

Carboxymethylcellulose Calcium

Add the following:

▲Portions of this monograph that are national *USP* text, and are not part of the harmonized text, are marked with symbols (♣, ♠) to specify this fact. ▲ (NF 1-Aug-2024)

Cellulose, carboxymethyl ether, calcium salt;

Cellulose carboxymethyl ether calcium salt

CAS RN[®]: 9050-04-8.

DEFINITION

Carboxymethylcellulose Calcium is the calcium salt of a polycarboxymethyl ether of cellulose.

IDENTIFICATION

• A.

Sample solution: Shake thoroughly 0.1 g of Carboxymethylcellulose Calcium with 10 mL of water, followed by 2 mL of 1 N sodium hydroxide, and allow to stand for 10 min. [NOTE—Save the unused portion of the *Sample solution* for use in *Identification B* and *C*.]

Analysis: To 1 mL of the *Sample solution* add water to make 5 mL. To 1 drop of the resulting solution, add 0.5 mL of chromotropic acid TS, and heat in a water bath for 10 min.

Acceptance criteria: A red-purple color develops.

• B.

Analysis: Shake 5 mL of the *Sample solution* prepared in *Identification A* with 10 mL of acetone.

Acceptance criteria: A white, flocculent precipitate is formed.

• C.

Analysis: Shake 5 mL of the *Sample solution* prepared in *Identification A* with 1 mL of ferric chloride TS.

Acceptance criteria: A brown, flocculent precipitate is formed.

Change to read:

• D. **IDENTIFICATION TESTS—GENERAL** (191), *Chemical Identification Tests, Calcium*

Analysis: Ignite 1 g to ash, dissolve the residue in 10 mL of water and 5 mL of 6 N acetic acid, and filter, if necessary. Boil the filtrate, cool, ▲add 2 drops of methyl red TS, ▲ (NF 1-Aug-2024) and neutralize with 6 N ammonium hydroxide. ▲Add 3 N hydrochloric acid dropwise until the solution is acid to the indicator. Upon the addition of ammonium oxalate TS, a white precipitate is formed. This precipitate is insoluble when 6 N acetic acid is added but dissolves in hydrochloric acid. ▲ (NF 1-Aug-2024)

Acceptance criteria: Meets the requirements

IMPURITIES

• **RESIDUE ON IGNITION** (281): 10.0%–20.0%; use 1.0 g, previously dried

• **CHLORIDE AND SULFATE** (221), *Chloride*

Sample stock solution: Shake thoroughly 0.80 g with 50 mL of water, dissolve in 10 mL of 1 N sodium hydroxide, and add water to make 100 mL. [NOTE—Retain a portion of the *Sample stock solution* for use in the test for *Sulfate*.]

Sample solution: Heat 20 mL of the *Sample stock solution* with 10 mL of 2 N nitric acid in a water bath until a flocculent precipitate is formed, cool, centrifuge, and remove the supernatant. Wash the precipitate with three 10-mL portions of water by centrifuging each time, combine the supernatant and the washings, add water to make 100 mL, and mix.

Acceptance criteria: A 25-mL portion of the *Sample solution* shows no more chloride than is contained in 0.20 mL of 0.020 N hydrochloric acid (0.36%).

Change to read:

- **CHLORIDE AND SULFATE** (221), *Sulfate*

▲ [NOTE—This test is only necessary if sulfuric acid is utilized in the manufacturing process, as indicated on the labeling.] ▲ (NF 1-Aug-2024)

Sample solution: Heat 10 mL of the *Sample stock solution* prepared in the test for *Chloride* with 1 mL of hydrochloric acid in a water bath until a flocculent precipitate is formed. Cool, centrifuge, and remove the supernatant. Wash the precipitate with three 10-mL portions of water by centrifuging each time, combine the supernatant and the washings, add water to make 100 mL, and mix.

Acceptance criteria: A 25-mL portion of the *Sample solution* shows no more sulfate than is contained in 0.21 mL of 0.020 N sulfuric acid (1.0%).

SPECIFIC TESTS

- **ALKALINITY:** Shake thoroughly 1.0 g with 50 mL of freshly boiled and cooled water, and add 2 drops of phenolphthalein TS: no red color develops.

Change to read:

- **LOSS ON DRYING** (731): Dry ▲ 1.0 g of ▲ (NF 1-Aug-2024) a sample at 105° for 4 h: it loses NMT 10.0% of its weight.

ADDITIONAL REQUIREMENTS

Change to read:

- ▲▲ (NF 1-Aug-2024) **PACKAGING AND STORAGE:** Preserve in tight containers. ▲▲ (NF 1-Aug-2024)

Add the following:

- ▲ • **LABELING:** Label to indicate if sulfuric acid is utilized in the manufacturing process. ▲ (NF 1-Aug-2024)

Page Information:

Not Applicable

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