– *size*: *l* = 25 m, Ø = 0.25 mm,

– *stationary phase*: *poly(dimethyl)siloxane R* or another suitable polar phase.

Carrier gas: *nitrogen for chromatography R*.

Flow rate: 1 ml/min.

Split ratio: 1:100.

Temperature:

	Time (min)	Temperature (°C)
Column	0 - 20	150 → 250
Injection port		250
Detector		250

Detection: flame ionisation.

Elution order: cetyl alcohol, heptadecanol (internal standard) and stearyl alcohol.

Inject 1 µl of test solution (a) and test solution (b). If the chromatogram obtained with test solution (b) shows a peak with the same retention time as the peak due to the internal standard in the chromatogram obtained with test solution (a), calculate the ratio *r* using the following expression:

$$\frac{S_{ci}}{S_i}$$

S_{ci} = area of the peak due to cetyl alcohol in the chromatogram obtained with test solution (b),

S_i = area of the peak with the same retention time as the peak due to the internal standard in the chromatogram obtained with test solution (a).

If *r* is less than 300, calculate the corrected area $S_{Ha(corr)}$ of the peak due to the internal standard in the chromatogram obtained with test solution (a) using the following expression:

$$S'_{Ha} - \frac{S_i \times S_c}{S_{ci}}$$

S'_{Ha} = area of the peak due to the internal standard in the chromatogram obtained with test solution (a),

S_c = area of the peak due to cetyl alcohol in the chromatogram obtained with test solution (a).

Inject 1 µl of test solution (c) and test solution (d). Carry out the correction for interference in the same manner as for test solution (a) and calculate the corrected area $S_{Hc(corr)}$ of the peak due to the internal standard in the chromatogram obtained with test solution (c).

Inject equal volumes of the reference solution, test solution (c) and test solution (d). Identify the peaks in the chromatograms obtained with the test solutions by comparison of their retention times with those of the peaks in the chromatogram obtained with the reference solution. Determine the area of each peak.

Calculate the percentage content of sodium cetyl sulphate in the substance to be examined, using the following expression:

$$\frac{(A \times 1.421) \times m'_H \times 100}{S_{Hc(corr)} \times m'}$$

A = area of the peak due to cetyl alcohol in the chromatogram obtained with test solution (c),

m'_H = mass of the internal standard added in the preparation of test solution (c), in milligrams,

$S_{Hc(corr)}$ = corrected area of the peak due to the internal standard in the chromatogram obtained with test solution (c),

m' = mass of the substance to be examined in test solution (c), in milligrams.

Calculate the percentage content of sodium stearyl sulphate in the substance to be examined, using the following expression:

$$\frac{(B \times 1.377) \times m'_H \times 100}{S_{Hc(corr)} \times m'}$$

B = area of the peak due to stearyl alcohol in the chromatogram obtained with test solution (c).

The percentage content of sodium cetostearyl sulphate corresponds to the sum of the percentage content of sodium cetyl sulphate and the percentage content of sodium stearyl sulphate.

LABELLING

The label states, where appropriate, the name and concentration of any added buffer.

01/2008:0193
corrected 6.0

SODIUM CHLORIDE

Natrii chloridum

NaCl M_r 58.44
[7647-14-5]

DEFINITION

Content: 99.0 per cent to 100.5 per cent (dried substance).

CHARACTERS

Appearance: white or almost white, crystalline powder or colourless crystals or white or almost white pearls.

Solubility: freely soluble in water, practically insoluble in anhydrous ethanol.

IDENTIFICATION

A. It gives the reactions of chlorides (*2.3.1*).

B. It gives the reactions of sodium (*2.3.1*).

TESTS

If the substance is in the form of pearls crush before use.

Solution S. Dissolve 20.0 g in *carbon dioxide-free water R* prepared from *distilled water R* and dilute to 100.0 ml with the same solvent.

Appearance of solution. Solution S is clear (*2.2.1*) and colourless (*2.2.2, Method II*).

Acidity or alkalinity. To 20 ml of solution S add 0.1 ml of *bromothymol blue solution R1*. Not more than 0.5 ml of *0.01 M hydrochloric acid* or *0.01 M sodium hydroxide* is required to change the colour of the indicator.

Bromides: maximum 100 ppm.

To 0.5 ml of solution S add 4.0 ml of *water R*, 2.0 ml of *phenol red solution R2* and 1.0 ml of a 0.1 g/l solution of *chloramine R* and mix immediately. After exactly 2 min, add 0.15 ml of *0.1 M sodium thiosulphate*, mix and dilute to 10.0 ml with *water R*. The absorbance (*2.2.25*) of the solution measured at 590 nm, using *water R* as the compensation liquid, is not greater than that of a standard prepared at the same time and in the same manner, using 5.0 ml of a 3.0 mg/l solution of *potassium bromide R*.

Ferrocyanides. Dissolve 2.0 g in 6 ml of *water R*. Add 0.5 ml of a mixture of 5 ml of a 10 g/l solution of *ferric ammonium sulphate R* in a 2.5 g/l solution of *sulphuric acid R* and 95 ml of a 10 g/l solution of *ferrous sulphate R*. No blue colour develops within 10 min.

