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**Original Research Article**

# Evaluation of the Acid Neutralizing Capacity of Some Commercially Available Brands of Antacid Tablets in Nigeria

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**Abstract:** Antacids are commonly used as over - the - counter (OTC) drugs or prescribed medications. Some antacid products may neutralize more acid in the stomach than others. The ability of an antacid to neutralize acid is expressed as its Acid Neutralizing Capacity (ANC). This study was undertaken with the objective of assessing the quality of different brands of antacid tablets. The assessment parameters included the evaluation of uniformity of weight, uniformity of thickness, crushing strength, friability, as well as the ANC (using pH and titrimetric method), which is easy to use, accurate, reproducible, simple, and inexpensive. The study revealed that all the brands complied with the compendia specification for uniformity of weight and friability. The acid neutralizing capacity of the brands were in the order Brand E > Brand D > Brand C > Brand A > Brand F > Brand B > Brand G. The average final pH of the mixture of Antacid and acid after 10 minutes is as follows: Brand E 8.30, Brand D 7.46, Brand C 7.37, Brand A 6.67, Brand F 6.35, Brand B 6.02 and finally Brand G 5.88. It can be concluded from the study that two of the brands (D and E) evaluated in this study could be regarded as being of highest quality with Brand E having the highest ANC value. This study could help prescribers to make informed choices for their patients. The titrimetric procedure used in this study is simple, inexpensive, easy to use and could be used in routine monitoring or periodic evaluation of the quality of Antacid tablets, especially in the absence of high technology equipment that are not easily available in most developing countries.

**Keywords:** Antacid, Acid neutralizing capacity (ANC), Chewable tablets, *Helicobacter pylori*.

## INTRODUCTION

Antacids are commonly used worldwide as over - the - counter (OTC) drugs or prescribed medications. Antacids are drugs that neutralize excess gastric acids (Allen et al., 2005). They have been used as the mainstay of treatment for peptic ulcers, gastritis, gastro oesophageal reflux disease (GERD), and functional dyspepsia (Maton *et al.*, 1999). Approximately 20% of the population in the United Kingdom visits their general practitioner each year with dyspeptic symptoms, while in Nigeria the prevalence rates range between 70% and 90% (Moayyedi *et al.*, 1999).

Gastric ulcer is normally caused by a gram negative bacterium known as *Helicobacter pylori* a micro-aerophilic bacterium which means it requires oxygen to function. *Helicobacter pylori* is known to inhabit various areas of the stomach and duodenum, infection caused by it leads to chronic inflammation in the stomach lining. Although the pathogenesis of gastroesophageal reflux disease (GERD) is multifactorial (Scapignato, 1988) the damaging power of the refluxed material depends primarily on gastric acid secretion and the nature of refluxate in most of patients with GERD [Mittal *et al.*, 1992).

Some antacid products may neutralize more acid in the stomach than others. The way to express the ability of an antacid to neutralize acid is by determining the antacid's neutralizing capacity (ANC). ANC measures the ability of the antacid to neutralize acids (pH of 3.5 to 4). The US FDA requirement is that an antacid must have a neutralizing capacity of ≥5 mEq per dose. The most effective antacids should have a high acid neutralization capacity and rapid gastric acid neutralization qualities. Most antacids contain magnesium hydroxide, aluminium hydroxide, calcium carbonate, or a combination of these.

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Post market surveillance or monitoring involves all activities undertaken to obtain more data and information about a product after it had been granted marketing authorization and made available for public use. It is imperative to conduct post market surveillance or monitoring of approved medicines in order to adequately assess the quality of therapeutic effectiveness and safety of medicine. Routine laboratory testing of drug in the market is crucial to protect the public especially in developing countries where counterfeit and substandard drug have become a major challenge to health care services (Ngwuluka *et a*l., 2009).

