Certificate of Analysis

Product Name	Sodium Hyaluronate	Report No.	SH05201002_0402
Batch No.	SH05201002_04	Test Date	2020.10.16
Quantity	6.08 kg	Report Date	2020.11.02
Origin	Fermentation	Manufacturing Date	2020.10.12
Grade	Eye-drop Grade	Retest Date	2022.10.11
Standard	Ph.Eur.10.0 and customer standards		

Items	Specifications	Results
Appearance	White or almost white powder or fibrous aggregate	White powder
Identification A. Infrared absorption B. Reaction (a) 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	 Comply Positive
Appearance of solution	Clear and the absorbance is NMT 0.01 at 600 nm	Clear, $A_{600\ nm}$ = 0.0005
pH	5.0 ~ 8.5 (0.5% solution)	6.8
Intrinsic viscosity	2.0 m^3/kg~2.6 m^3/kg	2.44 m^3/kg
Molecular weight	121×10^4 Da ~ 158×10^4Da	156×10^4 Da
Nucleic acids	The absorbance is NMT 0.5 at 260 nm	0.01
Protein	≤ 0.1% (on the dried substance)	< LOD(0.03%)
Chlorides	≤ 0.5%	< 0.5%
Heavy metals	≤ 10 ppm	<10 ppm
Iron	≤ 80 ppm (on the dried substance)	1.2 ppm
Loss on drying	≤ 15.0%	8.5%
Assay	95.0% ~105.0% (on the dried substance)	101.9%
Residual solvents: Ethanol	≤ 0.5%	0.02%
Microbial contamination	TAMC ≤ 100 cfu/g	4 cfu/g
Bacterial Endotoxins	< 0.05 IU/mg	< 0.05 IU/mg
Conclusions	**The product complies with Ph.Eur.10.0 and customer standards**	

Storage Condition: 5±3℃ in an airtight container, protected from light and humidity.