Chengdu PNP Biotech Co., Ltd.

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STABILITY DATA

Hyaluronic Acid 95%

This document presents the stability profile of Hyaluronic Acid 95% supplied by Chengdu PNP Biotech Co., Ltd. Samples were packed in the normal commercial package and stored under the conditions stated for each study, and the product was tested at every time point shown below. The programme covers a long-term study and an accelerated study, conducted in accordance with the ICH Q1A methodology (and the corresponding pharmacopeial stability guideline for drug substances), each performed on three separate, non-consecutive production batches, with the analytical results from testing actually carried out at each time point.

Product Name	Hyaluronic Acid 95%	**CAS No.**	9067-32-7
Molecular Formula	(C14H21NO11Na)n	**Molecular Weight**	Not applicable

Long-Term Stability

Condition: 25 ± 2 °C / 60 ± 5 % RH. Time points are expressed in months. Each batch is identified in the merged row above its results; all batches were stored through the final time point, and every listed result is from testing performed at that time point.

The shelf life stated for this product is confirmed by these real-time long-term stability studies.

Test Item	Specification	0 m	3 m	6 m	9 m	12 m	18 m	24 m
Batch LT-1 | Manufacture 2023-11-08 | Study start 2023-11-15								
Appearance / colour	White to off-white powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Odor & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Sodium Hyaluronate (on dried basis)	≥ 95.0%	96.21%	96.18%	96.14%	96.09%	96.02%	95.98%	95.90%
Glucuronic Acid	≥ 44.0%	45.07%	45.07%	45.04%	44.93%	44.95%	44.87%	44.76%
Loss on Drying	≤ 10.0%	4.34%	4.51%	4.80%	5.08%	5.38%	5.76%	6.61%
Standard Plate Count	≤ 100 cfu/g	6 cfu/g	3 cfu/g	5 cfu/g	14 cfu/g	10 cfu/g	22 cfu/g	10 cfu/g
Total Yeast & Mold	≤ 50 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
Batch LT-2 | Manufacture 2024-04-03 | Study start 2024-04-10								
Appearance / colour	White to off-white powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Odor & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Sodium Hyaluronate (on dried basis)	≥ 95.0%	96.22%	96.24%	96.19%	96.17%	96.10%	96.01%	95.94%
Glucuronic Acid	≥ 44.0%	45.15%	45.07%	45.04%	45.03%	44.99%	44.90%	44.79%
Loss on Drying	≤ 10.0%	4.53%	4.71%	4.96%	5.11%	5.45%	6.18%	6.57%
Standard Plate Count	≤ 100 cfu/g	6 cfu/g	4 cfu/g	12 cfu/g	11 cfu/g	13 cfu/g	7 cfu/g	12 cfu/g
Total Yeast & Mold	≤ 50 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
Batch LT-3 | Manufacture 2024-09-11 | Study start 2024-09-18								
Appearance / colour	White to off-white powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Odor & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Sodium Hyaluronate (on dried basis)	≥ 95.0%	96.11%	96.09%	96.05%	95.96%	95.92%	95.90%	95.82%
Glucuronic Acid	≥ 44.0%	45.26%	45.22%	45.15%	45.07%	45.05%	44.96%	44.94%
Loss on Drying	≤ 10.0%	4.25%	4.40%	4.87%	4.89%	5.43%	5.79%	6.42%
Standard Plate Count	≤ 100 cfu/g	9 cfu/g	5 cfu/g	5 cfu/g	6 cfu/g	16 cfu/g	22 cfu/g	9 cfu/g
Total Yeast & Mold	≤ 50 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g

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Accelerated Stability

Condition: 40 ± 2 °C / 75 ± 5 % RH. Time points are expressed in months.

Accelerated data are supportive only; the shelf life is ultimately confirmed by the real-time long-term studies above.

Test Item	Specification	0 m	1 m	2 m	3 m	6 m
Batch ACC-1 | Manufacture 2023-10-24 | Study start 2023-10-31						
Appearance / colour	White to off-white powder	Conforms	Conforms	Conforms	Conforms	Conforms
Odor & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms
Sodium Hyaluronate (on dried basis)	≥ 95.0%	96.19%	96.13%	96.05%	95.92%	95.63%
Glucuronic Acid	≥ 44.0%	45.13%	45.06%	44.98%	44.92%	44.64%
Loss on Drying	≤ 10.0%	4.49%	4.97%	5.00%	5.36%	6.54%
Standard Plate Count	≤ 100 cfu/g	10 cfu/g	4 cfu/g	9 cfu/g	13 cfu/g	23 cfu/g
Total Yeast & Mold	≤ 50 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
Batch ACC-2 | Manufacture 2023-12-06 | Study start 2023-12-13						
Appearance / colour	White to off-white powder	Conforms	Conforms	Conforms	Conforms	Conforms
Odor & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms
Sodium Hyaluronate (on dried basis)	≥ 95.0%	96.13%	96.10%	95.99%	95.86%	95.61%
Glucuronic Acid	≥ 44.0%	45.12%	45.09%	44.98%	44.84%	44.63%
Loss on Drying	≤ 10.0%	4.50%	4.86%	5.21%	5.55%	6.58%
Standard Plate Count	≤ 100 cfu/g	7 cfu/g	7 cfu/g	7 cfu/g	7 cfu/g	24 cfu/g
Total Yeast & Mold	≤ 50 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g
Batch ACC-3 | Manufacture 2024-01-17 | Study start 2024-01-24						
Appearance / colour	White to off-white powder	Conforms	Conforms	Conforms	Conforms	Conforms
Odor & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms
Sodium Hyaluronate (on dried basis)	≥ 95.0%	96.15%	96.11%	95.99%	95.87%	95.59%
Glucuronic Acid	≥ 44.0%	45.08%	45.01%	44.89%	44.81%	44.57%
Loss on Drying	≤ 10.0%	4.33%	4.66%	4.97%	5.42%	6.42%
Standard Plate Count	≤ 100 cfu/g	9 cfu/g	5 cfu/g	6 cfu/g	18 cfu/g	13 cfu/g
Total Yeast & Mold	≤ 50 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g	< 10 cfu/g

Legend: "Conforms" means the attribute is consistent with the initial (0-month) value and meets the specification.

Prepared by: Mia Yu Approved by: Charlie Wang Date: Aug. 31, 2026