Reference suspension: Transfer 5.0 mL of the *Opalescence standard* to a 100-mL volumetric flask, and dilute with water to volume.

Sample: Methylpyrrolidone (neat)

Analysis: Transfer a sufficient portion of the *Sample* to a test tube of colorless, transparent, neutral glass with a flat base and an internal diameter of 15–25 mm to obtain a depth of 40 mm. Similarly transfer portions of the *Reference suspension* and water to separate matching test tubes. Compare the *Sample, Reference suspension*, and water in diffused daylight, viewing vertically against a black background (see *Spectrophotometry and Light-Scattering* ⟨851⟩*, Visual Comparison*). [NOTE—The diffusion of light must be such that the *Reference suspension* can readily be distinguished from water.]

Acceptance criteria: The *Sample* shows the same clarity as that of water, or its opalescence is not more pronounced than that of the *Reference suspension.*

- **COLOR OF SOLUTION**

Sample Methylpyrrolidone (neat)

Analysis: Transfer a sufficient portion of the *Sample* to a test tube of colorless, transparent, neutral glass with a flat base and an internal diameter of 15–25 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 *Sample* with that of water in diffused daylight, viewing vertically against a white background (see *Spectrophotometry and Light-Scattering* ⟨851⟩*, Visual Comparison*).

Acceptance criteria: The *Sample* has the color of water.

- **WATER,** *Method Ic* ⟨**921**⟩**:** NMT 0.1%, determined on 1.0 g

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in light-resistant containers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Methylpyrrolidone RS

Mineral Oil—*see Mineral Oil General Monographs*

Light Mineral Oil

» Light Mineral Oil is a purified mixture of liquid hydrocarbons obtained from petroleum. It may contain a suitable stabilizer.

Packaging and storage—Preserve in tight, light-resistant containers. No storage requirements specified.

Labeling—Label it to indicate the name and quantity of any substance added as a stabilizer, and label packages intended for direct use by the public to indicate that it is not intended for internal use.

USP Reference standards ⟨11⟩**—**
USP Mineral Oil RS
USP Naphthalene RS

Identification—

A: *Infrared Absorption* ⟨197F⟩.

B: It meets the requirements of the test for *Viscosity*.

Specific gravity ⟨841⟩: between 0.818 and 0.880.

Viscosity ⟨911⟩**—**Perform the test at 40.0±0.1° using a suitable capillary viscometer: the kinematic viscosity is between 3.0 and 34.4 $mm^2 \cdot s^{-1}$.

Acidity, Readily carbonizable substances, Limit of polycyclic aromatic hydrocarbons, Limit of sulfur compounds, and Solid paraffin—It meets the requirements of the tests for *Acidity, Readily carbonizable substances, Limit of polycyclic aromatic hydrocarbons, Limit of sulfur compounds*, and *Solid paraffin* under *Mineral Oil*.

Mono- and Di-glycerides

» Mono- and Di-glycerides is a mixture of glycerol mono- and di-esters, with minor amounts of tri-esters, of fatty acids from edible oils. It contains not less than 40.0 percent of monoglycerides. The monoglyceride content is not less than 90.0 percent and not more than 110.0 percent of the value indicated in the labeling. It may contain suitable stabilizers.

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

Labeling—The labeling indicates the monoglyceride content, hydroxyl value, iodine value, saponification value, and name and quantity of any stabilizers.

USP Reference standards ⟨11⟩**—**
USP Glycerin RS

Acid value ⟨401⟩**:** not more than 4.

Hydroxyl value ⟨401⟩**:** not less than 90.0% and not more than 110.0% of the value indicated in the labeling.

Iodine value ⟨401⟩**:** not less than 90.0% and not more than 110.0% of the value indicated in the labeling. If the value stated in the labeling is less than 10, the *Iodine value* is not more than 10.

Saponification value ⟨401⟩**:** not less than 90.0% and not more than 110.0% of the value indicated in the labeling.

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

Arsenic, *Method II* ⟨211⟩**:** 3 ppm.

Heavy metals, *Method II* ⟨231⟩**:** 0.001%.

