



## Certificate of Analysis

Name	Hyaluronic Acid	Grade	Injection Grade
Origin	Fermentation	Test Method	EP10.0
Lot No.	I202104102	Report Date	2021/04/11
MFG Date	2021/04/10	EXP Date	2023/04/09

### Physical & Chemical Test

	Test Items	Specification	Results
1	Appearance	White or almost white powder or fibrous aggregate	Complies
2	Identification		
	A. Infrared absorption	The IR spectrum of the sample exhibits maxima at the same wavelength as that of Ph. Eur. Reference spectrum of hyaluronic acid	Complies
	B. Reaction of sodium	Positive	Positive
3	Appearance of solution	Clear and the absorbance is NMT 0.01 at 600 nm	Clear, $A_{600}$ nm=0.002
4	Ph	5.0~8.5(0.5% solution)	7.1
5	Intrinsic viscosity	Actual value	2.60 m <sup>3</sup> /kg
6	Molecular weight	Actual value	1.53×10 <sup>6</sup> Da

### Purity Test

7	Nucleic acids	The absorbance is NMT 0.05 at 260 nm	0.016
8	Protein	≤0.1%	0.080%
9	Chlorides	≤0.5%	<0.5%
10	Loss on drying	≤20%	6.00%
11	Iron	≤80ppm	<80ppm
12	Residual solvents(Ethanol)	≤5000ppm	113ppm
13	Assay	95.0%-105.0%	97.75%



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### Bacterial Endotoxins Test

14	Bacterial endotoxins	$\leq 0.05\text{IU/g}$	$< 0.05\text{IU/g}$
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### Microbiological Test

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

**Conclusion: The results meet the requirements of the specifications.**