

01/2008:0193  
corrected 7.0

## SODIUM CHLORIDE

Natrii chloridum

M, 58.44

NaCl  
[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

**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 thiosulfate, 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 sulfate R in a 2.5 g/L solution of sulfuric acid R and 95 mL of a 10 g/L solution of ferrous sulfate 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 sulfuric 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.

**Sulfates (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 sulfuric 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 500 ppm, if intended for use in the manufacture of parenteral preparations 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 solution.** 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.

### ASSAY

Dissolve 1.0000 g in water R and dilute to 100.0 mL with the same solvent. To 10 mL of the solution add 50 mL of water R, 5 mL of dilute nitric acid R, 25 mL of 0.1 M silver nitrate and 2 mL of dibutyl phthalate R. Shake. Titrate with 0.1 M ammonium thiocyanate, using 2 mL of ferric ammonium sulfate solution R2 as indicator and shaking vigorously towards the end-point.

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