the chamber (or tube), and ensure that the temperature of the test specimen is at 20 ± 0.1°. The shear rate under the test condition is NLT 1 s^{-1} and NMT 100 s^{-1}.[4] Measure the apparent viscosity, following the instrument manufacturer's directions.

Acceptance criteria: The viscosity is between 2 and 20 mPa · s.

- **COAGULUM**

Sample: 100 g of Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion

Analysis: Weigh a stainless steel sieve having 125-µm openings or a suitable single-woven wire cloth with a mesh width of 125 µm, and filter the *Sample* through it.

[NOTE—Suitable single-woven wire cloth mesh meets the requirements set in ISO 9044.]

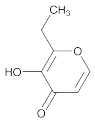
Wash the sieve or the cloth with distilled water until a clear filtrate is obtained, and dry the sieve or the cloth to constant weight at 105°.

Acceptance criteria: The weight of the residue does not exceed 1000 mg (1%).

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in well-closed containers. Store between 5° and 25°, with excursions permitted up to 30°. Do not freeze.
- **LABELING:** Label it to indicate the name and quantity of any added emulsifiers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Ethyl Acrylate and Methyl Methacrylate Copolymer Dispersion RS

Ethyl Maltol



$C_7H_8O_3$ 140.14

2-Ethyl-3-hydroxy-4-pyrone;
2-Ethyl-3-hydroxy-4*H*-pyran-4-one;
2-Ethyl pyromeconic acid [4940-11-8].

DEFINITION

Ethyl Maltol contains NLT 99.0% of $C_7H_8O_3$, calculated on the anhydrous basis.

IDENTIFICATION

- **A. INFRARED ABSORPTION** ⟨**197S**⟩**:** 1:50 solution in chloroform

ASSAY

- **PROCEDURE**

Standard solution: 10.0 µg/mL of USP Ethyl Maltol RS in 0.1 N hydrochloric acid

Sample solution: 10.0 µg/mL of Ethyl Maltol in 0.1 N hydrochloric acid

Instrumental conditions

(See *Spectrophotometry and Light-Scattering* ⟨851⟩.)

Mode: UV

Analytical wavelength: 276 nm

Cell: 1 cm

Blank: 0.1 N hydrochloric acid

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of ethyl maltol ($C_7H_8O_3$) in the portion of Ethyl Maltol taken:

$$\text{Result} = (A_U/A_S) \times (C_S/C_U) \times 100$$

A_U = absorbance of the *Sample solution*
A_S = absorbance of the *Standard solution*
C_S = concentration of USP Ethyl Maltol RS in the *Standard solution* (µg/mL)
C_U = concentration of Ethyl Maltol in the *Sample solution* (µg/mL)

Acceptance criteria: NLT 99.0% on the anhydrous basis

IMPURITIES

- **RESIDUE ON IGNITION** ⟨**281**⟩**:** NMT 0.2% at 800° for 15 min

SPECIFIC TESTS

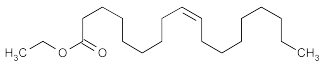
- **WATER DETERMINATION,** *Method I* ⟨**921**⟩**:** NMT 0.5%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- **USP REFERENCE STANDARDS** ⟨**11**⟩
  USP Ethyl Maltol RS

[4]The cylindrical spindle rotates at 30 rpm.

Ethyl Oleate



$C_{20}H_{38}O_2$ 310.51

9-Octadecenoic acid, (*Z*)-, ethyl ester;
Ethyl oleate [111-62-6].

DEFINITION

Ethyl Oleate consists of esters of ethyl alcohol and high molecular weight fatty acids, principally oleic acid.

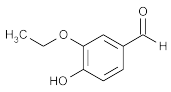
SPECIFIC TESTS

- **SPECIFIC GRAVITY** ⟨**841**⟩**:** 0.866–0.874 at 20°
- **VISCOSITY** ⟨**911**⟩**:** NLT 5.15 centipoises
- **FATS AND FIXED OILS,** *Acid Value* ⟨**401**⟩**:** NMT 0.5
- **FATS AND FIXED OILS,** *Iodine Value* ⟨**401**⟩**:** 75–85
- **FATS AND FIXED OILS,** *Saponification Value* ⟨**401**⟩**:** 177–188
- **REFRACTIVE INDEX** ⟨**831**⟩**:** 1.443–1.450

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.

Ethyl Vanillin



$C_9H_{10}O_3$ 166.17

Benzaldehyde, 3-ethoxy-4-hydroxy-;
3-Ethoxy-4-hydroxybenzaldehyde [121-32-4].

DEFINITION

Ethyl Vanillin, dried over phosphorus pentoxide for 4 h, contains NLT 98.0% and NMT 101.0% of $C_9H_{10}O_3$.

IDENTIFICATION
- **A. INFRARED ABSORPTION** ⟨197K⟩
- **B. ULTRAVIOLET ABSORPTION** ⟨197U⟩

Sample solution: 8 µg/mL in methanol
Acceptance criteria: Meets the requirements

ASSAY
- **PROCEDURE**

Sample: 300 mg of Ethyl Vanillin (previously dried)
Titrimetric system
(See *Titrimetry* ⟨541⟩.)
Mode: Direct titration
Titrant: 0.1 N sodium methoxide VS
Blank: 50 mL of dimethylformamide, accurately measured
Endpoint detection: Visual
Analysis: Transfer the *Sample solution* to a 125-mL conical flask, and dissolve in 50 mL of dimethylformamide. Add thymol blue TS and titrate, using a magnetic stirrer and taking precautions against the absorption of atmospheric carbon dioxide. Perform a blank determination. Calculate the percentage of ethyl vanillin ($C_9H_{10}O_3$) in the *Sample* taken:

$$\text{Result} = \{[(V_S - V_B) \times N \times F]/W\} \times 100$$

V_S = *Titrant* volume consumed by the *Sample* (mL)
V_B = *Titrant* volume consumed by the *Blank* (mL)
N = actual normality of the *Titrant* (mEq/mL)
F = equivalency factor, 166.2 mg/mEq
W = *Sample* weight (mg)

