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STABILITY DATA

Lutein Beadlets 5%

This document presents the stability profile of Lutein Beadlets 5% 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	Lutein Beadlets 5%	**Country of Origin**	China
Botanical Source	*Tagetes erecta*	**Part Used**	Flower

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	Orange-red granule	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Lutein	≥ 5.0%	1.72%	1.93%	2.16%	2.11%	2.33%	2.59%	2.85%
Zeaxanthin	0.2 - 0.5%	0.55%	0.46%	0.49%	0.46%	0.39%	0.33%	0.24%
Loss on Drying	≤ 7.0%	2.81%	2.94%	3.25%	3.28%	3.56%	3.87%	4.27%
Standard Plate Count	≤ 10,000 cfu/g	273 cfu/g	846 cfu/g	955 cfu/g	966 cfu/g	1,365 cfu/g	724 cfu/g	670 cfu/g
Total Yeast & Mold	≤ 1,000 cfu/g	46 cfu/g	96 cfu/g	75 cfu/g	93 cfu/g	154 cfu/g	119 cfu/g	90 cfu/g
Batch LT-2 | Manufacture 2024-04-03 | Study start 2024-04-10								
Appearance / colour	Orange-red granule	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Lutein	≥ 5.0%	1.58%	1.61%	1.86%	2.08%	1.95%	2.36%	2.52%
Zeaxanthin	0.2 - 0.5%	0.47%	0.43%	0.40%	0.32%	0.33%	0.31%	0.26%
Loss on Drying	≤ 7.0%	2.63%	2.97%	3.03%	3.13%	3.53%	3.71%	4.22%
Standard Plate Count	≤ 10,000 cfu/g	239 cfu/g	897 cfu/g	1,099 cfu/g	705 cfu/g	683 cfu/g	1,714 cfu/g	1,759 cfu/g
Total Yeast & Mold	≤ 1,000 cfu/g	38 cfu/g	76 cfu/g	36 cfu/g	141 cfu/g	83 cfu/g	184 cfu/g	205 cfu/g
Batch LT-3 | Manufacture 2024-09-11 | Study start 2024-09-18								
Appearance / colour	Orange-red granule	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms	Conforms
Lutein	≥ 5.0%	1.66%	1.88%	1.89%	1.95%	1.91%	2.35%	2.33%
Zeaxanthin	0.2 - 0.5%	0.47%	0.43%	0.40%	0.35%	0.36%	0.29%	0.28%
Loss on Drying	≤ 7.0%	2.60%	2.76%	3.04%	3.27%	3.27%	3.85%	4.14%
Standard Plate Count	≤ 10,000 cfu/g	560 cfu/g	543 cfu/g	823 cfu/g	1,262 cfu/g	1,158 cfu/g	1,777 cfu/g	780 cfu/g
Total Yeast & Mold	≤ 1,000 cfu/g	86 cfu/g	45 cfu/g	65 cfu/g	52 cfu/g	158 cfu/g	191 cfu/g	126 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	Orange-red granule	Conforms	Conforms	Conforms	Conforms	Conforms
Lutein	≥ 5.0%	1.79%	1.86%	1.91%	1.94%	2.61%

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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						
Zeaxanthin	0.2 - 0.5%	0.43%	0.39%	0.40%	0.36%	0.29%
Loss on Drying	≤ 7.0%	2.59%	2.90%	3.14%	3.49%	4.08%
Standard Plate Count	≤ 10,000 cfu/g	256 cfu/g	757 cfu/g	542 cfu/g	1,035 cfu/g	1,237 cfu/g
Total Yeast & Mold	≤ 1,000 cfu/g	39 cfu/g	37 cfu/g	78 cfu/g	144 cfu/g	152 cfu/g
Batch ACC-2 | Manufacture 2023-12-06 | Study start 2023-12-13						
Appearance / colour	Orange-red granule	Conforms	Conforms	Conforms	Conforms	Conforms
Lutein	≤ 5.0%	1.86%	2.05%	1.87%	2.27%	2.63%
Zeaxanthin	0.2 - 0.5%	0.45%	0.40%	0.41%	0.40%	0.28%
Loss on Drying	≤ 7.0%	2.65%	3.02%	3.27%	3.41%	4.33%
Standard Plate Count	≤ 10,000 cfu/g	603 cfu/g	747 cfu/g	540 cfu/g	1,174 cfu/g	922 cfu/g
Total Yeast & Mold	≤ 1,000 cfu/g	57 cfu/g	44 cfu/g	117 cfu/g	82 cfu/g	68 cfu/g
Batch ACC-3 | Manufacture 2024-01-17 | Study start 2024-01-24						
Appearance / colour	Orange-red granule	Conforms	Conforms	Conforms	Conforms	Conforms
Lutein	≤ 5.0%	1.59%	1.61%	1.82%	2.03%	2.30%
Zeaxanthin	0.2 - 0.5%	0.42%	0.43%	0.40%	0.36%	0.31%
Loss on Drying	≤ 7.0%	2.57%	2.74%	3.02%	3.32%	4.13%
Standard Plate Count	≤ 10,000 cfu/g	763 cfu/g	312 cfu/g	1,129 cfu/g	877 cfu/g	2,052 cfu/g
Total Yeast & Mold	≤ 1,000 cfu/g	28 cfu/g	99 cfu/g	49 cfu/g	66 cfu/g	95 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