antacid packing	Antacid marketed sample			
	AS-1	AS-2	AS-3	AS-4
Primary packing				
Packaging condition	Sealed	Sealed	Sealed	Sealed
Active ingredient names	+	+	+	+
Amounts of active ingredients per dosage unit or packaging	+	+	+	+
The intactness of primary packaging	+	+	+	+
Category mentioned	+	+	+	+
Storage conditions are mentioned	+	+	+	+

Legibility of the label details	+	+	+	+
Dosing device provided with the product	+	+	+	+
Batch number	+	+	+	+
License number	+	+	+	+
Manufactured date	+	+	+	+
Expiration date	+	+	+	+
Name and address of the manufacturer	+	+	+	+
Secondary packaging				
Active ingredient names	+	+	+	+
Amounts of active ingredients per dosage unit or packaging	+	+	+	+
Availability of the secondary packaging	+	+	+	+
The intactness of secondary packaging	+	+	+	+
Does the label on the secondary packing match with a primary label	+	+	+	+
Batch number	+	+	+	+
License number	+	+	+	+
Manufactured date	+	+	+	+
Expiration date	+	+	+	+
Name and address of the manufacturer	+	+	+	+

Information regarding the antacids, including the amount (volume) per pack, price per bottle, lot number, date of manufacture, and expiration date, was also noted in addition to the minimum prescribed dose (a few were not displayed for not to criticize any manufacturer). The active elements of the products were exposed (Table 2).

Table 2. Compositions and manufacturing details

Sample	Composition	Pack (mL)	Dose (mL)	Price (INR)
AS-1	Aluminium hydroxide, magnesium hydroxide, activated dimethicone	200	10	92.00
AS-2	Magnesium hydroxide, Aluminium hydroxide, simethicone, sodium carboxy methyl cellulose	200	10	131.00
AS-3	Magaldrate, simethicone, oxetacaine	170	10	126.46
AS-4	Sodium alginate, sodium bicarbonate, calcium carbonate	150	10	165.00

Evaluation of antacids

The antacids were assessed for the following parameters

Evaluation of pH

The pH of each antacid was determined using a calibrated digital pH metre (Konvio Neer pH Test Meter). To measure the pH, 10 mL of the suspension was put into a 25 mL beaker after each antacid had been vigorously shaken (Table 3)[9,10].

Determination of flow rate and viscosity

The time required for 10 mL of each suspension to flow through a 10 mL pipette was measured to compute this. The sample viscosities were measured using a digital rotating viscometer (TA instruments, India). The test was conducted using Spindle #2 at a speed of 30 rpm[11,12]. The test was performed using 100 mL of highly agitated solution. Three sets of measurements were made on each sample in each experiment, all at room temperature (Table 3).

$$Flow\ rate \frac{volume\ of\ pipette\ (ml)}{flow\ time\ (sec)} \text{---(1)}$$

Determination of ANC

The acid neutralizing capacity (ANC) was evaluated by USP/NF. To ensure that the sample's composition was homogeneous, it was first vigorously shaken. The homogenous suspension was then accurately measured to the minimal dose specified on the bottle label and transferred to a 250 mL beaker. The sample was diluted with water to create a 70 mL slurry, which was then stirred vigorously with a magnetic stirrer for one minute. The suspension was then precisely infused with 30 mL of 1.0 N HCl after 15 minutes of stirring the mixture. Up until pH 3.5, excess HCl was titrated against 0.5 N NaOH (Table 3). Equation 2 was used to determine how many milliequivalents (mEq) of acid each antacid consumed[13].

$$Total\ mEq = \frac{V\ HCl\ X\ N\ HCl}{V\ NaOH\ X\ N\ Na\ OH} \text{--- (2)}$$

Where N HCl and N NaOH are the normalities of HCl and NaOH; V HCl and V NaOH are the volumes of HCl and NaOH.

Table 3. The findings of physical parameters assessed

Samples	pH	Viscosity (centipoise)	Acid-neutralizing capacity (mEq)	Flow rate (mL/s)
AS-1	8.0±0.2	116.5±0.08	15.13±0.09	3.20±0.02
AS-2	7.0±0.2	452.5±6.06	8.00±0.02	4.06±0.02
AS-3	7.1±0.2	4400±9.04	5.00±0.02	4.20±0.03
AS-4	8.5±0.1	929.8±2.07	8.50±0.06	2.07±0.01

Values in mean ±SD; n= 3

Evaluation of sedimentation volume and rate

50 mL of each sample were carefully transferred to two distinct 50 mL graduated cylinders after sufficiently extended shaking to mix the samples evenly. The samples were maintained whole and at room temperature for a week on the lab bench (Table 4). The sedimentation volume was calculated using the difference between the volume of the entire suspension and the equilibrium or final volume of the sediment. A sediment volume vs. time plot was made for each sample. The slope of the line was used to calculate the sedimentation rate. estimated rates of sedimentation[14-16].

