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

Sodium Alginate

General Notices

(Ph. Eur. monograph 0625)

Action and use

Excipient.

Preparations

Alginate Raft-forming Oral Suspension

Compound Alginate Antacid Oral Suspension

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DEFINITION

Sodium alginate consists mainly of the sodium salt of alginic acid, which is a mixture of polyuronic acids $[(C_6H_8O_6)_n]$ composed of units of D-mannuronic acid and L-guluronic acid. Sodium alginate is obtained mainly from algae belonging to the Phaeophyceae.

CHARACTERS

Appearance

White or pale yellowish-brown powder.

Solubility

Slowly soluble in water forming a viscous, colloidal solution, practically insoluble in ethanol (96 per cent).

IDENTIFICATION

A. Dissolve 0.2 g with shaking in 20 mL of *water R*. To 5 mL of this solution add 1 mL of *calcium chloride solution R*. A voluminous gelatinous mass is formed.
B. To 10 mL of the solution prepared in identification test A add 1 mL of *dilute sulfuric acid R*. A 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 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.
D. Sulfated ash (see Tests). The residue obtained, dissolved in 2 mL of *water R*, gives reaction (a) of sodium (*2.3.1*).

TESTS

Solution S

Dissolve 0.10 g in *water R* with constant stirring, dilute to 30 mL with the same solvent and allow to stand for 1 h.

Appearance of solution

The solution is not more opalescent than reference suspension II (*2.2.1*) and not more intensely coloured than intensity 6 of the range of reference solutions of the most appropriate colour (*2.2.2, Method II*).

Dilute 1 mL of solution S to 10 mL with *water R*.

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.

Calcium

Maximum 1.5 per cent.

Atomic absorption spectrometry (*2.2.23, Method II*).

Test solution Dissolve 0.10 g in 50 mL of *dilute ammonia R2*, heating on a water-bath. Allow to cool and dilute to 100.0 mL with *distilled water R* (solution (a)). Dilute 3.0 mL of solution (a) to 100.0 mL with *distilled water R*.

Reference solutions Prepare 3 reference solutions in the same manner as the test solution but add 0.75 mL, 1.0 mL and 1.5 mL respectively of *calcium standard solution (100 ppm Ca) R* to the 3.0 mL of solution (a).

Set the zero of the instrument using a mixture of 1.5 volumes of *dilute ammonia R2* and 98.5 volumes of *distilled water R*.

Source Calcium hollow-cathode lamp.

Wavelength 422.7 nm.

Atomisation device Air-acetylene flame.

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*)

30.0 per cent to 36.0 per cent (dried substance), determined on 0.1000 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*).

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 characteristic may be relevant for sodium alginate used as viscosity-increasing agent or binder.

Apparent viscosity (*2.2.10*)

Carry out the test on a 10 g/L solution (dried substance). Determine the dynamic viscosity at 20 °C using a rotating viscometer at 20 r/min.

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