Status: Currently Official on 14-Feb-2025
Official Date: Official as of 01-Jan-2018
Document Type: USP Monographs
DocId: GUID-1CA702AA-9628-4EF8-A3CE-24B85665D809_3_en-US
DOI: https://doi.org/10.31003/USPNF_M13240_03_01
DOI Ref: c1h0a



# Carboxymethylcellulose Sodium Paste

**DEFINITION**
Carboxymethylcellulose Sodium Paste contains NLT 16.0% and NMT 17.0% of carboxymethylcellulose sodium.

**IDENTIFICATION**

• **A.**

**Sample solution:** Digest a quantity of Paste, equivalent to 1 g of carboxymethylcellulose sodium, with 50 mL of water until the solution is virtually complete. Filter.

**Analysis:** To 30 mL of the *Sample solution* add 3 mL of hydrochloric acid. Filter the solution, and save the filtrate for *Identification* test *C*.

**Acceptance criteria:** A white precipitate is formed.

• **B.**

**Sample solution:** The remainder of the *Sample solution* prepared in *Identification* test *A*

**Analysis:** To 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⟩:** The filtrate from *Identification* test *A* meets the requirements of the tests.

**ASSAY**

• **Procedure**

**Sample:** 2 g

**Titrimetric system**

(See *Titrimetry* ⟨541⟩.)

**Mode:** Direct titration

**Titrant:** 0.1 N perchloric acid in dioxane VS

**Endpoint detection:** Potentiometric

**Analysis:** Transfer the *Sample* to a glass-stoppered, 250-mL conical flask. Add 75 mL of glacial acetic acid, attach a condenser, and reflux for 2 h. Cool, transfer the mixture to a 250-mL beaker with the aid of small volumes of glacial acetic acid. Titrate with *Titrant*. Each mL of 0.1 N perchloric acid is equivalent to 29.67 mg of carboxymethylcellulose sodium.

**Acceptance criteria:** 16.0%–17.0%

**SPECIFIC TESTS**

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** The total bacterial count does not exceed $10^3$ cfu/g, and the tests for *Salmonella* species and *Escherichia coli* are negative.

• **Consistency**

**Apparatus:** A penetrometer fitted with a polished cone-shaped metal plunger weighing 150 g, having a detachable steel tip of the following dimensions: the tip of the cone has an angle of 30°; the point of the tip is truncated to a diameter of 0.381 ± 0.025 mm; the base of the tip is 8.38 ± 0.05 mm in diameter; and the length of the tip is 14.94 ± 0.05 mm.

The remaining portion of the cone has an angle of 90°, is 28 mm in height, and has a maximum diameter at the base of 65 mm. The containers for the test are flat-bottom metal cylinders that are 100 ± 6 mm in diameter and NLT 65 mm in height. They are constructed of at least 1.6-mm (16-gauge) metal, and are provided with well-fitting, water-tight covers.

**Sample:** Paste

**Analysis:** Place the required number of containers in an oven, bring them and a quantity of the *Sample* to a temperature of 82 ± 2.5°, and pour the *Sample* into one or more of the containers, filling to within 6 mm of the rim. Cool to 25 ± 2.5° over a period of NLT 16 h, protected from drafts. Two h before the test, place the containers in a water bath at 25 ± 0.5°. If the room temperature is below 23.5° or above 26.5°, adjust the temperature of the cone to 25 ± 0.5° by placing it in the water bath.

Without disturbing the surface of the substance under test, place the container on the penetrometer table, and lower the cone until the tip just touches the top surface of the test substance at a spot 25–38 mm from the edge of the container. Adjust the zero setting and quickly release the plunger, then hold it free for 5 s. Secure the plunger, and read the total penetration from the scale. Make three or more trials, each so spaced that there is no overlapping of the areas of penetration. Where the penetration exceeds 20 mm, use a separate container of the test substance for each trial. Read the penetration to the nearest 0.1 mm.

Calculate the average of the three or more readings, and conduct further trials to a total of 10 if the individual results differ from the average by more than ±3%.

**Acceptance criteria:** The final average of the trials is 30.0–36.0 mm, indicating a consistency value of between 300 and 360.

- **Loss on Drying** ⟨731⟩

  **Analysis:** Dry at 105° for 3 h.

  **Acceptance criteria:** NMT 2.0%

## ADDITIONAL REQUIREMENTS

- **Packaging and Storage:** Preserve in well-closed containers, and avoid prolonged exposure to temperatures exceeding 30°.

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

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

**Chromatographic Database Information:** Chromatographic Database

**Most Recently Appeared In:**
Pharmacopeial Forum: Volume No. PF 31(5)

**Current DocID: GUID-1CA702AA-9628-4EF8-A3CE-24B85665D809_3_en-US**
**Previous DocID: GUID-1CA702AA-9628-4EF8-A3CE-24B85665D809_1_en-US**
**DOI: https://doi.org/10.31003/USPNF_M13240_03_01**
**DOI ref: c1h0a**