



Application Note AN-T-192

根据 USP<301> 确定酸中和能力

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

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CONFIGURATION



OMNIS Professional Titrator

创新型、模块式电位分析 OMNIS Titrator,适于独立运行或作为 OMNIS 滴定系统的核心元件运行,用于终点和等当点滴定(单一/动态)。由于采用 3S OMNIS Liquid Adapter 技术,处理化学品从未像现在一样安全。可以使用测量模块和计量管单元自由配置滴定仪,并在需要时扩展一台棒式搅拌器。包括用于使用其他滴定或加液模块平行滴定的“Professional”功能许可证。

- 通过计算机或本地网络控制
- 可以为其他应用或辅助溶液另外连接最多四个滴定模块或加液模块
- 棒式搅拌器的连接方式
- 可提供不同大小的计量管:5、10、20 或 50 mL
- 采用 3S 技术的 OMNIS Liquid Adapter:安全处理化学品,自动传输生产厂家的原始试剂数据

测量模式和软件选项:

- 终点设定滴定:“Basic” 功能许可证
- 终点和等当点滴定(单一/动态):“Advanced” 功能许可证
- 终点和等当点滴定(单一/动态),包括 5 路平行滴定:“Professional” 功能许可证



dUnitrode Pt1000

数字式、组合 pH 电极,用于集成有 Pt1000 温度传感器的 OMNIS。其特别适用于:

- 在较重、粘稠或碱性样品中进行 pH-测量和滴定
- 温度提升时
- 长时间测量

固定套管式隔膜对污染不敏感。

参比电解质: $c(\text{KCl}) = 3 \text{ mol/L}$,储存在保存液中。

替代方法: $T > 80 \text{ }^{\circ}\text{C}$ 时的测量用参比电解质:Idrolyt,储存在 Idrolyt 中。

dTodes 可在 OMNIS Titratoren 上使用。