

Amyl alcohol and nonvolatile, carbonizable substances—Allow 25 mL to evaporate spontaneously from a porcelain dish, carefully protected from dust, until the surface of the dish is barely moist; no red or brown color is produced immediately upon the addition of a few drops of sulfuric acid.

Ultraviolet absorbance—Record the UV absorption spectrum between 340 nm and 235 nm in a 1-cm cell, with water in a matched cell in the reference beam: the absorbance is not more than 0.08 at 240 nm, and 0.02 between 270 nm and 340 nm, and the curve drawn through these points is smooth.

Limit of acetone and isopropyl alcohol—To 1.0 mL add 1 mL of water, 1 mL of a saturated solution of dibasic sodium phosphate, and 3 mL of a saturated solution of potassium permanganate. Warm the mixture to 45° to 50°, and allow to stand until the permanganate color is discharged. Add 3 mL of 2.5 N sodium hydroxide, and filter, without washing, through a sintered glass filter. Prepare a control containing 1 mL of the saturated solution of dibasic sodium phosphate, 3 mL of 2.5 N sodium hydroxide, and 80 µg of acetone in 9 mL. To each solution add 1 mL of furfural solution (1 in 100), and allow to stand for 10 minutes, then to 1.0 mL of each solution add 3 mL of hydrochloric acid: any pink color produced in the test solution is not more intense than that in the control.

Methanol—To 1 drop add 1 drop of water, 1 drop of dilute phosphoric acid (1 in 20), and 1 drop of potassium permanganate solution (1 in 20). Mix, allow to stand for 1 minute, and add sodium metabisulfite solution (1 in 20), dropwise, until the permanganate color is discharged. If a brown color remains, add 1 drop of the dilute phosphoric acid. To the colorless solution add 5 mL of freshly prepared chromotropic acid TS, and heat on a water bath at 60° for 10 minutes: no violet color appears.

▲Dehydrated Alcohol



C₂H₆O 46.07

Ethanol.

Ethyl alcohol [64-17-5].

» Dehydrated Alcohol contains not less than 99.2 percent, by weight, corresponding to not less than 99.5 percent, by volume, at 15.56°, of C₂H₅OH.

Packaging and storage—Preserve in tight containers, protected from light. ~~remote from fire.~~

USP Reference standards <11>—*USP Dehydrated Alcohol RS.*

Clarity of solution—[NOTE—*Test solution* is to be compared to *Reference suspension A* and to water in diffused daylight 5 minutes after preparation of *Reference suspension A*.]

Hydrazine solution—Transfer 1.0 g of hydrazine sulfate to a 100-mL volumetric flask, dissolve in water, dilute with water to volume, and mix. Allow to stand for 4 to 6 hours.

Methenamine solution—Transfer 2.5 g of methenamine to a 100-mL glass-stoppered flask, add 25.0 mL of water, insert the glass stopper, and mix to dissolve.

Primary opalescent suspension—[NOTE—This suspension is stable for 2 months, provided it is stored in a glass container free from surface defects. The suspension must not adhere to the glass and must be well mixed before use.] Transfer 25.0 mL of *Hydrazine solution* to the *Methenamine solution* in the 100-mL glass-stoppered flask. Mix, and allow to stand for 24 hours.

Opalescence standard—[NOTE—This suspension should not be used beyond 24 hours after preparation.] Transfer 15.0 mL of the *Primary opalescent suspension* to a 100-mL volumetric flask, dilute with water to volume, and mix.

Reference suspensions—Transfer 5.0 mL of the *Opalescence standard* to a 100-mL volumetric flask, dilute with water to volume, and mix to obtain *Reference suspension A*. Transfer 10.0 mL of the *Opalescence standard* to a second 100-mL volumetric flask, dilute with water to volume, and mix to obtain *Reference suspension B*.

Test solution A—The substance to be examined.

Test solution B—Dilute 1.0 mL of *Test solution A* to 20 mL with water and allow to stand for 5 minutes before testing.

Procedure—Transfer a sufficient portion of *Test solution A* and *Test solution B* to separate test tubes of colorless, transparent, neutral glass with a flat base and an internal diameter of 15 to 25 mm to obtain a depth of 40 mm. Simi-

larly transfer portions of *Reference suspension A*, *Reference suspension B*, and water to separate, matching test tubes. Compare *Test solution A*, *Test solution B*, *Reference suspension A*, *Reference suspension B*, and water in diffused daylight, viewing vertically against a black background (see *Visual Comparison* under *Spectrophotometry and Light-Scattering* <851>). [NOTE—The diffusion of light must be such that *Reference suspension A* can readily be distinguished from water, and *Reference suspension B* can readily be distinguished from *Reference suspension A*.] *Test solution A* and *Test solution B* show the same clarity as that of water, or their opalescence is not more pronounced than that of *Reference suspension A*.

Color of solution—

Standard stock solution—Combine 3.0 mL ferric chloride CS, 3.0 mL cobaltous chloride CS, 2.4 mL cupric sulfate CS, and 1.6 mL dilute hydrochloric acid (10 g per L).

Standard solution—[NOTE—Prepare the *Standard solution* immediately before use.] Transfer 1.0 mL of *Standard stock solution* to a 100-mL volumetric flask, dilute with dilute hydrochloric acid (10 g per L) to volume, and mix.