Acceptance criteria: 98.0%–101.0% on the previously dried basis

IMPURITIES
- **RESIDUE ON IGNITION** ⟨281⟩**:** NMT 0.1%

SPECIFIC TESTS
- **MELTING RANGE OR TEMPERATURE** ⟨741⟩**:** 76°–78°
- **LOSS ON DRYING** ⟨731⟩**:** Dry a sample over phosphorus pentoxide for 4 h: it loses NMT 1.0% of its weight.

ADDITIONAL REQUIREMENTS
- **PACKAGING AND STORAGE:** Preserve in tight, light-resistant containers.
- **USP REFERENCE STANDARDS** ⟨11⟩

USP Ethyl Vanillin RS

Ethylcellulose

Cellulose, ethyl ether;
Cellulose ethyl ether [9004-57-3].

DEFINITION
Ethylcellulose is a partly *O*-ethylated cellulose. It contains NLT 44.0% and NMT 51.0% of ethoxy ($–OC_2H_5$) groups, calculated on the dried basis.

IDENTIFICATION
- **INFRARED ABSORPTION** ⟨197K⟩

ASSAY
- **PROCEDURE**

[NOTE—Hydriodic acid and its reaction byproducts are highly toxic. Perform all steps of the *Sample solution* preparation and the *Standard solution* preparation in a properly functioning hood.]

Internal standard solution: Dilute 120 µL of toluene with *o*-xylene to 10 mL.
Standard solution: Transfer 100.0 mg of adipic acid, 4.0 mL of the *Internal standard solution*, and 4.0 mL of hydriodic acid into a suitable 10-mL thick-walled reaction vial with a pressure-tight septum closure. Close the vial tightly, and weigh the vial and contents accurately. Afterwards inject 50 µL of iodoethane through the septum with a syringe, weigh the vial again, and calculate the mass of iodoethane added, by difference. Shake well, and allow the layers to separate. Use the upper layer for analysis.
Sample solution: Transfer 50.0 mg of Ethylcellulose, 50 mg of adipic acid, and 2.0 mL of the *Internal standard solution* into a suitable 5-mL thick-walled reaction vial with a pressure-tight septum closure. Cautiously add 2.0 mL of hydriodic acid, immediately close the vial tightly, and weigh the contents and the vial accurately. Shake the vial for 30 s, heat to 125° for 10 min, allow to cool for 2 min, shake again for 30 s, and heat to 125° for 10 min. Afterwards allow to cool for 2 min, and repeat shaking and heating for a third time. Allow the vial to cool for 45 min, and reweigh. If the loss is greater than 10 mg, discard the mixture and prepare another. Use the upper layer for analysis.
Chromatographic system
(See *Chromatography* ⟨621⟩, *System Suitability*.)
Mode: GC
Detector: Flame ionization
Column: 2-mm × 5.0-m stainless steel column packed with 3% G2 on 150–180-µm mesh support S1A
Temperature
Column: 80°
Injector: 200°
Detector: 200°
Carrier gas: Nitrogen
Flow rate: 15 mL/min
Injection volume: 1 µL
System suitability
Sample: *Standard solution*
[NOTE—The relative retention times for iodoethane, toluene, and *o*-xylene are 0.6, 1.0, and 2.3, respectively.]
Suitability requirements
Resolution: NLT 2.0 between iodoethane and toluene
Analysis
Samples: *Standard solution* and *Sample solution*
Calculate the percentage of ethoxy content of the Ethylcellulose as declared in the labeling:

$$\text{Result} = (451{,}000/312) \times (R_U \times m_2)/[(R_S \times m_1) \times (100 - d)]$$

R_U = ratio of the iodoethane peak area to the toluene peak area from the *Sample solution*
m_2 = mass of iodoethane used in the *Standard solution* (mg)
R_S = ratio of the iodoethane peak area to the toluene peak area from the *Standard solution*
m_1 = mass of Ethylcellulose used in the *Sample solution* (mg)
d = loss on drying as a percentage

Acceptance criteria: 44.0%–51.0% on the dried basis

IMPURITIES
Inorganic Impurities
- **RESIDUE ON IGNITION** ⟨281⟩**:** NMT 0.5%, determined on 1.0 g
- **HEAVY METALS,** *Method II* ⟨231⟩**:** NMT 20 ppm
- **CHLORIDES**

Solution A: Nitric acid in water (1 in 5)
Standard stock solution: 0.824 mg/mL of sodium chloride
Standard solution: 8.24 µg/mL of sodium chloride, prepared from the *Standard stock solution.* [NOTE—Prepare immediately before use.]
Sample solution: Disperse 250 mg in 50 mL of water, heat to boiling, and allow to cool, shaking occasionally. Filter, and discard the first 10 mL of the filtrate.
Analysis
Samples: *Standard solution* and *Sample solution*
Separately dilute 10 mL of the *Sample solution* and *Standard solution* with water to 15 mL, add 1 mL of *Solution A*, and pour the mixtures as a single addition into test tubes containing 1 mL of 0.1 N silver nitrate VS. Examine the tubes laterally against a black background.
Acceptance criteria: After standing for 5 min protected from light, any opalescence in the *Sample solution* is not more intense than that in the *Standard solution* (0.1%).