In Nigeria several attempt have been made to combat counterfeit and fake drugs (Ochekpe *et al.,* 2006 and Raufu, 2003). Counterfeit and fake drugs are a major cause of morbidity, mortality and loss of public confidence in drugs and health system (Cockburn *et al*, 2005).

The aim of the study is to assess the product quality of different brands of antacid tablets, by evaluating their acid neutralizing capacity (ANC) using the titrimetric method in order to determine the appropriateness of their inter-changeability.

## MATERIALS AND METHODS

### Materials

Seven different brands of Antacid tablet were purchased from Pharmacies. Hydrochloric acid (HCL), Standardized Sodium Hydroxide (NaOH) were supplied by Pharmaceutics department, faculty of pharmacy, Delta State University Abraka. All other reagents used for the analysis were of analytical grade and standard.

### Weight Variation Test

Twenty tablets were selected at random, from each of the seven brands, they were weighed and average weight was calculated. Not more than two of the individual weights should deviate from the average weight by more than ±5 %.( USP, 2007)

### Hardness Test

The crushing strength was determined with a tablet hardness tester (digital tester machine (Veego digital hardness tester Mumbai India. Model no: VDIGITAB-1). Five tablets were randomly selected from each brand and the pressure at which each tablet cracked, was recorded and the standard mean error was calculated. (Indian pharmacopoeia 2007).

### Friability Test

Six tablet of each brand were weight individually and the weight was recorded. The tablets were subjected to friabilation at 25rpm for four minutes, the tablets were then weighed and compared with the initial weight. Conventional compressed tablet that lose greater than 0.5 to 1% of the weight are considered accepted (USP, 2007).

### Uniformity of Thickness

This is the measure of the thickness of a tablet. Six tablets from each brand were randomly selected and the thickness of each tablet was determined using a micrometer screw gauge. Thickness among a tablet batch should be within the range of ± 0.5 % of the standard value.

### Acid Neutralizing Capacity Test

The acid neutralizing capacity of the brands of antacid were assessed using two method.

### pH Meter Method

60ml of 0.1M HCL was poured into a beaker. The pH of the 0.1M HCL was measured using a pH meter and the reading was recorded. Three tablets from each Brand were triturated using a mortar and pestle and transferred carefully into the beaker. The 0.1M HCL and the antacid mixture was then Stirred for 10mins. The final pH of the 0.1M HCL and the antacid mixture was then measured using a pH meter. Data was recorded.

### *Back Titration method*

One tablet from each Antacid brand was crushed using a mortar and pestle. 0.01g was weighed out and transferred into a 250ml Erlenmeyer flask. Exactly 50ml of 0.1M hydrochloric acid was added to the flask and was gently swirled to dissolve the crushed tablet as completely as possible. 2-5 drops of bromophenol blue indicator solution was added to the flask and a yellow color was observed which was noted, this colour was an indication that there was excess hydrochloric acid needed to be titrated with the standardized NaOH. The solution is then titrated with the Standardized NaOH until the solution just turn blue and the volume of NaOH solution required to neutralize the excess acid was recorded. The number of moles of HCL neutralized by each tablet was calculated and the result expressed in milliequivalent (mEq).

**Table- 1: Label Constituents of the different Antacid Brands**

| Brand Code | Constituents |
|---|---|
| Brand A | Magnesium trisilicate (250 mg), Dried aluminium hydroxide (120 mg), Peppermint flavour |
| Brand B | Dried Aluminium Hydroxide gel (250 mg), Magnesium trisilicate (500 mg) |
| Brand C | Dried Aluminium Hydroxide Gel (400 mg), Magnesium Hydroxide (200 mg), Simethicone (25 mg) |
| Brand D | Bismuth Salicylate (262 mg) |
| Brand E | Sodium alginate (500 mg), Sodium bicarbonate (267 mg), Calcium carbonate (160 mg) |
| Brand F | Dried aluminium hydroxide (300 mg) Magnesium trisilicate (50 mg), Magnesium hydroxide (25 mg), Simethicone (10 mg) |
| Brand G | Dried aluminium hydroxide (300 mg), Magnesium aluminium silicate hydrate (50 mg), magnesium hydroxide (25 mg), Simethicone (25 mg) |

