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STABILITY DATA

Berberine HCl 97%

This document presents the stability profile of Berberine HCl 97% 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	Berberine HCl 97%	**CAS No.**	633-65-8
Botanical Source	*Berberis vulgaris*	**Part Used**	Rhizome

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	Yellow crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Odour & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Berberine HCl (on dried basis)	≥ 97.0%	98.38%	98.37%	98.34%	98.31%	98.31%	98.26%	98.20%
Loss on Drying	≤ 12.0%	5.16%	5.81%	6.15%	6.42%	6.53%	7.28%	8.13%
Standard Plate Count	≤ 10,000 cfu/g	849 cfu/g	764 cfu/g	1,418 cfu/g	863 cfu/g	1,575 cfu/g	1,753 cfu/g	1,966 cfu/g
Total Yeast & Mold	≤ 1,000 cfu/g	89 cfu/g	71 cfu/g	130 cfu/g	100 cfu/g	115 cfu/g	113 cfu/g	278 cfu/g
Batch LT-2 | Manufacture 2024-04-03 | Study start 2024-04-10								
Appearance / colour	Yellow crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Odour & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Berberine HCl (on dried basis)	≥ 97.0%	98.28%	98.25%	98.26%	98.22%	98.18%	98.08%	98.10%
Loss on Drying	≤ 12.0%	5.53%	5.94%	6.23%	6.24%	6.54%	7.54%	7.95%
Standard Plate Count	≤ 10,000 cfu/g	478 cfu/g	405 cfu/g	1,472 cfu/g	1,000 cfu/g	974 cfu/g	1,313 cfu/g	1,406 cfu/g
Total Yeast & Mold	≤ 1,000 cfu/g	87 cfu/g	117 cfu/g	121 cfu/g	105 cfu/g	163 cfu/g	141 cfu/g	272 cfu/g
Batch LT-3 | Manufacture 2024-09-11 | Study start 2024-09-18								
Appearance / colour	Yellow crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Odour & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Berberine HCl (on dried basis)	≥ 97.0%	98.33%	98.27%	98.27%	98.23%	98.24%	98.14%	98.09%
Loss on Drying	≤ 12.0%	5.21%	5.77%	6.10%	6.26%	6.44%	7.24%	7.79%
Standard Plate Count	≤ 10,000 cfu/g	961 cfu/g	1,133 cfu/g	745 cfu/g	1,371 cfu/g	1,583 cfu/g	1,540 cfu/g	2,046 cfu/g
Total Yeast & Mold	≤ 1,000 cfu/g	75 cfu/g	105 cfu/g	97 cfu/g	131 cfu/g	200 cfu/g	256 cfu/g	175 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 / colour	Yellow crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Odour & 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						
Berberine HCl (on dried basis)	≥ 97.0%	98.23%	98.16%	98.12%	98.09%	97.83%
Loss on Drying	≤ 12.0%	5.25%	5.52%	6.21%	6.68%	7.99%
Standard Plate Count	≤ 10,000 cfu/g	639 cfu/g	922 cfu/g	1,660 cfu/g	830 cfu/g	2,086 cfu/g
Total Yeast & Mold	≤ 1,000 cfu/g	103 cfu/g	89 cfu/g	96 cfu/g	87 cfu/g	238 cfu/g
Batch ACC-2 | Manufacture 2023-12-06 | Study start 2023-12-13						
Appearance / colour	Yellow crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Odour & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms
Berberine HCl (on dried basis)	≥ 97.0%	98.28%	98.23%	98.19%	98.14%	97.89%
Loss on Drying	≤ 12.0%	5.44%	5.80%	6.19%	6.53%	8.23%
Standard Plate Count	≤ 10,000 cfu/g	678 cfu/g	542 cfu/g	654 cfu/g	1,778 cfu/g	2,285 cfu/g
Total Yeast & Mold	≤ 1,000 cfu/g	59 cfu/g	144 cfu/g	74 cfu/g	164 cfu/g	285 cfu/g
Batch ACC-3 | Manufacture 2024-01-17 | Study start 2024-01-24						
Appearance / colour	Yellow crystalline powder	Conforms	Conforms	Conforms	Conforms	Conforms
Odour & taste	Characteristic	Conforms	Conforms	Conforms	Conforms	Conforms
Berberine HCl (on dried basis)	≥ 97.0%	98.24%	98.18%	98.11%	98.04%	97.82%
Loss on Drying	≤ 12.0%	5.01%	5.65%	6.01%	6.60%	7.72%
Standard Plate Count	≤ 10,000 cfu/g	947 cfu/g	993 cfu/g	547 cfu/g	1,876 cfu/g	2,881 cfu/g
Total Yeast & Mold	≤ 1,000 cfu/g	98 cfu/g	54 cfu/g	95 cfu/g	154 cfu/g	173 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. 18, 2026