Limit of free glycerin—

Mobile phase and *Chromatographic system*—Proceed as described in the *Assay for monoglycerides.*

Standard solutions—Dissolve an accurately weighed quantity of USP Glycerin RS in tetrahydrofuran, and dilute with tetrahydrofuran, as necessary, to obtain solutions having known concentrations of about 0.5 mg per mL, 1.0 mg per mL 2.0 mg per mL, and 4.0 mg per mL.

Test solution—Use the *Assay preparation.*

Procedure—Separately inject equal volumes (about 40 µL) of each of the *Standard solutions* and the *Test solution* into the chromatograph, record the chromatograms, and measure the responses for the glycerin peaks. Plot the concentration, in mg per mL, of USP Glycerin RS in the *Standard solutions* versus the glycerin peak responses obtained. From the standard curve so obtained, determine the glycerin concentration, *C,* in mg per mL, in the *Test solution.* Calculate the percentage of glycerin in the portion of Mono- and Di-glycerides taken by the formula:

$$500(C/W)$$

in which *C* is as obtained above; and *W* is the amount, in mg, of Mono- and Di-glycerides taken to prepare the *Test solution:* not more than 7.0% of free glycerin is found.

Assay for monoglycerides—

Mobile phase—Use filtered and degassed tetrahydrofuran. Make adjustments if necessary (see *System Suitability* under *Chromatography* ⟨621⟩).

Assay preparation—Transfer about 200 mg of Mono- and Di-glycerides, accurately weighed, to a 5-mL volumetric flask, dissolve in and dilute with tetrahydrofuran to volume, and mix.

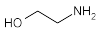
Chromatographic system (see *Chromatography* ⟨621⟩)—The liquid chromatograph is equipped with a refractive index detector and a 7-mm × 60-cm column that contains 5-µm packing L21 (100Å). The flow rate is about 1 mL per minute. The column and detector temperatures are maintained at 40°. [NOTE—Two or three 7.5-mm × 30-cm L21 columns may be used in place of one 60-cm column provided that system suitability requirements are met.] Chromatograph the *Assay preparation,* and record the peak responses as directed for *Procedure.* The order of elution is triglycerides, diglycerides, monoglycerides, and glycerin. The relative standard deviation for replicate injections determined from the monoglycerides peak is not more than 1.0%.

Procedure—Inject a volume (about 40 µL) of the *Assay preparation* into the chromatograph, record the chromatogram, and measure the responses for the major peaks. Calculate the percentage of monoglycerides in the portion of Mono- and Diglycerides taken by the formula:

$$100(r_U / r_S)$$

in which r_U is the peak response for monoglycerides; and r_S is the sum of the responses of all the peaks, except the solvent peak.

Monoethanolamine



C_2H_7NO 61.08
Ethanol, 2-amino-.
2-Aminoethanol [141-43-5].

» Monoethanolamine contains not less than 98.0 percent and not more than 100.5 percent, by weight, of C_2H_7NO.

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

USP Reference standards ⟨11⟩**—**
USP Monoethanolamine RS

Identification, *Infrared Absorption* ⟨197F⟩.

Specific gravity ⟨841⟩: between 1.013 and 1.016.

Distilling range, *Method II* ⟨721⟩**—**Not less than 95% of it distills between 167° and 173°, a correction factor of 0.052° per mm being applied as necessary.

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

Assay—Accurately weigh a glass-stoppered weighing bottle containing 25 mL of water. Add 1 g of Monoethanolamine, and weigh. Transfer to a suitable flask, add a mixed indicator of 5 parts bromocresol green TS and 6 parts methyl red TS for a total of approximately 11 parts of solution, mix, and titrate with 0.5 N hydrochloric acid VS. Each mL of 0.5 N hydrochloric acid is equivalent to 30.54 mg of C_2H_7NO.

Monoglyceride Citrate

Citric acid ester of glyceryl monooleate [36291-32-4].

DEFINITION

Monoglyceride Citrate is a mixture of glyceryl monooleate and its citric acid monoester, manufactured by the reaction of glyceryl monooleate with citric acid under controlled conditions. It contains NLT 14.0% and NMT 17.0% of total citric acid, calculated on the anhydrous basis.

