BLOOMAGE

CERTIFICATE OF ANALYSIS

25-E062306

Product Name:	Sodium hyaluronate	Standard:	HX/ZL-001-025
Grade:	HA-EP2	Manufacture Date:	June 05, 2025
Batch No.:	J101250083	Retest Date:	June 05, 2027
Batch Size:	16.460 kg	Origin:	Bacterial fermentation
Storage:	Kept airtightly, protected from light. For I.V. <2.8 m^3/kg, store at [below +8 °C] for I.V. ≥2.8 m^3/kg, store at [below -10 °C].	Intended Use:	For the manufacture of parenteral preparations, including intra-articular and intra-ocular preparations

Test Items	Test Method	Acceptance criteria	Results
1. Characters	Visual Inspection	White or almost white powder or fibrous aggregate	Complies
2. Identification			
A. Infrared absorption	Ph. Eur. 2.2.24	Consistent with the Ph. Eur. reference spectrum of sodium hyaluronate	Complies
B. Reaction of sodium	Ph. Eur. 2.3.1	Positive	Complies
3. Appearance of solution	Ph. Eur. 2.2.1	Solution is clear	Clear
	Ph. Eur. 2.2.25	A_{600nm}≤0.01	0.001
4. pH	Ph. Eur. 2.2.3	5.0～8.5	6.2
5. Intrinsic viscosity	Ph. Eur. 2.2.9	Measured value	2.02 m^3/kg
6. Nucleic acids	Ph. Eur. 2.2.25	A_{260nm}≤0.5	0.01
7. Protein	Ph. Eur. 2.2.25	≤0.1%	<0.003%
8. Chlorides	Ph. Eur. 2.4.4	≤0.5%	<0.5%
9. Iron	Ph. Eur. 2.2.23	≤80 ppm	<80 ppm
10. Loss on drying	In-house method	≤20.0%	9.7%
11. Ethanol residue	In-house method	≤0.4%	<0.002%
12. Bacterial endotoxins	Ph. Eur. 2.6.14	<0.05 IU/mg	<0.05 IU/mg
13. Sterility	Ch.P 1101	Complies with the test for sterility	Complies
14. Sodium hyaluronate	In-house method	95.0%～105.0%	100.1%

Conclusion: up to the standard

QA Manager: 2025.06.23 **Reviewed by:** 2025.06.23 **Reported by:** 2025.06.23

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