# Dextran 1

Dextran 1 is a low molecular weight fraction of dextran, consisting of a mixture of isomaltooligosaccharide.It is obtained by controlled hydrolysis and fractionation of dextrans produced by fermentation of *Leuconostoc mesenteroides* in the presence of sucrose. It is a glucose polymer in which the linkages between glucose units are almost exclusively α-1,6. Its weight-average molecular weight is about 1000.

**Category.** Plasma substitute.

**Description**. A white to off white hygroscopic powder.

**Identification**
A. To 2 mg of substance under examination, add 2 drops of *water,* grind in an agate mortar for 2 minutes, add 0.3 g of *potassium bromide* and mix to slurry. (*NOTE-Do not grind).* Dry under vaccum at 40°. On the residue, determine by infrared absorption spectrophotometry (2.4.6).Compare the spectrum with that obtained with *dextran 1 IPRS* treated in the same manner or with the reference spectrum of dextran 1.

B. Specific optical rotation (see Test).

C. Molecular mass distribution (See Test), the peaks in the chromatogram obtained with the test solution corresponds to peaks in the chromatogram obtained with reference solution.

**Tests**

**pH**(2.4.24).4.5 to 7.0,determined in a15 per cent w/v solution.

**Specific optical rotation** (2.4.22). +148° to +164°, determined on 1.0 per cent w/v solution at 20°.

**Light absorbance**. A 15 per cent w/v solution, determined at 375 nm (2.4.7), shows absorbance not more than 0.12.

**Molecular-mass distribution.** Determined by size-exclusion chromatography (2.4.16).

*Test solution*. Dissolve 6 mg of the substance under examination in 1.0 ml of the mobile phase.

*Reference solution (a).* Dissolve 6 mg of *dextran 1 IPRS* in 1.0 ml of the mobile phase.

*Reference solution (b).* A solution containing 0.045 per cent w/v of isomaltotriose (3 glucose units), isomaltononaose (9 glucose units) and 0.060 per cent w/v of sodium chloride in the mobile phase.

Chromatographic system
- a stainless steel column 30 cm x 10 mm, dextran covalently bound to highly cross-linked porous agarose beads, allowing resolution of oligosaccharides in the molecular mass range of 180 to 3000 (two columns coupled in series),
- temperature: 20-25°,
- mobile phase: a 0.292 per cent w/v solution of *sodium chloride,*
- flow rate: 0.07-0.08 ml per minute,
- differential refractometer,
- injection volume: 100 µl.

Identification of peaks, use the chromatogram obtained with reference solution (b) to identify the peaks due to isomaltotriose, isomaltononaose and sodium chloride.

Determine the peak areas. Disregard any peak due to sodium chloride. Calculate the average relative molecular mass $M_w$ and the amount of the fraction with less than 3 and more than 9 glucose units, of*dextran1 RS* and of the substance under examination, using the following expression:

$M_w = \sum w_i \times m_i$

$M_w$ =average molecular mass of the dextran 1;
$m_i$=molecular mass of oligosaccharide *i*;
$w_i$=weight proportion of oligosaccharide *i.*

Use the following $m_i$ values for the calculation:

| **Oligosaccharide *i*** | $m_i$ |
|---|---|
| glucose | 180 |
| isomaltose | 342 |
| isomaltotriose | 504 |
| isomaltotetraose | 666 |
| isomaltopentaose | 828 |
| isomaltohexaose | 990 |
| isomaltoheptaose | 1152 |
| isomaltooctaose | 1314 |
| isomaltononaose | 1476 |
| isomaltodecaose | 1638 |
| isomaltoundecaose | 1800 |
| isomaltododecaose | 1962 |
| isomaltotridecaose | 2124 |
| isomaltotetradecaose | 2286 |
| isomaltopentadecaose | 2448 |
| isomaltohexadecaose | 2610 |
| isomaltoheptadecaose | 2772 |
| isomaltooctadecaose | 2934 |
| isomaltononadecaose | 3096 |



Inject reference solution (a). The test is not valid unless the values obtained for dextran 1 RS are within the values stated on the label.

The average molecular mass range between 850 and 1150; fraction with less than 3 glucose units less than 15.0 per cent and fraction with more than 9 glucose units less than 20.0 per cent.

**Nitrogen-containing substances**.Not more than110 ppm of N.

Determine the content of nitrogen, method A(2.3.30),using 0.2 g and heating for 2 hours. Collect the distillate in a mixture of 0.5 ml of *bromocresol green solution*, 0.5 ml of *methyl red solution*and 20 ml of *water*. 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.

**Sodium chloride.** Not more than 1.5 per cent.

Dissolve 5 g of the substance under examination in 100 ml of *water*. Titrate with *0.1 M silver nitrate*, using 0.2 ml of *potassium chromate* solution as indicator.
1 ml of *0.1 M silver nitrate* is equivalent to 5.844 mg of NaCl.

**Residual solvents** (5.4).Not more than 0.5 per cent *ethanol*, 0.05 per cent *methanol* and sum of solvents other than *ethanol*, *methanol* and *propanol* is not more than 0.5 per cent calculated as *propanol*.

**Loss on drying** (2.4.19).Not more than 1.0 per cent, determined on 1.0 g by drying in an oven at 105° for 5 hours.

*Dextran 1 intended for use in the manufacture of parenteral preparations without a further appropriate sterilization procedure complies with the following additional requirement*.

**Sterility** (2.2.11). Complies with the test for sterility.

*Dextran 1 intended for use in the manufacture of parenteral preparations without a further appropriate procedure for the removal of bacterial endotoxins complies with the following additional requirement.*

**Bacterial endotoxins** (2.2.3). Not more than 25 Endotoxin Unit per g of dextran.

**Microbial contamination** (2.2.9). Total aerobic viable count is not more than $10^2$CFU per g and the total combined moulds and yeasts count is not more than 10 CFU per g.

**Storage**. Store protected from moisture, at a temperature between 4° and 30°.

**Labelling**. Where it is intended for use in preparing injectable dosage forms, the label states that it is sterile or must be subjected to further processing during the preparation of injectable dosage forms.

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**Solubility:** Very soluble in *water* and very slightly soluble in *ethanol*.