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

2.0 g complies with test D. Prepare the reference solution using 2 ml of *lead standard solution (10 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 0.120 g in 20 ml of *anhydrous acetic acid R*. Titrate with *0.1 M perchloric acid* using 0.1 ml of *crystal violet solution R* as indicator until the colour changes from violet to bluish-green.

1 ml of *0.1 M perchloric acid* is equivalent to 15.02 mg of $C_6H_7KO_2$.

STORAGE

Protected from light.

01/2008:1622
corrected 6.0

POTASSIUM SULPHATE

Kalii sulfas

K_2SO_4 M_r 174.3
[7778-80-5]

DEFINITION

Content: 98.5 per cent to 101.0 per cent of K_2SO_4 (dried substance).

CHARACTERS

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

Solubility: soluble in water, practically insoluble in ethanol.

IDENTIFICATION

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

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

TESTS

Solution S. Dissolve 10.0 g in 90 ml of *carbon dioxide-free water R* prepared from *distilled water R*, heating gently. Allow to cool and dilute to 100 ml with *carbon dioxide-free water R* prepared from *distilled water R*.

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.

Chlorides (*2.4.4*): maximum 40 ppm.

Dilute 12.5 ml of solution S to 15 ml with *water R*.

Calcium (*2.4.3*): maximum 200 ppm.

Dilute 5 ml of solution S to 15 ml with *distilled water R*.

Iron (*2.4.9*): maximum 10 ppm, determined on 10 ml of solution S.

Magnesium: maximum 20 ppm.

To 5 ml of solution S add 5 ml of *water R*, 1 ml of *glycerol (85 per cent) R*, 0.15 ml of *titan yellow solution R*, 0.25 ml of *ammonium oxalate solution R* and 5 ml of *dilute sodium hydroxide solution R* and shake. Any pink colour in the test solution is not more intense than that in a standard prepared at the same time and in the same manner using a mixture of 1 ml of *magnesium standard solution (10 ppm Mg) R* and 9 ml of *water R*.

Sodium: maximum 0.10 per cent.

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

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

Reference solutions. Dissolve in *water R* 0.50 g of *sodium chloride R*, previously dried at 100-105 °C for 3 h, and dilute to 1000.0 ml with the same solvent (200 µg of Na per millilitre). Dilute as required.

Wavelength: 589 nm.

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

12 ml of solution S complies with limit test A. Prepare the standard using *lead standard solution (2 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 130 °C for 4 h.

ASSAY

Dissolve 0.150 g in 40 ml of *water R*. Add 0.2 ml of *0.1 M hydrochloric acid* and 80 ml of *methanol R*. Carry out a potentiometric titration (*2.2.20*), using *0.1 M lead nitrate* and as indicator electrode a lead-selective electrode and as reference electrode a silver-silver chloride electrode.

1 ml of *0.1 M lead nitrate* is equivalent to 17.43 mg of K_2SO_4.

01/2008:0355
corrected 6.0

POTATO STARCH

Solani amylum

DEFINITION

Potato starch is obtained from the tuber of *Solanum tuberosum* L.

CHARACTERS

Appearance: very fine, white or almost white powder which creaks when pressed between the fingers.

Solubility: practically insoluble in cold water and in alcohol.

Potato starch does not contain starch grains of any other origin. It may contain a minute quantity, if any, of tissue fragments of the original plant.

IDENTIFICATION

A. Examined under a microscope using a mixture of equal volumes of *glycerol R* and *water R*, it presents granules, either irregularly shaped, ovoid or pear-shaped, usually 30 µm to 100 µm in size but occasionally exceeding 100 µm, or rounded, 10 µm to 35 µm in size. There are occasional compound granules having 2 to 4 components. The ovoid and pear-shaped granules have an eccentric hilum and the rounded granules acentric or slightly eccentric hilum. All granules show clearly visible concentric striations. Between crossed nicol prisms, the granules show a distinct black cross intersecting at the hilum.

B. Suspend 1 g in 50 ml of *water R*, boil for 1 min and cool. A thick, opalescent mucilage is formed.

C. To 1 ml of the mucilage obtained in identification test B, add 0.05 ml of *iodine solution R1*. An orange-red to dark blue colour is produced which disappears on heating.

TESTS

pH (*2.2.3*): 5.0 to 8.0.

Shake 5.0 g with 25.0 ml of *carbon dioxide-free water R* for 60 s. Allow to stand for 15 min.

Foreign matter. Examined under a microscope using a mixture of equal volumes of *glycerol R* and *water R*, not more than traces of matter other than starch granules are present. No starch grains of any other origin are present.

Oxidising substances (*2.5.30*): maximum 20 ppm, calculated as H_2O_2.

Sulphur dioxide (*2.5.29*): maximum 50 ppm.

Iron (*2.4.9*): maximum 10 ppm.

Shake 1.5 g with 15 ml of *dilute hydrochloric acid R*. Filter. The filtrate complies with the limit test for iron.

Loss on drying (*2.2.32*): maximum 20.0 per cent, determined on 1.000 g by drying in an oven at 130 °C for 90 min.

