



**PRODUCTO: HEPARINA SÓDICA (GRADO INYECTABLE)**

ITEMS	SPECIFICATIONS
<b>ASSAY=&gt; Potency</b>	≥180 IU/mg (dry)
<b>APPEARANCE</b>	A white or almost white powder, hygroscopic
<b>SOLUBILITY</b>	Freely soluble in water
<b>IDENTIFICATION</b>	<ul style="list-style-type: none"> <li>a) Delay of clotting of recalcified citrated sheep plasma</li> <li>b) The large heparin sodium signals must be present at 2.04 ppm, 3.27 ppm (double), 4.34 ppm, 5.22 ppm and 5.42 ppm, all within ±0.03 ppm. A signal, corresponding to N-acetyl protons of dermatan sulfate, may show near 2.08±0.02 ppm. No unidentified signals larger than 4 per cent compared to the height of the heparin signal at 5.42 ppm are present in the ranges 0.10~2.00 ppm, 2.10~3.10 ppm and 5.70~8.00 ppm. Signals from the solvent may be present</li> <li>c) The principal peak in the chromatogram obtained with test solution (a) is similar in retention time and shape to the principal peak in the chromatogram obtained with reference solution (c)</li> <li>d) It complies with the test for sodium</li> </ul>
<b>APPEARANCE OF SOLUTION</b>	A solution containing 5000 IU/ml Clear Colour: BY5 or better
<b>PH</b>	5.5~8.0
<b>NUCLEOTIDIC IMPURITIES</b>	0.4% aqueous solution : $A_{260nm} \leq 0.15$

<b>PROTEIN</b>	≤0.5% (dry)
<b>RELATED SUBSTANCES</b>	<ul style="list-style-type: none"> <li>➤ Sum of dermatan sulfate and chondroitin sulfate: not more than the area of the corresponding peak in the chromatogram obtained with reference solution (e) (2.0 per cent)</li> <li>➤ Any other impurity: no peaks other than the peak due to dermatan sulfate + chondroitin sulfate are detected</li> </ul>
<b>NITROGEN</b>	1.5%~2.5% (dry)
<b>SODIUM</b>	9.5%~12.5% (dry)
<b>HEAVY METALS</b>	≤30 ppm
<b>LOSS ON DRYING</b>	≤8.0%
<b>BACTERIAL ENDOTOXINS</b>	<0.01 IU/IU Heparin
<b>MICROBIOLOGICAL EXAMINATION</b>	<ul style="list-style-type: none"> <li>a) Total viable aerobic count: ≤100 cfu/g Total combined yeast/moulds count: ≤10 cfu/g</li> <li>b) Specified micro-organisms: Bile-tolerant gram-negative bacteria, Escherichia coli, pseudomonas aeruginosa, staphylococcus aureus: not detectable/g Salmonella: not detectable/10g</li> </ul>
<b>ORGANIC VOLATILE IMPURITIES=&gt; Residual ethanol</b>	≤1000 ppm
<b>OXIDIZING SUBSTANCES</b>	≤20 ppm
<b>PHOSPHATE</b>	≤100 ppm
<b>EDTA</b>	≤0.1%