Chengdu PNP Biotech Co., Ltd.

No. 13, South Section 1, Second Ring Road
Suite 709, Wuhou District, Chengdu
Sichuan 610041, P.R. China
info@pnpbiotech.com
www.pnpbiotech.com

STABILITY DATA

Benfotiamine 99%

This document presents the stability profile of Benfotiamine 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	Benfotiamine 99%	**CAS No.**	22457-89-2
Molecular Formula	C19H23N4O6PS	**Molecular Weight**	466.45

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	White crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Assay	98.0%~102.0%	99.25%	99.32%	99.22%	99.24%	99.22%	99.17%	99.24%
Loss on Drying	≤ 1.2%	0.58%	0.63%	0.64%	0.71%	0.72%	0.81%	0.84%
Standard Plate Count	≤ 1,000 cfu/g	64 cfu/g	55 cfu/g	68 cfu/g	69 cfu/g	66 cfu/g	147 cfu/g	154 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	7 cfu/g	5 cfu/g	10 cfu/g	10 cfu/g	12 cfu/g	17 cfu/g	14 cfu/g
Batch LT-2 | Manufacture 2024-04-03 | Study start 2024-04-10								
Appearance	White crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Assay	98.0%~102.0%	99.25%	99.28%	99.22%	99.25%	99.21%	99.23%	99.23%
Loss on Drying	≤ 1.2%	0.61%	0.64%	0.65%	0.71%	0.74%	0.80%	0.86%
Standard Plate Count	≤ 1,000 cfu/g	69 cfu/g	43 cfu/g	78 cfu/g	53 cfu/g	134 cfu/g	147 cfu/g	96 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	6 cfu/g	6 cfu/g	5 cfu/g	7 cfu/g	7 cfu/g	9 cfu/g	10 cfu/g
Batch LT-3 | Manufacture 2024-09-11 | Study start 2024-09-18								
Appearance	White crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Assay	98.0%~102.0%	99.29%	99.24%	99.23%	99.28%	99.17%	99.15%	99.16%
Loss on Drying	≤ 1.2%	0.60%	0.61%	0.67%	0.68%	0.73%	0.79%	0.84%
Standard Plate Count	≤ 1,000 cfu/g	47 cfu/g	41 cfu/g	66 cfu/g	92 cfu/g	86 cfu/g	112 cfu/g	106 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	8 cfu/g	9 cfu/g	10 cfu/g	8 cfu/g	6 cfu/g	18 cfu/g	8 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 crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Assay	98.0%~102.0%	99.23%	99.25%	99.18%	99.29%	99.21%
Loss on Drying	≤ 1.2%	0.57%	0.62%	0.64%	0.68%	0.81%
Standard Plate Count	≤ 1,000 cfu/g	35 cfu/g	90 cfu/g	113 cfu/g	83 cfu/g	166 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	8 cfu/g	9 cfu/g	14 cfu/g	11 cfu/g	15 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	White crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Assay	98.0%~102.0%	99.25%	99.21%	99.27%	99.25%	99.15%
Loss on Drying	≤ 1.2%	0.54%	0.60%	0.65%	0.70%	0.84%
Standard Plate Count	≤ 1,000 cfu/g	40 cfu/g	94 cfu/g	89 cfu/g	107 cfu/g	106 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	4 cfu/g	5 cfu/g	13 cfu/g	7 cfu/g	22 cfu/g
Batch ACC-3 | Manufacture 2024-01-17 | Study start 2024-01-24						
Appearance	White crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Assay	98.0%~102.0%	99.28%	99.30%	99.20%	99.23%	99.24%
Loss on Drying	≤ 1.2%	0.60%	0.61%	0.67%	0.74%	0.85%
Standard Plate Count	≤ 1,000 cfu/g	37 cfu/g	53 cfu/g	36 cfu/g	132 cfu/g	143 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	4 cfu/g	8 cfu/g	12 cfu/g	15 cfu/g	17 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. 13, 2026