against a white background (see *Nephelometry, Turbidimetry, and Visual Comparison* ⟨855⟩, *Visual Comparison*).

Acceptance criteria: The *Sample solution* has the appearance of water or is not more intensely colored than the *Standard solution*.◆

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, protected from light.
- **USP REFERENCE STANDARDS** ⟨11⟩
  USP Dehydrated Alcohol RS

Dehydrated Alcohol Injection

» Dehydrated Alcohol Injection is Dehydrated Alcohol suitable for parenteral use.

Packaging and storage—Preserve in tight, single-dose containers, preferably of Type I glass, and store at controlled room temperature. The container may contain an inert gas in the headspace.

Identification—

A: Mix 5 drops in a small beaker with 1 mL of potassium permanganate solution (1 in 100) and 5 drops of 2 N sulfuric acid, and cover the beaker immediately with a filter paper moistened with a solution recently prepared by dissolving 0.1 g of sodium nitroferricyanide and 0.25 g of piperazine in 5 mL of water: an intense blue color is produced on the filter paper, the color becoming paler after a few minutes.

B: To 5 mL of a solution (1 in 10) add 1 mL of 1.0 N sodium hydroxide, then slowly (over a period of 3 minutes) add 2 mL of 0.1 N iodine: the odor of iodoform develops, and a yellow precipitate is formed within 30 minutes.

Specific gravity ⟨841⟩**:** not more than 0.8035 at 15.56°, indicating not less than 96.8%, by weight, of C_2H_5OH.

Acidity—To 50 mL, in a glass-stoppered flask, add 50 mL of recently boiled water. Add phenolphthalein TS, and titrate with 0.020 N sodium hydroxide to a pink color that persists for 30 seconds: not more than 10.0 mL of 0.020 N sodium hydroxide is required for neutralization.

Limit of nonvolatile residue—Evaporate 40 mL in a tared dish on a water bath, and dry at 105° for 1 hour: the weight of the residue does not exceed 1 mg.

Water-insoluble substances—Dilute it with an equal volume of water: the mixture is clear and remains clear for 30 minutes after cooling to 10°.

Aldehydes and other foreign organic substances—Place 20 mL in a glass-stoppered cylinder that has been thoroughly cleaned with hydrochloric acid, then rinsed with water and finally with the dehydrated alcohol to be tested. Cool the contents to approximately 15°, and add, by means of a carefully cleaned pipet, 0.10 mL of 0.10 N potassium permanganate, noting accurately the time of addition. Mix at once by inverting the stoppered cylinder, and allow it to stand at 15° for 5 minutes: the pink color does not entirely disappear.

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 pass, 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.

Other requirements—It meets the requirements under *Injections and Implanted Drug Products* ⟨1⟩.

Alcohol in Dextrose Injection

DEFINITION

Alcohol in Dextrose Injection is a sterile solution of Alcohol and Dextrose in Water for Injection. It contains NLT 90.0% and NMT 110.0% of the labeled amount of alcohol (C_2H_5OH), and NLT 95.0% and NMT 105.0% of the labeled amount of dextrose ($C_6H_{12}O_6 \cdot H_2O$).

IDENTIFICATION

- **A.**
  Sample solution: A few drops of Injection (1 in 20) in water
  Analysis: Add the *Sample solution* to 5 mL of hot alkaline cupric tartrate TS.
  Acceptance criteria: A copious red precipitate of cuprous oxide is formed.
- **B. SPECIFIC GRAVITY** ⟨841⟩**:** NMT 0.7962 at 15.56°, indicating NLT 99.2% of alcohol (C_2H_5OH) by weight
- **C. INFRARED ABSORPTION** ⟨197S⟩ or ⟨197F⟩**:** Meets the requirements

ASSAY

- **ALCOHOL DETERMINATION,** *Method 1—Distillation Method* ⟨611⟩
  Sample solution: 50.0 mL
  Acceptance criteria: 90.0%–110.0%
- **DEXTROSE**
  Sample: *Equivalent to 2–5 g of dextrose from a suitable volume of injection*
  Analysis: Transfer the *Sample solution* to a 100-mL volumetric flask, add 0.2 mL of 6 N ammonium hydroxide, and dilute with water to volume. Determine the angular rotation in a suitable polarimeter tube (see *Optical Rotation* ⟨781⟩).
  Calculate the percentage of dextrose ($C_6H_{12}O_6 \cdot H_2O$) in the portion of Injection taken:

$$\text{Result} = [(M_{r1}/M_{r2})/R_{mid}]AR \times 100$$

M_{r1} = molecular weight of dextrose monohydrate, 198.17

M_{r2} = molecular weight of anhydrous dextrose, 180.16