

Wavelength: 589 nm.

Atomisation device: air-acetylene flame.

Heavy metals (2.4.8): maximum 10 ppm.

Dilute 10 mL of solution S2 to 20 mL with *water R*. 12 mL of the solution complies with test A. Prepare the reference solution using *lead standard solution (1 ppm Pb) R*.

ASSAY

Dissolve 2.000 g in 25 mL of *carbon-dioxide free water R*. Add 25 mL of freshly prepared *barium chloride solution R1* and 0.3 mL of *phenolphthalein solution R*. Add slowly while shaking 25.0 mL of *1 M hydrochloric acid* and continue the titration with *1 M hydrochloric acid* until the colour changes from pink to colourless. Add 0.3 mL of *bromophenol blue solution R* and continue the titration with *1 M hydrochloric acid* until the colour changes from violet-blue to yellow.

1 mL of *1 M hydrochloric acid* used in the 2nd part of the titration is equivalent to 69.11 mg of K₂CO₃.

1 mL of *1 M hydrochloric acid* used in the combined titrations is equivalent to 56.11 mg of total alkali, calculated as KOH.

STORAGE

In an airtight, non-metallic container.

LABELLING

The label states, where applicable, that the substance is suitable for use in the manufacture of haemodialysis solutions.

Iron (2.4.9): maximum 20 ppm.

Dilute 5 mL of solution S to 10 mL with *water R*.

Heavy metals (2.4.8): maximum 10 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 1.0 per cent, determined on 1.00 g of previously powdered substance by drying in an oven at 105 °C for 3 h.

ASSAY

Dissolve 1.500 g in *water R* and dilute to 100.0 mL with the same solvent. To 20.0 mL of the solution add 40 mL of *hydrochloric acid R* and titrate with *0.05 M potassium iodate* until the colour changes from red to yellow. Add 5 mL of *chloroform R* and continue the titration, shaking vigorously, until the chloroform layer is decolourised.

1 mL of *0.05 M potassium iodate* is equivalent to 16.60 mg of KI.

STORAGE

Protected from light.

01/2008:2075
corrected 7.0

POTASSIUM METABISULFITE

Kalii metabisulfis

01/2008:0186
corrected 6.0

K₂S₂O₅
[16731-55-8]

*M*_r 222.3

POTASSIUM IODIDE

Kalii iodidum

KI
[7681-11-0]

166.0

DEFINITION

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

CHARACTERS

Appearance: white or almost white powder or colourless crystals.

Solubility: very soluble in water, freely soluble in glycerol, soluble in ethanol (96 per cent).

IDENTIFICATION

- Solution S (see Tests) gives the reactions of iodides (2.3.1).
- Solution S gives the reactions of potassium (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*).

Alkalinity. To 12.5 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* is required to change the colour of the indicator.

Iodates. To 10 mL of solution S add 0.25 mL of *iodide-free starch solution R* and 0.2 mL of *dilute sulfuric acid R* and allow to stand protected from light for 2 min. No blue colour develops.

Sulfates (2.4.13): maximum 150 ppm.

Dilute 10 mL of solution S to 15 mL with *distilled water R*.

Thiosulfates. To 10 mL of solution S add 0.1 mL of *starch solution R* and 0.1 mL of *0.005 M iodine*. A blue colour is produced.

DEFINITION

Potassium metabisulfite (potassium disulfite).

Content: 95.0 per cent to 101.0 per cent.

CHARACTERS

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

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

IDENTIFICATION

- pH (see Tests).
- To 5 mL of solution S (see Tests), add 0.5 mL of *0.05 M iodine*. The mixture is colourless and gives reaction (a) of sulfates (2.3.1).
- Solution S gives reaction (a) of potassium (2.3.1).

TESTS

Solution S. Dissolve 5.0 g in *carbon dioxide-free 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 I*).

pH (2.2.3): 3.0 to 4.5 for solution S.

Thiosulfates. To 2.00 g add 25 mL of a 42.5 g/L solution of *sodium hydroxide R* and 75 mL of *water R*. Shake until dissolved and add 10 mL of *formaldehyde R* and 10 mL of *acetic acid R*. After 5 min, titrate with *0.05 M iodine* using 1 mL of *starch solution R*. Carry out a blank titration. The difference between the volumes consumed in the 2 titrations is not more than 0.15 mL.

Iron: maximum 10 ppm.

Atomic absorption spectrometry (2.2.23, *Method I*).

Test solution. Dilute 20 mL of solution S to 50 mL with *water R*.

Reference solutions. Prepare the reference solutions using *iron standard solution (20 ppm Fe) R*, diluted as necessary with *water R*.

Source: iron hollow-cathode lamp.

Wavelength: 248.3 nm.

