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Ethylcellulose Dispersion Type B

DEFINITION

A stabilized dispersion of ethylcellulose in water. It contains NLT 90.0% and NMT 110.0% of the labeled amount of Ethylcellulose. It may contain suitable amounts of plasticizers, stabilizers, and glidants.

IDENTIFICATION

• **A. Film Formation**

Analysis: Transfer an appropriate quantity of Ethylcellulose Dispersion Type B to a clear glass plate, distribute evenly, and place in a laboratory oven at about 60° until dry. [Note—It may take less than 60 min.]

Acceptance criteria: A continuous transparent or translucent film is formed.

• **B. Infrared Absorption**

Change to read:

Analysis: Use the film prepared in *Identification* test *A* and perform ▲*Spectroscopic Identification Tests ⟨197⟩, Infrared Spectroscopy: 197A*▲ (CN 1-May-2020)

Standard spectrum: Perform ▲*Spectroscopic Identification Tests ⟨197⟩, Infrared Spectroscopy: 197A*▲ (CN 1-May-2020) using USP Ethylcellulose RS.

Acceptance criteria: The IR absorption spectrum of the film so formed in the 3600–2600 cm^{-1} and 1500–800 cm^{-1} regions exhibits maxima corresponding to the same wave numbers as the *Standard spectrum*.

• **C.** The retention time of the ethylcellulose peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*. [Note—Plasticizer and/or stabilizer peaks may be present in the chromatogram.]

ASSAY

• **Procedure**

Mobile phase: Tetrahydrofuran

Standard solution: Transfer 375 mg of USP Ethylcellulose RS to a 100-mL volumetric flask, and add 70 mL of tetrahydrofuran. Shake by mechanical means until the ethylcellulose is dissolved, and dilute with tetrahydrofuran to volume. The *Standard solution* contains 3.75 mg/mL of USP Ethylcellulose RS.

Sample solution: Add 30 mL of tetrahydrofuran to 1.0 g of Ethylcellulose Dispersion Type B in a 50-mL volumetric flask, and mix the mixture on a suitable shaker for 15 min. Dilute with tetrahydrofuran to volume, and mix. The *Sample solution* contains 20 mg/mL of Ethylcellulose Dispersion Type B in tetrahydrofuran. [Note—If Ethylcellulose Dispersion Type B contains inorganic insoluble material, a portion of the *Sample solution* should be centrifuged at 15,800 × *g* for NLT 15 min.]

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: Refractive index

Column: 8.0-mm × 30-cm; 6-µm packing L21

Temperature

Detector: 45°

Column: 45°

Flow rate: 0.5 mL/min

Injection size: 20 µL

System suitability

Sample: *Standard solution*

Suitablity requirements

Relative standard deviation: NMT 5.0% determined for the ethylcellulose peak

Tailing factor: NMT 2.0 for the ethylcellulose peak

Analysis

Samples: *Standard solution* and *Sample solution*

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Calculate the percentage of the labeled amount of ethylcellulose in the portion of Ethylcellulose Dispersion Type B taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of ethylcellulose from the *Sample solution*

r_S = peak response of ethylcellulose from the *Standard solution*

C_S = concentration of USP Ethylcellulose RS in the *Standard solution* (mg/mL)

C_U = concentration of Ethylcellulose Dispersion Type B in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

OTHER COMPONENTS

[NOTE—Perform the test for individual plasticizers, stabilizers, or glidants only if they are included in the *Labeling*.]

• **CONTENT OF MEDIUM-CHAIN TRIGLYCERIDES**

Mobile phase, Sample solution, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: Transfer 375 mg of USP Ethylcellulose RS, 60 mg of medium-chain triglycerides, and 40 mg of oleic acid to a 100-mL volumetric flask. Add 70 mL of tetrahydrofuran, and shake by mechanical means until the ethylcellulose is dissolved. Dilute with tetrahydrofuran to volume. The *Standard solution* contains 3.75 mg/mL of USP Ethylcellulose RS, 0.6 mg/mL of medium-chain triglycerides, and 0.4 mg/mL of oleic acid. [NOTE—Oleic acid is included in the *Standard solution* to assist with consistent integration between *Standard* and *Sample solutions*.]

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for ethylcellulose, medium-chain triglycerides, and oleic acid are 1.00, 1.18, and 1.25, respectively.]

Suitability requirements

Relative standard deviation: NMT 5.0% determined for the medium-chain triglycerides peak

Resolution: NLT 2.0 between ethylcellulose and medium-chain triglycerides

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of medium-chain triglycerides in the portion of Ethylcellulose Dispersion Type B taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of medium-chain triglycerides from the *Sample solution*

r_S = peak response of medium-chain triglycerides from the *Standard solution*

C_S = concentration of medium-chain triglycerides in the *Standard solution* (mg/mL)

C_U = concentration of Ethylcellulose Dispersion Type B in the *Sample solution* (mg/mL)

Acceptance criteria: The percentage content of medium-chain triglycerides falls within the quantity range indicated by the *Labeling*. The ratio of medium-chain triglycerides to ethylcellulose is less than 0.25.

