

10298 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

6505-890-2218 (P. D. No. 2)

Procedure. Pipet 10 ml of the sample preparation into a 125-ml Erlenmeyer flask and add the following reagents in the order specified: 50 ml of purified water, 5 ml of triethanolamine solution, 5 ml of 0.1N EDTA solution, 4 drops of Eriochrome Black T indicator, and 5 ml of ammonia-ammonium chloride buffer T.S. Titrate with 0.1N EDTA solution to a blue endpoint (titrating slowly as endpoint color change occurs). Record the total volume of EDTA used (including the original 5 ml added previous to titration), and calculate the amount of magnesium present in 5 cc of finished suspension, as follows:

$$\frac{N \times V_1 \times 1.216 \times 500}{S} = \text{mg Magnesium per 5 ml}$$

Where:

- N = actual normality of EDTA solution
- V = total volume of EDTA solution, in ml
- S = sample size, in ml
- 1.216 = equivalent weight of magnesium, in mg per ml.

4.3.3 Acid-consuming capacity. The acid-consuming capacity shall be determined as follows:

Reagents.

1. 0.1N hydrochloric acid (accurately standardized).
2. Bromophenol blue indicator - Dissolve 100 mg bromophenol blue in sufficient 50 percent SDA 3-A alcohol to make 100 ml of solution.
3. 0.1N sodium hydroxide (accurately standardized).

Procedure. Pipet 1.0 ml of finished suspension into a 125-ml Erlenmeyer flask containing exactly 50 ml of the accurately standardized 0.1N hydrochloric acid. Rinse the pipet thoroughly into the flask using the dilute acid. Place the flask in a suitable shaker and shake for one hour at 37° C. Filter the samples immediately after shaking and titrate a 10 ml aliquot of the filtrate with the accurately standardized 0.1N sodium hydroxide, using four drops of bromophenol indicator. Titrate 10 ml of the 0.1N hydrochloric acid with the 0.1N sodium hydroxide to the same endpoint using the same amount of indicator. Record the titers of base used for both the sample and the acid. Calculate the acid-consuming capacity of the sample.