## RESULTS AND DISCUSSION

**Table- 2: Characterization of different Brands of Antacid Tablet**

| Brand Code | Weight (g) ± SD | Thickness (mm) ± SD | Hardness(Kg) ± SD | Friability (%) |
|---|---|---|---|---|
| Brand A | 1.1539±0.06 | 16.13±0.02 | 14.34±0.2 | 0.10 |
| Brand B | 1.3983±0.05 | 16.81±0.02 | 13.5±0.6 | 0.15 |
| Brand C | 1.1745±0.02 | 16.82±0.01 | 9.24±0.8 | 0.56 |
| Brand D | 1.0123±0.005 | 16.81±0.02 | 7.0±0.3 | 0.71 |
| Brand E | 0.8119±0.006 | 13.26±0.03 | 7.8±0.5 | 0.60 |
| Brand F | 1.1907±0.01 | 16.93±0.02 | 13.94±0.05 | 0.13 |
| Brand G | 1.1283±0.009 | 16.96±0.02 | 10.46±0.6 | 0.29 |

**Table 3: Acid neutralizing properties of Antacid brands**

| Brand code | pH of Antacid – Acid mixture | ANC (mEq) |
|---|---|---|
| Brand A | 6.67 | 6.27 |
| Brand B | 6.02 | 5.80 |
| Brand C | 7.37 | 7.25 |
| Brand D | 7.46 | 7.75 |
| Brand E | 8.30 | 8.75 |
| Brand F | 6.35 | 5.55 |
| Brand G | 5.88 | 5.35 |

