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

Maltodextrin

General Notices

(Ph. Eur. monograph 1542)

Action and use

Excipient.

Ph Eur

DEFINITION

Mixture of glucose, disaccharides and polysaccharides, obtained by the partial hydrolysis of starch.

The degree of hydrolysis, expressed as dextrose equivalent (DE), is less than 20 (nominal value).

CHARACTERS

Appearance

White or almost white, slightly hygroscopic powder or granules.

Solubility

Freely soluble in water.

IDENTIFICATION

A. Dissolve 0.1 g in 2.5 mL of *water R* and heat with 2.5 mL of *cupri-tartaric solution R*. A red precipitate is formed.
B. Dip, for 1 s, a suitable stick with a reactive pad containing glucose-oxidase, peroxidase and a hydrogen-donating substance, such as tetramethylbenzidine, in a 100 g/L solution of the substance to be examined. Observe the colour of the reactive pad; within 60 s a colour change is observed, characteristic of the hydrogen-donating substance used (from yellow to green or blue if tetramethylbenzidine is used).
C. It is a powder or granules.
D. Dextrose equivalent (see Tests).

TESTS

Solution S

Dissolve 12.5 g in *carbon dioxide-free water R* and dilute to 50.0 mL with the same solvent.

pH (*2.2.3*)

4.0 to 7.0.

Mix 1 mL of a 223.6 g/L solution of *potassium chloride R* and 30 mL of solution S.

Sulfur dioxide (*2.5.29*)

Maximum 20 ppm.

Loss on drying (*2.2.32*)

Maximum 6.0 per cent, determined on 10.00 g by drying in an oven at 105 °C.

Sulfated ash (*2.4.14*)

Maximum 0.5 per cent, determined on 1.0 g.

Dextrose equivalent

(DE): within 2 DE units of the nominal value.

Weigh an amount of the substance to be examined equivalent to 2.85-3.15 g of reducing carbohydrates, calculated as dextrose equivalent, into a 500 mL volumetric flask. Dissolve in *water R* and dilute to 500.0 mL with the same solvent. Transfer the solution to a 50 mL burette.

Pipette 25.0 mL of *cupri-tartaric solution R* into a 250 mL flask and add 18.5 mL of the test solution from the burette, mix and add a few glass beads. Place the flask on a hot plate, previously adjusted so that the solution begins to boil within 2 min ± 15 s. Allow to boil for exactly 120 s, add 1 mL of a 1 g/L solution of *methylene blue R* and titrate with the test solution (V_1) until the blue colour disappears. Maintain the solution at boiling throughout the titration.

Standardise the cupri-tartaric solution using a 6.00 g/L solution of *glucose R* (V_0).

Calculate the dextrose equivalent using the following expression:

V_0	=	total volume of glucose standard solution, in millilitres;
V_1	=	total volume of test solution, in millilitres;
M	=	sample mass, in grams;
D	=	percentage content of dry matter in the substance.

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 dextrose equivalent (DE) (= nominal value).

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 maltodextrin used as filler and binder in tablets and capsules.

Dextrose equivalent

(see Tests).

Particle-size distribution (2.9.31 or 2.9.38)

Powder flow (2.9.36)