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Edition: BP 2025 (Ph. Eur. 11.6 update)

Wheat Starch[1]

General Notices

(Ph. Eur. monograph 0359)

Action and use

Excipient.

When Starch is specified and the type is not indicated, Maize Starch, Potato Starch, Rice Starch, Wheat Starch or, in tropical countries where these are not available, Tapioca Starch may be supplied or used.

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DEFINITION

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

PRODUCTION

The gluten content is monitored and stated on the label.◊

♦ 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 granules 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 shows 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 in surface view. The central hilum and striations are invisible or barely visible and the granules sometimes show cracks on the edges. In side view, 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.

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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 granules of any other origin are present.◊

Total protein

Maximum 0.3 per cent (corresponding to 0.048 per cent of nitrogen).

Determine the nitrogen content by sulfuric acid digestion as follows, and calculate the quantity of protein by multiplying by 6.25.

Carry out a blank determination by placing 4 g of a powdered mixture of 100 g of *dipotassium sulfate R*, 3 g of *copper sulfate pentahydrate R* and 3 g of *titanium dioxide R*, and 3 glass beads in a combustion flask. Wash any adhering particles from the neck of the flask with a fine jet of *water R*. Add 25 mL of *sulfuric acid R*, allowing it to run down the sides of the flask, and swirl to mix the contents. Close the mouth of the flask loosely, for example by means of a glass bulb with a short stem, to avoid excessive loss of sulfuric acid. Heat gradually at first, then increase the temperature until there is vigorous boiling with condensation of sulfuric acid in the neck of the flask; take precautions to prevent the upper part of the flask from becoming overheated. Continue heating until a clear solution is obtained and the inside wall of the flask is free from carbonaceous material. Cool, dissolve the solid material by cautiously adding 25 mL of *water R* to the mixture, cool again and place in a steam-distillation apparatus. Add a suitable volume of *strong sodium hydroxide solution R* to change the colour of the solution from bluish-green to brown or black, and distil immediately by passing steam through the mixture. Collect about 40 mL of distillate in 50.0 mL of *0.01 M hydrochloric acid*, adding enough *water R* if necessary to cover the tip of the condenser. Towards the end of the distillation, lower the receiver so that the tip of the condenser is above the surface of the acid and rinse the end of the condensing tube with a small quantity of *water R*. Take precautions to prevent any water on the outer surface of the condenser from reaching the contents of the receiver. Titrate the distillate with *0.025 M sodium hydroxide* (n_1 mL), using *methyl red mixed solution R* as indicator.

Repeat the test adding 3.0 g (*m* g) of the substance to be examined to the combustion flask, and using the same volume of *strong sodium hydroxide solution R*. Titrate the distillate as described for the blank determination with *0.025 M sodium*

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hydroxide (n_2 mL). Calculate the percentage content of nitrogen using the following expression:

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*).◊

LABELLING

The label states the gluten content.◊

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

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