



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

Dextranomer



[General Notices](#)

(Ph. Eur. monograph 2238)

56087-11-7

Action and use

Fluid absorber; treatment of burns, wounds and skin ulcers; preparation for skin grafting.

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DEFINITION

Three-dimensional network made of dextran chains O,O'-cross-linked with 2-hydroxypropane-1,3-diyl bridges and O-substituted with 2,3-dihydroxypropyl and 2-hydroxy-1-(hydroxymethyl)ethyl groups.

CHARACTERS

Appearance

White or almost white, spherical beads.

Solubility

Practically insoluble in water. It swells in water and in electrolyte solutions.

PRODUCTION

The absorption capacity is determined using a 9.0 g/L solution of [sodium chloride R](#) containing 20 µL/L of [polysorbate 20 R](#) or another suitable solution, with a suitable, validated method.

The particle size is controlled to a minimum of 80 per cent of the number of dry beads within 100-300 µm and a maximum of 7 per cent of their number below 100 µm using a suitable, validated method.

IDENTIFICATION

- A. The substance to be examined is practically insoluble in [water R](#). It swells in [water R](#).
- B. Infrared absorption spectrophotometry ([2.2.24](#)).

Preparation Grind the substance to be examined in [acetone R](#). Evaporate the solvent at room temperature and use the residue.

Comparison [dextranomer CRS](#).

TESTS

pH (2.2.3)

5.3 to 7.5.

Introduce 0.50 g to 30 mL of a freshly prepared 74.6 g/L solution of [potassium chloride R](#). Allow to stand for 2 min. Determine the pH on the mucilage obtained.

Boron

Maximum 30 ppm.

Inductively coupled plasma-atomic emission spectrometry (ICP-AES) (2.2.57).

Test solution Introduce 3.0 g into a platinum dish and moisten with 5 mL of a 32.1 g/L solution of [magnesium nitrate R](#) in a mixture of equal volumes of [ethanol \(96 per cent\) R](#) and [distilled water R](#). Evaporate to dryness on a water-bath. Ignite at 550 °C for 5 h. Take up the residue with 5 mL of [6 M hydrochloric acid R](#) and transfer to a 50 mL volumetric flask. Add about 20 mL of [distilled water R](#) and allow to digest for 1 h on a water-bath. Allow to cool and dilute to 50.0 mL with [distilled water R](#).

Reference solutions Prepare the reference solutions using a solution of [boric acid R](#) containing 10 ppm of boron. Proceed as described for the test solution.

Wavelength 249.773 nm.

Loss on drying (2.2.32)

Maximum 10.0 per cent, determined on 1.000 g by drying in an oven at 105 °C for 15 h.

Sulfated ash (2.4.14)

Maximum 0.4 per cent, determined on 1.0 g.

Microbial contamination

TAMC: acceptance criterion 10^2 CFU/g (2.6.12), determined using the pour-plate method.

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