Carmellose

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Manufacturers, regulatory authorities, health authorities, researchers, and other stakeholders are invited to provide their feedback and comments on this draft proposal. Comments and samples received after the last date will not be considered by the IPC before finalizing the monograph.

Please send any comments you may have on this draft document to arnd-ipc@gov.in , with a copy to Dr. Gaurav Pratap Singh (email: gpsingh.ipc@gov.in) before the last date for comments.

Document History and Schedule for the Adoption Process

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Further follow-up action as required.	

Carmellose

Carboxymethylcellulose

This Monograph has been harmonized with corresponding texts of the European Pharmacopoeia, the Japanese Pharmacopoeia and the United States Pharmacopoeia. Portion of the IP text that are not part of the PDG harmonized text, are marked with symbols (♦ ♦).

Carmellose is a carboxymethyl ether of cellulose; partly *O*-carboxymethylated cellulose.

Category. Pharmaceutical aid.

Description. A white or almost white powder, hygroscopic.

Identification

Determine by infrared absorption spectrophotometry (2.4.6). Compare the spectrum with that obtained with *carmellose IPRS* or with the reference spectrum of carmellose.

Tests

pH (2.4.24). 3.5 to 5.0, determined in a 1.0 per cent w/v suspension in *carbon dioxide-free water*.

Chloride. Not more than 0.36 per cent.

Shake 0.8 g with 50 ml of *water* dissolve in 10 ml of *1 M sodium hydroxide* and dilute to 100 ml with *water.* Heat on a water-bath a mixture of 10 ml of *dilute nitric acid* and 20 ml of this solution until a flocculent precipitate is produced. Cool, centrifuge and take out the supernatant. Wash the precipitate with 3 quantities, each of 10 ml, of *water,* centrifuging each time. Combine the supernatant and the washings and dilute to 100 ml with *water.* To 25 ml of this solution add 6 ml of *dilute nitric acid* and dilute to 50 ml with *water* (test solution). Prepare the reference solution in the same manner, using 0.4 ml of *0.01 M hydrochloric acid.* Add 1 ml of *silver nitrate solution* to the test solution and the reference solution. Allow to stand protected from light for 5 minutes. Any opalescence in the test solution is not more intense than that in the reference solution.

Sulphates. Not more than 0.72 per cent.

Shake 0.4 g with 25 ml of *water,* dissolve in 5 ml of *1 M sodium hydroxide* 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 3 quantities, each of 10 ml, of *water,* centrifuging each time. Combine the supernatant and the washings, and dilute to 100 ml with *water.* Filter, and discard the first 5 ml of the filtrate. To 25 ml of the filtrate add 1 ml of *dilute hydrochloric acid* and dilute to 50 ml with *water* (test solution). Prepare the reference solution in the same manner, using 1.5 ml of *0.005 M sulphuric acid*. Add 2 ml of a 12 per cent w/v g per litter solution of *barium chloride* to the test solution and the reference solution. Mix and allow to stand for 10 minutes. The white turbidity produced in the test solution is not thicker than that in the reference solution.

Sulphated ash (2.3.18). Not more than 1.5 per cent.

Loss on drying (2.4.19). Not more than 8.0 per cent, determined on 1.0 g by drying in an oven at 105° for 4 hours.

Storage. Store protected from moisture.

Solubility. Practically insoluble in *anhydrous ethanol*. It swells with *water* to form a suspension and becomes viscid in 1 *M sodium hydroxide.*