01/2009:0344

MAIZE STARCH

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. Examined under a microscope, using not less than 20 × magnification and using equal volumes of *glycerol R* and *water 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. 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.

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.

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 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.

Sulphated 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*).

01/2009:2391

MALLOW LEAF

Malvae folium

DEFINITION

Whole or fragmented, dried leaf of *Malva sylvestris* L., *Malva neglecta* Wallr. or a mixture of both species.

IDENTIFICATION

A. The leaves of *M. sylvestris* are up to 12 cm long and up to 15 cm wide with 3, 5 or 7 lobes and sinuate at the base; the leaves of *M. neglecta* are up to 9 cm long and wide, round or kidney-shaped with 5-7 indistinct lobes. The leaves of both species have irregular dentate margins and are green or brownish-green. The abaxial surface of the lamina bears more hairs and shows a more prominent venation than the adaxial surface. The major veins on the upper surface of the leaves and the petioles may be violet. The petioles are as long as the leaves, up to 2 mm wide, rounded and somewhat flattened, longitudinally slightly grooved, green or brownish-green or violet. The fragmented drug consists of occasionally agglomerated crumpled pieces of leaves showing prominent veins.

B. Reduce to a powder (710) (*2.9.12*). The powder is green or yellowish-green. Examine under a microscope using *chloral hydrate solution R*. The powder shows the following diagnostic characters: fragments of the upper and lower epidermises of the lamina, in surface view, with straight or more or less sinuous anticlinal walls; stomata, mostly anisocytic (*2.8.3*), on both surfaces; fragments of long covering trichomes with thickened walls and tapering to a point at the apex, usually unicellular but in *M. sylvestris* they may be stellate with 2-8 components, each strongly pitted at the base; club-shaped glandular trichomes occur in both species, composed of 2-4 cells; fragments of the mesophyll consisting of palisade parenchyma and spongy mesophyll cells containing mucilage and cluster crystals of calcium oxalate; occasional spherical pollen grains, 130-170 µm in diameter, with a spiny exine.

C. Thin-layer chromatography (*2.2.27*).

Test solution. To 2.0 g of the powdered drug (710) (*2.9.12*), add 20 ml of an 80 per cent *V/V* solution of *tetrahydrofuran R*; extract for 10 min using sonication and filter.

Reference solution. Dissolve 3 mg of *rutin R* and 3 mg of *hyperoside R* in 20 ml of *methanol R*.

Plate: *TLC silica gel plate R* (5-40 µm) [or *TLC silica gel plate R* (2-10 µm)].

Mobile phase: *anhydrous formic acid R, anhydrous acetic acid R, water R, ethyl formate R, 3-pentanone R* (4:11:14:20:50 *V/V/V/V/V*).

Application: 10 µl [4 µl] as bands of 10 mm [or 8 mm].

Development: over a path of 10-12 cm [or 6 cm].

Drying: in air.

Detection: heat at 100 °C for 10 min; spray or dip the warm plate in a 10 g/l solution of *diphenylboric acid aminoethyl ester R* in *methanol R*. Remove the solvent with cold air. Spray or dip the plate in a 50 g/l solution of *macrogol 400 R* in *methanol R*. Dry in air and examine after 15 min in ultraviolet light at 365 nm.