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Microcrystalline Cellulose and Carboxymethylcellulose Sodium

DEFINITION

Microcrystalline Cellulose and Carboxymethylcellulose Sodium is a colloid-forming, attrited mixture of Microcrystalline Cellulose and Carboxymethylcellulose Sodium. It contains NLT 75.0% and NMT 125.0% of the labeled amount of carboxymethylcellulose sodium, calculated on the dried basis. The viscosity of its aqueous dispersion of percent by weight stated on the label is NLT 60.0% and NMT 140.0% of that stated on the label in centipoises.

IDENTIFICATION

• A.

Sample: 6 g

Analysis: Mix the *Sample* with 300 mL of water in a blender at 18,000 rpm for 5 min.

Acceptance criteria: A white, opaque dispersion is produced that does not settle on standing.

• B.

Sample: The dispersion obtained in *Identification* test A

Analysis: Add several drops of the *Sample* to a solution of aluminum chloride (100 mg/mL).

Acceptance criteria: Each drop forms a white, opaque globule that does not disperse on standing.

• C.

Sample: The dispersion obtained in *Identification* test A

Analysis: Add 3 mL of iodine TS to the *Sample*.

Acceptance criteria: No blue or purplish-blue color is produced.

ASSAY

• CARBOXYMETHYLCELLULOSE SODIUM

Sample solution: Transfer 2000 mg of Microcrystalline Cellulose and Carboxymethylcellulose Sodium to a glass-stoppered, 250-mL conical flask. Add 75 mL of glacial acetic acid, attach a condenser, and reflux for 2 h. Cool, and transfer the mixture to a 250-mL beaker with the aid of small volumes of glacial acetic acid.

Titrimetric conditions

Mode: Direct titration

Titrant: 0.1 N perchloric acid in dioxane VS

Endpoint detection: Potentiometry

Analysis: Titrate the *Sample solution* and calculate the percentage of carboxymethylcellulose sodium in the sample taken:

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

V_s = *Titrant* volume consumed by the *Sample* (mL)

N = actual normality of the *Titrant* (mEq/mL)

F = equivalency factor, 296.0 mg/mEq

W = *Sample* weight (mg)

Acceptance criteria: 75.0%–125.0% on the dried basis

IMPURITIES

• [RESIDUE ON IGNITION \(281\)](#): NMT 5.0%

SPECIFIC TESTS

• [VISCOSITY—ROTATIONAL METHODS \(912\)](#)

Analysis: Determine the amounts of Microcrystalline Cellulose and Carboxymethylcellulose Sodium needed to prepare 600 g of a suitable dispersion, calculated on the dried basis. Transfer an amount of water to a 1000-mL blender bowl. Begin stirring with an 18,000 rpm blender at a reduced speed obtained by adjusting the voltage to 30 volts by means of a suitable transformer, and immediately add the accurately weighed portion of Microcrystalline Cellulose and Carboxymethylcellulose Sodium, taking care to avoid contacting the sides of the bowl

with the powder. Continue stirring at this speed for 15 s following the addition of the powder, then increase the transformer setting to 115 volts, and mix for 2 min, accurately timed, at 18,000 rpm. Stop the blender, and lower the appropriate spindle of a suitable rotational viscometer into the dispersion. Thirty s after cessation of mixing, start the viscometer, and determine the viscosity using the appropriate spindle to obtain a scale reading between 10% and 90% of full-scale at a speed of 20 rpm. Determine the scale reading after 30 s of rotation, and calculate the viscosity, in centipoises, by multiplying the scale reading by the constant for the spindle used at 20 rpm.

Acceptance criteria: 60.0%–140.0% of that stated on the label, in centipoises

• [pH \(791\)](#)

Sample solution: The dispersion prepared in the test for [Viscosity—Rotational Methods \(912\)](#).

Acceptance criteria: 6.0–8.0

• [Loss on Drying \(731\)](#)

Analysis: Dry a sample at 105° to constant weight.

Acceptance criteria: NMT 8.0%

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers, store in a dry place, and avoid exposure to excessive heat.
- **LABELING:** Label it to indicate the percentage content of carboxymethylcellulose sodium and the viscosity of the dispersion in water of the designated weight percentage composition.

Auxiliary Information - Please [check for your question in the FAQs](#) before contacting USP.

Topic/Question	Contact	Expert Committee
MICROCRYSTALLINE CELLULOSE AND CARBOXYMETHYLCELLULOSE SODIUM	Documentary Standards Support	CE2020 Complex Excipients

Chromatographic Database Information: [Chromatographic Database](#)

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