В Е Ж Б А Б Р . 1

С К Р О Б О В И (A M Y L U M)

1. Maize starch (Maydis amylum)

   - Дефиниција, карактеристики, идентификација А/Б и Ц

2. Wheat starch (Triticu amylum)

   - Дефиниција, карактеристики, идентификација А/Б и Ц

3. Rice starch (Oryzae amylum)

   - Дефиниција, карактеристики, идентификација А/Б и Ц

4. Potato starch (Solani amylum)

   - Дефиниција, карактеристики, идентификација А/Б и Ц

B. Composition of fatty acids (see Tests).

TESTS

Acid value (*2.5.1*): maximum 0.5, or maximum 0.3 if intended for use in the manufacture of parenteral preparations, determined on 10.0 g.

Peroxide value (*2.5.5, Method A*): maximum 10.0, or maximum 5.0 if intended for use in the manufacture of parenteral preparations.

Unsaponifiable matter (*2.5.7*): maximum 2.8 per cent, determined on 5.0 g.

Alkaline impurities (*2.4.19*). It complies with the test.

Composition of fatty acids (*2.4.22, Method A*). Use the mixture of calibrating substances in Table 2.4.22.-3.

Composition of the fatty-acid fraction of the oil:

- *fatty acids of chain length less than* C_{16}: maximum 0.6 per cent;
- *palmitic acid*: 8.6 per cent to 16.5 per cent;
- *stearic acid*: maximum 3.3 per cent;
- *oleic acid*: 20.0 per cent to 42.2 per cent;
- *linoleic acid*: 39.4 per cent to 65.6 per cent;
- *linolenic acid*: 0.5 per cent to 1.5 per cent;
- *arachidic acid*: maximum 0.8 per cent;
- *eicosenoic acid*: maximum 0.5 per cent;
- *behenic acid*: maximum 0.5 per cent;
- *other fatty acids*: maximum 0.5 per cent.

Sterols (*2.4.23*): maximum 0.3 per cent of brassicasterol in the sterol fraction of the oil.

Water (*2.5.32*): maximum 0.1 per cent, determined on 1.00 g.

STORAGE

Protected from light, at a temperature not exceeding 25 °C.

LABELLING

The label states:

- where applicable, that the substance is suitable for use in the manufacture of parenteral preparations;
- whether the oil is obtained by mechanical expression or by extraction.

01/2014:0344

MAIZE STARCH(1)

Maydis amylum

DEFINITION

Maize starch is obtained from the caryopsis of *Zea mays* L.

♦CHARACTERS

Appearance: matt, white to slightly yellowish, very fine powder that creaks when pressed between the fingers.

Solubility: practically insoluble in cold water and in ethanol (96 per cent).

The presence of granules with cracks or irregularities on the edge is exceptional.♦

IDENTIFICATION

A. Microscope examination (*2.8.23*), using a 50 per cent *V/V* solution of *glycerol R*. It appears as either angular polyhedral granules of irregular sizes with diameters ranging from about 2 µm to about 23 µm or as rounded or spheroidal granules of irregular sizes with diameters ranging from about 25 µm to about 35 µm (Figure 0344.-1). The central hilum consists of a distinct cavity or 2- to 5-rayed cleft and there are no concentric striations. Between orthogonally orientated polarising plates or prisms, the starch granules show a distinct black cross intersecting at the hilum.

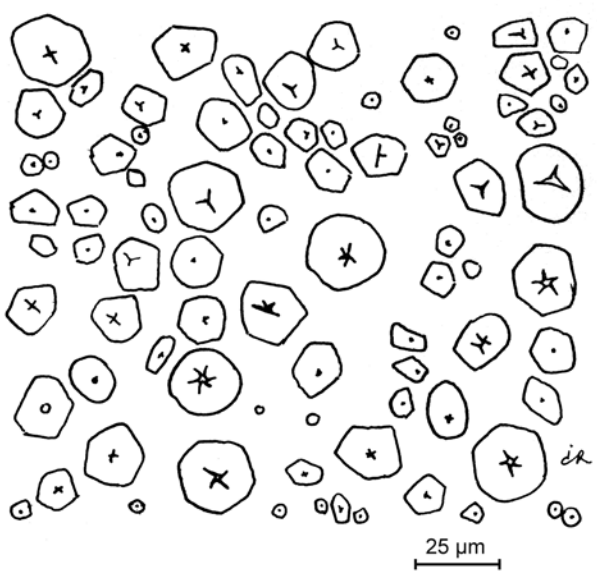


Figure 0344.-1. – *Illustration for identification test A of maize starch*

B. Suspend 1 g in 50 mL of *water R*, boil for 1 min and cool. A thin, cloudy 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*): 4.0 to 7.0.