Atomisation device: air-acetylene flame.

Selenium: maximum 10 ppm.

To 3.0 g add 10 mL of *formaldehyde R*. Carefully add 2 mL of *hydrochloric acid R* in small portions. Heat on a water-bath for 20 min. Any pink colour in the solution is not more intense than that of a reference solution prepared at the same time in the same manner using 1.0 g of the substance to be examined to which 0.2 mL of *selenium standard solution (100 ppm Se) R* has been added.

Zinc: maximum 25 ppm.

Atomic absorption spectrometry (2.2.23, *Method I*).

Test solution. Dilute 20 mL of solution S to 50 mL with *water R*.

Reference solutions. Prepare the reference solutions using *zinc standard solution (100 ppm Zn) R*, diluted as necessary with *water R*.

Source: zinc hollow-cathode lamp.

Wavelength: 213.9 nm.

Atomisation device: air-acetylene flame.

Heavy metals (2.4.8): maximum 10 ppm.

Introduce 40 mL of solution S into a silica crucible, add 10 mL of *hydrochloric acid R* and evaporate to dryness. Dissolve the residue in 19 mL of *water R* and add 1 mL of a 40 g/L solution of *sodium fluoride R*. The solution complies with test E. Prepare the reference solution using 20 mL of *lead standard solution (1 ppm Pb) R*.

ASSAY

In a 500 mL conical flask containing 50.0 mL of 0.05 M *iodine* introduce 0.150 g and add 5 mL of *hydrochloric acid R*. Titrate the excess of iodine with 0.1 M *sodium thiosulfate* using 0.1 mL of *starch solution R*.

1 mL of 0.05 M *iodine* is equivalent to 5.558 mg of $K_2S_2O_5$.

STORAGE

In an airtight container, protected from light.

01/2008:1465
corrected 7.0

POTASSIUM NITRATE

Kalii nitras

KNO_3
[7757-79-1]

M_r 101.1

DEFINITION

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

CHARACTERS

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

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

IDENTIFICATION

A. It gives the reaction of nitrates (2.3.1).

B. Solution S (see Tests) gives the reactions of potassium (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 0.05 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.

Reducible substances. To 10 mL of solution S, add 0.5 mL of *dilute sulfuric acid R* and 2 mL of *zinc iodide and starch solution R*. The solution does not become blue within 2 min.

Chlorides (2.4.4): maximum 20 ppm, if intended for ophthalmic use.

Dissolve 2.5 g in *water R* and dilute to 15 mL with the same solvent.

Sulfates (2.4.13): maximum 150 ppm.

Dilute 10 mL of solution S to 15 mL with *distilled water R*.

Ammonium (2.4.1): maximum 100 ppm, determined in 1 mL of solution S; maximum 50 ppm if intended for ophthalmic use.

Calcium (2.4.3): maximum 100 ppm; maximum 50 ppm if intended for ophthalmic use.

Dilute 10 mL of solution S to 15 mL with *distilled water R*.

Iron (2.4.9): maximum 20 ppm; maximum 10 ppm if intended for ophthalmic use.

Dilute 5 mL of solution S to 10 mL with *water R*.

Sodium: maximum 0.1 per cent.

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

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

Reference solutions. Prepare the reference solutions using *sodium standard solution (200 ppm Na) R*, diluted as necessary with *water R*.

Wavelength: 589 nm.

Heavy metals (2.4.8): maximum 10 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.

ASSAY

Prepare a chromatography column 0.3 m long and 10 mm in internal diameter and filled with 10 g of *strongly acidic cation-exchange resin R* covered with *carbon dioxide-free water R*. Maintain a 1 cm layer of liquid above the resin at all times. Allow 100 mL of *dilute hydrochloric acid R* to run through the column at a flow rate of about 5 mL/min. Wash the column (with the tap completely open) with *carbon dioxide-free water R* until neutral to *blue litmus paper R*. Dissolve 0.200 g of the substance to be examined in 2 mL of *carbon dioxide-free water R* in a beaker and transfer it to the column reservoir, allow the solution to run through the column at a flow rate of about 3 mL/min and collect the eluate. Wash the beaker with 10 mL of *carbon dioxide-free water R* and transfer this solution at the same flow rate to the column before it runs dry. Finally wash the column with 200 mL of *carbon dioxide-free water R* (with the tap completely open) until neutral to *blue litmus paper R*. Titrate the combined eluate and washings with 0.1 M *sodium hydroxide*, using 1 mL of *phenolphthalein solution R* as indicator.

1 mL of 0.1 M *sodium hydroxide* is equivalent to 10.11 mg of KNO_3 .

LABELLING

The label states, where applicable, that the substance is suitable for ophthalmic use.