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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)

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

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

Chromatographic Database Information: Chromatographic Database

Most Recently Appeared In:
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