Application Note AN-T-192

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

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

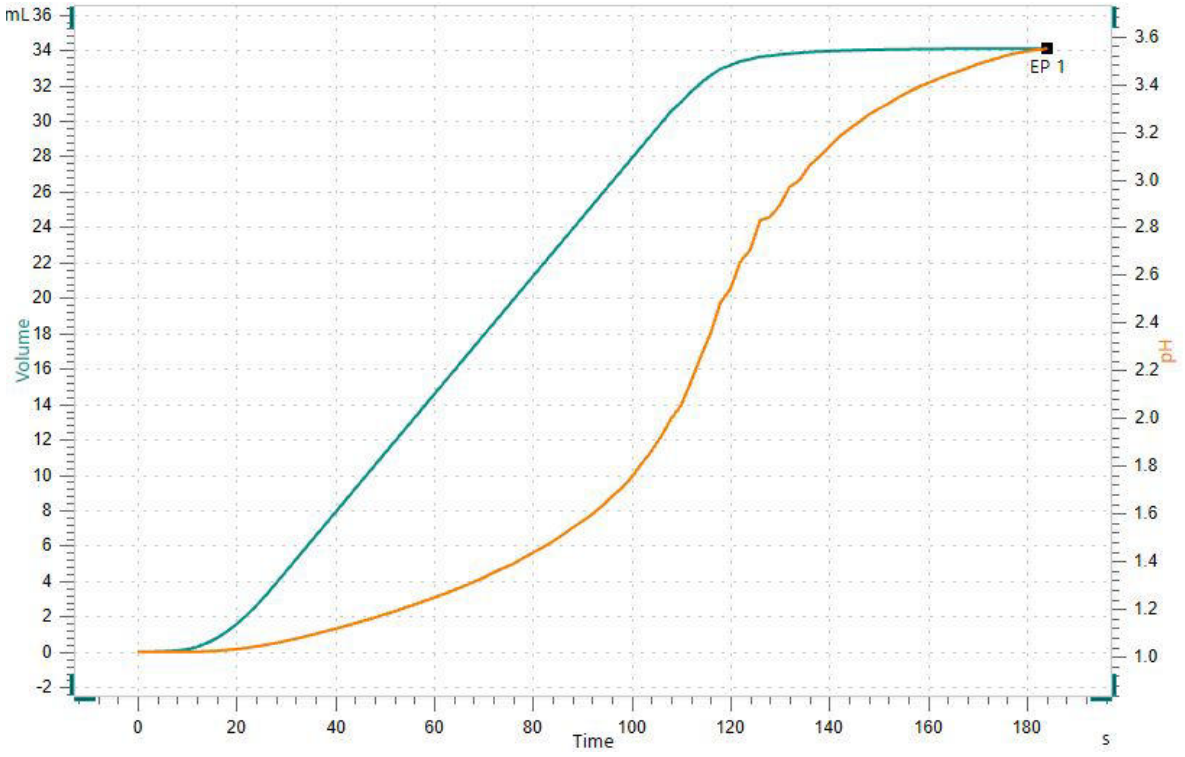

Figure 2. Determination of the ANC of magaldrate and simethicone oral suspension to an equivalence point at pH 3.5.

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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