USP 41

Reagents / Reagent Specifications 5701

and programmed to rise 10° per minute to 280°. The area of the $C_7H_8O_2$ peak is not less than 99% of the total peak area.

MELTING RANGE (741): between 83° and 85°.

4-Hydroxybutane-1-sulfonic Acid (4-Hydroxy-1-butanesulfonic Acid), $C_4H_{10}O_4S$ —**154.19** [26978-64-3]—Use a suitable grade with a content of NLT 95%. [NOTE—A suitable grade is available as catalog number RM-967-C50 from www.anaxlab.com.]

N-(2-Hydroxyethyl)piperazine-N'-(2-ethanesulfonic acid), $C_8H_{18}N_2O_4S$ —238.3 [7365-45-9]—Use a suitable grade.

Hydroxylamine Hydrochloride, NH₂OH · HCl—69.49 [5470-11-1]—Use ACS reagent grade.

5-Hydroxymethylfurfural, $C_6H_6O_3$ —**126.11** [67-47-0]— Use a suitable grade with a content of NLT 99.0%.

10 β -Hydroxynorandrostenedione (10 β -Hydroxy-19-norandrost-4-ene-3,17-dione), C₁₈H₂₄O₃—288.38—Use a suitable grade.

4-(4-Hydroxyphenyl)-2-butanone, $C_{10}H_{12}O_2$ —**164.20** [5471-51-2]—White powder.

Assay: Inject an appropriate volume into a gas chromatograph (see *Chromatography* (621)) equipped with a flameionization detector, helium being used as the carrier gas. The following conditions have been found suitable: a 0.25mm × 30-m capillary column coated with a 1-µm layer of phase G43; the injection port temperature is maintained at 280°; the detector temperature is maintained at 300°; the column temperature is maintained at 180° and programmed to rise 10° per minute to 280°. The area of the $C_{10}H_{12}O_2$ peak is not less than 98.5% of the total peak area.

MELTING RANGE (741): between 81° and 87°.

3-Hydroxyphenyldimethylethyl Ammonium Chloride [Dimethylethyl(3-hydroxyphenyl)ammonium Chloride]—Use Edrophonium Chloride.

 $p-\alpha$ -4-Hydroxyphenylglycine, C₈H₉NO₃—167.16 [22818-40-2]—Shiny leaflets. Sparingly soluble in water, in alcohol, in acetone, in ether, in chloroform, in ethyl acetate, in benzene, and in glacial acetic acid; soluble in alkalies and in mineral acids; freely soluble in warm 20% v/v hydrochloric acid.

MELTING RANGE (741): between 220° and 247°, with decomposition.

2'-(4-Hydroxyphenyl)-5-(4-methyl-1-piperazinyl)-2,5'-bi-1H-benzimidazole Trihydrochloride Pentahydrate— 623.97 [23491-44-3]—Dark yellow to tan powder with a green cast. Use a suitable grade.

Hydroxypropyl-β-cyclodextrin (Hydroxypropylbetadex), $C_{42}H_{70}O_{35}(C_3H_6O)_x$ with x = 7 molar substitution [128446-35-5]—Use a suitable grade with a substitution degree between 0.40 and 1.50.

Hydroxypropyl Cellulose—Average molecular weight approximately 100,000 [9004-64-2] VISCOSITY: Dissolve 5.0 g of Hydroxypropyl Cellulose with

VISCOSITY: Dissolve 5.0 g of Hydroxypropyl Cellulose with 95.0 mL of water by stirring. If necessary, centrifuge the solution to expel any entrapped air bubbles. Determine the viscosity of the solution as directed in *Viscosity—Rotational Methods* (912) at $25 \pm 0.1^{\circ}$. The viscosity is between 75 and 150 centipoises.

8-Hydroxyquinoline (*Oxine*), C₉H₇NO—**145.16** [148-24-3]—Use ACS reagent grade 8-Quinolinol. $\begin{array}{l} \mbox{Hypophosphorous Acid, 50 Percent (Hypophosphorous Acid), $$ HPH_2O_2-66.00$ [6303-21-5]-A colorless to faintly yellow liquid. Miscible with water and with alcohol. \\ \end{array}$

ASSAY: Accurately weigh about 4 mL, dilute with 25 mL of water, add methyl red TS, and titrate with 1 N sodium hydroxide VS: each mL of 1 N sodium hydroxide is equivalent to 66.00 mg of HPH₂O₂. Not less than 48% is found. CHLORIDE: Add 0.2 mL to a mixture of 10 mL of silver nitrate TS and 5 mL of nitric acid, and heat until brown fumes are no longer evolved: any white, insoluble residue remaining is negligible.

PHOSPHATE: Dilute 1 mL with water to 50 mL, render alkaline with ammonia TS, filter if a precipitate is formed, and add to the filtrate 5 mL of magnesia mixture TS: not more than a slight precipitate is formed within 5 minutes. **SULFATE** (Reagent test, *Method I*): Dilute 1 mL with water to 50 mL: 20 mL of the solution shows not more than 0.2 mg of SO₄.

Hypoxanthine, $C_{s}H_{4}N_{4}O$ —136.11 [68-94-0]—White to yellowish-white powder. Soluble in 1 N sodium hydroxide. Use a suitable grade.

IgG-Coated Red Cells: Red cells coated with human immunoglobulin (IgG). The reagent must be obtained from manufacturers or suppliers licensed by the Center for Biologics Evaluation and Research, Food and Drug Administration. The use of reagents from an unlicensed manufacturer or supplier may invalidate the results.

[NOTE—There are many manufacturers and suppliers of these reagents that are licensed by the Center for Biologics Evaluation and Research, Food and Drug Administration. Some examples of licensed manufacturers or suppliers are the following: Gamma Biologics, Houston, TX; and Ortho Diagnostics, Raritan, NJ.]

Imidazole, $C_3H_4N_2$ —68.08 [288-32-4]—White to light yellow crystals. Freely soluble in water. Use ACS reagent grade.

Iminodiacetic Acid, C₄H₇NO₄—**133.10** [142-73-4]—Use a suitable grade with a content of NLT 98.0%.

Indene, C_9H_8 —116.16 [95-13-6]—Colorless liquid. Assay: Inject an appropriate specimen into a suitable gas chromatograph (see *Chromatography* (621)) equipped with a flame-ionization detector, helium being used as the carrier gas. The following conditions have been found suitable: a 0.25-mm × 10-m capillary column coated with a 1-µm layer of methylsilicone; the injection port temperature is maintained at 200°; the detector temperature is maintained at 300°; the column temperature is maintained at 100° and programmed to rise 10° per minute to 250°. The area of the indene peak is not less than 99% of the total peak area.

REFRACTIVE INDEX (831): between 1.5749 and 1.5769 at 20° .

Indicators—See separate subsection.

Indigo Carmine—Use Indigotindisulfonate Sodium (USP monograph).

Indole (*2*, *3-Benzopyrrole*), C₈H₇N—**117.14** [120-72-9]— Use a suitable grade.

Indole-3-carboxylic Acid, C₉H₇NO₂—161.2 [771-50-6]—Use a suitable grade.

Inosine, $C_{10}H_{12}N_4O_5$ —268.23 [58-63-9]—White, crystalline powder.