Analysis of antacid tablets using the alkalimetric titration method

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Abstract

Titrimetry is a quantitative analysis concerned with measuring the volume of a solution of known concentration required to react with the substance to be determined. On the other hand, alkalimetry is used to determine the levels of acidic compounds that are reacted with essential standard solutions. Antacids can treat stomach disorders resulting from excess stomach acid production. The active ingredient is a mixture of magnesium hydroxide and aluminum hydroxide which is a weak base that reacts with acids. This study aims to determine whether the levels of antacid tablets in several pharmacies in Bandar Lampung City by looking at the expiration date meet USP30_NF25 requirements, namely between 90.0% - 110% of the amount stated on the label. The method used is alkalimetry with a back titration technique, in which excess acid is added to the sample to react with antacids, and the excess acid is titrated using sodium hydroxide with phenolphthalein solution as an indicator.

Keywords: Titration, Alkalimetry, Regulation, Validation

Introduction

Along with technological advances and changes in people's lifestyles that tend to pay less attention to health, disease development in society is inevitable. One of the diseases often experienced by the community is stomach ulcers. Almost 7,000 Indonesians suffer from stomach ulcers. It is known that 85% suffer from active stomach ulcers and 15% from organic ulcers. About 80% of gastric ulcers are of the active type. No abnormalities in the gastrointestinal tract are caused by stress, lack of sleep, workload, and irregular eating. The remaining 20% is organic. Namely, there are digestive organ abnormalities, such as stomach or throat injuries [1-5].

Heartburn is a pain caused by excess acid produced by the stomach, which causes irritation in the mucous membrane of the stomach. Under normal conditions, acid is needed to help digestion in processing the food we eat. However, acid production in the stomach can be more excellent than needed if our lifestyle is not regular and healthy. One of the drugs used to treat heartburn is antacids. Antacids contain ingredients that effectively neutralize acid in the stomach and are not absorbed into the body, so they are pretty safe to use (as recommended). The use of antacids aims to relieve symptoms of nausea, pain, bloating, or twisting due to gastric irritation. Antacids generally contain compounds that can neutralize stomach acid, thus reducing stomach acidity [6-10].

Stomach Acid Disease

(Gastroesophageal Reflux Disease) is a disease caused by an increase in stomach acid production due to poor stomach work. Irregular eating
patterns and stress are factors that cause acid reflux disease. Irregular eating patterns can cause the stomach to become more sensitive when stomach acid increases so that the mucosal and submucosal layers of the stomach experience irritation or injury. Stress factors or excessive mind load can accelerate and increase the production of gastric acid, thus causing gastric acid disease [11-13].

**Antacids and their benefits**

Antacids are drugs that can be used to treat stomach disorders resulting from excess stomach acid production. The active ingredient is a mixture of magnesium hydroxide and aluminum hydroxide which is a weak base so it reacts with acids. Antacids are a class of drugs that have activity in neutralizing excess stomach acid by increasing the pH of the gastric lumen and reducing pepsin activity [14-15].

Antacids are drugs that are quite easy to obtain and inexpensive, so they are widely used to treat gastritis complaints. However, a study that has been conducted shows that the knowledge of non-medical students in Surabaya about how to use antacids is still lacking, especially how to use antacid tablets and measuring devices for the consumption of liquid antacid preparations [16-17].

Antacids are compounds that can neutralize hydrochloric acid (stomach). Antacid preparations may contain aluminum and magnesium. Antacids with this content are relatively insoluble in water. Such as magnesium carbonate, hydroxide, and tricyclic, as well as glycerin and hydroxide, work longer when they are in the stomach so that most of the goals of giving antacids are achieved. Magnesium preparations may cause diarrhea, while aluminum ones may cause constipation. So a combination of both is used to cover the effects produced by both [18-20].

Antacid tablets are chewable tablets that contain a combination of the active substances magnesium hydroxide (Mg(OH)₂) and aluminum hydroxide (Al(OH)₃) which are a type of weak base that will react with gastric hydrochloric acid to form salt and water. Antacids include over-the-counter drugs that can be purchased by every individual on the market. The problem that may arise is the lack of drug-related information, which can lead to inaccuracies in drug use [21-22].

Antacid tablets are dosage forms of antacid drugs in tablet form. Antacids themselves are a type of drug used to reduce the symptoms of indigestion, especially in problems with excess stomach acid, such as stomach ulcers or heartburn [23].

Antacid tablets contain compounds that aim to neutralize excess stomach acid in the stomach. Aluminum hydroxide is commonly found in antacid tablets: This compound can neutralize stomach acid by producing water and aluminum salts. Magnesium hydroxide: This compound also neutralizes stomach acid, producing water and magnesium salts. Calcium carbonate: This compound can reduce stomach acidity by producing water, calcium salts, and carbon dioxide. Antacid tablets are usually taken by mouth and taken with water. The recommended dosage may vary depending on the type of antacid and the severity of your symptoms. Therefore, it is essential to follow the dosing instructions given by the doctor or those listed on the drug packaging [24-28].

