

ANALYTICAL SPECIFICATION

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Dextran sulfate 5 HS, Ph. grade

Catalogue No. DS5 HS PG

Description: A polyanionic derivative of dextran with a weight average molecular weight of approximately 5000. Supplied as the sodium salt as a white to off white powder which is readily soluble in water.

| TEST/CHARACTERISTIC | LIMITS | TEST METHOD |
|---|-------------------------|----------------|
| Appearance, colour | White to off white | 02037 |
| Appearance, form | Powder | 02037 |
| Weight average molecular weight (Mw) | 3000–6000 | 02030 |
| Number average molecular weight (Mn) | To be noted | 02030 |
| Sulphur content | 16–20 % | 02050 |
| pH | 5.0–7.5 | 02009 |
| Free sulfate | ≤ 0.2 % | 02013 |
| Loss on drying | ≤ 7 % | 02018 |
| Specific optical rotation | +65° to +95° | 02008 |
| Turbidity | < 5 NTU | 02021 |
| Residual solvents | | |
| EtOH | To be noted | Ph.Eur. 2.4.24 |
| Formamide | To be noted | Ph.Eur. 2.4.24 |
| Total aerobic microbial count (TAMC) | ≤ 10 ³ CFU/g | Ph.Eur. 2.6.12 |
| Total combined yeasts/mould count (TYMC) | ≤ 10 ² CFU/g | Ph.Eur. 2.6.12 |
| Bacterial endotoxins (BET) | < 5 IU/mg | Ph.Eur. 2.6.14 |

We hereby confirm that no metal catalysts or metal reagents are used in the manufacturing of this product. Therefore, elemental impurities, classified according to ICH Q3D, are unlikely to be present.

We hereby confirm that no class 1 solvent, classified according to Ph.Eur. 5.4 and USP <467> Residual solvents, is used in the manufacturing of this product.