



Application Note AN-T-192

根据 USP<301> 定酸中和能力

Fast and accurate potentiometric back titration of the acid-neutralizing capacity (ANC) of commercial antacids

Antacids neutralize excess stomach acid to relieve heartburn, sour stomach, acid indigestion, and upset stomach symptoms. They are also used to relieve the pain due to stomach and duodenal ulcers. The acid neutralizing capacity (ANC) of an antacid describes the amount of acid it can neutralize. Antacids are available in various formulations (both weak bases and strong bases) as over-the-counter (OTC) medications. OTC antacids containing one or more bases are available to treat the

previously mentioned stomach conditions by neutralizing any excess acid present. USP<301> describes a method for back titration of an antacid to a fixed endpoint of pH 3.5 to determine acid-neutralizing capacity.

In this Application Note, the determination of the ANC of alumina-magnesia, magaldrate, as well as simethicone oral suspension and simethicone chewable tablets is presented. The presented method conforms to USP<301>.

SAMPLE AND SAMPLE PREPARATION

This application is demonstrated on magaldrate, simethicone oral suspension, alumina-magnesia, and simethicone chewable tablets. A list is provided in the Comments section with many other pharmaceutical samples that can be analyzed in the

same way.

The samples are homogenized according to their dosage form (e.g., tablets are crushed, gels are shaken, etc.) and dissolved in carbon dioxide-free water.

EXPERIMENTAL

The determinations are carried out on an OMNIS Professional Titrator equipped with a pre-calibrated dUnitrode with integrated Pt1000 (**Figure 1**).

A defined volume of HCl solution is dosed into an appropriate amount of prepared sample. The excess HCl is back titrated with standardized NaOH solution until reaching a stable pH value of 3.5.



Figure 1. OMNIS Professional Titrator equipped with a dUnitrode with integrated Pt1000.

RESULTS

This method offers very accurate results, as displayed in **Table 1**. An exemplary acid-base

titration curve of magaldrate and simethicone oral suspension is given in **Figure 2**.

Table 1. Results for the ANC determination of magaldrate and simethicone oral suspension (sample 1) and alumina-magnesia, and simethicone chewable tablets (sample 2) by potentiometric titration according to USP<301>.