• **CONTENT OF OLEIC ACID**

Standard solution: 1.68 mg/mL of USP Oleic Acid RS in tetrahydrofuran

Sample solution: Add 15 mL of tetrahydrofuran to 2.0 g of Ethylcellulose Dispersion Type B in a 25-mL volumetric flask, and mix the mixture on a suitable shaker for 15 min. Dilute with tetrahydrofuran to volume, and mix. The *Sample solution* contains 80 mg/mL of Ethylcellulose Dispersion Type B in tetrahydrofuran.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m capillary column; 0.25-µm layer of phase G25 (or G35)

Temperature

Detector: 280°

Injector port: 280°

Column: See the temperature program table below.

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
120	—	120	5

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Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
120	10	250	20

Carrier gas: Helium

Flow rate: 7.0 mL/min

Injection size: 1.0 µL

Injection type: Splitless

System suitability

Sample: *Standard solution*

[NOTE—The retention time for oleic acid is about 18.5 min.]

Suitability requirements

Relative standard deviation: NMT 5.0%

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of oleic acid in the portion of Ethylcellulose Dispersion Type B taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of oleic acid from the *Sample solution*

r_S = peak response of oleic acid from the *Standard solution*

C_S = concentration of USP Oleic Acid RS in the *Standard solution* (mg/mL)

C_U = concentration of Ethylcellulose Dispersion Type B in the *Sample solution* (mg/mL)

Acceptance criteria: The percentage content of oleic acid falls within the quantity range indicated by the *Labeling*. The ratio of oleic acid to ethylcellulose is less than 0.15.

- **CONTENT OF DIBUTYL SEBACATE AND OLEIC ACID**

Standard solution: 0.74 mg/mL of USP Dibutyl Sebacate RS and 0.48 mg/mL of USP Oleic Acid RS in tetrahydrofuran

Sample solution: Add 25 mL of tetrahydrofuran to 1.0 g of Ethylcellulose Dispersion Type B in a 50-mL volumetric flask, and mix the mixture on a suitable shaker for 15 min. Dilute with tetrahydrofuran to volume, and mix. The *Sample solution* contains 20 mg/mL of Ethylcellulose Dispersion Type B in tetrahydrofuran. [NOTE—If Ethylcellulose Dispersion Type B contains inorganic insoluble material, a portion of the *Sample solution* should be centrifuged at 15,800 × *g* for NLT 15 min.]

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 15-m capillary column; 0.1-µm layer of phase G25 (or G35)

Temperature

Detector: 280°

Injector port: 280°

Column: See the temperature program table below.

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
150	—	150	2
150	10	250	10

Carrier gas: Helium

Flow rate: 5.0 mL/min

Injection size: 0.5 µL

Injection type: Split (ratio about 10:1)

System suitability

Sample: *Standard solution*

[NOTE—The relative retention times for dibutyl sebacate and oleic acid are 1.00 and 1.45, respectively.]

Suitability requirements

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Relative standard deviation: NMT 5.0%

Resolution: NLT 2.0 between dibutyl sebacate and oleic acid

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of each component (dibutyl sebacate or oleic acid) in the portion of Ethylcellulose Dispersion Type B taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of each component (dibutyl sebacate or oleic acid) from the *Sample solution*

r_S = peak response of each component (dibutyl sebacate or oleic acid) from the *Standard solution*

C_S = concentration of each component (USP Dibutyl Sebacate RS or USP Oleic Acid RS) in the *Standard solution* (mg/mL)

C_U = concentration of Ethylcellulose Dispersion Type B in the *Sample solution* (mg/mL)

Acceptance criteria

Dibutyl sebacate: The percentage content falls within the quantity range indicated by the *Labeling*. The ratio of dibutyl sebacate to ethylcellulose is less than 0.25.

Oleic acid: The percentage content falls within the quantity range indicated by the *Labeling*. The ratio of oleic acid to ethylcellulose is less than 0.15.

IMPURITIES

Inorganic Impurities

- **Residue on Ignition ⟨281⟩:** NMT 1.95%. [Note—Perform this test only if Ethylcellulose Dispersion Type B contains inorganic nonvolatile material.]

Organic Impurities

- **Procedure 1: Limit of Glycerin**

[Note—Perform this test only if Ethylcellulose Dispersion Type B contains glycerides.]

Standard solution: 0.05 mg/mL of USP Glycerin RS in methanol

Sample solution: Add 15 mL of methanol to 2.0 g of Ethylcellulose Dispersion Type B in a 25-mL volumetric flask, and mix the mixture on a suitable shaker for 15 min. Dilute with methanol to volume, and mix. The *Sample solution* contains 80 mg/mL of Ethylcellulose Dispersion Type B in methanol.

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m capillary column; 3.0-µm layer of phase G43

Temperature

Detector: 280°

Injector port: 280°

Column: See the temperature program table below.

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
120	10	150	2
150	15	240	20

Carrier gas: Helium

Flow rate: 10.0 mL/min

Injection size: 1.0 µL

Injection type: Splitless

System suitability

Sample: *Standard solution*

[Note—The retention time for glycerin is about 3.8 min.]

