Carboxymethylcellulose Calcium

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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. Manufacturers are also invited to submit samples of their products to the IPC to ensure that the proposed monograph adequately controls the quality of the product(s) they manufacture. 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 lab.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.	

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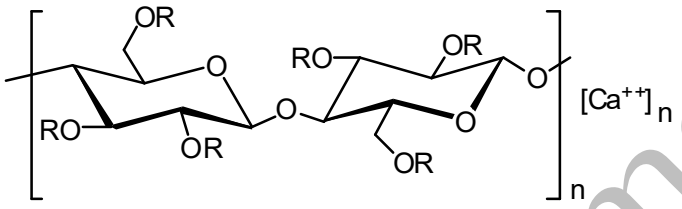
Change **to:**

Carboxymethylcellulose Calcium

Carmellose Calcium

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



R = H ; R = CH_2COOH

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

♦**Category**. Pharmaceutical aid.

Description. A white to yellowish-white powder.♦

Identification

A. Shake 0.1 g thoroughly with 10 ml of *water*, add 2 ml of *1 M sodium hydroxide* and allow to stand for 10 minutes (Solution A). Dilute 1 ml of solution A to 5 ml with *water.* To 0.05 ml of the solution, add 0.5 ml of a 0.05 per cent w/v solution of *chromotropic acid sodium salt* in 75 per cent w/w solution of *sulphuric acid* and heat on a water-bath for 10 minutes; a red-purple colour develops.

B. Shake 5 ml of solution A with 10 ml of *acetone*; a white, flocculent precipitate is produced.

C. Shake 5 ml of solution A with 1 ml of *ferric chloride solution*; a brown, flocculent precipitate is formed.

D. Ignite 1 g to ash and dissolve the residue in a mixture of 5 ml of *6 M acetic acid* and 10 ml of *water,* filter if necessary. Boil and cool, add 0.2 ml of 1 per cent w/v *methyl red* in *ethanol* and neutralise with *6M ammonium hydroxide*. Add *3 M hydrochloric acid* drop wise until the indicator colour changes. Upon the addition of *ammonium oxalate solution*; a white precipitate is formed which is insoluble in *acetic acid* but dissolves in *hydrochloric acid*.

Tests

Alkalinity. Shake 1.0 g thoroughly with 50 ml of *carbon dioxide-free water* and add 0.2 ml of *phenolphthalein solution*. No red colour develops.

Chlorides (2.3.12). Not more than 0.36 per cent.

Test stock solution. Shake thoroughly 0.8 g with 50 ml of *water*, dissolve in 10 ml of *1 M sodium hydroxide* and dilute to 100 ml with *water*. [*NOTE – Retain a portion of the test stock solution for use in the test for Sulphate*.]

Heat 20 ml of the test stock solution with 10 ml of *2 M nitric acid* in a water-bath until a flocculent precipitate 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 washings and dilute to 100 ml with *water*; a 25-ml portion of the test solution shows no more chloride than is contained in 0.2 ml of *0.2 M hydrochloric acid*.

Sulphates (2.3.17). Not more than 1.0 per cent

NOTE – Carry out this test if sulfuric acid is used in manufacturing process.

Heat 10 ml of the test 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 washings and dilute to 100 ml with *water*; a 25-ml portion of the test solution shows no more sulphate than is contained in 0.2 ml of *0.02 M sulphuric acid*.

Sulphated ash (2.3.18). 10.0 per cent to 20.0 per cent, determined on 1.0 g of the dried substance.

Loss on drying (2.4.19). Not more than 10.0 per cent, determined on 1.0 g by drying in an oven at 105° for 4 hours.

♦**Storage**. Store protected from moisture.♦