

Draft Proposal for Comments and Inclusion in The Indian Pharmacopoeia

Sodium Polystyrene Sulphonate

Published on: 17.03.2023

Last date for comments: 16.04.2023

This draft proposal contains monograph text for inclusion in the Indian Pharmacopoeia (IP). The content of this draft document is not final, and the text may be subject to revisions before publication in the IP. This draft does not necessarily represent the decisions or the stated policy of the IP or Indian Pharmacopoeia Commission (IPC).

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

Description	Details
Document version	2.0
Monograph proposed for inclusion	IP Addendum 2024
Tentative effective date of monograph	April, 2024
First draft published on IPC website for public comments	18 October, 2022
Draft revision published on IPC website for public comments	Version 2.0 17.03.2023
Further follow-up action as required.	

Sodium Polystyrene Sulphonate

$C_8H_8O_3S$

Mol. Wt. 184.2

Sodium Polystyrene Sulphonate is a cation-exchange resin prepared in the sodium form. Each g of sodium polystyrene sulphonate exchanges not less than 110 mg and not more than 135 mg of potassium, calculated on the anhydrous basis.

Category. Pharmaceutical aid; Treatment of hyperkalaemia

Description. A golden brown, fine powder.

Tests

Limit of ammonium salts. Disperse 1 g of the substance under examination in 5 ml of 1 M sodium hydroxide in a 50 ml beaker. Cover the beaker with a watch glass containing a moistened strip of red litmus paper on the underside and allow to stand for 15 minutes, the litmus paper shows no blue color.

Sodium content. Not less than 9.4 per cent and not more than 11.5 per cent, calculated on the anhydrous basis.

Solution A. A 2.0 per cent w/v solution of low-sodium, low potassium non-ionic surfactant (Such as Activator 90) in water.

Reference solution. Dissolve a quantity of sodium chloride in water to obtain a solution containing 5.0 mg of sodium per ml.

Reference solution graph. Into four 1-liter flasks, pipet, respectively 0, 1, 2, and 3 ml of reference solution. To each flask, add 0.1 ml of nitric acid, 0.1 ml of sulphuric acid, and 10 ml of solution A, dilute with water to volume, and mix. Adjust the scale of a suitable flame spectrophotometer to a reading of 100 at a wavelength of 588 nm with the solution containing 15 mg of sodium per litre. Determine the instrument readings on the other three solutions, and plot the observed readings, on ruled coordinate paper, as the ordinate, and the concentration of sodium, in mg per litre, as the abscissa. The line intersects the ordinate at, or below, a scale reading of 25 ("blank reading").

Procedure. Ash the equivalent of 1 g of substance under examination, with a slight excess of sulphuric acid. Add 1 ml of nitric acid and a few ml of water to the residue. Warm to dissolve, and transfer with water to a 1 liter volumetric flask, dilute with water to volume, and mix. Pipet 10.0 ml of the solution into a 100-ml volumetric flask, add 1 ml of solution A, dilute with water to volume, and mix. Determine the instrument reading concomitantly with the readings obtained for plotting the reference solution, and determine the sodium concentration, in mg per litre, by interpolation from the reference solution graph. Calculate the percentage of sodium, using following expression:

$$A/W$$

Where, A is the weight, in mg, of sodium found per litre and W is the weight, in g, of sodium polystyrene sulphonate taken.

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

Water (2.3.43). Not more than 10 per cent.

Potassium exchange capacity

Solution A. A 2.0 per cent w/v solution of low-sodium, low potassium non ionic surfactant (such as Activator 90) in water.

Reference solution (a). Dissolve a quantity of potassium chloride in water to obtain a solution containing 5.0 mg of potassium per ml.

Reference solution (b). Dissolve a quantity of sodium chloride in water to obtain a solution containing 4.0 mg of sodium per ml.

Reference solution graph. Identify five 1-liter volumetric flasks by the numbers 1, 2, 3, 4, and 5. In that order pipet into the flasks 4, 3, 2, 1, and 0 ml, respectively, of reference solution (b), and in the same order 0, 1, 2, 3, and 4 ml, respectively, of reference solution (a). To each flask add 10 ml of solution A, dilute with water to volume, and mix. Adjust the scale of a suitable flame spectrophotometer to 100 with solution from flask 5 at 766 nm. Determine the instrument readings with solutions from flasks 4, 3, 2, and 1. On ruled coordinate paper, plot the observed instrument readings as the ordinate, and the concentrations, in mg per liter, of potassium as the abscissa.

Procedure. Pipet 100 ml of reference solution (a) into a glass-stoppered flask containing about 1.6 g of sodium polystyrene sulphonate, accurately weighed, shake by mechanical means for 15 minutes, filter, and discard the first 20 ml of the filtrate. Pipet 5 ml of the filtrate into a 1-liter volumetric flask, add 10 ml of solution A, dilute with water to volume, and mix. Observe the flame spectrophotometer readings of the exchanged solution concomitantly with those obtained for plotting the reference solution graph, and determine the potassium concentration, in mg per liter, by interpolation from the reference solution graph. Calculate the

quantity, in mg per g, of potassium adsorbed on the resin using following expression:

$$(X - 20Y)/W$$

Where, X is the weight, in mg, of potassium in 100 ml of reference solution (a) before exchange; Y is the weight, in mg, of potassium per liter as interpolated from the reference solution graph; and W is the weight, in g, of sodium polystyrene sulphonate taken, expressed on the anhydrous basis.

Solubility. Page 293

Insert before, Sodium Propylparaben

Sodium polystyrene sulphonate. Practically insoluble in *water*, in *ethanol (95 per cent)*.

DRAFT FOR COMMENTS