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STABILITY DATA

Magnesium Malate 20% Magnesium

This document presents the stability profile of Magnesium Malate 20% Magnesium 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	Magnesium Malate 20% Magnesium	**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 / colour	White or off-white powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Magnesium (on dried basis)	≥ 20.0%	20.58%	20.61%	20.53%	20.47%	20.44%	20.40%	20.35%
Loss on Drying	≤ 20.0%	8.28%	8.69%	9.52%	9.69%	10.75%	11.28%	12.68%
Aerobic Bacterial Count	≤ 1,000 cfu/g	35 cfu/g	36 cfu/g	101 cfu/g	117 cfu/g	69 cfu/g	93 cfu/g	100 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	4 cfu/g	11 cfu/g	12 cfu/g	7 cfu/g	15 cfu/g	9 cfu/g	11 cfu/g
Batch LT-2 | Manufacture 2024-04-03 | Study start 2024-04-10								
Appearance / colour	White or off-white powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Magnesium (on dried basis)	≥ 20.0%	20.61%	20.54%	20.53%	20.44%	20.47%	20.34%	20.29%
Loss on Drying	≤ 20.0%	7.91%	8.45%	8.93%	9.23%	10.43%	11.18%	12.50%
Aerobic Bacterial Count	≤ 1,000 cfu/g	83 cfu/g	69 cfu/g	71 cfu/g	119 cfu/g	92 cfu/g	212 cfu/g	245 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	9 cfu/g	4 cfu/g	6 cfu/g	16 cfu/g	6 cfu/g	13 cfu/g	12 cfu/g
Batch LT-3 | Manufacture 2024-09-11 | Study start 2024-09-18								
Appearance / colour	White or off-white powder	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Magnesium (on dried basis)	≥ 20.0%	20.57%	20.58%	20.53%	20.53%	20.45%	20.37%	20.33%
Loss on Drying	≤ 20.0%	7.31%	8.25%	8.64%	9.30%	9.38%	10.71%	11.59%
Aerobic Bacterial Count	≤ 1,000 cfu/g	72 cfu/g	55 cfu/g	55 cfu/g	57 cfu/g	100 cfu/g	78 cfu/g	190 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	7 cfu/g	8 cfu/g	10 cfu/g	11 cfu/g	6 cfu/g	9 cfu/g	19 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	White or off-white powder	Conforms	Conforms	Conforms	Conforms	Conforms
Magnesium (on dried basis)	≥ 20.0%	20.65%	20.54%	20.51%	20.44%	20.15%
Loss on Drying	≤ 20.0%	8.02%	8.80%	9.55%	9.89%	12.31%
Aerobic Bacterial Count	≤ 1,000 cfu/g	55 cfu/g	62 cfu/g	94 cfu/g	114 cfu/g	166 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	5 cfu/g	11 cfu/g	6 cfu/g	11 cfu/g	27 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 / colour	White or off-white powder	Conforms	Conforms	Conforms	Conforms	Conforms
Magnesium (on dried basis)	≥ 20.0%	20.67%	20.57%	20.45%	20.42%	20.17%
Loss on Drying	≤ 20.0%	8.29%	9.11%	9.44%	10.61%	12.46%
Aerobic Bacterial Count	≤ 1,000 cfu/g	33 cfu/g	90 cfu/g	46 cfu/g	55 cfu/g	98 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	6 cfu/g	6 cfu/g	13 cfu/g	8 cfu/g	16 cfu/g
Batch ACC-3 | Manufacture 2024-01-17 | Study start 2024-01-24						
Appearance / colour	White or off-white powder	Conforms	Conforms	Conforms	Conforms	Conforms
Magnesium (on dried basis)	≥ 20.0%	20.65%	20.60%	20.54%	20.41%	20.22%
Loss on Drying	≤ 20.0%	7.61%	8.59%	9.18%	9.97%	11.96%
Aerobic Bacterial Count	≤ 1,000 cfu/g	46 cfu/g	118 cfu/g	151 cfu/g	106 cfu/g	111 cfu/g
Total Yeast & Mold	≤ 100 cfu/g	9 cfu/g	9 cfu/g	10 cfu/g	11 cfu/g	21 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. 19, 2026