



Edition: BP 2025 (Ph. Eur. 11.6 update)

Calcium Polystyrene Sulfonate

[General Notices](#)

Calcium Polystyrene Sulphonate

Action and use

Used in the treatment of hyperkalaemia.

DEFINITION

Calcium Polystyrene Sulfonate is a cation-exchange resin prepared in the calcium form containing not less than 6.5% w/w and not more than 9.5% w/w of calcium, calculated with reference to the dried substance. Each g exchanges not less than 1.3 mEq and not more than 2.0 mEq of potassium, calculated with reference to the dried substance.

CHARACTERISTICS

A cream to light brown, fine powder.

Practically insoluble in [water](#) and in [ethanol \(96%\)](#).

IDENTIFICATION

- A. The [infrared absorption spectrum, Appendix II A](#), is concordant with the *reference spectrum* of calcium polystyrene sulfonate ([RS 037](#)).
- B. Yields reaction C characteristic of *calcium salts*, [Appendix VI](#).

TESTS

Particle size

Not more than 1% w/w is retained on a 150-µm sieve, [Appendix XVII B](#). Use 20 g and sieve for 5 minutes.

Potassium

Not more than 0.1% of K when determined by *atomic emission spectrophotometry*, [Appendix II D](#), measuring at 766.5 nm and using a solution prepared in the following manner. To 1.1 g of the substance being examined add 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 washings to 25 mL with [water](#). Use [potassium standard solution \(100 ppm K\)](#), suitably diluted with [water](#), to prepare the [standard solutions](#).

Sodium

Not more than 0.1% of Na when determined by *atomic emission spectrophotometry*, [Appendix II D](#), measuring at 589.0 nm and using a solution prepared in the following manner. To 1.1 g of the substance being examined add 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 washings to 25 mL with [water](#). Use *sodium solution (200 ppm Na)*, suitably diluted with [water](#), to prepare the [standard solutions](#).

Arsenic

1 g dispersed in 25 mL of [water](#) complies with the [limit test for arsenic](#), [Appendix VII](#) (1 ppm).

Styrene

Carry out the method for [liquid chromatography](#), [Appendix III D](#), using the following solutions.

- (1) Shake 10 g of the substance being examined with 10 mL of [acetone](#) for 30 minutes, centrifuge and use the supernatant liquid.
- (2) 0.0001% w/v of [styrene](#) in [acetone](#).

CHROMATOGRAPHIC CONDITIONS

- (a) Use a stainless steel column (30 cm × 4 mm) packed with [octadecylsilyl silica gel for chromatography](#) (μ Bondapak C18 is suitable).
- (b) Use isocratic elution and the mobile phase described below.
- (c) Use a flow rate of 2 mL per minute.
- (d) Use an ambient column temperature.
- (e) Use a detection wavelength of 254 nm.
- (f) Inject 20 μ L of each solution.

MOBILE PHASE

Equal volumes of [acetonitrile](#) and [water](#).

LIMITS

In the chromatogram obtained with solution (1):

the area of any peak corresponding to styrene is not greater than the area of the peak in the chromatogram obtained with solution (2) (1 ppm).

Potassium exchange capacity

To 3 g of the substance being examined in a dry 250 mL glass-stoppered flask add 100 mL of a solution containing 0.7455% w/v of [potassium chloride](#) and 0.4401% w/v of [potassium hydrogen carbonate](#) in [water](#) (solution A), stopper and shake for 15 minutes. Filter and dilute 2 mL of the filtrate to 1000 mL with [water](#). Determine the concentration of unbound potassium in this solution by *atomic emission spectrophotometry*, [Appendix II D](#), measuring at 766.5 nm and using solution A suitably diluted with [water](#), to prepare the [standard solutions](#). Calculate the potassium exchange capacity of the substance being examined in milliequivalents taking the concentration of potassium in solution A as 144 milliequivalents of K per litre.

Loss on drying

When dried at 70° at a pressure not exceeding 0.7 kPa for 16 hours, loses not more than 8.0% of its weight. Use 2 g.

Microbial contamination

Carry out a quantitative evaluation for Enterobacteria and certain other Gram-negative bacteria, [Appendix XVI B1](#). 0.01 g of the substance being examined gives a negative result, [Table I](#) (most probable number of bacteria per gram fewer than 10^2).

ASSAY

For calcium

Carefully heat 1 g in a platinum 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 mL of [0.05M disodium edetate VS](#), 20 mL of [ammonia buffer pH 10.9](#) and titrate the excess of disodium edetate with [0.02M zinc sulfate VS](#), using a 0.5% w/v solution of [mordant black 11](#) in [ethanol \(96%\)](#) as indicator to a red purple end point. Each mL of [0.05M disodium edetate VS](#) is equivalent to 2.004 mg of Ca.

STORAGE

Calcium Polystyrene Sulfonate should be kept in an airtight container.