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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*

Suitability 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*

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