Calcium Polystyrene Sulphonate

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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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Calcium Polystyrene Sulphonate

$C_8H_7CaO_3S$ Mol. Wt. 223.3

Calcium Polystyrene Sulphonate is a cation-exchange resin prepared in the calcium form containing not less than 6.5 per cent w/w and not more than 9.5 per cent w/w of calcium, calculated on the dried basis. Each g exchanges not less than 1.3 mEq and not more than 2.0 mEq of potassium, calculated on the dried basis.

Category. ~~Pharmaceutical aid;~~ Treatment of hyperkalemia.

Description. A cream to light brown, fine powder.

Identification

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

B. It gives reaction (A) of calcium (2.3.1).

Tests

Particle size. Sieve 20 g of the substance under examination for 5 minutes. Not more than 1 per cent w/w is retained on a 150 µm sieve.

Potassium. Not more than 0.1 per cent of K, determine by Method A for atomic emission spectrophotometry (2.4.3) measuring at 767 nm or by Method A of flame photometry (2.4.4), using a solution prepared by dissolving 1.1 g of the substance under examination in 5 ml of *hydrochloric acid*, heat to boiling. Cool and add 10 ml of *water*, filter. Wash the filter and residue with *water* and dilute the filtrate and washing to 25.0 ml with *water*. Use *potassium solution AAS (100 ppm K) or potassium solution FP*, suitably diluted with water to prepare the reference solutions.

Sodium. Not more than 0.1 per cent of Na, determine by Method A for atomic emission spectrophotometry (2.4.3) measuring at 589 nm or by Method A of flame photometry (2.4.4), using a solution prepared by dissolving 1.1 g of the substance under examination in 5 ml of *hydrochloric acid*, heat to boiling. Cool and add 10 ml of *water*, filter. Wash the filter and residue with *water* and dilute the filtrate and washing to 25.0 ml with *water*. Use *sodium solution AAS (200 ppm K) or sodium solution FP* suitably diluted with *water* to prepare the reference solutions.

Arsenic. (2.3.10). 10 g complies with the limit test for arsenic (1 ppm).

Heavy metal. (2.3.13). 1.0 g complies with limit test for heavy metals, method B (20 ppm).

Loss on drying. (2.4.19). Not more than 8.0 per cent, determined on 2.0 g by drying, in an oven at 70º at a pressure not exceeding 0.7 KPa for 16 hours.

Styrene. Determine by liquid chromatography (2.4.14).

Test solution. Disperse 10 g of the substance under examination in 10 ml of *acetone* with the aid of mechanical shaker for 30 minutes. Centrifuge and use the supernatant liquid.

Reference solution. A 0.0001 per cent w/v solution of *styrene IPRS* in *acetone*.

Chromatographic system

- a stainless steel column 30 cm x 4.0 mm, packed with octadecylsilane bonded to porous silica (10 µm) (Such as µBondapak),
- mobile phase: a mixture of 50 volumes of *acetonitrile* and 50 volumes of *water*,
- flow rate: 2 ml per minute,
- spectrophotometer set at 254 nm,
- injection volume: 20 µl.

Inject the reference solution and the test solution. In the chromatogram obtained with test solution, the area of any peak corresponding to styrene is not more than the area of the peak in the chromatogram obtained with the reference solution (1

ppm).

Potassium exchange capacity. Transfer 3 g of the substance under examination to a dry 250-ml glass-stoppered flask, add 100.0 ml of a solution containing 0.7455 per cent w/v of *potassium chloride* and 0.4401 per cent w/v of *potassium hydrogen carbonate* in *water* (solution A), stopper and shake for 15 minutes. Filter and dilute 2.0 ml of the filtrate to 1000.0 ml with *water*. Determine the unbound potassium in this solution by using Method A for atomic absorption spectrophotometry (2.4.2) measuring at 767 nm or Method A of flame photometry (2.4.4), using solution A, suitably diluted with *water* to prepare the reference solutions. Calculate the potassium exchange capacity of the substance under examination in milliequivalents taking the concentration of potassium in solution A as 144 milliequivalents of K per liter.

Calcium. Ignite c~~C~~arefully ~~heat~~ 1.0 g in a crucible until a white ash is obtained and dissolve in 10 ml of *2M hydrochloric acid* with the aid of heat. Transfer the resulting solution to a conical flask using 20 ml of *water*. Add 50.0 ml of *0.05M disodium edetate*, 20 ml of *ammonia buffer pH 10.9* and titrate the excess of *disodium edetate* with *0.02M zinc sulphate*, using a 0.5 per cent w/v solution of *mordant black 11* in *ethanol (95 per cent)* as indicator to a red purple end point. Carry out a blank titration.

Each ml of *0.05M disodium edetate* is equivalent to 0.002~~.~~004 ~~m~~g of Ca.

Storage. Store protected from moisture.

Solubility.

Calcium polystyrene sulphonate. Practically insoluble in *water* and in *ethanol (95 per cent)*.