Suitability requirements

Relative standard deviation: NMT 5.0%

Tailing factor: NMT 2.5

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of glycerin in the portion of Ethylcellulose Dispersion Type B taken:

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$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of glycerin from the *Sample solution*

r_S = peak response of glycerin from the *Standard solution*

C_S = concentration of USP Glycerin RS in the *Standard solution* (mg/mL)

C_U = concentration of Ethylcellulose Dispersion Type B in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 0.6%

- **Procedure 2: Limit of 1-Butanol**

[Note—Perform this test only if Ethylcellulose Dispersion Type B contains butyl esters.]

Standard solution: 0.1 mg/mL of USP 1-Butanol RS in methanol

Sample solution: Add 15 mL of methanol to 2.0 g of Ethylcellulose Dispersion Type B in a 25-mL volumetric flask, and mix the mixture on a suitable shaker for 15 min. Dilute with methanol to volume, and mix. The *Sample solution* contains 80 mg/mL of Ethylcellulose Dispersion Type B in methanol. [Note—If Ethylcellulose Dispersion Type B contains inorganic insoluble material, a portion of the *Sample solution* should be centrifuged at 15,800 × *g* for 30 min.]

Chromatographic system

(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: GC

Detector: Flame ionization

Column: 0.53-mm × 30-m capillary column; 1.0-µm layer of phase G16

Temperature

Detector: 250°

Injector port: 250°

Column: See the temperature program table below.

Initial Temperature (°)	Temperature Ramp (°/min)	Final Temperature (°)	Hold Time at Final Temperature (min)
45	—	45	5
45	10	80	—
80	20	220	10

Carrier gas: Helium

Flow rate: 10.0 mL/min

Injection size: 0.5 µL

Injection type: Splitless

System suitability

Sample: *Standard solution*

[Note—The retention time for 1-butanol is about 7.8 min.]

Suitability requirements

Relative standard deviation: NMT 5.0%

Tailing factor: NMT 2.0

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of 1-butanol in the portion of Ethylcellulose Dispersion Type B taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of 1-butanol from the *Sample solution*

r_S = peak response of 1-butanol from the *Standard solution*

C_S = concentration of USP 1-Butanol RS in the *Standard solution* (mg/mL)

C_U = concentration of Ethylcellulose Dispersion Type B in the *Sample solution* (mg/mL)

Acceptance criteria: NMT 0.2%

SPECIFIC TESTS

- **pH ⟨791⟩:** 9.5–11.5

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• **Total Solids**

Analysis: Place 3 g (4 mm in diameter) of glass beads in an aluminum dish, and weigh. Add 10 g of Ethylcellulose Dispersion Type B, and again weigh. Dry at about 105° for 3 h. Determine the percentage of total solids in Ethylcellulose Dispersion Type B.

Acceptance criteria: 23.0%–26.0%

• **Viscosity—Rotational Methods ⟨912⟩**

Sample: 500 mL of Ethylcellulose Dispersion Type B

Analysis: Transfer the *Sample* to a beaker with an inside diameter of 83 mm. Place the beaker in a water bath, cover with a watchglass, allow to equilibrate at 25 ± 0.1°, and let air bubbles dissipate. Keep the sample free from entrapped air bubbles and uniform in temperature. Stir the dispersion in the beaker at low agitation speed to ensure homogeneity, making sure that no air bubbles are incorporated. Determine viscosity at 25 ± 0.1°, using a suitable rotational viscometer with a spindle having a cylinder 4.7 cm in diameter and 0.2 cm high attached to a shaft 0.3 cm in diameter, the distance from the top of the cylinder to the lower tip of the shaft being 2.7 cm, and the immersion depth being 4.9 cm.[1] Operate the viscometer at 20 rpm. Follow the instrument manufacturer's directions to measure the apparent viscosity.

Acceptance criteria: 400–1500 mPa · s

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight containers at a temperature below 25°. Protect from freezing.

• **Labeling:** The labeling states the percentage of ethylcellulose. Label it to indicate the names and quantity ranges of any added plasticizers, stabilizers, and glidants. Label it to indicate whether any fatty acid components, or fatty acid-containing components are derived from animal, vegetable, or synthetic sources.

• **USP Reference Standards ⟨11⟩**

USP 1-Butanol RS
1-Butanol.
$C_4H_{10}O$ 74.12

USP Dibutyl Sebacate RS
Decanedioic acid; Dibutyl ester.
$C_{18}H_{34}O_4$ 314.46

USP Ethylcellulose RS
Cellulose, ethyl ether; Cellulose ethyl ether.

USP Glycerin RS
1,2,3-Propanetriol; Glycerol.

USP Oleic Acid RS
9-Octadecenoic acid, (*Z*)-; Oleic acid.
$C_{18}H_{34}O_2$ 282.46

[1] A commercial instrument is available as an RV2 spindle from Brookfield.

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
ETHYLCELLULOSE DISPERSION TYPE B	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: Chromatographic Database

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