



Certificate of Analysis

Name	Sodium Hyaluronate	Grade	Eye Drops Grade
Origin	Fermentation	Test Method	EP11.0
Lot No.	SH02241019_19	Quantity	9.1 kg
MFG Date	2024/10/23	EXP Date	2026/10/22

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=0.005
4	Ph	5.0~8.5(0.5% solution)	7.6
5	Intrinsic viscosity	Test value	3.459 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	0.01
8	Protein	≤0.05%	<LOD(0.02%)
9	Chlorides	≤0.125%	<0.125%
10	Loss on drying	≤10%	5.5%
11	As	≤2ppm	<2ppm
12	Heavy metals	≤10ppm	<10ppm
13	Residual solvents (Ethanol)	≤0.1%	0.04%
14	Assay	95.0%-105.0%	101.8%

Bacterial Endotoxins Test

15	Bacterial endotoxins	≤0.05IU/mg	<0.05IU/mg
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Microbiological Test

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ACROSS BIOTECH

MAKE A DIFFERENCE

16	Total bacterial count	≤ 100 CFU/g	<20CFU/g
17	Yeasts & mold	≤ 20 CFU/g	<20CFU/g
18	E. coli	Negative/g	Negative/g
19	Staph	Negative/g	Negative/g
20	Pseudomonas aeruginosa	Negative/g	Negative/g
21	Hemolysis	Negative	Negative
22	Hemolytic streptococcus	Negative	Negative

Conclusion: The results meet the requirements of the specifications.

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