Table 4. Evaluation of sedimentation values

Sedimentation volume (%)					**Sedimentation rate (mL/day)**			
Days	**AS-1**	**AS-2**	**AS-3**	**AS-4**	**AS-1**	**AS-2**	**AS-3**	**AS-4**
1	100±0.00	100±0.00	100±0.00	100±0.00	1.00±0.00	1.00±0.00	1.00±0.00	1.00±0.00
2	100±0.00	99±2.32	100±0.00	100±0.00	1.00±0.00	0.99±0.00	1.00±0.00	1.00±0.00
3	99±1.25	98±1.25	99±6.37	99±6.37	0.99±0.00	0.98±0.00	0.99±0.00	0.99±0.00
4	98±2.60	97±6.25	97±5.64	98±3.69	0.98±0.00	0.97±0.00	0.97±0.00	0.98±0.00
5	96±0.00	95±2.38	95±2.37	97±0.84	0.96±0.00	0.96±0.00	0.95±0.00	0.97±0.00
6	94±0.00	93±3.15	93±0.08	95±0.89	0.94±0.00	0.95±0.00	0.93±0.00	0.95±0.00
7	92±2.25	91±3.38	91±2.25	93±3.35	0.92±0.00	0.94±0.00	0.91±0.00	0.93±0.00

Values in mean ± SD; n=3

Determination of zeta potential

Zeta potential of AS-1, AS-2, AS-3, and AS-4 were measured (HORIBA scientific, SZ-100). All measurements were done thrice and the mean was calculated at room temperature[17,18].

Determination of particle size

The mean particle sizes of AS-1, AS-2, AS-3, and AS-4 at room temperature were determined using photon correlation spectroscopy and a zeta sizer (HORIBA scientific, SZ-100). Before adding the tested compounds to the electrophoretic measuring cuvette, deionized water was used to dilute them to the necessary

concentration. After looking at particle size, the polydispersity index (PDI) was calculated[19,20].

Statistical Assessment

Analysis of variance (ANOVA) was used to statistically assess the test results with a 0.05 p-value. Spreadsheets and Microsoft Excel were used for data analysis during the trial.

RESULTS AND DISCUSSION

Visual inspection of products

The results of the ocular inspection are presented. The outer/secondary packaging was found to be complete and featured information on the active substances and how much of each was present in the items that contained them. AS-1, AS-2, AS-3, and AS-4 were packaged in plastic bottles with additional packing as further physical protection. The same products lacked dosage apparatus as well. Therefore, patients may use dose-measuring devices at home, which could result in improper dosing. This might not be the greatest choice because handmade teaspoons and tablespoons are unreliable measuring devices. Inaccurate dosing can lead to underdosing and no improvement in symptoms or overdosing with related effects, even though the medications in antacids frequently do not create clinically significant toxicity when given in high amounts.

All product labels (AS-1, AS-2, AS-3, and AS-4) provide storage recommendations. Although every label included information that could be read, more than half of them had temporary information, putting those products vulnerable to duplication. To determine the labels' indelibility, cotton that had been soaked in 96% ethanol was used to rub them five times. It was determined that a label was erasable if a section of it could be completely removed after testing. All of the antacids had information on their active ingredients, dose, dates of production, and expiration dates on the inside of the package.

Composition and manufacturing details

The major ingredients in the antacid suspensions are trisilicates, carbonates, and aluminium/magnesium hydroxides. Sodium bicarbonate, simethicone, dimethicone, oxetazaine, and sodium alginate were also discovered to be present

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Active ingredients in the study products.

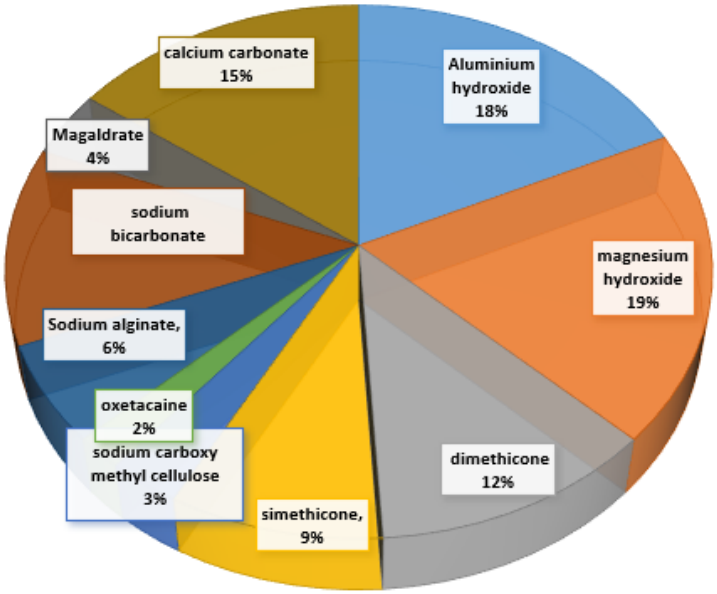

Figure 1: The active contents present in the samples tested

Cost analysis

The adult dosage for AS-1 across the samples was 10mL, and a 200mL pack costing INR 92.00 was discovered to be more affordable when compared to the other brands. The cost of AS-1 is roughly twice as low as that of the other samples considered.