IDENTIFICATION

- **A.**
  Sample: 1 g
  Analysis: Reflux the *Sample* with 15 mL of 0.5 N potassium hydroxide solution in dehydrated alcohol for 1 h. Add 15 mL of water, and acidify with diluted hydrochloric acid (about 6 mL). Dissolve any oil drops or solid produced in 5 mL of hexane. Remove the hexane layer, extract again with 5 mL of hexane, and again remove the hexane layer. [NOTE—Keep the resulting aqueous layer for *Identification* tests *B* and *C*.]
  Acceptance criteria: Oil drops or a white to yellowish-white solid are produced that are soluble in 5 mL of hexane.
- **B. IDENTIFICATION TESTS—GENERAL,** *Citrate* ⟨**191**⟩
  Sample: 1 mL of the aqueous layer resulting from *Identification* test *A*
  Analysis: Evaporate the *Sample* in a porcelain dish.
  Acceptance criteria: The residue meets the requirements.
- **C.**
  Sample: 5 mL of the aqueous layer resulting from *Identification* test *A*
  Analysis: Transfer the *Sample* to a test tube. Add excess calcium hydroxide as a powder, place in boiling water for 5 min, shaking several times, cool, and filter. Transfer one drop of the filtrate into a test tube, and add about 50 mg of potassium hydrogen sulfate. On top of the test tube, place a filter paper moistened with a reagent for acrolein consisting of a mixture of 5% nitroprusside solution in water and 20% piperidine solution in water (1:1). Heat the test tube.
  Aceptance criteria: The filter paper turns blue (presence of glycerin). The color changes to light red after addition of sodium hydroxide TS.

ASSAY

- **CONTENT OF CITRIC ACID**
  Standard solution: 0.23 mg/mL of USP Citric Acid RS
  Sample solution: Transfer 150 mg of Monoglyceride Citrate into a saponification flask, add 50 mL of 4% potassium hydroxide solution in dehydrated alcohol, and reflux for 1 h. Acidify the reaction mixture with hydrochloric acid to a pH of 2.8–3.2, transfer into a 400-mL beaker, and evaporate to dryness on a steam bath. Quantitatively transfer the contents of the beaker into a separator, using NMT 50 mL of water, and extract with three 50-mL portions of petroleum ether, discarding the extracts. Transfer the water layer to a 100-mL volumetric flask, and dilute with water to volume.
  Blank: Water
  Instrumental conditions
  Mode: UV-Vis
  Analytical wavelength: 450 nm
  Cell: 1 cm
  Analysis
  Samples: *Standard solution*, *Sample solution*, and *Blank*
  Pipet 2.0 mL each of the *Standard solution*, *Sample solution*, and *Blank* into separate 40-mL graduated centrifuge tubes. Add 2 mL of a 1 in 2 sulfuric acid solution and 11 mL of water to each tube. Boil for 3 min, cool, and add 5 mL of bromine TS to each tube. Dilute to 20 mL, allow to stand for 10 min, and centrifuge. Transfer 4.0 mL of the supernatant from each tube into separate 19- × 110-mm test tubes, add 1 mL of water, 0.5 mL of a 1 in 2 sulfuric acid solution, and 0.3 mL of 1 M potassium bromide, and shake. Add 0.3 mL of 1.5 N potassium permanganate, shake, and allow to stand for 2 min. Add 1 mL of a saturated solution of ferrous sulfate, shake, allow to stand for 2 min, and then dilute with water to 10 mL. Add 10.0 mL of *n*-hexane (previously washed with sulfuric acid, followed by a water wash, and then dried over anhydrous sodium sulfate), shake vigorously for 2 min, and centrifuge at low speed for 1 min. Transfer 5.0 mL of the hexane extract into a 20- × 145-mm tube containing 10.0 mL of 4% sodium sulfide solution, and briefly shake vigorously (three oscillations only). Centrifuge the mixture at low speed for 1 min. Immediately determine the absorbance of each aqueous