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Hymetellose

Methylhydroxyethylcellulose;
Cellulose 2-hydroxyethyl methyl ether
CAS RN®: 9032-42-2.

DEFINITION

Hymetellose is a partly *O*-(methylated) and *O*-(2-hydroxyethylated) cellulose.

IDENTIFICATION

- **A.**

Sample solution: Use the *Sample solution* prepared in the test for *Color of Solution*.

Analysis: Heat the *Sample solution* in a water bath while stirring.

Acceptance criteria: At a temperature above 50°, the solution becomes cloudy or a flocculent precipitate is formed. The solution becomes clear again on cooling.

- **B.**

Sample solution: 1 mL of the solution from *Identification* test *A*

Analysis: Transfer the *Sample solution* to a glass plate, and allow the water to evaporate.

Acceptance criteria: A thin film is formed.

- **C.**

Sample solution: 10 mL of the solution from *Identification* test *A*

Analysis: To the *Sample solution* add 0.3 mL of 2 N acetic acid and 2.5 mL of tannic acid TS.

Acceptance criteria: A yellowish-white, flocculent precipitate is formed that dissolves in ammonia TS.

- **D.**

Sample: 1 g

Diethanolamine–sodium nitroprusside solution: 50 mg/mL of sodium nitroprusside solution adjusted with 1 N hydrochloric acid to a pH of 9.8. Mix 11 mL of this solution with 1 mL of a diethanolamine solution (200 mg/mL) in water.

Analysis: In a test tube about 160 mm long, thoroughly mix the *Sample* with 2 g of finely powdered manganese sulfate. Introduce, to a depth of 2 cm into the upper part of the tube, a strip of filter paper impregnated with a freshly prepared *Diethanolamine–sodium nitroprusside solution*. Insert the tube 8 cm into a silicone-oil bath at 190°–200°. Perform a blank test without the addition of Hymetellose.

Acceptance criteria: The filter paper becomes blue within 10 min.

- **E.**

Sample: 0.2 g

Analysis: Dissolve the *Sample* completely, without heating, in 15 mL of 70% sulfuric acid. Pour the solution while stirring into 100 mL of ice water, and dilute with ice water to 250 mL. Transfer 1 mL of this solution to a test tube, and while cooling in ice water, add dropwise 8 mL of sulfuric acid, and mix thoroughly. Heat in a water bath for exactly 3 min, and immediately cool in ice water. While the mixture is cold, carefully add 0.6 mL of ninhydrin TS, and mix well. Allow to stand at 25°.

Acceptance criteria: A pink color is produced immediately and does not become violet within 100 min.

IMPURITIES

- **Residue on Ignition** ⟨281⟩

Sample: 1.0 g

Acceptance criteria: NMT 1.0%

Change to read:

- **Chloride and Sulfate,** *Chloride* ⟨221⟩

Sample solution: Dilute 1.0 mL of the *Sample solution* from the test for *Color of Solution* with water to 20 mL, and add 1 mL of nitric acid and 1 mL of silver nitrate TS. Mix, and allow to stand for 5 min, protected from direct sunlight.

Control solution: Dilute 0.71 mL of 0.020 N hydrochloric acid to 100 mL. Mix 10 mL of this solution with water to 20 mL, and add 1 mL of nitric acid and 1 mL of silver nitrate TS. Mix, and allow to stand for 5 min, protected from direct sunlight.

Analysis

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(See ▲*Visual Comparison ⟨630⟩*▲ (CN 1-May-2019) .)

Compare the turbidity of the *Sample solution* and *Control solution*, if any.

Acceptance criteria: 0.5%. Any turbidity produced by the *Sample solution* does not exceed that of the *Control solution*.

SPECIFIC TESTS

- **pH ⟨791⟩**

Sample solution: Use the *Sample solution* from the test for *Color of Solution*.

Acceptance criteria: 5.5–8.0

- **Loss on Drying ⟨731⟩**

Sample: 1.0 g

Analysis: Dry the *Sample* at 105° to constant weight.

Acceptance criteria: NMT 10.0%

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

Sample: An amount equivalent to 6.0 g of dried Hymetellose

Analysis: While stirring, add the *Sample* to 150 g of carbon dioxide-free water heated to 90°. Stir with a propeller-type stirrer for 10 min, place the flask in a bath of ice water, continue the stirring, and allow to remain in the bath of ice water for 40 min to ensure that dissolution is complete. Adjust the mass of the solution to 300 g, and centrifuge the solution to expel any entrapped air. Adjust the temperature of the solution to 20 ± 0.1°, and determine the viscosity using a rotational viscometer with a shear rate of 10/s.

Acceptance criteria: The apparent viscosity is 75%–140% of the value stated on the label.

- **Color of Solution**

Diluent: 27.5 mL of hydrochloric acid in 1000 mL of water

Standard solution: Prepare immediately before use. Mix 2.4 mL of ferric chloride CS and 0.6 mL of cobaltous chloride CS with *Diluent* to make 10 mL, and dilute 5 mL of this solution with *Diluent* to make 100 mL.

Sample solution: While stirring, add a portion equivalent to 1.0 g of dried Hymetellose to 50 g of carbon dioxide-free water heated to 90°. Allow to cool, adjust the weight of the solution to 100 g with carbon dioxide-free water, and stir until dissolution is complete.

Analysis: Make the comparison by viewing the substance and the solution downward in matched color-comparison tubes against a white surface (see *Color and Achromicity ⟨631⟩*).

Acceptance criteria: The *Sample solution* is not more intensely colored than the *Standard solution*.

Change to read:

- **Clarity of Solution**

Hydrazine sulfate solution: 10 mg/mL of hydrazine sulfate. Allow to stand for 4–6 h before use.

[**Caution—**Hydrazine sulfate is highly toxic. Avoid skin contact.]

Methenamine solution: Transfer 2.5 g of methenamine to a 100-mL glass-stoppered flask, add 25.0 mL of water, insert the glass stopper, and mix to dissolve.

Primary opalescent mixture: To the flask containing *Methenamine solution* add 25.0 mL of *Hydrazine sulfate solution*, mix, and allow to stand for 24 h. This suspension is stable for 2 months. Mix before use, and do not use if it adheres to the container.

Opalescence standard: Dilute 15.0 mL of *Primary opalescent mixture* with water to 1000.0 mL. Use this suspension within 24 h after preparation.

Reference suspension: Transfer 30.0 mL of *Opalescence standard* to a 100-mL volumetric flask, and dilute with water to volume.

Sample solution: Use the solution from the test for *Color of Solution*.

Analysis: Transfer a sufficient portion of the *Sample solution* 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 the *Reference suspension* to a separate matching test tube. Compare the *Sample solution* and the *Reference suspension* in diffused daylight, viewing vertically against a black background (see ▲*Visual Comparison ⟨630⟩*▲ (CN 1-May-2019)) 5 min after preparation of the *Reference suspension*.

Acceptance criteria: The *Sample solution* is not more opalescent than the *Reference suspension*.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers. No storage requirements are specified.
- **Labeling:** Label it to indicate the viscosity of the solution (1 in 50) at 20°.

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

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HYMETELLOSE	Documentary Standards Support	CE2020 Complex Excipients

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