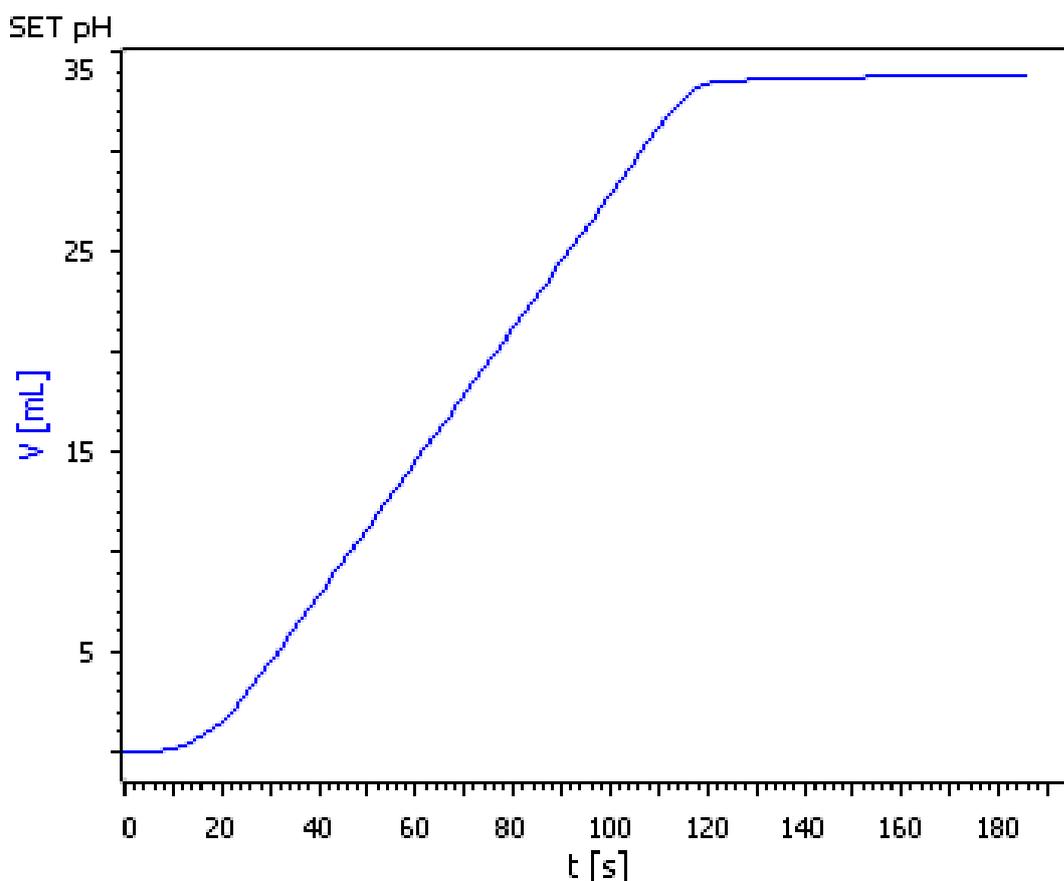


Determination of acid-neutralizing capacity according to USP general chapter <301>



Antacids neutralize excess stomach acidity to relieve heartburn, sour stomach, acid indigestion, and stomach upset. They are also used to relieve the pain of stomach and duodenal ulcers. The acid-neutralizing capacity (ANC) of an antacid is the amount of acid that can be neutralized. Commercial antacids containing one or more bases are available to treat this condition by neutralizing the excess acid in the stomach. Antacids are available with various formulations as over the counter drugs (OTC). USP<301> describes a back titration method to a set endpoint of pH 3.5 to determine the acid-neutralizing capacity. This Application Note shows the determination of the ANC of alumina magnesia, magaldrate as well as simethicone oral suspension and simethicone chewable tablet.

Method description

Sample

Magaldrate and simethicone oral suspension
Alumina, magnesia, and simethicone chewable tablets

Sample preparation

Magaldrate and simethicone oral suspension

Sample container is shaken well. 5.63 g (equivalent to 5 mL, single dose) of sample is weighed accurately and transferred into 150 mL glass beaker. 70 mL of carbon dioxide free water is added and the content is stirred well for 1 minute.