However, remember that long-term use of antacids or inappropriate doses can cause side effects such as diarrhea, constipation, electrolyte disturbances, or poor absorption of minerals. If symptoms do not improve or worsen after taking antacid tablets, you should consult your doctor for further evaluation [29-30].

Antacids are a drug used to reduce the symptoms of indigestion caused by excess stomach acid. This drug works by neutralizing excess stomach acid and reducing irritation to the stomach wall. Usually, antacids relieve symptoms such as stomach pain, heartburn, nausea, and a burning feeling in the chest caused by stomach acid rising into the esophagus (GERD). Antacids may also help reduce symptoms associated with peptic ulcers, acid reflux, and other digestive disorders [31-35].

Antacids are available in many forms, including tablets, capsules, suspensions, and liquids. Common active antacid ingredients include aluminum hydroxide, magnesium hydroxide, calcium carbonate, and sodium bicarbonate. However, it is essential to note that antacids only provide temporary relief and do not cure the underlying condition. If you experience prolonged or severe symptoms, it is best to consult a doctor for proper diagnosis and treatment. Your doctor can also advise you on the appropriate dosage and use of antacids for your condition [36-38].
Detection of antacid compounds

Alkalimetry is a volumetric method with the principle of acid-base neutralization reactions. Alkalimetry is the determination of the levels of alkaline compounds using acid standards. The hydroxide is a weak base that can be titrated with a standard solution which is a strong base [39-40].

In determining this level using the indirect alkalimetry method. Indirect alkalimetry, namely the excess of hydrochloric acid is titrated with sodium hydroxide where to see the endpoint of the titration. The indicator used is phenolphthalein because the pH range of phenolphthalein is 8.0 – 9.6 indicated by a color change from colorless to pink. The standard solution used in this Alkalimetry titration is sodium hydroxide. Indicators are needed in this method to determine the end point of the titration. For weak acids with standard solutions of solid bases the pH of the equivalence point is above 7 [41-42].

The titration method for analyzing the levels of antacid tablets by alkalimetry is used to determine the levels of the active ingredient of antacids in tablets using titration with an acidic or alkaline solution as the titrant. This method is based on the reaction between the active ingredients of antacids and acids or bases that react in solution [43-44].

The following are the general steps in the titration method for analyzing the levels of antacid tablets by alkalimetry: Sample preparation: The antacid tablets are crushed and a certain amount is taken that represents the active ingredient to be analyzed. End point determination: Choose the right indicator to show the end point of the titration. The indicator commonly used in antacid titrations is phenolphthalein or methyl orange. Phenolphthalein changes color from colorless to pink when the pH reaches a certain range. Preparation of titrant solution: Prepare a standard acid or base solution of known concentration. A known hydrochloric acid (HCl) concentration is usually used if an acidic solution is used as the titrant. When an alkaline solution is used as the titrant, sodium hydroxide (NaOH) of known concentration is usually used. Titration: The titrant solution is slowly added to the antacid sample which is placed in an Erlenmeyer flask. The titration is carried out until the end point is reached, which is marked by a change in the color of the indicator. At this point, the reaction between the active ingredients of the antacid and the titrant is considered complete. Assay: The volume of titrant solution used to reach the endpoint is recorded. The levels of active ingredients in antacid tablets can be calculated using a titration equation corresponding to the chemical reactions involved. Following proper procedures and using accurate equipment in this method is essential. In addition, method validation, including backtesting and quality control, is also necessary to ensure the accuracy and precision of the analysis results [45-46].

Analysis of levels of antacid tablets by alkalimetry is used to determine the amount of antacid substances contained in these tablets. The alkalimetric method involves using a standard strong acid solution to measure a tablet's antacid substance. The following are some of the uses of alkalimetric assay of antacid tablets: Quality control of production: Alkalimetric assay of antacid tablets is used by manufacturers to ensure the consistency and quality of the antacid tablets produced. By measuring the levels of antacid substances, manufacturers can ensure that each tablet contains the amount according to established specifications [47].

Research and development: In the research and development of new antacid formulations, alkalimetric analysis of antacid tablet concentrations assist scientists and researchers in studying the effect of various additives, formulation changes, or production methods on the levels of antacid substances in tablets. This helps them in choosing the most effective formulation. Determination of the correct dose: Alkalimetry analysis of antacid tablet levels can also be used to determine the correct dose for the patient. By knowing the levels of antacid substances in each tablet, the doctor or pharmacist can recommend the appropriate dose according to the patient's condition [48-49].

