



Certificate of Analysis

Name	Sodium Hyaluronate	Grade	Injection Grade
Origin	Fermentation	Test Method	EP11.0
Lot No.	SH02240819_31	Quantity	13.19 kg
MFG Date	2024/08/19	EXP Date	2026/08/18

Physical & Chemical Test

1	Appearance	White or almost white powder or fibrous aggregate	Complies
2	Identification A. Infrared absorption Reaction of sodium	The IR spectrum of the sample exhibits maxima at the same wavelength as that of Ph. Eur. Reference spectrum of sodium hyaluronate Positive	Complies Positive
3	Appearance of solution	Clear and the absorbance is NMT 0.01 at 600 nm	Clear, A_{600} nm=0.003
4	Ph	5.0~8.5(0.5% solution)	7.8
5	Intrinsic viscosity	Test value	3.85 m ³ /kg
6	Molecular weight	Test value	2.55×10 ⁶ Da

Purity Test

7	Nucleic acids	The absorbance is NMT 0.05 at 260 nm	0.02
8	Protein	≤0.05%	<LOD(0.03%)
9	Chlorides	≤0.1%	<0.1%
10	Loss on drying	≤10%	9.7%
11	Iron	≤20ppm	8.5 ppm
12	Heavy metals	≤10ppm	<10ppm
13	Residual solvents(Ethanol)	≤0.1%	0.06%
14	Assay	95.0%-105.0%	102.7%

Bacterial Endotoxins Test

15	Bacterial endotoxins	≤0.015IU/g	<0.015IU/g
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Microbiological Test

16	Total bacterial count	$\leq 100\text{CFU/g}$	$<20\text{CFU/g}$
17	Yeasts & mold	$\leq 20\text{CFU/g}$	$<20\text{CFU/g}$
18	E. coli	Negative	Negative
19	Staph	Negative	Negative
20	Pseudomonas aeruginosa	Negative	Negative

Conclusion: The results meet the requirements of the specifications.