Alumina, magnesia and simethicone chewable tablets

20 tablets are weighed accurately and transferred into a clean mortar. The average weight is noted. Tablets are grinded into fine powder. From this, 1 g (single dose) of sample is weighed accurately and transferred into 150 mL glass beaker. 70 mL of carbon dioxide free water is added and the content is stirred well for 1 minute.

Configuration

905 Titrand	2.905.0010
801 Magnetic stirrer	2.801.0040
800 Dosino, 2x	2.800.0010
Unitrode with Pt1000	6.0258.600
50 mL Dosing unit, 2x	6.3032.250
Tiamo 2.5 full CD: 1licence	6.6056.252
Buffer solution pH 4	6.2307.100
Buffer solution pH 7	6.2307.110
Buffer solution pH 9	6.2307.120

Solutions

Titrand	c(NaOH) = 0.5 mol/L (0.5 N) Around 20 g sodium hydroxide is weighed accurately and transferred into a clean 1000 mL volumetric flask. It is then dissolved and diluted up to the mark with carbon dioxide free water.
HCl solution	c(HCl) = 1 mol/L (1 N) 87 ml hydrochloric acid (37%) is taken in a clean 1 L volumetric flask. It is diluted to the mark with carbon dioxide free water.

Calibration

pH calibration is done using Metrohm buffer solutions (pH buffer 4, 7 and 9)

Analysis

30 mL of c(HCl) = 1 mol/L (1 N) is accurately dosed to the prepared sample. The content is stirred well for 15 min. The excess hydrochloric acid is titrated immediately with c(NaOH) = 0.5 mol/L (0.5 N) until a stable pH of 3.5 is achieved.

Parameters

Titration mode	SET pH
Stirring rate	9
Pause	900 s
EP1 at pH	3.5
Dynamics pH	1.5
Maximum rate	20 mL/min
Minimum rate	5 µL/min
Stop criterion	Drift
Stop drift	30 µL/min
Titration direction	Auto
Extraction time	0 s
Stop volume	50 mL

Results

Magaldrate and simethicone oral suspension

Acid neutralization capacity / (mEq), (n = 5)	s(rel) / %
11.56	0.29

*USP criteria - Acid neutralization capacity NLT 9.02.

Alumina, magnesia and simethicone chewable tablets

Acid neutralization capacity / (mEq), (n = 5)	s(rel) / %
7.67	0.87

*USP criteria - Acid neutralization capacity NLT 7.00.

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Method description

Comments

Besides the herein described alumina magnesia, magaldrate as well as simethicone oral suspension and simethicone chewable tablets, the following samples can be analyzed:

- Alumina and magnesia oral suspension,
- Alumina and magnesia tablets,
- Alumina and magnesium carbonate OS,
- Alumina and magnesium carbonate tablets,
- Alumina and magnesium trisilicate OS,
- Alumina and magnesium trisilicate tablets,
- Alumina, magnesia and calcium carbonate chewable tablets,
- Alumina, magnesia and calcium carbonate oral suspension,
- Alumina, magnesia and simethicone chewable tablets,
- Alumina, magnesia and simethicone oral suspension,
- Alumina, magnesium carbonate and magnesium oxide tablets,
- Aluminum hydroxide gel,
- Aspirin effervescent tablets for OS,
- Aspirin, alumina and magnesia tablets,
- Aspirin, alumina and magnesium oxide tablets,
- Aspirin, codeine phosphate, alumina and magnesia tablet,
- Buffered aspirin tablets,
- Calcium and magnesium carbonates oral Suspension,
- Calcium and magnesium carbonates tablets.
- Calcium carbonate and magnesia chewable tablets,
- Calcium carbonate and magnesia tablets,
- Calcium carbonate lozenges,
- Calcium carbonate tablets,
- Calcium carbonate, magnesia, and simethicone chewable tablets,
- Didanosine tablets for OS,
- Dihydroxyaluminum aminoacetate magma,
- Dihydroxyaluminum sodium carbonate chewable tablets,
- Dihydroxyaluminum sodium carbonate,
- Dried aluminum hydroxide gel capsules,
- Dried aluminum hydroxide gel tablet,
- Dried aluminum hydroxide gel,
- Magaldrate oral suspension
- Magaldrate tablets,
- Magnesia tablets,
- Magnesium oxide capsules,
- Magnesium oxide tablets

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