

ALADDIN SCIENTIFIC CORPORATION

14078 Meridian Parkway, Riverside, CA. 92518

Certificate of Analysis

Date of Testing: 2022-06-14 19:08:09
 Date of Next Testing: 2025-06-13 19:08:09
 Product Name: **Enoxaparin sodium (from Hog intestine)**
 CAS Number: 9041-08-1
 Specifications & Purity:
 Lot #: F2205527
 SKU #: **H284086**
Analysis: 091050
 Storage Temperature: Store at 2-8°C, Argon charged

Parameter	Limit Values	Result
Anti-FXa/Anti-FIIa	3.3-5.3	3.70000
The mass-average relative molecular mass ranges between 3800 and 5000	3800-5000	4214.00000
weight-average molecular weight:2000	12-20 (%)	16.10000 %
weight-average molecular weight:2000-8000	68-82 (%)	75.90000 %
weight-average molecular weight:8000	≤18 (%)	16.00000 %
PH (10% Water)	6.2-7.7	6.90
Benzyl alcohol content	≤0.1 (%)	0.01000 %
Specific absorbance The specific absorbance at 231±2nm (dried substance)	14-20	17.20000
Sodium(Na)	11.3-13.5 (%)	12.20 %
Nitrogen	1.8-2.5 (%)	2.10 %
Loss on drying	0-10 (%)	2.00 %
SO42-/COO-	≥1.8	2.30000
Microbiological examination TAMC	≤10 (cfu/g)	9.00000 cfu/g
Microbiological examination TYMC	≤10 (cfu/g)	9.00000 cfu/g
Solvents(Ethanol)	≤5000 (ppm)	123.00000 ppm
Solvents(DMF)	≤880 (ppm)	880.00000 ppm
Anti-Factor Xa activity The potency is NLT 90 and NMT 125 Anti-Factor Xa IU/mg on the dried basis	90-125	104.00000
Anti-Factor IIa activity It has a potency of NLT 20.0 and NMT 35.0 Anti-Factor IIa IU/mg on the dried basis	20-35	28.20000
1,6-anhydro derivate	15-25 (%)	22.00000 %
Appearance(H284086)	White to almost white powder	White to almost white powder
Identification	pass	Pass
Ultraviolet absorption	Conforms	Conforms
13C-NMR Spectrum	Pass	Pass

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Parameter	Limit Values	Result
Positive sodium reaction	Complies	complies
Bacterial endotoxins It contains NMT 0.01 USP Endotoxin Unit/IU of Anti-	Pass	Pass
Factor Xa activity		
Escherichia coli	negative	Negative
Salmonella	negative	Negative
Pseudomonas Aeruginosa	Negative	Negative

A handwritten signature in black ink that reads "John Su".

John Su
QA & QC Manager