

mately 10 µg of hydroflumethiazide per mL. Concomitantly determine the absorbances of this solution and of a Standard solution of USP Hydroflumethiazide RS, in the same medium having a known concentration of about 10 µg per mL in 1-cm cells at the wavelength of maximum absorbance at about 273 nm, with a suitable spectrophotometer, using methanol as the blank. Calculate the quantity, in mg, of $C_8H_8F_3N_3O_4S_2$ in the Tablet taken by the formula:

$$(TC/D)(A_U/A_S)$$

in which *T* is the labeled quantity, in mg, of hydroflumethiazide in the Tablet; *C* is the concentration, in µg per mL, of USP Hydroflumethiazide RS in the Standard solution; *D* is the concentration, in µg per mL, of hydroflumethiazide in the test solution, based upon the labeled quantity per Tablet and the extent of dilution; and *A_U* and *A_S* are the absorbances of the solution from the Tablet and the Standard solution, respectively.

Assay—

Standard preparation—Transfer about 30 mg of USP Hydroflumethiazide RS, accurately weighed, to a 100-mL volumetric flask, add sodium hydroxide solution (1 in 100) to volume, and mix. Transfer 5.0 mL of this solution to a second 100-mL volumetric flask, dilute with sodium hydroxide solution (1 in 100) to volume, and mix. The concentration of USP Hydroflumethiazide RS in the *Standard preparation* is about 15 µg per mL.

Chromatographic column—Proceed as directed for *Column Partition Chromatography* under *Chromatography* (621), packing a chromatographic tube with two segments of packing material. The lower segment is a mixture of 1 g of *Solid Support* and 1 mL of sodium hydroxide solution (1 in 100), and the upper segment is a mixture prepared as directed under *Assay preparation*.

Assay preparation—Weigh and finely powder not less than 20 Tablets. Transfer an accurately weighed portion of the powder, equivalent to about 75 mg of hydroflumethiazide, to a 50-mL volumetric flask, add about 35 mL of sodium hydroxide solution (1 in 100), shake vigorously, dilute with sodium hydroxide solution (1 in 100) to volume, and mix. Mix 2.0 mL of this solution with 3 g of *Solid Support* as directed under *Chromatographic column*, and transfer to the column. Wash the column with 50 mL of water-saturated chloroform, then with 50 mL of water-saturated ether, and discard the eluates. Elute the hydroflumethiazide from the column with 100 mL of glacial acetic acid in ether (1 in 1000), collecting the eluate in a 250-mL separator. Add 100 mL of a 1 in 1000 solution of glacial acetic acid in ether to a second 250-mL separator to provide a blank, and treat each as follows: Add 60 mL of isooctane to each separator, mix, and extract the resulting solution with three 50-mL portions of sodium hydroxide solution (1 in 100), collecting the extracts in a 200-mL volumetric flask. Dilute with sodium hydroxide solution (1 in 100) to volume, and mix.

Procedure—Concomitantly determine the absorbances of the solutions in 1-cm cells at the wavelength of maximum absorbance at about 273 nm, with a suitable spectrophotometer, using the blank. Calculate the quantity, in mg, of hydroflumethiazide ($C_8H_8F_3N_3O_4S_2$) in the portion of Tablets taken by the formula:

$$5C(A_U/A_S)$$

in which *C* is the concentration, in µg per mL, of USP Hydroflumethiazide RS in the *Standard preparation*; and *A_U* and *A_S* are the absorbances of the *Assay preparation* and the *Standard preparation*, respectively.

Hydrogen Peroxide Concentrate

H₂O₂ 34.01

Hydrogen peroxide.

Hydrogen peroxide [7722-84-1].

» Hydrogen Peroxide Concentrate contains not less than 29.0 per cent and not more than 32.0 percent, by weight, of H₂O₂. It contains not more than 0.05 percent of a suitable preservative or preservatives.

Caution—Hydrogen Peroxide Concentrate is a strong oxidant.

Packaging and storage—Preserve in partially-filled containers having a small vent in the closure, and store in a cool place.

Labeling—Label it to indicate the name and amount of any added preservative. The label states that this article is not intended for direct administration to humans or animals.

Acidity—Dilute 25 g with water to 250 mL, and mix thoroughly. Take 25 mL of the solution, add phenolphthalein TS, and titrate with 0.10 N sodium hydroxide: not more than 2.5 mL is required for neutralization.

Chloride (221): 1.5 g diluted with water to 25 mL shows no more chloride than 0.10 mL of 0.020 N hydrochloric acid (0.005%).

Other requirements—It responds to the *Identification* test and meets the requirements of the tests for *Nonvolatile residue*, *Heavy metals*, and *Limit of preservative* (90 mL of it being used) under *Hydrogen Peroxide Topical Solution*.

Assay—Accurately weigh about 1 mL of Concentrate in a tared 100-mL volumetric flask, dilute with water to volume, and mix. To 20.0 mL of this solution add 20 mL of 2 N sulfuric acid, and titrate with 0.1 N potassium permanganate VS. Each mL of 0.1 N potassium permanganate is equivalent to 1.701 mg of H₂O₂.

Hydrogen Peroxide Topical Solution

H₂O₂ 34.01

Hydrogen peroxide.

Hydrogen peroxide [7722-84-1].

» Hydrogen Peroxide Topical Solution contains, in each 100 mL, not less than 2.5 g and not more than 3.5 g of H₂O₂. It contains not more than 0.05 percent of a suitable preservative or preservatives.

Packaging and storage—Preserve in tight, light-resistant containers, at controlled room temperature.

Identification—Shake 1 mL with 10 mL of water containing 1 drop of 2 N sulfuric acid, and add 2 mL of ether: the subsequent addition of a drop of potassium dichromate TS produces an evanescent blue color in the water layer which upon agitation and standing passes into the ether layer.

Acidity—To 25 mL add phenolphthalein TS, and titrate with 0.10 N sodium hydroxide: not more than 2.5 mL is required for neutralization.

Barium—To 10 mL add two drops of 2 N sulfuric acid: no turbidity or precipitate is produced within 10 minutes.

Heavy metals (231)—Dilute 4 mL, previously shaken, with 20 mL of water, add 2 mL of 6 N ammonium hydroxide, and gently boil the solution until the volume is reduced to about 5 mL. Dilute with water to 25 mL: the limit is 5 ppm.

Limit of nonvolatile residue—Evaporate 20 mL, previously shaken, on a steam bath to dryness, and dry the residue at 105° for 1 hour: the weight of the residue does not exceed 30 mg.

Limit of preservative—Extract 100 mL of well-mixed Topical Solution in a separator with a mixture of 3 volumes of chloroform and 2 volumes of ether, using 50 mL, 25 mL, and 25 mL, respectively. Evaporate the combined extracts at room temperature in a tared glass dish to dryness, and dry over silica gel for