

〈301〉 ACID-NEUTRALIZING CAPACITY

[NOTE—All tests shall be conducted at a temperature of $37 \pm 3^\circ$.]

Standardization of pH meter: Standardize a pH meter using the 0.05 m potassium biphthalate and 0.05 m potassium tetraoxalate standardizing buffers as described under *pH* (791).

Magnetic stirrer: Transfer 100 mL of water to a 250-mL beaker containing a 40- × 10-mm (or other suitable size) magnetic stirring bar that is coated with solid perfluorocarbon and has a spin ring at its center. Adjust the power setting of the magnetic stirrer to produce a stirring rate of 300 ± 30 rpm when the stirring bar is centered in the beaker, as determined by a suitable optical tachometer.

Test preparation

Powders: Transfer the accurately weighed portion of the substance specified in the individual monograph to a 250-mL beaker, add 70 mL of water, and mix on the *Magnetic stirrer* for 1 minute.

Effervescent solids: Transfer an accurately weighed quantity, equivalent to the minimum labeled dosage, to a 250-mL beaker, add 10 mL of water, and swirl the beaker gently while allowing the reaction to subside. Add another 10 mL of water, and swirl gently. Wash the walls of the beaker with 50 mL of water, and mix on the *Magnetic stirrer* for 1 minute.

Suspensions and other liquids: Shake the container until the contents are uniform, and determine the density. Transfer an accurately weighed quantity of the uniform mixture, equivalent to the minimum labeled dosage, to a 250-mL beaker, add water to make a total volume of about 70 mL, and mix on the *Magnetic stirrer* for 1 minute.

Lozenges: Accurately weigh not fewer than 20 lozenges, and determine the average weight. Select and weigh 2 lozenges, and transfer them to a 250-mL beaker containing 70 mL of water.

Nonchewable tablets: Weigh not fewer than 20 tablets, and determine the average tablet weight. Grind the tablets to a fine powder, mix to obtain a uniform mixture, and transfer an accurately weighed quantity of it, equivalent to the minimum labeled dosage, to a 250-mL beaker. If wetting is desired, add not more than 5 mL of alcohol (neutralized to an apparent pH of 3.5), and mix to wet the specimen thoroughly. Add 70 mL of water, and mix on the *Magnetic stirrer* for 1 minute.

Chewable tablets: Prepare as directed for *Nonchewable tablets*.

Tablets that are required to be chewed: Transfer 1 Tablet to a 250-mL beaker, add 50 mL of water, and mix on the *Magnetic stirrer* for 1 minute.

Capsules: Weigh accurately not fewer than 20 capsules. Remove the capsule contents completely, with the aid of a cotton swab if necessary. Accurately weigh the empty capsules, and determine the average weight of the contents per capsule. Mix the combined capsule contents to obtain a uniform mixture, and proceed as directed for *Nonchewable tablets*, beginning with "transfer an accurately weighed quantity of it."

PROCEDURES

• PROCEDURE FOR POWDERS, EFFERVESCENT SOLIDS, SUSPENSIONS AND OTHER LIQUIDS, LOZENGES, NONCHEWABLE TABLETS, CHEWABLE TABLETS, AND CAPSULES

Pipet 30.0 mL of 1.0 N hydrochloric acid VS into the *Test preparation* while continuing to stir with the *Magnetic stirrer*.

[NOTE—Where the acid-neutralizing capacity of the specimen under test is greater than 25 mEq, use 60.0 mL of 1.0 N hydrochloric acid VS, and make the appropriate modifications in the calculation.] Stir for 15 minutes, accurately timed, after the addition of the acid, begin to titrate immediately, and in a period not to exceed an additional 5 minutes, titrate the excess hydrochloric acid with 0.5 N sodium hydroxide VS to attain a stable (for 10 to 15 seconds) pH of 3.5. Calculate the number of mEq of acid consumed by the formula:

$$\text{Total mEq} = (30 \times N_{\text{HCl}}) - (V_{\text{NaOH}} \times N_{\text{NaOH}})$$

N_{HCl} = normality of hydrochloric acid VS

V_{NaOH} = volume of sodium hydroxide VS used for titration

N_{NaOH} = normality of sodium hydroxide VS

Express the result in terms of mEq of acid consumed per g of the substance tested.

• PROCEDURE FOR TABLETS THAT ARE REQUIRED TO BE CHEWED

Pipet 30.0 mL of 1.0 N hydrochloric acid VS into the *Test preparation* while continuing to stir with the *Magnetic stirrer* for 10 minutes, accurately timed, after the addition of the acid. Discontinue stirring briefly, and without delay remove any gum base from the beaker using a long needle. Promptly rinse the needle with 20 mL of water, collecting the washing in the beaker, and resume stirring for 5 minutes, accurately timed, then begin to titrate immediately, and in a period not to exceed an additional 5 minutes, titrate the excess hydrochloric acid with 0.5 N sodium hydroxide VS to attain a stable (for 10 to 15 seconds) pH of 3.5. Calculate the number of mEq of acid consumed by the Tablet tested by the formula:

$$\text{Total mEq} = (30 \times N_{\text{HCl}}) - (V_{\text{NaOH}} \times N_{\text{NaOH}})$$