R_{mid} = midpoint of the specific rotation range for anhydrous dextrose, 52.9°
A = 100 mm divided by the length of the polarimeter tube (mm)
R = observed rotation (°)
Acceptance criteria: 95.0%–105.0%

IMPURITIES

Delete the following:

• **Heavy Metals** ⟨231⟩
Test preparation: Equivalent to 4.0 g of dextrose from a volume of Injection
Analysis: Transfer the *Sample* to a vessel, and adjust the volume to 25 mL by evaporation or by addition of water, as necessary.
Acceptance criteria: NMT 5 × *C* ppm, where *C* is the labeled amount, in g, of dextrose ($C_6H_{12}O_6 \cdot H_2O$) per mL of Injection • (Official 1-Jan-2018)

• **Limit of 5-Hydroxymethylfurfural and Related Substances**
Sample solution: Equivalent to 2 mg/mL of dextrose in water from a suitable volume of Injection
Instrumental conditions
Mode: UV
Analytical wavelength: 284 nm
Cell: 1 cm
Blank: Water
Acceptance criteria: The absorbance is NMT 0.25.

SPECIFIC TESTS
• **pH** ⟨791⟩**:** 3.5–6.5
Sample solution: A portion of Injection to which 0.30 mL of saturated potassium chloride solution has been added for each 100 mL and which previously has been diluted with water, if necessary, to a concentration of NMT 5% of dextrose
• **Bacterial Endotoxins Test** ⟨85⟩**:** NMT 0.5 USP Endotoxin unit/mL
• **Other Requirements:** Meets the requirements in *Injections and Implanted Drug Products* ⟨1⟩

ADDITIONAL REQUIREMENTS
• **Packaging and Storage:** Preserve in tight, single-dose containers, preferably of Type I or Type II glass, and store at controlled room temperature.
• **Labeling:** The label states the total osmolarity of the solution expressed in mOsmol/L.

Delete the following:

• **USP Reference Standards** ⟨11⟩
USP Endotoxin RS
• (CN 1-May-2018)

Rubbing Alcohol

DEFINITION
Rubbing Alcohol and all preparations under the classification of Rubbing Alcohols are manufactured in accordance with the requirements of the U.S. Treasury Department, Bureau of Alcohol, Tobacco, and Firearms, Formula 23-H (8 parts by volume of acetone, 1.5 parts by volume of methyl isobutyl ketone, and 100 parts by volume of ethyl alcohol) being used. It contains NLT 68.5% and NMT 71.5% by volume of dehydrated alcohol, the remainder consisting of water and the denaturants, with or without color additives, and perfume oils. Rubbing Alcohol contains, in each 100 mL, NLT 355 mg of sucrose octaacetate or NLT 1.40 mg of denatonium benzoate. The preparation may be colored with one or more color additives, listed by the FDA for use in drugs. A suitable stabilizer may be added. Rubbing Alcohol complies with the requirements of the Bureau of Alcohol, Tobacco, and Firearms of the U.S. Treasury Department.
[NOTE—Rubbing Alcohol is packaged, labeled, and sold in accordance with the regulations issued by the U.S. Treasury Department, Bureau of Alcohol, Tobacco, and Firearms.]

ASSAY
• **Denatonium Benzoate**
Buffer: 9.23 g of anhydrous dibasic sodium phosphate in 800 mL of water. Adjust with saturated citric acid solution to a pH of 4 ± 0.1, dilute with water to 1000 mL, and mix.
Standard solution: 50 µg/mL of USP Denatonium Benzoate RS in water
Sample solution: Dissolve the residue obtained in the test for *Limit of Nonvolatile Residue* in 50.0 mL of water, and transfer to a suitable flask.
Instrumental conditions
Analytical wavelength: Maximum absorbance at about 410 nm
Cell: 1 cm
Analysis
Samples: *Buffer*, *Standard solution*, and *Sample solution*
Transfer 10.0 mL each of *Buffer*, *Standard solution*, and *Sample solution* to individual 250-mL separators. Add to each 40 mL of *Buffer* 10 mL of a 1-in-1000 solution of bromophenol blue in chloroform and 60 mL of chloroform. Shake the separators vigorously for 2 min, allow to stand for 15 min, then withdraw the chloroform layers through chloroform-washed cotton into 100-mL volumetric flasks. Repeat the extraction with 20 mL of chloroform, adding the filtered chloroform extracts to the respective volumetric flasks, and dilute with chloroform to volume. Without delay, concomitantly determine the absorbances of the solutions, using the blank to set a suitable spectrophotometer.
Calculate the quantity, in mg, of denatonium benzoate ($C_{28}H_{34}N_2O_3 \cdot H_2O$) in 100 mL of Rubbing Alcohol:

$$\text{Result} = (A_U/A_S) \times C_S \times 0.025$$

A_U = absorbance of the *Sample solution*
A_S = absorbance of the *Standard solution*
C_S = concentration of USP Denatonium Benzoate RS in the *Standard solution* (µg/mL)
Acceptance criteria: NLT 1.40 mg
• **Sucrose Octaacetate**
Sample solution: Using about 50 mL of 70% alcohol, transfer the residue obtained in the test for *Limit of Nonvolatile Residue* to a 500-mL conical flask.
Analysis: Neutralize the *Sample solution* with 0.1 N sodium hydroxide VS, using phenolphthalein TS as the indicator. Add 25.0 mL of 0.1 N sodium hydroxide, attach an air condenser to the flask, and reflux on a steam bath for 1 h. Remove from the steam bath, cool quickly, and titrate the excess alkali with 0.1 N sulfuric acid VS, using phenolphthalein TS as the indicator. Perform a blank determination (see *Titrimetry* ⟨541⟩, *Residual Titrations*). Each mL of 0.1 N sodium hydroxide is equivalent to 8.483 mg of sucrose octaacetate ($C_{28}H_{38}O_{19}$).
Acceptance criteria: NLT 355 mg of sucrose octaacetate per 100 mL of Rubbing Alcohol

IMPURITIES
• **Methanol**
Sample solution: Dilute 0.50 mL of Rubbing Alcohol with water to 1.0 mL.
Analysis: To 0.50 mL of the *Sample solution* add 1 drop of dilute phosphoric acid (1 in 20) and 1 drop of potassium permanganate solution (1 in 20). Mix, allow to