



## Certificate of Analysis

### A. General Information

Product name:	Melatonin/Chamomile Tablet	Description:	Convex round off-white tablet with dark specks
Batch No:	222432S	Date of Mfg.:	11/14/2022
Quantity:	225.99 kg	Certificate No / Code:	30110
Re-evaluation Date:	11/2024	Analysis Date:	12/7/2022

### B. Active Ingredients

Active [*LC/Tablet]	Procedure	Specification	Result
Chamomile PE 1.2% (flower heads) [2 mg]	QA025	>90% of LC*	2 mg
Melatonin [0.5 mg]	HPLC-UV	>90% of LC*	451.7 mcg/tablet

\*LC- Label Claim QA025-Quantification by Input

The analytical and manufacturing quality records of this lot have been reviewed by our Quality Assurance department and verified to meet the established specifications before being released. The product was formulated to be at least equal to the value for each nutrient declared on the label, with reasonable excesses acceptable within current Good Manufacturing Practices (GMP) according to 21 CFR 101.9(g)(4)(i) and (g)(6).

### C. Physical-Chemical Tests

Test	Procedure	Specification	Result
Appearance	QC 001	Convex round off-white tablet with dark specks	Conforms
Tablet Weight Variation	QC 003	± 7.5%	Conforms
Average Tablet Weight	QC 003	287 mg ± 22 mg	282.15 mg
Moisture Analysis	QC 004	<2.5% LOD @ 105°C	1.5%
Heavy Metals		Methods Limits (µg/g)	(µg/g)
- Mercury	ICP-MS/ USP <730>	1.5 Max.	<0.001
- Lead		0.5 Max.	0.005
- Arsenic		1.5 Max.	0.010
- Cadmium		0.5 Max.	0.005

### D. Microbiological Test

Test	Procedure	Specification	Results
Aerobic Plate Count USP Alert Limit Release Limit	USP <2021>	<10,000 CFU/g (a) <1,000,000 CFU/g	50 CFU/g
Total Yeast and Mold USP Alert Limit Release Limit	USP <2021>	<1,000 CFU/g (a) <10,000 CFU/g	<10/<10 CFU/g
E. coli	USP <2022>	Absent	Absent/10g
Salmonella	USP <2022>	Absent	Absent/10g
Staphylococcus aureus (coag+)	USP <2022>	Absent	Absent/10g
Pseudomonas	USP <62>	Absent	Absent/10g

(a) Any lot which exceeds the USP Alert Limit, must be investigated as per SOP QA019 (Specifications) which includes a risk assessment that will identify the microbiological species and potential impact to consumer safety.

*Anabel Sanchez* 12/07/2022  
Quality Control/Date