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Carmellose

Attributes	EP	JP	USP
Definition	+	+	+
Identification A*	+	+	+
Identification B	+	+	+
Chloride	+	+	+
Sulfate	+	+	+
Loss on Drying	+	+	+
Residue on Ignition	+	+	+

* EP and USP will adopt Carmellose Reference Standard; JP will adopt a Reference spectrum.

Legend: + will adopt and implement; – will not stipulate

Nonharmonized attributes: Heavy Metals and Packaging and Storage (USP)

Reagents and reference materials: Each pharmacopeia will adapt the text to take account of local reference substances and spectra and reagent specifications.

Carboxymethylcellulose
CAS RN®: 9000-11-7.

DEFINITION

Carmellose is a carboxymethyl ether of cellulose.

IDENTIFICATION

Change to read:

- **A.** [▲ SPECTROSCOPIC IDENTIFICATION TESTS \(197\), Infrared Spectroscopy: 197K▲](#) (CN 1-MAY-2020)
- **B.** [pH \(791\)](#)
Sample solution: 10 mg/mL of Carmellose suspension
Acceptance criteria: 3.5–5.0

IMPURITIES

Inorganic Impurities

- [RESIDUE ON IGNITION \(281\)](#): NMT 1.5% on 1 g, calculated on the dried basis
- **CHLORIDES**

Sample solution: Shake well 0.8 g of Carmellose with 50 mL of water, dissolve in 10 mL of sodium hydroxide TS, and add water to make 100 mL. Heat 20 mL of this solution with 10 mL of nitric acid, diluted on a water bath until a flocculent precipitate is produced. Cool, centrifuge, and take out the supernatant. Wash the precipitate with three 10-mL portions of water by centrifuging each time, combine the supernatant and the washings, and add water to make 100 mL. Take 25 mL of this solution, add 6 mL of nitric acid, diluted, and dilute with water to make 50 mL.

Control solution: 0.40 mL of 0.01 N hydrochloric acid VS and 6 mL of nitric acid, diluted. Add water to make 50 mL.

Analysis: Add 1 mL of silver nitrate TS to the *Sample solution* and to the *Control solution*, mix well, and allow to stand for 5 min protected from direct sunlight. Compare the opalescence developed in both solutions against a black background by viewing downward or transversely.

Acceptance criteria: The turbidity produced in the *Sample solution* is NMT that in the *Control solution* (NMT 0.36%).

• **SULFATES**

Sample solution: Shake well 0.40 g of Carmellose with 25 mL of water, dissolve in 5 mL of sodium hydroxide TS, and add 20 mL of water. Heat this solution with 2.5 mL of hydrochloric acid in a water bath until a flocculent precipitate is produced. Cool, centrifuge, and take out the supernatant. Wash the precipitate with three 10-mL portions of water by centrifuging each time, combine the supernatant and the washings, and add water to make 100 mL. Filter this solution, discard 5 mL of the first filtrate, take 25 mL of the subsequent filtrate, add 1 mL of hydrochloric acid, and dilute with water to make 50 mL.

Control solution: 1.5 mL of 0.01 N sulfuric acid VS and 1 mL of dilute hydrochloric acid. Add water to make 50 mL.

Analysis: Add 2 mL of barium chloride TS to the *Sample solution* and to the *Control solution*, mix well, and allow to stand for 10 min. Compare the turbidity developed in both solutions against a black background by viewing downward or transversely.

Acceptance criteria: The turbidity produced in the *Sample solution* is NMT that of the *Control solution* (NMT 0.72%).

SPECIFIC TESTS

- [Loss on Drying \(731\)](#): Dry 1 g at 105° for 4 h: it loses NMT 8.0% of its weight.

ADDITIONAL REQUIREMENTS

- **PACKAGING AND STORAGE:** Preserve in tight containers.
- [USP REFERENCE STANDARDS \(11\)](#)
[USP Carmellose RS](#)

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

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

Chromatographic Database Information: [Chromatographic Database](#)

Most Recently Appeared In:

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