Chengdu PNP Biotech Co., Ltd.

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STABILITY DATA

Melatonin 99%

This document presents the stability profile of Melatonin 99% 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	Melatonin 99%	**CAS No.**	73-31-4
Molecular Formula	C13H16N2O2	**Molecular Weight**	232.28

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	30 m	36 m
Batch LT-1 | Manufacture 2023-11-08 | Study start 2023-11-15										
Appearance	White or off-white crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Assay	98.5%~101.5%	99.40%	99.40%	99.38%	99.41%	99.41%	99.36%	99.39%	99.37%	99.40%
Loss on Drying	≤ 1.0%	0.41%	0.43%	0.44%	0.49%	0.52%	0.57%	0.60%	0.62%	0.60%
Standard Plate Count	≤ 1,000 cfu/g	40 cfu/g	64 cfu/g	69 cfu/g	135 cfu/g	159 cfu/g	96 cfu/g	190 cfu/g	233 cfu/g	176 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	4 cfu/g	3 cfu/g	8 cfu/g	4 cfu/g	9 cfu/g	8 cfu/g	8 cfu/g	7 cfu/g	10 cfu/g
Batch LT-2 | Manufacture 2024-04-03 | Study start 2024-04-10										
Appearance	White or off-white crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Assay	98.5%~101.5%	99.46%	99.38%	99.41%	99.43%	99.39%	99.41%	99.39%	99.36%	99.37%
Loss on Drying	≤ 1.0%	0.36%	0.40%	0.42%	0.47%	0.50%	0.53%	0.58%	0.60%	0.58%
Standard Plate Count	≤ 1,000 cfu/g	73 cfu/g	75 cfu/g	104 cfu/g	64 cfu/g	121 cfu/g	84 cfu/g	213 cfu/g	107 cfu/g	83 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	4 cfu/g	5 cfu/g	10 cfu/g	11 cfu/g	9 cfu/g	13 cfu/g	12 cfu/g	15 cfu/g	11 cfu/g
Batch LT-3 | Manufacture 2024-09-11 | Study start 2024-09-18										
Appearance	White or off-white crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Assay	98.5%~101.5%	99.41%	99.42%	99.39%	99.40%	99.36%	99.34%	99.36%	99.32%	99.36%
Loss on Drying	≤ 1.0%	0.37%	0.40%	0.45%	0.49%	0.49%	0.56%	0.59%	0.59%	0.62%
Standard Plate Count	≤ 1,000 cfu/g	62 cfu/g	61 cfu/g	78 cfu/g	69 cfu/g	143 cfu/g	188 cfu/g	147 cfu/g	226 cfu/g	268 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	6 cfu/g	6 cfu/g	4 cfu/g	10 cfu/g	14 cfu/g	9 cfu/g	15 cfu/g	6 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	White or off-white crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Assay	98.5%~101.5%	99.38%	99.40%	99.37%	99.42%	99.40%
Loss on Drying	≤ 1.0%	0.38%	0.42%	0.46%	0.50%	0.61%
Standard Plate Count	≤ 1,000 cfu/g	57 cfu/g	114 cfu/g	103 cfu/g	108 cfu/g	97 cfu/g

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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						
Total Yeast & Mold	≤ 100 cfu/g	5 cfu/g	7 cfu/g	6 cfu/g	11 cfu/g	11 cfu/g
Batch ACC-2 | Manufacture 2023-12-06 | Study start 2023-12-13						
Appearance	White or off-white crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Assay	98.5%~101.5%	99.39%	99.45%	99.41%	99.36%	99.32%
Loss on Drying	≤ 1.0%	0.39%	0.41%	0.46%	0.50%	0.60%
Standard Plate Count	≤ 1,000 cfu/g	98 cfu/g	67 cfu/g	79 cfu/g	79 cfu/g	264 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	3 cfu/g	9 cfu/g	5 cfu/g	7 cfu/g	6 cfu/g
Batch ACC-3 | Manufacture 2024-01-17 | Study start 2024-01-24						
Appearance	White or off-white crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Assay	98.5%~101.5%	99.44%	99.41%	99.42%	99.36%	99.35%
Loss on Drying	≤ 1.0%	0.36%	0.41%	0.44%	0.47%	0.57%
Standard Plate Count	≤ 1,000 cfu/g	89 cfu/g	120 cfu/g	53 cfu/g	67 cfu/g	135 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	6 cfu/g	4 cfu/g	9 cfu/g	14 cfu/g	15 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: Mar. 26, 2026