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STABILITY DATA

Dihydroberberine 98%

This document presents the stability profile of Dihydroberberine 98% 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	Dihydroberberine 98%	**Country of Origin**	China
Molecular Formula	Not applicable	**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 / color	Yellow crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Dihydroberberine	≥ 98.0%	99.10%	99.09%	99.00%	98.95%	98.97%	98.87%	98.79%
Loss on Drying	≤ 12.5%	5.86%	6.33%	6.66%	7.10%	7.19%	8.17%	8.93%
Standard Plate Count	≤ 10,000 cfu/g	468 cfu/g	1,291 cfu/g	810 cfu/g	1,409 cfu/g	1,456 cfu/g	1,782 cfu/g	2,068 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	6 cfu/g	10 cfu/g	4 cfu/g	5 cfu/g	15 cfu/g	22 cfu/g	21 cfu/g
Batch LT-2 | Manufacture 2024-04-03 | Study start 2024-04-10								
Appearance / color	Yellow crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Dihydroberberine	≥ 98.0%	99.19%	99.11%	99.13%	99.11%	99.04%	99.01%	98.94%
Loss on Drying	≤ 12.5%	5.89%	6.28%	6.56%	6.66%	7.21%	8.07%	8.36%
Standard Plate Count	≤ 10,000 cfu/g	840 cfu/g	1,041 cfu/g	606 cfu/g	1,646 cfu/g	1,253 cfu/g	1,175 cfu/g	960 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	3 cfu/g	10 cfu/g	8 cfu/g	5 cfu/g	14 cfu/g	9 cfu/g	22 cfu/g
Batch LT-3 | Manufacture 2024-09-11 | Study start 2024-09-18								
Appearance / color	Yellow crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Dihydroberberine	≥ 98.0%	99.22%	99.17%	99.10%	99.10%	99.08%	99.00%	98.92%
Loss on Drying	≤ 12.5%	5.80%	6.07%	6.57%	6.98%	7.43%	8.15%	8.85%
Standard Plate Count	≤ 10,000 cfu/g	1,002 cfu/g	745 cfu/g	554 cfu/g	852 cfu/g	1,443 cfu/g	1,886 cfu/g	2,609 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	5 cfu/g	9 cfu/g	13 cfu/g	11 cfu/g	15 cfu/g	10 cfu/g	11 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	Yellow crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Dihydroberberine	≥ 98.0%	99.19%	99.07%	98.99%	98.89%	98.69%
Loss on Drying	≤ 12.5%	6.04%	6.49%	6.86%	7.30%	8.40%
Standard Plate Count	≤ 10,000 cfu/g	520 cfu/g	849 cfu/g	1,115 cfu/g	1,872 cfu/g	1,130 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	9 cfu/g	8 cfu/g	6 cfu/g	17 cfu/g	25 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						
Batch ACC-2 | Manufacture 2023-12-06 | Study start 2023-12-13						
Appearance / color	Yellow crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Dihydroberberine	≥ 98.0%	99.14%	99.07%	98.97%	98.90%	98.65%
Loss on Drying	≤ 12.5%	5.82%	6.32%	6.70%	7.21%	8.79%
Standard Plate Count	≤ 10,000 cfu/g	566 cfu/g	408 cfu/g	856 cfu/g	919 cfu/g	2,823 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	3 cfu/g	12 cfu/g	12 cfu/g	10 cfu/g	11 cfu/g
Batch ACC-3 | Manufacture 2024-01-17 | Study start 2024-01-24						
Appearance / color	Yellow crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Dihydroberberine	≥ 98.0%	99.09%	99.04%	98.95%	98.89%	98.63%
Loss on Drying	≤ 12.5%	5.66%	6.33%	6.49%	7.03%	8.22%
Standard Plate Count	≤ 10,000 cfu/g	1,038 cfu/g	999 cfu/g	965 cfu/g	1,536 cfu/g	1,963 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	9 cfu/g	12 cfu/g	6 cfu/g	12 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: Sep. 30, 2026