To 5.0 g add 25.0 mL of *carbon dioxide-free water R*. Agitate continuously at a moderate rate for 60 s. Stop the agitation and allow to stand for 15 min.

◊**Foreign matter**. Examined under a microscope using a 50 per cent *V/V* solution of *glycerol 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.

Sulfur 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 test.

Loss on drying (*2.2.32*): maximum 15.0 per cent, determined on 1.000 g by drying in an oven at 130 °C for 90 min.

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

Microbial contamination

TAMC: acceptance criterion 10^3 CFU/g (*2.6.12*).

TYMC: acceptance criterion 10^2 CFU/g (*2.6.12*).

Absence of *Escherichia coli* (*2.6.13*).

◊Absence of *Salmonella* (*2.6.13*).◊

(1) This monograph has undergone pharmacopoeial harmonisation. See chapter *5.8. Pharmacopoeial harmonisation.*

Residue on evaporation: maximum 0.001 per cent.

Evaporate 100 mL to dryness on a water-bath and dry in an oven at 100-105 °C. The residue weighs a maximum of 1 mg.

Microbial contamination

TAMC: acceptance criterion 10^2 CFU/mL (*2.6.12*). Use casein soya bean digest agar.

LABELLING

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

01/2014:0359

WHEAT STARCH(1)

Tritici amylum

DEFINITION

Wheat starch is obtained from the caryopsis of *Triticum aestivum* L. (*T. vulgare* Vill.).

♦CHARACTERS

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

Solubility: practically insoluble in cold water and in ethanol (96 per cent).

Wheat 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. Microscopic examination (*2.8.23*) using a 50 per cent *V/V* solution of *glycerol R*. It presents large and small granules, and, very rarely, intermediate sizes (Figure 0359.-1). The large granules, 10-60 µm in diameter, are discoid or, more rarely, reniform when seen face-on. The central hilum and striations are invisible or barely visible and the granules sometimes show cracks on the edges. Seen in profile, the granules are elliptical and fusiform and the hilum appears as a slit along the main axis. The small granules, rounded or polyhedral, are 2-10 µm in diameter. Between orthogonally orientated polarising plates or prisms, the granules show a distinct black cross intersecting at the hilum.

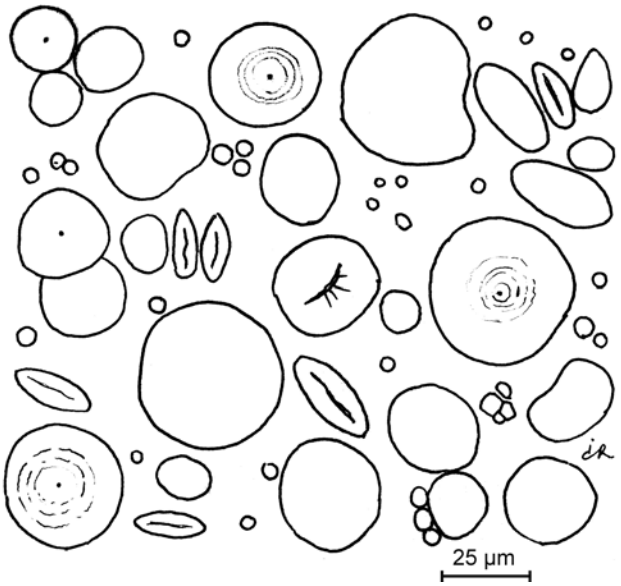


Figure 0359.-1. – *Illustration for identification test A of wheat starch*

B. Suspend 1 g in 50 mL of *water R*, boil for 1 min and cool. A thin, cloudy mucilage is formed.

C. To 1 mL of the mucilage obtained in identification test B add 0.05 mL of *iodine solution R1*. A dark blue colour is produced, which disappears on heating.

TESTS

pH (*2.2.3*): 4.5 to 7.0.

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 50 per cent *V/V* solution of *glycerol R*, not more than traces of matter other than starch granules are present. No starch grains of any other origin are present.◊

Total protein: maximum 0.3 per cent of total protein (corresponding to 0.048 per cent N_2, conversion factor: 6.25), determined on 6.0 g by sulfuric acid digestion (*2.5.9*) modified as follows: wash any adhering particles from the neck into the flask with 25 mL of *sulfuric acid R*; continue the heating until a clear solution is obtained; add 45 mL of *strong sodium hydroxide solution R*.

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

Sulfur 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 test.

Loss on drying (*2.2.32*): maximum 15.0 per cent, determined on 1.000 g by drying in an oven at 130 °C for 90 min.