Sample (n = 5)	Mean ANC in mEq	SD(rel) in %
Sample 1	11.56	0.3
Sample 2	7.67	0.9

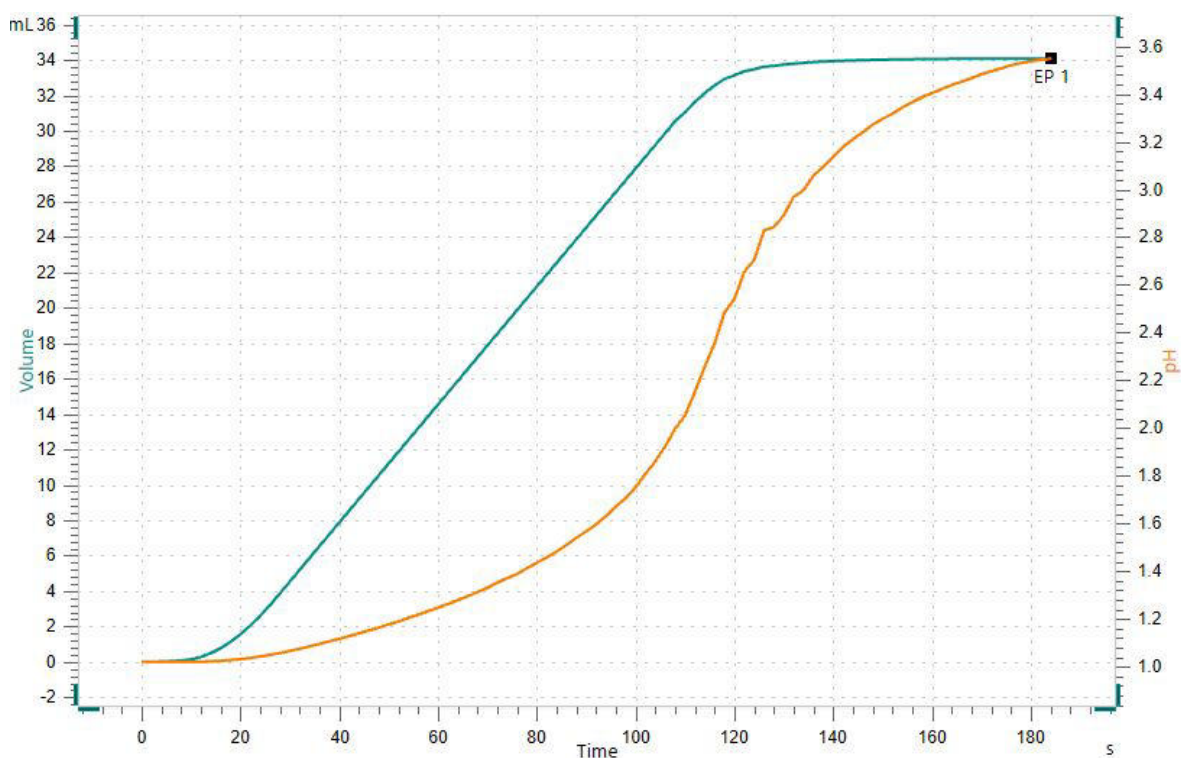


Figure 2. Determination of the ANC of magaldrate and simethicone oral suspension to an equivalence point at pH 3.5.

CONCLUSION

Precise and reliable determinations of the acid neutralizing capacity according to USP<301> can be achieved using an OMNIS Professional Titrator equipped with a dUnitrode with integrated Pt1000. This system offers users flexibility combined with high-end software. The dUnitrode is suitable for pH measurements as well as titrations in water samples. The fixed ground-joint diaphragm is resistant to

contamination and the electrode works even at elevated temperatures.

Aside from improving the precision and speed of the determinations, OMNIS delivers results on par with or better than other established titration systems and can be customized according to your needs and expanded for other titration applications required for quality control purposes.

COMMENTS

In addition to the alumina-magnesia, magaldrate, and simethicone oral suspension, as well as the simethicone chewable tablets described herein, 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 tablets • 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 tablets • Dried aluminum hydroxide gel • Magaldrate oral suspension • Magaldrate tablets • Magnesia tablets • Magnesium oxide capsules • Magnesium oxide tablets

CONTACT

Metrohm AG
Ionenstrasse
9100 Herisau

info@metrohm.com

CONFIGURATION



OMNIS Professional Titrator

新型、模式位分析 OMNIS Titrator,于独立行或作 OMNIS 滴定系的核心元件行,用于点和等当点滴定(一/). 由于采用 3S OMNIS Liquid Adapter 技,理化学产品从未像在一安全。可以使用量模和量管元自由配置滴定,并在需要展一台棒式拌器。包括用于使用其他滴定或加液模平行滴定的“Professional”功能可。

- 通算机或本地网控制
- 可以其他用或助溶液外接最多四个滴定模或加液模
- 棒式拌器的接方式
- 可提供不同大小的量管:5、10、20 或 50 mL
- 采用 3S 技的 OMNIS Liquid Adapter:安全理化学产品,自生厂家的原始数据

量模式和件:

- 点定滴定:“Basic” 功能可
- 点和等当点滴定(一/):“Advanced” 功能可
- 点和等当点滴定(一/),包括 5 路平行滴定:“Professional” 功能可



dUnitrode Pt1000

pH , Pt1000 OMNIS:

- pH-

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:c(KCl) = 3 mol/L,

:T>80 C :Idrolyt, Idrolyt

dTodes OMNIS Titratoren