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

Microcrystalline Cellulose and Carmellose Sodium

General Notices

(Ph. Eur. monograph 2050)

Action and use

Excipient.

Ph Eur

DEFINITION

Colloid-forming, powdered mixture of *Microcrystalline cellulose (0316)* with 5 per cent to 22 per cent of *Carmellose sodium (0472)*.

Content

75.0 per cent to 125.0 per cent of the nominal content of carmellose sodium (dried substance).

CHARACTERS

Appearance

White or off-white, coarse or fine, hygroscopic powder.

Solubility

Dispersible in water producing a white, opaque colloidal dispersion; practically insoluble in organic solvents and in dilute acids.

IDENTIFICATION

A. Mix 6 g with 300 mL of *water R* and stir at 18 000 r/min for 5 min. A white opaque dispersion is obtained which does not produce a supernatant.
B. Add several drops of the dispersion obtained in identification A to a 100 g/L solution of *aluminium chloride R*. Each drop forms a white, opaque globule which does not disperse on standing.
C. Add 2 mL of *iodinated potassium iodide solution R* to the dispersion obtained in test A. No blue or purplish colour is produced.
D. It complies with the limits of the assay.

TESTS

Solubility

Add 50 mg to 10 mL of *ammoniacal solution of copper tetrammine R* and shake. It dissolves completely, leaving no residue.

pH (*2.2.3*)

6.0 to 8.0 for the dispersion obtained in identification A.

Loss on drying (*2.2.32*)

Maximum 8.0 per cent, determined on 1.000 g by drying in an oven at 105 °C.

Sulfated ash (*2.4.14*)

Maximum 7.4 per cent, determined on 2.0 g.

ASSAY

Heat 2.00 g with 75 mL of *anhydrous acetic acid R* under a reflux condenser for 2 h, cool and titrate with *0.1 M perchloric acid*, determining the end-point potentiometrically (*2.2.20*).

1 mL of *0.1 M perchloric acid* is equivalent to 29.6 mg of carmellose sodium.

LABELLING

The label states the nominal content of carmellose sodium in per cent *m/m*.

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 microcrystalline cellulose and carmellose sodium used as a suspending agent.

Viscosity (*2.2.10*)

60 per cent to 140 per cent of the nominal value.

Calculate the quantity (*x* g) needed to prepare exactly 600 g of a dispersion of the stated percentage *m/m* (dried substance). To (600 - *x*) g of *water R* at 23-25 °C contained in a 1000 mL high-speed blender bowl, add *x* g of the substance to be examined and stir at reduced speed, taking care to avoid contacting the sides of the bowl with the powder. Continue stirring at low speed for 15 s after the addition of the powder and then stir at 18 000 r/min for exactly 2 min.

Determine the viscosity with a suitable relative rotational viscometer under the following conditions:

— spindle: as appropriate;

— speed: 20 r/min.

Immerse the spindle into the suspension immediately after preparation, switch on the rotation spindle after 30 s; after a further 30 s, take scale readings and calculate the viscosity according to the viscometer manual.

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