Benzyl Alcohol
C_7H_8O 108.14
Benzenemethanol.
Benzyl alcohol [*100-51-6*].
» Benzyl Alcohol contains not less than 98.0 percent and not more than 100.5 percent of C_7H_8O.

Labeling— Where Benzyl Alcohol is intended for use in the manufacture of injectable dosage forms, it is so labeled.

USP Reference standards ⟨ 11 ⟩ **—**
USP Benzyl Alcohol RS .

Clarity of solution— [NOTE—The *Test solution* is to be compared to *Reference suspension 1* in diffused daylight 5 minutes after preparation of *Reference suspension 1*.]
Hydrazine solution— Transfer 1.0 g of hydrazine sulfate to a 100-mL volumetric flask, dissolve in and dilute with water to volume, and mix. Allow to stand 4 to 6 hours before use.

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 1000-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 1*. 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 2.*

Test solution— Dissolve 2.0 g of Benzyl Alcohol in 60 mL of water, and mix.

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 mm to 25 mm, to obtain a depth of 40 mm. Similarly transfer portions of *Reference suspension 1, Reference suspension 2,* and water to separate matching test tubes. Compare the *Test solution, Reference suspension 1, Reference suspension 2,* 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 1* can readily be distinguished from water, and that *Reference suspension 2* can readily be distinguished

from *Reference suspension 1.*] The *Test solution* shows the same clarity as that of water, or its opalescence is not more pronounced than that of *Reference suspension 1.*

Color of solution—
Test solution— Use the *Test solution* prepared in the test for *Clarity of solution.*

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 mm to 25 mm, to obtain a depth of 40 mm. Similarly transfer a portion of water to a separate matching test tube. Compare the color of the *Test solution* with that of water in diffused daylight, viewing vertically against a white background (see *Visual Comparison* under *Spectrophotometry and Light-Scattering* ⟨ 851 ⟩). The *Test solution* has the color of water.

Identification— *Infrared Absorption* ⟨ 197F ⟩, on undried specimen.

Peroxide value ⟨ 401 ⟩**:** not more than 5.

Refractive index ⟨ 831 ⟩**:** between 1.538 and 1.541 at 20°.

Acidity— Neutralize 50 mL of alcohol containing 1 mL of phenolphthalein TS with 0.10 N sodium hydroxide. Dissolve 10 mL of Benzyl Alcohol in 10 mL of the neutralized alcohol, and titrate with 0.10 N sodium hydroxide to the first appearance of a pink color that persists for not less than 30 seconds: not more than 1.0 mL is consumed.

Limit of nonvolatile residue— [NOTE—Ensure that the Benzyl Alcohol to be examined complies with the test for *Peroxide value* ⟨ 401 ⟩ before performing this test.] Evaporate 10.0 g of Benzyl Alcohol on a water bath to dryness, and dry the residue at 105° for 1 hour. Cool in a desiccator, and weigh. The residue weighs not more than 5 mg: not more than 0.05% of nonvolatile residue is found.

Related compounds—
Test solution— Use the Benzyl Alcohol specimen under examination.

Ethylbenzene solution— Transfer 100 mg of ethylbenzene, accurately weighed, to a 10-mL volumetric flask, dissolve in and dilute with *Test solution* to volume, and mix. Transfer 1.0 mL of this solution to a 10-mL volumetric flask, dilute with *Test solution* to volume, and mix.

Dicyclohexyl solution— Transfer 2.0 g of dicyclohexyl to a 10-mL volumetric flask, dissolve in and dilute with *Test solution* to volume, and mix. Transfer 1.0 mL of this solution to a 10-mL volumetric flask, dilute with *Test solution* to volume, and mix.

Standard solution 1— Transfer 750 mg of benzaldehyde, accurately weighed, and 500 mg of cyclohexylmethanol, accurately weighed, to a 25-mL volumetric flask, dissolve in and dilute with *Test solution* to volume, and mix. Transfer 0.5 mL of this solution to a 10-mL volumetric flask, add 1.0 mL of *Ethylbenzene solution* and 1.5 mL of *Dicyclohexyl solution,* dilute with *Test solution* to volume, and mix.