Test solution—The substance to be examined.

Procedure—Transfer a sufficient portion of the *Test solution* to a test tube of colorless, transparent, neutral glass with a flat base and an internal diameter of 15 to 25 mm to obtain a depth of 40 mm. Similarly transfer portions of *Standard solution* and water to separate matching test tubes. Compare the *Test solution*, *Standard solution*, and water in diffused daylight, viewing vertically against a white background (see *Visual Comparison* under *Spectrophotometry and Light-Scattering* <851>). The *Test solution* has the appearance of water or is not more intensely colored than the *Standard solution*.

Identification—

A: It complies with the test for *Specific gravity*.

B: *Infrared Absorption* <197F> or <197S> neat.

Specific gravity <841>: not more than 0.7962 at 15.56°, indicating not less than 99.2% of C₂H₅OH, by weight.

Acidity or alkalinity—To 20 mL of alcohol, add 20 mL of freshly boiled and cooled water and 0.1 mL of *Phenolphthalein solution*. The solution is colorless. Add 1.0 mL of 0.01 N sodium hydroxide. The solution is pink (30 ppm, expressed as acetic acid).

Phenolphthalein solution—Dissolve 0.1 g of phenolphthalein in 80 mL of alcohol and dilute to 100 mL with water.

Ultraviolet absorption—Record the UV absorption spectrum of the test material from 200 to 400 nm in a 1-cm cell: maximum absorbance 0.40 at 240 nm, 0.30 between 250 and 260 nm, and 0.10 between 270 and 340 nm. Examine between 235 and 340 nm, in a 5-cm cell, using water as the compensation liquid. The absorption curve is smooth.

Volatile impurities—

Test solution A—The substance to be examined.

Test solution B—Add 150 µL of 4-methylpentan-2-ol to 500.0 mL of the substance to be examined.

Standard solution A—Dilute 100 µL of methanol to 50.0 mL with the substance to be examined. Dilute 5.0 mL of the solution to 50.0 mL with the substance to be examined.

Standard solution B—Dilute 50 µL of methanol and 50 µL of acetaldehyde to 50.0 mL with the substance to be examined. Dilute 100 µL of the solution to 10.0 mL with the substance to be examined.

Standard solution C—Dilute 150 µL of acetal to 50.0 mL with the substance to be examined. Dilute 100 µL of the solution to 10.0 mL with the substance to be examined.

Standard solution D—Dilute 100 μL of benzene to 100.0 mL with the substance to be examined. Dilute 100 μL of the solution to 50.0 mL with the substance to be examined.

Chromatographic system (see *Chromatography* (621))—The gas chromatograph is equipped with a flame ionization detector, maintained at about 280° , and a 0.32-mm \times 30-m fused silica capillary column bonded with a 1.8 μm layer of phase G43. The carrier gas is helium with a linear velocity of about 35 cm per second and a split ratio of 1:20. The column is maintained at 40° for the first 12 minutes after an injection is made and is increased from 40° to 240° from 12 to 32 minutes after injection. During the period of 32 to 42 minutes after an injection is made the column is maintained at 240° . The injector port is maintained at 200° .

Procedure—Inject about 1.0 μL of *Standard solution B* into a suitable gas chromatograph, and record the chromatogram. The resolution, R , between the first major peak (acetaldehyde) and the second major peak (methanol) is not less than 1.5. Separately inject equal volumes (1.0 μL) of *Test solution A* and *Test solution B* into the chromatograph, record the chromatograms, and measure the major peaks. Calculate the concentration of methanol in *Test solution A*: not more than half the area of the corresponding peak in the chromatogram obtained with *Standard solution A* (200 ppm).

Calculate the sum of the contents of acetaldehyde and acetal, expressed as acetaldehyde, using the following expression:

$$[(10 \times A_E)/(A_T - A_E)] + [(30 \times C_E)/(C_T - C_E)],$$

where A_E is the area of the acetaldehyde peak in the chromatogram obtained with the *Test solution*; A_T is the area of

the acetaldehyde peak in the chromatogram obtained with *Standard solution B*; C_E is the area of the acetal peak in the chromatogram obtained with *Test solution A*; and C_T is the area of the acetal peak in the chromatogram obtained with *Standard solution C*: not more than 10 ppm, expressed as acetaldehyde.

Calculate the content of benzene using the following expression:

$$(2B_E)/(B_T - B_E),$$

where B_E is the area of the benzene peak in the chromatogram obtained with *Test solution A*, and B_T is the area of the benzene peak in the chromatogram obtained with *Standard solution D*: not more than 2 ppm. If necessary, the identity of benzene can be confirmed using another suitable chromatographic system (stationary phase with a different polarity).

The total of all other impurities in the chromatogram obtained with *Test solution B* is not more than the area of the peak due to 4-methylpentan-2-ol in the chromatogram obtained with *Test solution B* (300 ppm). Disregard any peaks that are 0.03 times the area of the peak corresponding to 4-methylpentan-2-ol in the chromatogram obtained with *Test solution B* (9 ppm).

Limit of nonvolatile residue—Evaporate 100 mL in a tared dish on a water bath, and dry at 100° to 105° for 1 hour: the weight of the residue does not exceed 2.5 mg. ▲*USP28*