rity is found; and not more than 2.0% of total impurities, including mannitol and sorbitol, is found. Disregard any impurity peak that is less than 0.1%.

Assay—

Mobile phase—Use degassed water.

Standard preparation—Dissolve an accurately weighed quantity of USP Isomalt RS in water, and dilute quantitatively, and stepwise if necessary, with water to obtain a solution having a known concentration of about 20 mg per mL.

Assay preparation—Transfer about 1000 mg of Isomalt, accurately weighed, to a 50-mL volumetric flask, dissolve in and dilute with water to volume, and mix.

Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a refractive index detector maintained at a constant temperature, a 7.8-mm × 30-cm column that contains packing L19, and a 4.6-mm × 3-cm guard column that contains packing L19. The flow rate is about 0.5 mL per minute. The column temperature is maintained at 80 ± 1°. Chromatograph the *Standard preparation,* and record the peak responses as directed for *Procedure:* the relative retention times are about 1.2 for 1,6-GPS and 1.0 for 1,1-GPM; the resolution, *R,* between 1,1-GPM and 1,6-GPS is not less than 2.0; and the relative standard deviation for replicate injections is not more than 2.0%, determined from the 1,6-GPS and 1,1-GPM peak responses.

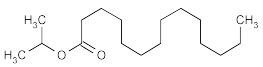
Procedure—Separately inject equal volumes (about 20 µL) of the *Standard preparation* and the *Assay preparation* into the chromatograph, record the chromatograms, and measure the responses for the 1,6-GPS and 1,1-GPM peaks. Calculate the quantity, in mg, of 1,6-GPS in the portion of Isomalt taken by the formula:

$$50C(r_U / r_S)$$

in which *C* is the concentration, in mg per mL, of 1,6-GPS in the *Standard preparation,* with calculation based on the declared 1,6-GPS content of USP Isomalt RS; and r_U and r_S are the 1,6-GPS peak responses obtained from the *Assay preparation* and the *Standard preparation,* respectively. Similarly, calculate the quantity, in mg, of 1,1-GPM in the portion of Isomalt taken.

Isopropyl Alcohol—*see Isopropyl Alcohol General Monographs*

Isopropyl Myristate



$C_{17}H_{34}O_2$ 270.46
Tetradecanoic acid, 1-methylethyl ester.
Isopropyl myristate [110-27-0].

» Isopropyl Myristate consists of esters of isopropyl alcohol and saturated high molecular weight fatty acids, principally myristic acid. It contains not less than 90.0 percent of $C_{17}H_{34}O_2$.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩**—**
USP Isopropyl Myristate RS
USP Isopropyl Palmitate RS

Identification—The retention time of the major peaks obtained in the *Assay* is the same as that of the corresponding peaks obtained from the *System suitability solution* employed in the *Assay*.

Specific gravity ⟨841⟩: between 0.846 and 0.854.

Acid value ⟨401⟩: not more than 1.

Iodine value ⟨401⟩: not more than 1.

Saponification value ⟨401⟩: between 202 and 212.

Refractive index ⟨831⟩: between 1.432 and 1.436 at 20°.

Residue on ignition ⟨281⟩: not more than 0.1%.

Assay—

System suitability solution—Dissolve about 45 mg of USP Isopropyl Myristate RS and 5 mg of USP Isopropyl Palmitate RS in 10.0 mL of *n*-hexane.

Assay preparation—Dissolve 125 mg of Isopropyl Myristate in 25.0 mL of *n*-hexane, and mix.

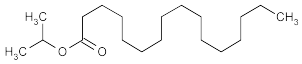
Chromatographic system (see *Chromatography* ⟨621⟩)—The gas chromatograph is equipped with a flame-ionization detector and a 4-mm × 1.8-m column packed with 10% liquid phase G8 on 100- to 120-mesh support S1A. The carrier gas is nitrogen, flowing at a rate of 45 mL per minute. The column temperature is programmed to rise from 90° to 210° at a rate of 2° per minute and then to maintain at 210° for 8 minutes. The detector temperature is maintained at 280°, and the injection port temperature is maintained at 240°. Chromatograph the *System suitability solution*, and record the peak responses as directed for *Procedure:* the relative retention times for isopropyl myristate and isopropyl palmitate are about 1 and 1.3, respectively; the resolution, *R,* is not less than 6.0 between the peaks due to isopropyl myristate and isopropyl palmitate; the tailing factor for the isopropyl palmitate peak is not more than 2; and the relative standard deviation for replicate injections is not more than 2.0%.

Procedure—Inject about 5 µL of the *Assay preparation* into the chromatograph, record the chromatogram, and measure the responses for the major peaks. Calculate the percentage of $C_{17}H_{34}O_2$ in the portion of Isopropyl Myristate taken by the formula:

$$100A/B$$

in which *A* is the isopropyl myristate peak response; and *B* is the sum of the responses of all the peaks in the chromatogram, except the solvent peak.

Isopropyl Palmitate



$C_{19}H_{38}O_2$ 298.51
Hexadecanoic acid, 1-methylethyl ester.
Isopropyl palmitate [142-91-6].

» Isopropyl Palmitate consists of esters of isopropyl alcohol and saturated high molecular weight fatty acids. It contains not less than 90.0 percent of $C_{19}H_{38}O_2$.

Packaging and storage—Preserve in tight, light-resistant containers.

USP Reference standards ⟨11⟩**—**
USP Isopropyl Myristate RS
USP Isopropyl Palmitate RS

Identification—The retention time of the major peaks obtained in the *Assay* is the same as that of the corresponding