

Specification

Technical Data Sheet

Product Name	Heparin sodium salt (PIM)
Product No	27109831
CAS Number	9041-08-1
Storage Temperature	2 to 8 °C
Molecular Weight	N/A
	Specification
Appearance	white or almost white, hygroscopic powder
Bacterial endotoxin	Less than 0.01 IU per International Unit of heparin
pH	5.5 - 8.0
Specific rotation	Dry goods should not be less than +50°
anti-factor IIa	≥180 IU/mg
anti-FXa/anti-FIIa	0.9-1.1
dry weight loss	≤ 5.0%

Specification

Liquid chromatography	Control sample solution in the chromatogram, dermatan sulfate (peak height and heparin and dermatan sulfate) between peak valley height ratio shall not be less than 1.3, obtained with test solution is similar in retention time and shape to the principal peak in the chromatogram obtained with reference solution. Retention time relative deviation shall not exceed 5%
Micro organisms	Total viable aerobic count: $<10^3$ cfu/g . Fungi/yeast $<10^2$ cfu/g
Molecular weight and molecular weight distribution	Weight average molecular weight should be 15000 - 19000. The molecular weight of more than 24000 of the grade shall not be greater than 20%, the molecular weight of 8000 - 16000 of the molecular weight of 24000 - 16000 of the ratio should not be less than 1
Nitrogen	1.3%-2.5% (dried substance)
Nucleotidic Impurities	260nm <0.10
Protein	$< 0.5\%$ (dried substance)
Residual solvent	According to the internal standard method with peak area calculation, methanol, ethanol, acetone, and, in turn, 0.3%, 0.5%, or less
Residue on Ignition	28.0%-41.0%
Sodium	10.5%-13.5% (dried substance)
Clarity and color of solution	Solution should be clear colorless; Such as turbidity, ultraviolet-visible spectrophotometry, determination of absorbance at the wavelength of 640 nm, shall not be over 0.018; Such as color, compared with standard colorimetric liquid yellow, shall not be deeper
Heavy Metal	≤ 30 ppm
Related Substance	Sum of dermatan sulfate and chondroitin sulphate: not more than the area of the corresponding peak in the chromatogram obtained with reference solution. Any other impurity: no peaks other than the peak due to dermatan sulfate and chondroitin sulfate are detected.