



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

Dextran 60 for Injection



[General Notices](#)

(Ph. Eur. monograph 1000)

Action and use

Plasma substitute.

Ph Eur

DEFINITION

Mixture of polysaccharides, principally of the α -1,6-glucan type.

Average relative molecular mass About 60 000.

PRODUCTION

It is obtained by hydrolysis and fractionation of dextrans produced by fermentation of sucrose using *Leuconostoc mesenteroides* strain NRRL B-512 = CIP 78.59 or substrains thereof (for example *L. mesenteroides* B-512F = NCTC 10817).

It is prepared in conditions designed to minimise the risk of microbial contamination.

CHARACTERS

Appearance

White or almost white powder.

Solubility

Very soluble in water, very slightly soluble in ethanol (96 per cent).

IDENTIFICATION

A. Specific optical rotation ([2.2.7](#)): + 195 to + 201 (dried substance).

Dissolve 1.0 g in [water R](#), heating on a water-bath, and dilute to 50.0 mL with the same solvent.

B. Infrared absorption spectrophotometry ([2.2.24](#)).

Comparison [dextran CRS](#).

C. Molecular-mass distribution (see Tests).

TESTS

Solution S

Dissolve 5.0 g in [distilled water R](#), heating on a water-bath, and dilute to 50 mL with the same solvent.

Appearance of solution

Solution S is clear ([2.2.1](#)) and colourless ([2.2.2, Method II](#)).

Acidity or alkalinity

To 10 mL of solution S add 0.1 mL of [phenolphthalein solution R](#). The solution remains colourless. Add 0.2 mL of [0.01 M sodium hydroxide](#). The solution is red. Add 0.4 mL of [0.01 M hydrochloric acid](#). The solution is colourless. Add 0.1 mL of [methyl red solution R](#). The solution is red or orange.

Nitrogen-containing substances

Maximum 110 ppm of N.

Carry out the determination of nitrogen by sulfuric acid digestion ([2.5.9](#)), using 0.200 g and heating for 2 h. Collect the distillate in a mixture of 0.5 mL of [bromocresol green solution R](#), 0.5 mL of [methyl red solution R](#) and 20 mL of [water R](#). Titrate with [0.01 M hydrochloric acid](#). Not more than 0.15 mL of [0.01 M hydrochloric acid](#) is required to change the colour of the indicator.

Residual solvents

Gas chromatography ([2.2.28](#)).

Internal standard [propanol R](#).

Test solution Dissolve 5 g of the substance to be examined in 100 mL of [water R](#) and distil. Collect the first 45 mL of the distillate, add 1 mL of a 25 g/L solution of [propanol R](#) and dilute to 50 mL with [water R](#).

Reference solution Mix 0.5 mL of a 25 g/L solution of [anhydrous ethanol R](#), 0.5 mL of a 25 g/L solution of [propanol R](#) and 0.5 mL of a 2.5 g/L solution of [methanol R](#) and dilute to 25.0 mL with [water R](#).

Column:

- *material*: stainless steel;
- *size*: $l = 1.8 \text{ m}$, $\varnothing = 2 \text{ mm}$;
- *stationary phase*: [ethylvinylbenzene-divinylbenzene copolymer R](#) (125-150 μm).

Carrier gas [nitrogen for chromatography R](#).

Flow rate 25 mL/min.

Temperature:

- *column*: 190 °C;
- *injection port*: 240 °C;
- *detector*: 210 °C.

Detection Flame ionisation.

Injection The chosen volume of each solution.

Limits:

- *ethanol*: not more than the area of the corresponding peak in the chromatogram obtained with the reference solution (0.5 per cent);

— *methanol*: not more than the area of the corresponding peak in the chromatogram obtained with the reference solution (0.05 per cent);

— *sum of solvents other than ethanol, methanol and propanol*: not more than the area of the peak due to the internal standard (0.5 per cent, calculated as propanol).

Molecular-mass distribution (2.2.39)

The average molecular mass (M_w) is 54 000 to 66 000. The average molecular mass of the 10 per cent high fraction is not greater than 180 000. The average molecular mass of the 10 per cent low fraction is not less than 14 000.

Loss on drying (2.2.32)

Maximum 7.0 per cent, determined on 0.200 g by heating in an oven at 105 ± 2 °C for 5 h.

Sulfated ash (2.4.14)

Maximum 0.3 per cent, determined on 0.50 g.

Bacterial endotoxins (2.6.14)

Less than 16 IU/g.

Microbial contamination

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

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