Monitoring of use: Alkalimetric analysis of antacid tablet levels can be used by health regulatory agencies to check manufacturers' compliance with quality and safety standards. This helps ensure that the antacid tablets available in the market are safe and effective for use by consumers. Comparison between brands: In the selection of antacids, alkalimetric analysis of antacid tablet levels can help consumers compare the effectiveness of various brands of antacids. By knowing the levels of antacid substances in each tablet, consumers can make a more informed decision in choosing the antacid that suits their needs [50-51].
In practice, an alkaliometric assay of antacid tablets involves preparing a strong standard acid solution and using an appropriate pH indicator. This alkaliometric method has become a standard method commonly used in the pharmaceutical industry to analyze the levels of antacid substances in tablets [52-53].

Identification of magnesium hydroxide and aluminum hydroxide from antacid tablets was carried out qualitatively using a color reaction, which was carried out separately between magnesium hydroxide and aluminum hydroxide. This ensures a positive or negative sample by comparing the results with standard magnesium and aluminum standards. The results obtained from this study were positive, samples containing magnesium and aluminum, with comparison, produced a white precipitate, but with the addition of excess reagent, the precipitate would dissolve. Identifying aluminum samples using an ammonium reagent produces bright red staining. Many factors can interfere in this test, so if it is not careful, a precipitate will only form. The addition of ammoniacal ammonium carbonate is to remove excess dye. Iron and phosphate should also not be present in the sample solution by adding ammonia, as this will prevent the formation of a specific stain for aluminum hydroxide [54-55].

Determination of levels using the titrimetric method by acid-base titration, namely alkaliometry with the back titration technique, antacids which are weak bases will react with a strong acid, namely 2N hydrochloric acid which then excess hydrochloric acid will be titrated again with a standard solution of 1 N sodium hydroxide. The sample is dissolved first with water, which is added little by little while stirring until well mixed and water can dissolve other additives in the sample. When adding 2 N hydrochloric acid 100 ml is poured little by little while continuing to stir, so that the sample can dissolve more entirely and the reaction between the antacids (magnesium hydroxide and aluminum hydroxide) with hydrochloric acid can work well. Judging from the solubility and slow reaction, stirring must be continued until it is completely dissolved. Because if it doesn't dissolve and reacts perfectly, when titrated using a standard 1N sodium hydroxide solution, not only the hydrochloric acid reacts, but the sample will also react with the sodium hydroxide so that the titrant obtained is very large and the levels not expected are obtained. Before titrating the sample is filtered first because there is still precipitate so it looks cloudy, with filtering the sample is clearer and it will make it easier to see the endpoint of the titration. To see the end point of the titration. Alkaliometric analysis of antacid tablets involves the use of a strong acid (usually hydrochloric acid) to determine the alkali content of antacid tablets. This alkaliometric method is based on the neutralization reaction between an acid and a base [56-57].

The following are general steps that can be taken to analyze the levels of antacid tablets by alkaliometry: Sample Preparation: Take several antacid tablets to be analyzed. Grind the tablet into a fine powder to facilitate sampling. Preparation of Standard Solution: Prepare a standard solution of a strong acid, such as hydrochloric acid (HCl), of a well-known concentration. This standard solution will be used as the titration reagent. Preparation of Titration Solution: Take a portion of the antacid tablet powder and dissolve it in water or a buffer solution according to the instructions in the method of analysis used. Make sure to measure the right volume and avoid contamination from other ingredients. Titration: Pour the titration solution (standard acid solution) into the burette. Add the titration solution slowly into the antacid tablet sample solution that has been prepared while stirring. A reaction between acid and base will occur, where the acid will react with the base in the antacid tablet. At the beginning of the titration, the antacid tablet solution will be alkaline or neutral in color. Add titration solution little by little until the equivalence point is reached. The equivalence point is when the amount of acid and base reacting in the solution is the same, which is indicated by a change in the color of the solution. Indicator or pH Meter: If the antacid tablet contains a compound that gives a clear color change when it reaches the equivalence point, then an indicator can be used to observe the color change. However, if the color change is not visible or not obvious, using a pH meter can help monitor changes in the pH of the solution during the titration. Data Processing: Record the volume of the titration solution used up to the equivalence point. In alkaliometric analysis, the amount of acid that reacts with the base in the sample solution will be equal to the amount of acid used in the standard solution. The alkali content in antacid tablets can be calculated using the volume and concentration of standard acid solutions. Calculation of Content: The alkali content in antacid tablets can be calculated using a basic equation involving the volume and concentration of a standard acid solution: Content (in appropriate units) = (Volume of standard acid solution) x (Concentration of standard acid solution) /
(Volume of sample solution). It is essential to follow proper methods and procedures in carrying out alkalimetric analysis to obtain accurate results [58-60].

**Conclusions**

Based on the review results above, it can be concluded that the titration method can be used to determine antacid compounds. However, there are some drawbacks such as low accuracy and selectivity. However, for small industries, the titration method can still be used as a reference for determining antacid levels.

**Conflicts of interest**

There are no conflicts to declare.

**References**