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

Microbial contamination

TAMC: acceptance criterion 10^3 CFU/g (*2.6.12*).

TYMC: acceptance criterion 10^2 CFU/g (*2.6.12*).

Absence of *Escherichia coli* (*2.6.13*).

◊Absence of *Salmonella* (*2.6.13*).◊

01/2010:1379

WHEAT-GERM OIL, REFINED

Tritici aestivi oleum raffinatum

DEFINITION

Fatty oil obtained from the germ of the grain of *Triticum aestivum* L. by cold expression or by other suitable mechanical means and/or by extraction. It is then refined. A suitable antioxidant may be added.

CHARACTERS

Appearance: clear, light yellow liquid.

Solubility: practically insoluble in water and in ethanol (96 per cent), miscible with light petroleum (bp: 40-60 °C).

Relative density: about 0.925.

Refractive index: about 1.475.

IDENTIFICATION

A. Identification of fatty oils by thin-layer chromatography (*2.3.2*).

Results: the chromatogram obtained is similar to the corresponding chromatogram shown in Figure 2.3.2.-1.

B. Composition of fatty acids (see Tests).

TESTS

Acid value (*2.5.1*): maximum 0.9, or maximum 0.3 if intended for use in the manufacture of parenteral preparations.

(1) This monograph has undergone pharmacopoeial harmonisation. See chapter *5.8. Pharmacopoeial harmonisation.*

5 mL of *buffered copper sulfate solution pH 4.0 R*, 2 mL of a 30 g/L solution of *ammonium molybdate R*, 1 mL of a freshly prepared solution containing 20 g/L of *4-methylaminophenol sulfate R* and 50 g/L of *sodium metabisulfite R*, and 1 mL of a 3 per cent *V/V* solution of *perchloric acid R*. Dilute to 25.0 mL with *water R* and measure, within 15 min of its preparation, the absorbance (*2.2.25*) of the solution at 800 nm, using as the compensation liquid a solution prepared in the same manner but without the substance to be examined. The absorbance is not greater than that of a solution prepared as follows: to 15 mL of *phosphate standard solution (5 ppm PO_4) R*, add 5 mL of *buffered copper sulfate solution pH 4.0 R*, 2 mL of a 30 g/L solution of *ammonium molybdate R*, 1 mL of a freshly prepared solution containing 20 g/L of *4-methylaminophenol sulfate R* and 50 g/L of *sodium metabisulfite R*, and 1 mL of a 3 per cent *V/V* solution of *perchloric acid R*; dilute to 25.0 mL with *water R*.

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

To 2.0 g in a silica crucible add 2 mL of *nitric acid R*, dropwise, followed by 0.25 mL of *sulfuric acid R*. Heat cautiously until white fumes are evolved and ignite. Extract the cooled residue with 2 quantities, each of 2 mL, of *hydrochloric acid R* and evaporate the extracts to dryness. Dissolve the residue in 2 mL of *dilute acetic acid R* and dilute to 20 mL with *water R*. 12 mL of the solution complies with test A. Prepare the reference solution using 10 mL of *lead standard solution (1 ppm Pb) R*.

Loss on drying (*2.2.32*): maximum 8.0 per cent, determined on 1.000 g by drying in an oven at 105 °C at a pressure not exceeding 0.7 kPa for 5 h.

ASSAY

Carry out the assay protected from light.

Dissolve 0.100 g in 150 mL of *water R*, add 2 mL of *glacial acetic acid R* and dilute to 1000.0 mL with *water R*. To 10.0 mL of this solution add 3.5 mL of a 14 g/L solution of *sodium acetate R* and dilute to 50.0 mL with *water R*. Measure the absorbance (*2.2.25*) at the absorption maximum at 444 nm.

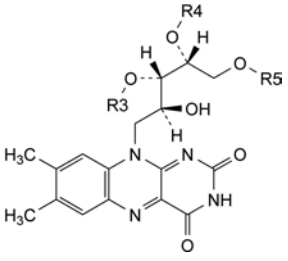
Calculate the content of $C_{17}H_{20}N_4O_6$ taking the specific absorbance to be 328.

STORAGE

In an airtight container, protected from light.

