CERTIFICATE OF ANALYSIS

Product Name	Sodium Hyaluronate – High MW (500-1000 kDa)		
Batch No.	SH02230206-19	Manufacturing date	2023.02.10
Test Date	2023.02.13	Retest Date	2026.02.09
Quantity	11.03kg	Report Date	2024.04.22
Origin	Fermentation	Grade	Eye-drop Grade
Standard	Ph.Eur.11.0		

Items	Specification	Results
Appearance	White or almost white powder or fibrous aggregate	White powder
Identification A. Infrared absorption	The IR spectrum of the sample exhibits maxima at the same wavelength as that of Ph.Eur. reference spectrum of Sodium Hyaluronate	Comply
B.Reaction of Sodium	Positive	Positive
Appearance of solution	Clear and the absorbance is NMT 0.01 at 600nm	Clear $A_{600\ nm}$: 0.001
Solubility	Sparingly soluble or soluble in water, practically insoluble in acetone and anhydrous ethanol	Comply
pH	5.4 ~ 8.2 (0.5% solution)	7.3
Intrinsic viscosity	1.2m^3/kg ~ 1.6m^3/kg	1.58m^3/kg
Molecular weight	6.28×10^5Da ~ 9.10×10^5Da	8.95×10^5Da
Nucleic acids	The absorbance is NMT 0.5 at 260nm	0.008
Protein	≤0.1% (On the dried substance)	<LOD(0.03%)
Chlorides	≤0.5%	<0.5%
Iron	≤80ppm (On the dried substance)	1.8ppm
Loss on drying	≤10.0%	7.6%
Assay	95.0%～105.0℃ (On the dried substance)	102.0%
Glucuronic acid	45.95%～50.79%	Comply
Residual solvents: Ethanol	≤0.5%	0.01%
Microbial contamination-TAMC	≤100 cfu/g	<10 cfu/g
Bacterial endotoxins	≤0.5 IU/mg	<0.5 IU/mg
Conclusion	The product complies with the standard of Ph.Eur.11.0	