All antacids had an ANC of more than 5 mEq, and the AS-1's ANC of 15.13±0.09 mEq was good.

Therefore, judging the value of antacids solely by the price of a packet may not be accurate. Therefore, the value for money of each antacid was determined using the ratio of the price per dose to the number of doses in a pack.

Samples	pH	Viscosity (centipoise)	Acid-neutralizing capacity (mEq)	Flow rate (mL/s)
AS-1	8.0±0.2	116.5±0.08	15.13±0.09	3.20±0.02
AS-2	7.0±0.2	452.5±6.06	8.00±0.02	4.06±0.02
AS-3	7.1±0.2	4400±9.04	5.00±0.02	4.20±0.03
AS-4	8.5±0.1	929.8±2.07	8.50±0.06	2.07±0.01

Values in mean ±SD; n= 3

The samples' pH was found to range from 7.0±0.2 (AS-2) to 8.5±0.1 (AS-4). This implies that every sample can increase the pH of digestive fluids. AS-4 has the greatest pH, while samples AS-1 and AS-3 have the lowest pHs. The flow rate was between 2.07±0.01 mL/s (AS-4) and 4.20±0.03 mL/s (AS-3). A substance's viscosity determines how swiftly it flows, and the AS-3 was found to have a higher viscosity (4400±9.04 centipoise). In all of the evaluated samples, the sedimentation volume was 1. (Figure 2).

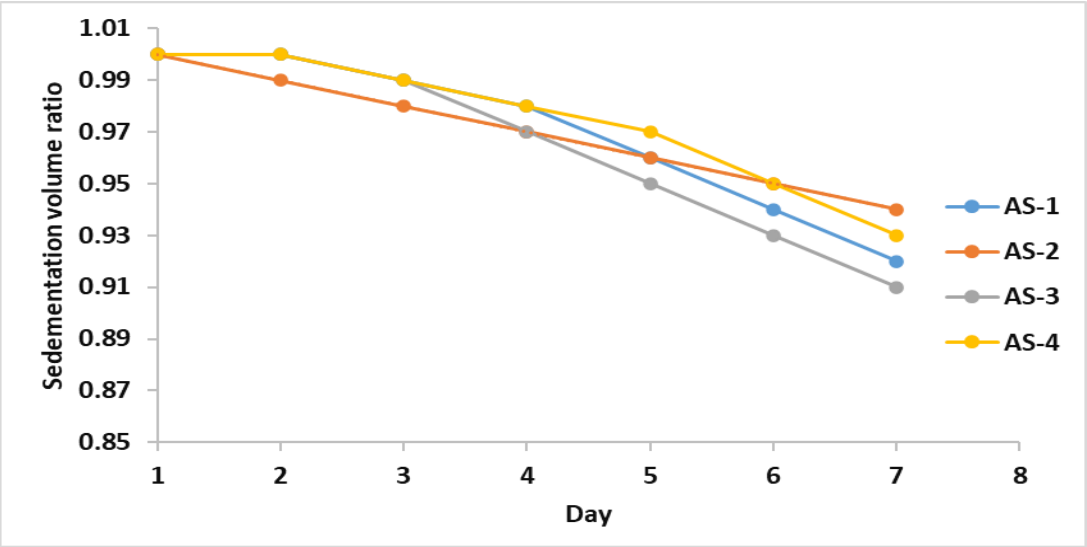

Figure 2: Sedimentation rate of AS-1, AS-2, AS-3, and AS-4

Particle size distribution and zeta potential of marketed samples were evaluated (Table 5) and they were found satisfactory

Table 5. Particle size distribution and zeta potential of AS-1, AS-2, AS-3, and AS-4

Samples	Particle size (nm)	Zeta potential (mv)
AS-1	1333.2±23.58	-46.4±1.29
AS-2	618.9±3.52	-59.0±2.54
AS-3	201.3±12.21	0.4±0.01
AS-4	304.7±26.27	-2.2±0.02

Values in mean±SD; n=3

Conclusion:

According to the study, choosing an antacid is not just dependent on the brand; even generic medicines are of comparable quality. The evaluation tests showed that the gastrointestinal suspensions are cost-efficient, therapeutically beneficial, and call for more patient care.

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