https://trungtamthuoc.com/

Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Jan-2018
Document Type: USP Monographs
DocId: GUID-F82470B6-EEAD-4523-9545-ED2CEEED01CB_3_en-US
DOI: https://doi.org/10.31003/USPNF_M13210_03_01
DOI Ref: s29dd

© 2025 USPC
Do not distribute

Carboxymethylcellulose Sodium

Cellulose carboxymethyl ether sodium salt

CAS RN®: 9004-32-4.

DEFINITION

Carboxymethylcellulose Sodium is the sodium salt of a polycarboxymethyl ether of cellulose. It contains NLT 6.5% and NMT 9.5% of sodium (Na), calculated on the dried basis.

IDENTIFICATION

- **A. Procedure**

Sample solution: Add 1 g of powdered Carboxymethylcellulose Sodium to 50 mL of water, while stirring to produce a uniform dispersion. Continue the stirring until a clear solution is produced.

Analysis: To 1 mL of the *Sample solution*, diluted with an equal volume of water in a small test tube, add 5 drops of 1-naphthol TS. Incline the test tube, and carefully introduce down the side of the tube 2 mL of sulfuric acid so that it forms a lower layer.

Acceptance criteria: A red-purple color develops at the interface.

- **B. Procedure**

Sample solution: Use the *Sample solution* from *Identification* test *A*.

Analysis: To 5 mL of the *Sample solution*, add an equal volume of barium chloride TS.

Acceptance criteria: A fine, white precipitate is formed.

- **C. Identification Tests—General, *Sodium*⟨191⟩:** A portion of the *Sample solution* meets the requirements.

Sample solution: Use the *Sample solution* from *Identification* test *A*.

ASSAY

- **Procedure**

Sample solution: Transfer to a beaker 500 mg of Carboxymethylcellulose Sodium, add 80 mL of glacial acetic acid, heat the mixture in a boiling water bath for 2 h, and cool to room temperature.

Analysis: Titrate the *Sample solution* with 0.1 N perchloric acid VS, determining the endpoint potentiometrically. Each mL of 0.1 N perchloric acid is equivalent to 2.299 mg of Na.

Acceptance criteria: NLT 6.5% and NMT 9.5% of Na, on the dried basis

SPECIFIC TESTS

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

Analysis: Determine the viscosity in a water solution at the concentration stated on the label. Using undried Carboxymethylcellulose Sodium, weigh the amount that, on the dried basis, will provide 200 g of solution of the stated concentration. Add the substance in small amounts to 180 mL of stirred water contained in a tared, wide-mouth bottle, continue stirring rapidly until the powder is well wetted, add sufficient water to make the mixture weigh 200 g, and allow to stand, with occasional stirring, until solution is complete. Adjust the temperature to 25 ± 0.2°, and determine the viscosity, using a rotational type of viscometer, making certain that the system reaches equilibrium before taking the final reading.

Acceptance criteria: The viscosity of solutions of 2% or higher concentration is NLT 80.0% and NMT 120.0% of that stated on the label; the viscosity of solutions of less than 2% concentration is NLT 75.0% and NMT 140.0% of that stated on the label.

- **pH ⟨791⟩:** 6.5–8.5 in a solution (1 in 100)
- **Loss on Drying ⟨731⟩:** Dry a sample at 105° for 3 h: it loses NMT 10.0% of its weight.

ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in tight containers.
- **Labeling:** Label it to indicate the viscosity in solutions of stated concentrations.

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

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

OFFICIAL

www.webofpharma.com

https://trungtamthuoc.com/

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
Pharmacopeial Forum: Volume No. 46(5)

Current DocID: GUID-F82470B6-EEAD-4523-9545-ED2CEEED01CB_3_en-US
Previous DocID: GUID-F82470B6-EEAD-4523-9545-ED2CEEED01CB_1_en-US
DOI: https://doi.org/10.31003/USPNF_M13210_03_01
DOI ref: s29dd

OFFICIAL