Acid value: maximum 3.0.

Add 1 mL of *phenolphthalein solution R* to 50 mL of solution S and titrate with *0.05 M potassium hydroxide* until the pink colour persists for 15 s. Calculate the acid value from the expression:

$$\frac{2.805V}{2}$$

V = number of millilitres of *0.05 M potassium hydroxide* used.

Ester value (*2.5.2*): 90 per cent to 110 per cent of the value stated on the label.

Saponify 1.00 g in a mixture of 25.0 mL of *0.5 M alcoholic potassium hydroxide* and 25.0 mL of *water R* (*2.5.6*).

Heavy metals (*2.4.8*): maximum 10 ppm.

1.0 g complies with test D. Prepare the reference solution using 1 mL of *lead standard solution (10 ppm Pb) R*.

Loss on drying (*2.2.32*): maximum 5.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 3 h.

Sulfated ash (*2.4.14*): maximum 1.0 per cent, determined on 1.0 g.

The following test concerning the pharmacotechnological properties may be carried out depending on the intended formulation. It is not a mandatory requirement.

Infrared absorption spectrum (*2.2.24*). The determination of the spectrum and comparison with a suitable sample is useful for ensuring suitable functionality-related properties. The intensities of the absorption maxima at 1720 cm^{-1} and 1260 cm^{-1} are inversely proportional to the degree of hydrolysis.

LABELLING

The label states:

– the viscosity for a 40 g/L solution,

– the ester value.

01/2008:1139
corrected 7.0

POTASSIUM ACETATE

Kalii acetas

$C_2H_3KO_2$ M_r 98.1
[127-08-2]

DEFINITION

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

CHARACTERS

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

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

IDENTIFICATION

A. It gives reaction (a) of acetates (*2.3.1*).

B. It gives reaction (a) of potassium (*2.3.1*).

TESTS

Solution S. Dissolve 10.0 g in *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*).

pH (*2.2.3*): 7.5 to 9.0.

Dissolve 1.0 g in *carbon dioxide-free water R* and dilute to 20 mL with the same solvent.

Reducing substances. Dilute 10 mL of solution S to 100 mL with *water R*. Add 5 mL of *dilute sulfuric acid R* and 0.5 mL of a 0.32 g/L solution of *potassium permanganate R*. Mix and boil gently for 5 min. The solution remains pink.

Chlorides (*2.4.4*): maximum 200 ppm.

Dilute 2.5 mL of solution S to 15 mL with *water R*.

Sulfates (*2.4.13*): maximum 200 ppm.

Dilute 7.5 mL of solution S to 15 mL with *distilled water R*.

Aluminium (*2.4.17*): maximum 1 ppm, if intended for use in the manufacture of peritoneal dialysis solutions, haemofiltration solutions or haemodialysis solutions.

Prescribed solution. Dissolve 2.0 g in 50 mL of *water R* and add 5 mL of *acetate buffer solution pH 6.0 R*.

Reference solution. Mix 1 mL of *aluminium standard solution (2 ppm Al) R*, 5 mL of *acetate buffer solution pH 6.0 R* and 49 mL of *water R*.

Blank solution. Mix 5 mL of *acetate buffer solution pH 6.0 R* and 50 mL of *water R*.

Iron (*2.4.9*): maximum 20 ppm.

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

Sodium: maximum 0.5 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 4 ppm.

Dissolve 5.0 g in *water R* and dilute to 20 mL with the same solvent. 12 mL of the solution complies with test A. Prepare the reference solution using *lead standard solution (1 ppm Pb) R*.

Loss on drying (*2.2.32*): maximum 3.0 per cent, determined on 1.000 g by drying in an oven at 105 °C.

ASSAY

Dissolve 80.0 mg in 20 mL of *anhydrous acetic acid R*. Add 0.2 mL of *naphtholbenzein solution R*. Titrate with *0.1 M perchloric acid*. Carry out a blank titration.

1 mL of *0.1 M perchloric acid* is equivalent to 9.81 mg of $C_2H_3KO_2$.

STORAGE

In an airtight container.

01/2008:0184
corrected 6.0

POTASSIUM BROMIDE

Kalii bromidum

KBr M_r 119.0
[7758-02-3]

DEFINITION

Content: 98.0 per cent to 100.5 per cent (dried substance).

CHARACTERS

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

Solubility: freely soluble in water and in glycerol, slightly soluble in alcohol.

IDENTIFICATION

A. It gives reaction (a) of bromides (*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 0.1 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.

Bromates. To 10 mL of solution S add 1 mL of *starch solution R*, 0.1 mL of a 100 g/L solution of *potassium iodide R* and 0.25 mL of *0.5 M sulfuric acid* and allow to stand protected from light for 5 min. No blue or violet colour develops.