Iodides. Moisten 5 g by the dropwise addition of a freshly prepared mixture of 0.15 ml of *sodium nitrite solution R*, 2 ml of *0.5 M sulphuric acid*, 25 ml of *iodide-free starch solution R* and 25 ml of *water R*. After 5 min, examine in daylight. The mixture shows no blue colour.

Nitrites. To 10 ml of solution S add 10 ml of *water R*. The absorbance (*2.2.25*) is not greater than 0.01 at 354 nm.

Phosphates (*2.4.11*): maximum 25 ppm.

Dilute 2 ml of solution S to 100 ml with *water R*.

Sulphates (*2.4.13*): maximum 200 ppm.

Dilute 7.5 ml of solution S to 30 ml with *distilled water R*.

Aluminium (*2.4.17*): maximum 0.2 ppm, if intended for use in the manufacture of peritoneal dialysis solutions, haemodialysis solutions or haemofiltration solutions.

Prescribed solution. Dissolve 20.0 g in 100 ml of *water R* and add 10 ml of *acetate buffer solution pH 6.0 R*.

Reference solution. Mix 2 ml of *aluminium standard solution (2 ppm Al) R*, 10 ml of *acetate buffer solution pH 6.0 R* and 98 ml of *water R*.

Blank solution. Mix 10 ml of *acetate buffer solution pH 6.0 R* and 100 ml of *water R*.

Arsenic (*2.4.2, Method A*): maximum 1 ppm, determined on 5 ml of solution S.

Barium. To 5 ml of solution S add 5 ml of *distilled water R* and 2 ml of *dilute sulphuric acid R*. After 2 h, any opalescence in the solution is not more intense than that in a mixture of 5 ml of solution S and 7 ml of *distilled water R*.

Iron (*2.4.9*): maximum 2 ppm, determined on solution S.

Prepare the standard using a mixture of 4 ml of *iron standard solution (1 ppm Fe) R* and 6 ml of *water R*.

Magnesium and alkaline-earth metals (*2.4.7*): maximum 100 ppm, calculated as Ca and determined on 10.0 g.

Use 150 mg of *mordant black 11 triturate R*. The volume of *0.01 M sodium edetate* used is not more than 2.5 ml.

Potassium: maximum 5.00×10^2 ppm, if intended for use in the manufacture of parenteral dosage forms or haemodialysis, haemofiltration or peritoneal dialysis solutions.

Atomic emission spectrometry (*2.2.22, Method I*).

Test solution. Dissolve 1.00 g in *water R* and dilute to 100.0 ml with the same solvent.

Reference solutions. Dissolve 1.144 g of *potassium chloride R*, previously dried at 100-105 °C for 3 h, in *water R* and dilute to 1000.0 ml with the same solvent (600 µg of K per millilitre). Dilute as required.

Wavelength: 766.5 nm.

Heavy metals (*2.4.8*): maximum 5 ppm.

12 ml of solution S complies with test A. Prepare the reference solution using *lead standard solution (1 ppm Pb) R*.

Loss on drying (*2.2.32*): maximum 0.5 per cent, determined on 1.000 g by drying in an oven at 105 °C for 2 h.

Bacterial endotoxins (*2.6.14*): less than 5 IU/g, if intended for use in the manufacture of parenteral dosage forms without a further appropriate procedure for removal of bacterial endotoxins.

ASSAY

Dissolve 50.0 mg in *water R* and dilute to 50 ml with the same solvent. Titrate with *0.1 M silver nitrate* determining the end-point potentiometrically (*2.2.20*).

1 ml of *0.1 M silver nitrate* is equivalent to 5.844 mg of NaCl.

LABELLING

The label states:

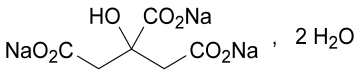
– where applicable, that the substance is suitable for use in the manufacture of parenteral dosage forms,

– where applicable, that the substance is suitable for use in the manufacture of peritoneal dialysis solutions, haemodialysis solutions or haemofiltration solutions.

01/2008:0412
corrected 6.0

SODIUM CITRATE

Natrii citras



$C_6H_5Na_3O_7,2H_2O$ M_r 294.1
[6132-04-3]

DEFINITION

Trisodium 2-hydroxypropane-1,2,3-tricarboxylate dihydrate.

Content: 99.0 per cent to 101.0 per cent (anhydrous substance).

CHARACTERS

Appearance: white or almost white, crystalline powder or white or almost white, granular crystals, slightly deliquescent in moist air.

Solubility: freely soluble in water, practically insoluble in ethanol (96 per cent).

IDENTIFICATION

A. To 1 ml of solution S (see Tests) add 4 ml of *water R*. The solution gives the reaction of citrates (*2.3.1*).

B. 1 ml of solution S gives reaction (a) of sodium (*2.3.1*).

TESTS

Solution S. Dissolve 10.0 g in *carbon dioxide-free water R* prepared from *distilled water R* and dilute to 100 ml with the same solvent.

Appearance of solution. Solution S is clear (*2.2.1*) and colourless (*2.2.2, Method II*).

Acidity or alkalinity. To 10 ml of solution S add 0.1 ml of *phenolphthalein solution R*. Not more than 0.2 ml of *0.1 M hydrochloric acid* or *0.1 M sodium hydroxide* is required to change the colour of the indicator.