Chengdu PNP Biotech Co., Ltd.

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STABILITY DATA

Spermidine Trihydrochloride 98.0%

This document presents the stability profile of Spermidine Trihydrochloride 98.0% 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	Spermidine Trihydrochloride 98.0%	**CAS No.**	334-50-9
Molecular Formula	C7H22Cl3N3	**Molecular Weight**	254.59

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 / color	White to off-white crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Odor & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Assay (on dried basis)	≥ 98.0%	99.26%	99.22%	99.13%	99.14%	99.04%	98.96%	98.91%
Loss on Drying	≤ 1.0%	0.44%	0.46%	0.48%	0.51%	0.55%	0.61%	0.65%
Standard Plate Count	≤ 1,000 cfu/g	74 cfu/g	52 cfu/g	71 cfu/g	56 cfu/g	104 cfu/g	225 cfu/g	277 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	4 cfu/g	4 cfu/g	10 cfu/g	7 cfu/g	5 cfu/g	15 cfu/g	24 cfu/g
Batch LT-2 | Manufacture 2024-04-03 | Study start 2024-04-10								
Appearance / color	White to off-white crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Odor & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Assay (on dried basis)	≥ 98.0%	99.25%	99.28%	99.21%	99.18%	99.09%	99.03%	98.94%
Loss on Drying	≤ 1.0%	0.43%	0.47%	0.51%	0.53%	0.53%	0.60%	0.64%
Standard Plate Count	≤ 1,000 cfu/g	91 cfu/g	57 cfu/g	58 cfu/g	101 cfu/g	83 cfu/g	120 cfu/g	94 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	8 cfu/g	3 cfu/g	9 cfu/g	13 cfu/g	14 cfu/g	13 cfu/g	7 cfu/g
Batch LT-3 | Manufacture 2024-09-11 | Study start 2024-09-18								
Appearance / color	White to off-white crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Odor & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Assay (on dried basis)	≥ 98.0%	99.14%	99.10%	99.10%	99.06%	98.95%	98.88%	98.81%
Loss on Drying	≤ 1.0%	0.43%	0.46%	0.51%	0.52%	0.56%	0.61%	0.65%
Standard Plate Count	≤ 1,000 cfu/g	36 cfu/g	54 cfu/g	69 cfu/g	169 cfu/g	156 cfu/g	204 cfu/g	298 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	5 cfu/g	11 cfu/g	12 cfu/g	4 cfu/g	11 cfu/g	11 cfu/g	14 cfu/g

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 / color	White to off-white crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Odor & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms

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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						
Assay (on dried basis)	≥ 98.0%	99.29%	99.13%	99.03%	99.02%	98.72%
Loss on Drying	≤ 1.0%	0.41%	0.46%	0.49%	0.51%	0.62%
Standard Plate Count	≤ 1,000 cfu/g	107 cfu/g	125 cfu/g	169 cfu/g	114 cfu/g	114 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	4 cfu/g	11 cfu/g	8 cfu/g	15 cfu/g	8 cfu/g
Batch ACC-2 | Manufacture 2023-12-06 | Study start 2023-12-13						
Appearance / color	White to off-white crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Odor & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms
Assay (on dried basis)	≥ 98.0%	99.21%	99.09%	99.04%	98.88%	98.64%
Loss on Drying	≤ 1.0%	0.47%	0.48%	0.54%	0.56%	0.66%
Standard Plate Count	≤ 1,000 cfu/g	58 cfu/g	84 cfu/g	123 cfu/g	88 cfu/g	275 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	4 cfu/g	8 cfu/g	7 cfu/g	13 cfu/g	23 cfu/g
Batch ACC-3 | Manufacture 2024-01-17 | Study start 2024-01-24						
Appearance / color	White to off-white crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Odor & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms
Assay (on dried basis)	≥ 98.0%	99.20%	99.05%	99.02%	98.93%	98.59%
Loss on Drying	≤ 1.0%	0.41%	0.44%	0.49%	0.52%	0.66%
Standard Plate Count	≤ 1,000 cfu/g	55 cfu/g	91 cfu/g	139 cfu/g	174 cfu/g	223 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	9 cfu/g	4 cfu/g	12 cfu/g	7 cfu/g	22 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: Nov. 04, 2026