Chlorides: maximum 0.6 per cent.

In a conical flask, dissolve 1.000 g in 20 mL of *dilute nitric acid R*. Add 5 mL of *strong hydrogen peroxide solution R* and heat on a water-bath until the solution is completely decolorised. Wash down the sides of the flask with a little *water R* and heat on a water-bath for 15 min. Allow to cool, dilute to 50 mL with *water R* and add 5.0 mL of *0.1 M silver nitrate* and 1 mL of *dibutyl phthalate R*. Shake and titrate with *0.1 M ammonium thiocyanate*, using 5 mL of *ferric ammonium sulfate solution R2* as indicator. Not more than 1.7 mL of *0.1 M silver nitrate* is used. Note the volume of *0.1 M silver nitrate* used (see Assay). Carry out a blank test.

Iodides. To 5 mL of solution S add 0.15 mL of *ferric chloride solution R1* and 2 mL of *methylene chloride R*. Shake and allow to separate. The lower layer is colourless (*2.2.2, Method I*).

Sulfates (*2.4.13*): maximum 100 ppm.

15 mL of solution S complies with the limit test for sulfates.

Iron (*2.4.9*): maximum 20 ppm.

5 mL of solution S diluted to 10 mL with *water R* complies with the limit test for iron.

Magnesium and alkaline-earth metals (*2.4.7*): maximum 200 ppm, calculated as Ca.

10.0 g complies with the limit test for magnesium and alkaline-earth metals. The volume of *0.01 M sodium edetate* used does not exceed 5.0 mL.

Heavy metals (*2.4.8*): maximum 10 ppm.

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

Loss on drying (*2.2.32*): maximum 1.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 3 h.

ASSAY

Dissolve 2.000 g in *water R* and dilute to 100.0 mL with the same solvent. To 10.0 mL of the solution add 50 mL of *water R*, 5 mL of *dilute nitric acid R*, 25.0 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 11.90 mg of KBr.

Calculate the percentage content of KBr from the expression:

$$a - 3.357\,b$$

a = percentage content of KBr and KCl obtained in the assay and calculated as KBr,

b = percentage content of Cl in the test for chlorides.

01/2008:1557
corrected 6.0

POTASSIUM CARBONATE

Kalii carbonas

K_2CO_3 M_r 138.2
[584-08-7]

DEFINITION

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

CHARACTERS

Appearance: white or almost white granular powder, hygroscopic.

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

IDENTIFICATION

A. Dissolve 1 g in 10 mL of *water R*. The solution is strongly alkaline (*2.2.4*).

B. 2 mL of the solution prepared for identification test A gives the reaction of carbonates and bicarbonates (*2.3.1*).

C. 1 mL of the solution prepared for identification test A gives reaction (b) of potassium (*2.3.1*).

TESTS

Solution S. Dissolve 10.0 g in 25 mL of *distilled water R*. Slowly add 14 mL of *hydrochloric acid R*. When the effervescence has ceased, boil for a few minutes. Allow to cool and dilute to 50 mL with *distilled water R*.

Appearance of solution. Solution S is not more opalescent than reference suspension II (*2.2.1*) and not more intensely coloured than reference solution Y_6 (*2.2.2, Method II*).

Chlorides (*2.4.4*): maximum 100 ppm.

Dissolve 0.50 g in 10 mL of *water R*. Carefully add dropwise 1 mL of *nitric acid R*. Boil. Cool, add 5 mL of *dilute nitric acid R* and dilute to 15 mL with *water R*.

Sulfates (*2.4.13*): maximum 100 ppm.

Dilute 7.50 mL of solution S to 15 mL with *distilled water R*.

Calcium (*2.4.3*): maximum 100 ppm.

To 5 mL of solution S add 1 mL of *concentrated ammonia R*. Boil. Cool. Dilute to 15 mL with *distilled water R*.

Iron (*2.4.9*): maximum 10 ppm.

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

Heavy metals (*2.4.8*): maximum 20 ppm.

Dilute 10 mL of solution S to 20 mL with *water R*. 12 mL of the solution complies with test A. Prepare the reference solution using *lead standard solution (2 ppm Pb) R*.

Loss on drying (*2.2.32*): maximum 5.0 per cent, determined on 0.300 g by drying in an oven at 120-125 °C for 5 h.

ASSAY

Dissolve 0.500 g in 50 mL of *carbon dioxide-free water R*. Carry out a potentiometric titration (*2.2.20*), using *1 M hydrochloric acid*. Read the volume added at the 2nd point of inflexion.

1 mL of *1 M hydrochloric acid* is equivalent to 69.1 mg of K_2CO_3.

STORAGE

In an airtight container.