IMPURITIES

Specified impurities: *A, B, C, D, E.*

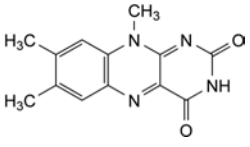


A. R3 = R4 = PO_3H_2, R5 = H: riboflavin 3′,4′-diphosphate,

B. R3 = R5 = PO_3H_2, R4 = H: riboflavin 3′,5′-diphosphate,

C. R3 = H, R4 = R5 = PO_3H_2: riboflavin 4′,5′-diphosphate,

D. R3 = R4 = R5 = H: riboflavin,



E. 7,8,10-trimethylbenzo[*g*]pteridine-2,4(3*H*,10*H*)-dione (lumiflavin).

01/2009:0349

RICE STARCH

Oryzae amylum

DEFINITION

Rice starch is obtained from the caryopsis of *Oryza sativa* 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 ethanol (96 per cent).

Rice starch does not contain starch grains of any other origin. It may contain traces of, if any, fragments of the endosperm tissue of the fruit.

IDENTIFICATION

A. Examined under a microscope using a mixture of equal volumes of *glycerol R* and *water R*, it presents polyhedral, simple grains 1-10 µm, mostly 4-6 µm, in size. These simple grains often gather in ellipsoidal, compound grains 50-100 µm in diameter. The grains have a poorly visible central hilum and there are no concentric striations. Between orthogonally orientated polarising plates or prisms, the starch grains 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 thin, cloudy 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.

Iron (*2.4.9*): maximum 10 ppm for the filtrate.

Shake 1.5 g with 15 mL of *dilute hydrochloric acid R*. Filter.

Foreign matter. Examine 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.

Loss on drying (*2.2.32*): maximum 15.0 per cent, determined on 1.00 g by drying in an oven at 130 °C for 90 min.

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

Oxidising substances (*2.5.30*): maximum 0.002 per cent, calculated as H_2O_2.

