Stanford Chemicals Company
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CERTIFICATE OF ANALYSIS

24-E082902

Product name:	Sodium hyaluronate	Standard:	Ph.Eur.11.0
Batch No.:	J101240115 (OC240930-19466)	Manufacture date:	Aug.19, 2024
Batch size:	12.290 kg	Retest date:	Aug.19, 2027
Intrinsic viscosity:	2.2～2.8 m³/kg	Origin:	Bacterial fermentation
Grade:	HA-EP 2.4	Intended use:	For the manufacture of parenteral preparations, including intra-articular and intra-ocular preparations

Items	Acceptance criteria	Results
1. Characters	White or almost white powder or fibrous aggregate	White powder
2. Identification		
A. Infrared absorption	Consistent with the reference substance spectrum of sodium hyaluronate	Complies
B. Reaction (a) of sodium	Positive	Positive
3. Appearance of solution	Clear	Clear
	A_{600nm}≤0.01	0.000
4. pH	5.0～8.5	6.4
5. Intrinsic viscosity	2.2～2.8 m³/kg	2.40 m³ /kg
6. Nucleic acids	A_{260nm}≤0.5	0.006
7. Protein	≤0.1%	<0.003%
8. Chlorides	≤0.5%	<0.5%
9. Iron	≤30 ppm	2 ppm
10. Loss on drying	≤18.0%	8.0%
11. Microbial contamination (TAMC)	≤100 cfu/g	<20 cfu/g
12. Bacterial Endotoxins	<0.05 IU/mg	<0.05 IU/mg
13. Residual solvents (Ethanol)	≤5000 ppm	99 ppm
14. Assay	95.0%～105.0% (dried substance)	100.4%

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