Standard solution 2 (where the Benzyl Alcohol under test is intended for use in the manufacture of injectable dosage forms)— Transfer about 250 mg of benzaldehyde, accurately weighed, and about 500 mg of cyclohexylmethanol, accurately weighed, to a 25-mL volumetric flask, dissolve in and dilute with *Test solution* to volume, and mix. Transfer 0.5 mL of this solution to a 10-mL volumetric flask, add 1.0 mL of *Ethylbenzene solution* and 1.0 mL of *Dicyclohexyl solution,* dilute with *Test solution* to volume, and mix.

Chromatographic system (see *Chromatography* ⟨ 621 ⟩)— The gas chromatograph is equipped with a flame-ionization detector and a 0.32-mm × 30-m column coated with a 0.5-µm film of G16. Helium is used as the carrier gas flowing at a rate of 1.2 mL per minute at 50°. The injection port and detector temperatures are maintained at about 200° and 310°, respectively. The column temperature is programmed to increase linearly from 50° to 220° at a rate of 5° per minute, and is maintained at 220° for 35 minutes. Chromatograph the appropriate *Standard solution,* and record the peak responses as directed for *Procedure:* the relative retention times are about 0.28 for ethylbenzene, 0.59 for dicyclohexyl, 0.68 for benzaldehyde, 0.71 for cyclohexylmethanol, and 1.0 for benzyl alcohol; and the resolution, *R,* between benzaldehyde and cyclohexylmethanol is not less than 3.0.

Procedure— Separately inject equal volumes (about 0.1 µL) of the appropriate *Standard solution* and the *Test solution* into the chromatograph, record the chromatograms, and measure the areas for the major peaks. [NOTE—Disregard any peak having an area less than 0.01 times the area of the ethylbenzene peak in the chromatogram of the appropriate *Standard solution*. In the chromatogram of the *Test solution,* verify that there are no peaks with the same retention times as those of ethylbenzene or dicyclohexyl.]
In the chromatogram of the *Test solution*, the area of any peak corresponding to benzaldehyde is not greater than the difference between the area of the peak due to benzaldehyde in the chromatogram of *Standard solution 1* (0.15%) or in the chromatogram of *Standard solution 2* (0.05%) and the area of the peak due to benzaldehyde in the chromatogram of the *Test solution.*

In the chromatogram of the *Test solution,* the area of any peak corresponding to cyclohexylmethanol is not greater than the difference between the area of the peak due to cyclohexylmethanol in the chromatogram of *Standard solution 1* (0.10%) or in the chromatogram of *Standard solution 2* (0.10%) and the area of the peak due to cyclohexylmethanol in the chromatogram of the *Test solution.*

In the chromatogram of the *Test solution,* the sum of the areas of any peaks with retention times less than that of benzyl alcohol, excluding the peaks due to benzaldehyde and cyclohexylmethanol, is not greater than four times the area of the ethylbenzene peak in the chromatogram of *Standard solution 1* (0.04%) or is not greater than two times the area of the ethylbenzene peak in the chromatogram of *Standard solution 2* (0.02%).

In the chromatogram of the *Test solution*, the sum of the areas of any peaks with retention times greater than that of benzyl alcohol is not greater than the area of the

dicyclohexyl peak in the chromatogram of *Standard solution 1* (0.3%) or in the chromatogram of *Standard solution 2* (0.2%).

Assay— To about 900 mg of Benzyl Alcohol, accurately weighed, add 15.0 mL of a freshly prepared mixture of pyridine and acetic anhydride (7:1), and boil under reflux for 30 minutes. Cool, add 25 mL of water, add 0.25 mL of a phenolphthalein solution prepared by dissolving 100 mg of phenolphthalein in 80 mL of alcohol and diluting with water to 100 mL, and titrate with 1 N sodium hydroxide VS. Perform a blank determination (see *Titrimetry* ⟨ 541 ⟩). Calculate the percentage of C_7H_8O taken by the formula:

$$10.81N(V_B - V_U)/W$$

in which V_U and V_B are the number of mL of 1 N sodium hydroxide used for the Benzyl Alcohol and the blank, respectively; and W is the weight, in g, of Benzyl Alcohol taken.

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