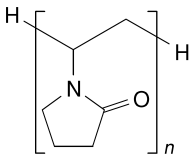
Sulphated ash (*2.4.14*): maximum 0.6 per cent, determined on 1.0 g.

Microbial contamination. Total viable aerobic count (*2.6.12*) not more than 10^3 bacteria and not more than 10^2 fungi per gram, determined by plate count. It complies with the test for *Escherichia coli* (*2.6.13*).

01/2008:0685

POVIDONE

Povidonum



$C_{6n}H_{9n+2}N_nO_n$
[9003-39-8]

DEFINITION

α-Hydro-ω-hydropoly[1-(2-oxopyrrolidin-1-yl)ethylene]. It consists of linear polymers of 1-ethenylpyrrolidin-2-one.

Content: 11.5 per cent to 12.8 per cent of nitrogen (N; A_r 14.01) (anhydrous substance).

The different types of povidone are characterised by their viscosity in solution, expressed as a *K*-value.

The *K*-value of povidone having a stated *K*-value of 15 or less is 85.0 per cent to 115.0 per cent of the stated value.

The *K*-value of povidone having a stated *K*-value or a stated *K*-value range with an average of more than 15 is 90.0 per cent to 108.0 per cent of the stated value or of the average of the stated range.

CHARACTERS

Appearance: white or yellowish-white, hygroscopic powder or flakes.

Solubility: freely soluble in water, in ethanol (96 per cent) and in methanol, very slightly soluble in acetone.

IDENTIFICATION

First identification: A, E.

Second identification: B, C, D, E.

A. Infrared absorption spectrophotometry (*2.2.24*).

Preparation: dry the substances beforehand at 105 °C for 6 h. Record the spectra using 4 mg of substance.

Comparison: *povidone CRS*.

B. To 0.4 ml of solution S1 (see Tests) add 10 ml of *water R*, 5 ml of *dilute hydrochloric acid R* and 2 ml of *potassium dichromate solution R*. An orange-yellow precipitate is formed.

C. To 1 ml of solution S1 add 0.2 ml of *dimethylaminobenzaldehyde solution R1* and 0.1 ml of *sulphuric acid R*. A pink colour is produced.

D. To 0.1 ml of solution S1 add 5 ml of *water R* and 0.2 ml of *0.05 M iodine*. A red colour is produced.

E. It is freely soluble in *water R*.

TESTS

Solution S. Dissolve 1.0 g in *carbon dioxide-free water R* and dilute to 20 ml with the same solvent. Add the substance to be examined to the water in small portions with magnetic stirring.

Solution S1. Dissolve 2.5 g in *carbon dioxide-free water R* and dilute to 25 ml with the same solvent. Add the substance to be examined to the water in small portions with magnetic stirring.

Appearance of solution. Solution S is clear (*2.2.1*) and not more intensely coloured than reference solution B_6, BY_6 or R_6 (*2.2.2, Method II*).

pH (*2.2.3*): 3.0 to 5.0 for solution S, for povidone having a stated *K*-value of not more than 30; 4.0 to 7.0 for solution S, for povidone having a stated *K*-value of more than 30.

Viscosity, expressed as *K*-value. For povidone having a stated value of 18 or less, use a 50 g/l solution. For povidone having a stated value of more than 18, use a 10 g/l solution. For povidone having a stated value of more than 95, use a 1.0 g/l solution. Allow to stand for 1 h and determine the viscosity (*2.2.9*) of the solution at 25 °C, using viscometer No.1 with a minimum flow time of 100 s. Calculate the *K*-value using the following expression:

$$\frac{1.5\log\eta - 1}{0.15 + 0.003c} + \frac{\sqrt{300c\log\eta + (c + 1.5c\log\eta)^2}}{0.15c + 0.003c^2}$$

c = concentration of the substance to be examined, calculated with reference to the anhydrous substance, in grams per 100 ml;

η = viscosity of the solution relative to that of *water R*.

Aldehydes: maximum 500 ppm, expressed as acetaldehyde.

Test solution. Dissolve 1.0 g of the substance to be examined in *phosphate buffer solution pH 9.0 R* and dilute to 100.0 ml with the same solvent. Stopper the flask and heat at 60 °C for 1 h. Allow to cool.

Reference solution. Dissolve 0.140 g of *acetaldehyde ammonia trimer trihydrate R* in *water R* and dilute to 200.0 ml with the same solvent. Dilute 1.0 ml of this solution to 100.0 ml with *phosphate buffer solution pH 9.0 R*.

Into 3 identical spectrophotometric cells with a path length of 1 cm, introduce separately 0.5 ml of the test solution, 0.5 ml of the reference solution and 0.5 ml of *water R* (blank). To each cell, add 2.5 ml of *phosphate buffer solution pH 9.0 R* and 0.2 ml of *nicotinamide-adenine dinucleotide solution R*. Mix and stopper tightly. Allow to stand at 22 ± 2 °C for 2-3 min and measure the absorbance (*2.2.25*) of each solution at 340 nm, using *water R* as the compensation liquid. To each cell, add 0.05 ml of *aldehyde*