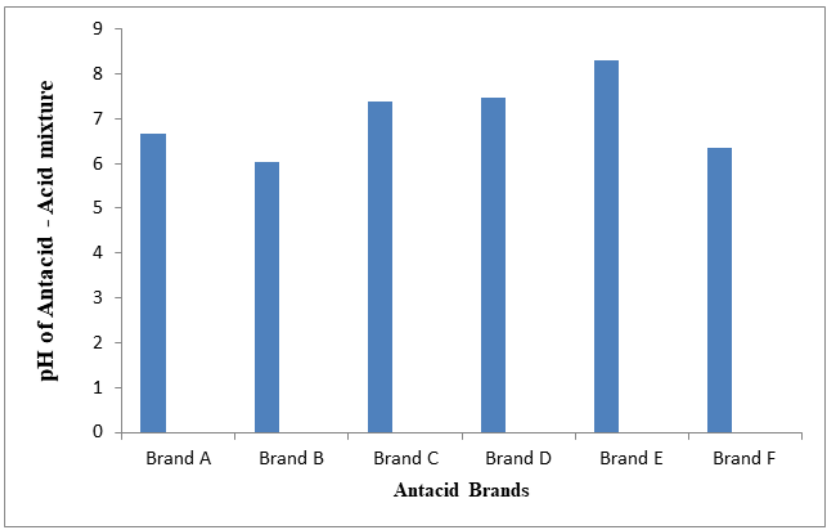


**Fig-1: Chart of pH of Antacid – Acid mixture against Antacid Brands**

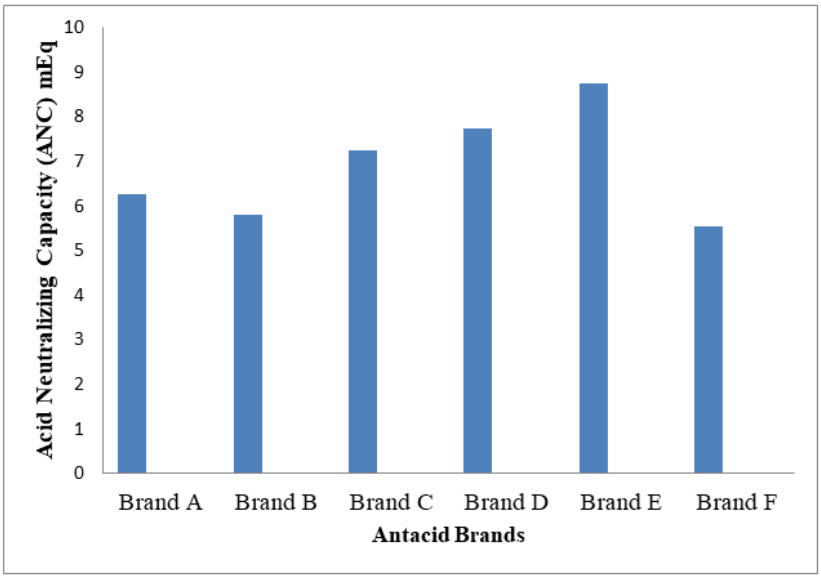


**Fig-2: Chart of Acid Neutralizing Capacity against Antacid Brands**

## DISCUSSION

All the brands of antacid tablets used were within their shelf life as at the time of the study and all have NAFDAC (National agency for food drug administration and control) registration number. All the brands of antacid tablets showed acceptable uniformity of weight. The significance of the uniformity of weight test was to ensure that the tablets were within the appropriate particle size range as well as uniformity in mixing and die filling.

The thickness of a tablet is critical to their therapeutic effectiveness, if the thickness of tablet is monitored at regular intervals potential problems relating to tablet weight can easily be detected at an early stage. The BP limit for tablet thickness should not exceed ± 5% deviation. Therefore, all tablet brands passed the thickness test from the result above.

The crushing strength and friability are the measure of strength or weakness of a tablet. Friability test was previously a non compendia test but has now been included in the United State Pharmacopoeia (USP, 2007). Friability test is used to evaluate the tablet's resistance to abrasion. The compendia specification for friability is ≤ 1%. All brands met the USP specification for friability (Table 2) and this indicates that the tablets can withstand abrasion without loss of tablet integrity; consequently the tablets can withstand the rigors of transportation and handling.

Hardness test is a non compendia test, the hardness or crushing strength assesses the ability of the tablet to withstand handling without fracturing or chipping. Hardness can also influence friability and disintegration in some cases. The harder the tablet the less friable and more time it takes in disintegrating. A force range of 5 - 8 kg is the standard requirement for a satisfactory tablet (Indian Pharmacopoeia, 2007). Hence from the mean crushing strength (Table 2) all tablet Brands failed the hardness test except Brand D and Brand E which had hardness value of 7 kg and 7.8 kg respectively.

The acid neutralizing capacity (ANC) as revealed by Table 2 and graphically depicted by figure 2 shows that Brand E neutralized the Hydrochloric acid the most in the order Brand E > Brand D > Brand C > Brand A > Brand F > Brand B > Brand G but all the brands met the US FDA requirement that an antacid must have an acid neutralizing capacity (ANC) of ≥5 mEq per dose. The average final pH of the mixture of Brand E and HCL after 10mins was 8.30, that of Brand D was 7.46, for Brand C 7.37, for Brand A 6.67 for Brand F 6.35 for Brand B 6.03 and finally for Brand G 5.99.

## CONCLUSION

The importance of an antacid preparation cannot be over emphasized in the health of an ulcer patient and those with heartburn. This study has revealed that different antacid preparations have different acid neutralizing capacities, Brand D and Brand E showed clearly the highest ANC values, Brand E which contained Sodium alginate, Sodium hydrogen carbon, Calcium carbonate neutralized the acid the most, but in cases of hypertension or restricted salt intake, this product could be substituted with other brands with equally high ANC values. This could help prescribers to make informed choices for their patients.

The titrimetric procedure used in this study is simple, inexpensive, and easy to use and could be used in routine monitoring of the quality of Antacid tablets, especially in the absence of high technology equipment

that are not easily available in most developing countries.

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