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

Dextrin

General Notices

(Ph. Eur. monograph 1507)

9004-53-9

Action and use

Excipient.

Ph Eur

DEFINITION

Maize, potato or cassava starch partly hydrolysed and modified by heating with or without the presence of acids, alkalis or pH-control agents.

CHARACTERS

Appearance

White or almost white, free-flowing powder.

Solubility

Very soluble in boiling water forming a mucilaginous solution, slowly soluble in cold water, practically insoluble in ethanol (96 per cent).

IDENTIFICATION

A. Suspend 1 g in 50 mL of *water R*, boil for 1 min and cool. To 1 mL of the solution add 0.05 mL of *iodine solution R1*. A dark blue or reddish-brown colour is produced, which disappears on heating.
B. Centrifuge 5 mL of the mucilage obtained in identification test A. To the upper layer add 2 mL of *dilute sodium hydroxide solution R* and, dropwise with shaking, 0.5 mL of *copper sulfate solution R* and boil. A red precipitate is produced.
C. It is very soluble in boiling *water R*, forming a mucilaginous solution.

TESTS

pH (*2.2.3*)

2.0 to 8.0.

Disperse 5.0 g in 100 mL of *carbon dioxide-free water R*.

Chlorides

Maximum 0.2 per cent.

Dissolve 2.5 g in 50 mL of boiling *water R*, dilute to 100 mL with *water R* and filter. Dilute 1 mL of the filtrate to 15 mL with *water R* and add 1 mL of *dilute nitric acid R*. Pour the mixture as a single addition into 1 mL of *silver nitrate solution R2* and allow to stand for 5 min protected from light. When viewed transversely against a black background any opalescence produced is not more intense than that obtained by treating a mixture of 10 mL of *chloride standard solution (5 ppm Cl) R* and 5 mL of *water R*, prepared in the same manner.

Reducing sugars

Maximum 10 per cent, calculated as glucose $C_6H_{12}O_6$.

To a quantity of dextrin equivalent to 2.0 g (dried substance) add 100 mL of *water R*, shake for 30 min, dilute to 200.0 mL with *water R* and filter. To 10.0 mL of alkaline *cupri-tartaric solution R* add 20.0 mL of the filtrate, mix, and heat on a hot plate adjusted to bring the solution to boil within 3 min. Boil for 2 min, and cool immediately. Add 5 mL of a 300 g/L solution of *potassium iodide R* and 10 mL of *dilute sulfuric acid R*, mix, and titrate immediately with *0.1 M sodium thiosulfate*, using *starch solution R*, added towards the end of the titration, as indicator. Repeat the procedure beginning with “To 10.0 mL of...”, using, in place of the filtrate, 20.0 mL of a 1 g/L solution of *glucose R*, accurately prepared. Perform a blank titration. (V_B -V_U) is not greater than (V_B -V_S), in which V_B, V_U and V_S are the number of millilitres of *0.1 M sodium thiosulfate* consumed in the titrations of the blank, the dextrin and the glucose, respectively.

Loss on drying (*2.2.32*)

Maximum 13.0 per cent, determined on 1.000 g by drying at 130 ± 5 °C for 90 min.

Sulfated ash (*2.4.14*)

Maximum 0.5 per cent, determined on 1.0 g.

FUNCTIONALITY-RELATED CHARACTERISTICS

This section provides information on characteristics that are recognised as being relevant control parameters for one or more functions of the substance when used as an excipient (see chapter 5.15). Some of the characteristics described in the Functionality-related characteristics section may also be present in the mandatory part of the monograph since they also represent mandatory quality criteria. In such cases, a cross-reference to the tests described in the mandatory part is included in the Functionality-related characteristics section. Control of the characteristics can contribute to the quality of a medicinal product by improving the consistency of the manufacturing process and the performance of the medicinal product during use. Where control methods are cited, they are recognised as being suitable for the purpose, but other methods can also be used. Wherever results for a particular characteristic are reported, the control method must be indicated.

The following characteristics may be relevant for dextrin used as filler and binder, in tablets and capsules.

Particle-size distribution (*2.9.31* or *2.9.38*)

Powder flow (*2.9.36*)

The following characteristic may be relevant for dextrin used as viscosity-increasing agent.

Apparent viscosity (*2.2.10*)

Typically 100 mPa·s to 350 mPa·s (dried substance), depending on the grade of dextrin.

In a beaker, prepare a 10-50 per cent slurry so that the viscosity value ranges from 100 mPa·s to 350 mPa·s. The total mass of the sample plus water must be 600 g. Mix with a plastic rod to obtain a homogeneous slurry. Place the beaker in a

water-bath at 100 ± 1 °C. Introduce the paddle of a stirrer into the beaker and close the beaker with a lid. Start agitation at 250 r/min as rapidly as possible and carry on for exactly 30 min. Transfer the paste immediately to the beaker to be used for viscosity measurement, placed in a water-bath at 40 ± 1 °C. Stir until the temperature in the beaker is 40 ± 1 °C then measure the apparent viscosity using spindle no. 2 and a rotation speed of 100 r/min.

Ph Eur