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

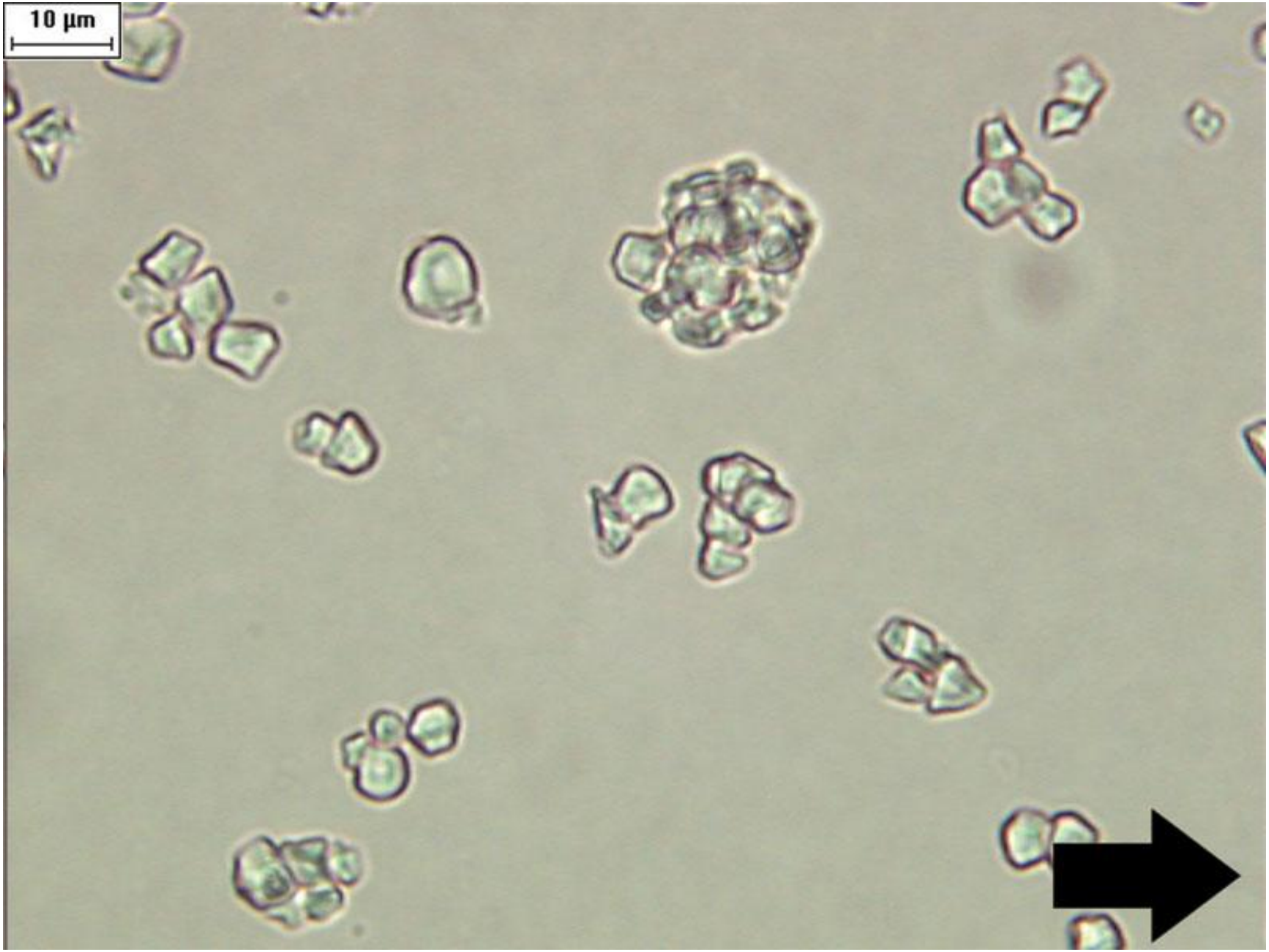
Microbial contamination

TAMC: acceptance criterion 10^3 CFU/g (*2.6.12*).

TYMC: acceptance criterion 10^2 CFU/g (*2.6.12*).

Absence of *Escherichia coli* (*2.6.13*).

Absence of *Salmonella* (*2.6.13*).


10 µm

01/2014:0355

POTATO STARCH(1)

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 ethanol (96 per cent).

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. Microscopic examination (*2.8.23*) using a 50 per cent *V/V* solution of *glycerol R*. It presents granules, either irregularly shaped, ovoid or pear-shaped, usually 30-100 µm in size but occasionally exceeding 100 µm, or rounded, 10-35 µm in size. There are occasional compound granules having 2-4 components (Figure 0355.-1). 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 orthogonally orientated polarising plates or 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 50 per cent *V/V* solution of *glycerol 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.

Sulfur 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.

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

Microbial contamination

TAMC: acceptance criterion 10^3 CFU/g (*2.6.12*).

TYMC: acceptance criterion 10^2 CFU/g (*2.6.12*).

Absence of *Escherichia coli* (*2.6.13*).

◊Absence of *Salmonella* (*2.6.13*).◊

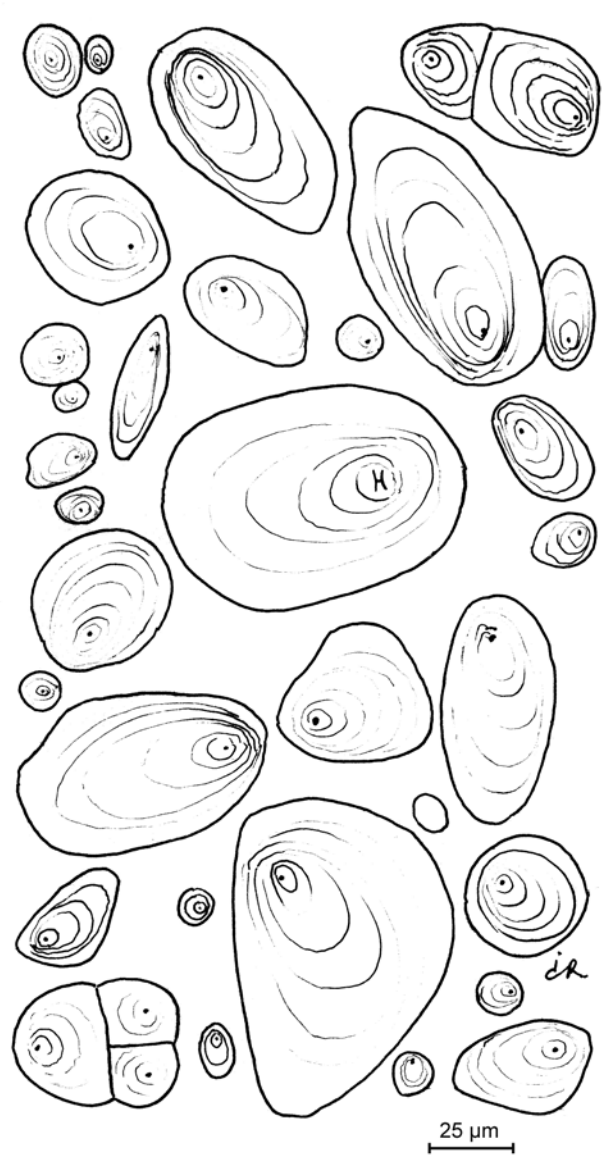
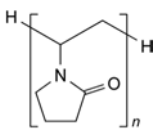


Figure 0355.-1. – *Illustration for identification test A of potato starch*

07/2011:0685

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.

(1) This monograph has undergone pharmacopoeial harmonisation. See chapter *5.8. Pharmacopoeial harmonisation.*

Monographs P