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Ethylcellulose Aqueous Dispersion

DEFINITION

Ethylcellulose Aqueous Dispersion is a colloidal dispersion of Ethylcellulose in water. It contains NLT 90.0% and NMT 110.0% of the labeled amount of ethylcellulose. It contains suitable amounts of Cetyl Alcohol and Sodium Lauryl Sulfate, which assist in the formation and stabilization of the dispersion. It may contain suitable antifoaming and antimicrobial agents.

IDENTIFICATION

- **A.**

Diluent: Toluene and alcohol (80:20)

Standard solution: 250 mg of USP Ethylcellulose RS in 5 mL of *Diluent*

Sample solution: A small quantity of Dispersion in 5 mL of *Diluent*

Analysis: Transfer a few mL of the *Standard solution* and the *Sample solution* to two separate silver chloride plates, and evaporate.

Acceptance criteria: The IR absorption spectrum of the residue in the regions 3600 to 2600 cm^{-1} and 1500 to 800 cm^{-1} exhibits maxima only at the same wavenumbers as that of a film of USP Ethylcellulose RS.

- **B.**

Sample: 2 mL

Analysis: Transfer the *Sample* to a Petri dish, 100 mm in diameter, so that the bottom of the dish is covered uniformly. Place the dish in an oven or on a hot plate to evaporate the water.

Acceptance criteria: A transparent film results.

- **C.**

Sample solution: Dissolve the film formed in *Identification* test *B* in 20 mL of chloroform.

Chromatographic system

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

Mode: GC

Detector: Flame ionization

Column: 2-mm × 1.8-m; 10% liquid phase G1 on support S1A

Temperatures

Injection port: 250°

Detector: 275°

Column: 220°

Injection volume: 2 µL

Acceptance criteria: The retention time of the major peak following the solvent peak from the sample corresponds to that from a similar solution of USP Cetyl Alcohol RS.

- **D.**

Indicator solution: To a 150-mL graduated beaker containing 0.7 mL of sulfuric acid and 5 g of anhydrous sodium sulfate slowly add water to the 90-mL mark. Add methylene blue solution (3 in 1000) to the 100-mL mark.

Analysis: To 1 mL of Dispersion in a 100-mL graduated mixing cylinder add 9 mL of water followed by 25 mL of *Indicator solution*. Add 15 mL of chloroform, and shake vigorously. Allow the two phases to separate.

Acceptance criteria: The lower phase is blue, indicating the presence of sodium lauryl sulfate.

ASSAY

- **Procedure**

Sample solution: Dispersion equivalent to 25 mg of ethylcellulose

Analysis: Determine the ethoxy content, as directed in *Methoxy Determination* ⟨431⟩. Calculate the ethylcellulose content from the ethoxy content found, and calculate the ethoxy content of the ethylcellulose as declared in the labeling. Each mL of 0.1 N sodium thiosulfate is equivalent to 0.7510 mg of ($-OC_2H_5$).

Acceptance criteria: 90.0%–110.0%

SPECIFIC TESTS

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

Sample: Neat

Analysis: Use a rotational viscometer equipped with a low-viscosity adapter. Mix the *Sample*, and pipet 20 mL of it into the low-viscosity small sample adapter. Start the viscometer, and take readings after 60, 90, and 120 s at a temperature of 25 ± 2° and at a spindle speed that results in readings of 10%–90% of full-scale. Multiply the average of the three readings by the factor specified for the selected spindle speed to obtain the viscosity in centipoises.

Acceptance criteria: NMT 150 centipoises

- **pH** ⟨791⟩**:** 4.0–7.0

- **Loss on Drying** ⟨731⟩

Sample: 5 mL

Analysis: Place 10 g of standard 20- to 30-mesh sand, previously dried for at least 30 min at 60°, into a tared Petri dish. Add the *Sample*, and again weigh. Dry at 60° to constant weight.

Acceptance criteria: NMT 71.0%

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers, and protect from freezing.

- **Labeling:** The labeling states the ethoxy content of the ethylcellulose and the percentage of ethylcellulose. The labeling also states the names and quantities of any added antifoaming and antimicrobial agents.

- **USP Reference Standards** ⟨11⟩

USP Cetyl Alcohol RS
USP Ethylcellulose RS

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

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

Chromatographic Database Information: Chromatographic Database

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