

Quality standards

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

Agar

General Notices

(Ph. Eur. monograph 0310)

Action and use

Excipient.

Ph Eur

DEFINITION

Polysaccharides from various species of Rhodophyceae mainly belonging to the genus *Gelidium*. It is prepared by treating the algae with boiling water; the extract is filtered whilst hot, concentrated and dried.

CHARACTERS

Appearance

Powder or crumpled strips 2-5 mm wide or sometimes flakes, colourless or pale yellow, translucent, somewhat tough and difficult to break, becoming more brittle on drying.

Mucilaginous taste.

IDENTIFICATION

- A. Examine under a microscope. When mounted in $0.005 \, \text{M}$ iodine, the strips or flakes are partly stained brownish-violet. Magnified 100 times, they show the following diagnostic characters: numerous minute, colourless, ovoid or rounded grains on an amorphous background; occasional brown, round or ovoid spores with a reticulated surface, measuring up to 60 μ m, may be present. Reduce to a powder, if necessary. The powder is yellowish-white. Examine under a microscope using $0.005 \, \text{M}$ iodine. The powder presents angular fragments with numerous grains similar to those seen in the strips and flakes; some of the fragments are stained brownish-violet.
- B. Dissolve 0.1 g with heating in 50 mL of <u>water R</u>. Cool. To 1 mL of the mucilage carefully add 3 mL of <u>water R</u> so as to form 2 separate layers. Add 0.1 mL of <u>0.05 M iodine</u>. A dark brownish-violet colour appears at the interface. Mix. The liquid becomes pale yellow.
- C. Heat 5 mL of the mucilage prepared for identification test B on a water-bath with 0.5 mL of <u>hydrochloric acid R</u> for 30 min. Add 1 mL of <u>barium chloride solution R1</u>. A white turbidity develops within 30 min.
- D. Heat 0.5 g with 50 mL of <u>water R</u> on a water-bath until dissolved. Only a few fragments remain insoluble. During cooling, the solution gels between 35 °C and 30 °C. Heat the gel thus obtained on a water-bath; it does not liquefy below 80 °C.

TESTS

https://nhathuocngocanh.com/bp

Swelling index (2.8.4)

Minimum 10 and within 10 per cent of the value stated on the label, determined on the powdered herbal drug (355) (2.9.12).

Insoluble matter

Maximum 1.0 per cent.

To 5.00 g of the powdered herbal drug (355) ($\underline{2.9.12}$) add 100 mL of $\underline{water\ R}$ and 14 mL of $\underline{dilute\ hydrochloric\ acid\ R}$. Boil gently for 15 min with frequent stirring. Filter the hot liquid through a tared, sintered-glass filter (160) ($\underline{2.1.2}$), rinse the filter with hot $\underline{water\ R}$ and dry at 100-105 °C. The residue weighs a maximum of 50 mg.

Gelatin

To 1.00 g add 100 mL of <u>water R</u> and heat on a water-bath until dissolved. Allow to cool to 50 °C. To 5 mL of this solution add 5 mL of <u>picric acid solution R</u>. No turbidity appears within 10 min.

Loss on drying (2.2.32)

Maximum 20.0 per cent, determined on 1.000 g of the powdered herbal drug (355) (2.9.12) by drying in an oven at 105 °C.

Total ash (2.4.16)

Maximum 5.0 per cent.

Microbial contamination

TAMC: acceptance criterion 10³ CFU/g (2.6.12).

TYMC: acceptance criterion 10² CFU/g (2.6.12).

Absence of *Escherichia coli* (2.6.13).

Absence of Salmonella (2.6.13).

LABELLING

The label states the swelling index.

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