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

Alginic Acid

General Notices

(Ph. Eur. monograph 0591)

Action and use

Treatment of gastro-oesophageal reflux disease; excipient; thickening agent.

Ph Eur

DEFINITION

Mixture of polyuronic acids $[(C_6H_8O_6)_n]$ composed of residues of D-mannuronic and L-guluronic acids, obtained mainly from algae belonging to the Phaeophyceae. A small proportion of the carboxyl groups may be neutralised.

Content

19.0 per cent to 25.0 per cent of carboxyl groups ($-CO_2H$) (dried substance).

CHARACTERS

Appearance

White or pale yellowish-brown, crystalline or amorphous powder.

Solubility

Very slightly soluble or practically insoluble in ethanol (96 per cent), practically insoluble in organic solvents. It swells in water but does not dissolve; it dissolves in solutions of alkali hydroxides.

IDENTIFICATION

A. To 0.2 g add 20 mL of *water R* and 0.5 mL of *sodium carbonate solution R*. Shake and filter. To 5 mL of the filtrate add 1 mL of *calcium chloride solution R*. A voluminous gelatinous mass is formed.
B. To 5 mL of the filtrate obtained in identification test A add 0.5 mL of a 123 g/L solution of *magnesium sulfate R*. No voluminous gelatinous mass is formed.
C. To 5 mg add 5 mL of *water R*, 1 mL of a freshly prepared 10 g/L solution of *1,3-dihydroxynaphthalene R* in *ethanol (96 per cent) R* and 5 mL of *hydrochloric acid R*. Boil gently for 3 min, cool, add 5 mL of *water R*, and shake with 15 mL of *di-isopropyl ether R*. Carry out a blank test. The upper layer obtained with the substance to be examined exhibits a deeper bluish-red colour than that obtained with the blank.

TESTS

Chlorides

Maximum 1.0 per cent.

To 2.50 g add 50 mL of *dilute nitric acid R*, shake for 1 h and dilute to 100.0 mL with *dilute nitric acid R*. Filter. To 50.0 mL of the filtrate add 10.0 mL of *0.1 M silver nitrate* and 5 mL of *toluene R*. Titrate with *0.1 M ammonium thiocyanate*, using 2 mL of *ferric ammonium sulfate solution R2* as indicator and shaking vigorously towards the end-point.

1 mL of *0.1 M silver nitrate* is equivalent to 3.545 mg of Cl.

Loss on drying (*2.2.32*)

Maximum 15.0 per cent, determined on 0.1000 g by drying in an oven at 105 °C for 4 h.

Sulfated ash (*2.4.14*)

Maximum 8.0 per cent (dried substance), determined on 0.100 g.

Microbial contamination

TAMC: acceptance criterion 10^2 CFU/g (*2.6.12*).

Absence of *Escherichia coli* (*2.6.13*).

Absence of *Salmonella* (*2.6.13*).

ASSAY

To 0.2500 g add 25 mL of *water R*, 25.0 mL of *0.1 M sodium hydroxide* and 0.2 mL of *phenolphthalein solution R*. Titrate with *0.1 M hydrochloric acid*.

1 mL of *0.1 M sodium hydroxide* is equivalent to 4.502 mg of carboxyl groups (-CO_2H).

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 alginic acid used as disintegrant and/or binder.

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

Settling volume

Place 75 mL of *water R* in a 100 mL graduated cylinder and add 1.5 g of the substance to be examined in 0.5 g portions, shaking vigorously after each addition. Dilute to 100.0 mL with *water R* and shake again until the substance is homogeneously distributed. Allow to stand for 4 h and determine the volume of the settled mass.

The following characteristic may be relevant for alginic acid used as gelling agent or viscosity-increasing agent.

Apparent viscosity

Determine the dynamic viscosity using a rotating viscometer (*2.2.10*).

Prepare a 20 g/L suspension of alginic acid (dried substance) and add *0.1 M sodium hydroxide* until a solution is obtained.

Ph Eur