

## BRIEFING

**Carmellose.** The Japanese Pharmacopoeia is the coordinating pharmacopoeia for the international harmonization of the compendial standards for the Carmellose monograph, as part of the process of international harmonization of monographs and general analytical methods of the European, Japanese, and United States pharmacopoeias. The following monograph, which represents the **ADOPTION STAGE 6** document, is based on the Official Inquiry Stage 4 document which appeared in PF 33(3). Because there is no existing monograph for this excipient, a new monograph based on the **ADOPTION STAGE 6** document is presented.

(EM2: K. Moore.)

RTS—C71283

### Add the following:

#### ▲ 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 pharmacopoeia will adapt the text to take account of local reference substances and spectra and reagent specifications.

Carboxymethylcellulose [9000-11-7].

### DEFINITION

Carmellose is a carboxymethyl ether of cellulose.

### IDENTIFICATION

- **A. INFRARED ABSORPTION** 〈 197K 〉

- **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, and dilute with water to make 50 mL.

**Control solution:** 0.40 mL of 0.01 N hydrochloric acid VS and 6 mL of dilute nitric acid. 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%).

- **HEAVY METALS, Method II** 〈 231 〉 : Proceed with 1.0 g of Carmellose and perform the test. Prepare the control solution with 2.0 mL of *Standard Lead Solution*.

**Acceptance criteria** NMT 20 ppm ◆

**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 ◆ ▲ NF28

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

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