

10720 COMPETITIVE PROBLEMS IN THE DRUG INDUSTRY

(v) Hydrochloric acid, concentrated reagent grade.

(vi) Hydrogen peroxide-methanol solution. On the day of use, dilute 2.0 milliliters of recently assayed 30 percent hydrogen peroxide, reagent grade, with methanol, absolute, analytical reagent grade to 100.0 milliliters. Store in a refrigerator. Just prior to use, dilute 2.0 milliliters of this solution with methanol to 100.0 milliliters.

(3) Procedure--(1) Dissolution. Place 500 milliliters of dissolution medium in the vessel, immerse it in the constant-temperature bath set at $37^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$., and allow the dissolution medium to assume the temperature of the bath. Position the shaft so that there is a distance of 2.5 centimeters $\pm$ 0.2 centimeter between the midpoint of the bottom of the blade and the bottom of the vessel. With the stirrer operating at a speed of $50\text{ rpm} \pm 2\text{ rpm}$, place 1 tablet into the flask. After 60 minutes, accurately timed, withdraw 25 milliliters, using a glass syringe connected to a glass sampling tube, of solution from a point midway between the stirring shaft and the wall of the vessel, and approximately midway in depth. Filter the solution promptly after withdrawal, using a suitable membrane filter of not greater than 0.8 micron porosity (Millipore AAWP 025 00, or equivalent), mounted in a suitable holder (Millipore Swinnex SX00 025 00, or equivalent), discarding the first 10 milliliters of filtrate. This is the test solution. Repeat the dissolution procedure on 5 additional tablets.