

**Certificate of Analysis**

**Batch: 1401024.2389**

**Product name:** Palmitoylethanolamide / OptiPEA®

**Country of Origin:** The Netherlands

**Manufacturing date:** Jan-2024

Critical process parameters		Acceptance criteria	Method	Results
Assay		98.0 % -102.0 %	Internal method (HPLC)	100.3 %
Related substances	Other Ethanolamides	≤ 1.0 %	Internal method (HPLC)	0.1 %
	Single unknown	≤ 0.1 %		< 0.1 %
	Total impurities	≤ 1.5 %		0.2 %
Residual solvents	Ethanol	≤ 5000 ppm	Internal method (GC)	96 ppm
Heavy metals				
Specific metals	Arsenic	≤ 1 ppm	Internal Method (ICP)	< 0.04 ppm
	Cadmium	≤ 1 ppm	Internal Method (ICP)	< 0.02 ppm
	Mercury	≤ 0.1 ppm	Internal Method (ICP)	< 0.002 ppm
	Lead	≤ 2 ppm	Internal Method (ICP)	< 0.04 ppm
Microbiology	TAMC aerobe	≤ 1000 CFU / g	ISO 4833-1	< 100 CFU / g
	TYMC	≤ 100 CFU / g	ISO 21527-1	< 10 CFU / g
	Escherichia Coli	≤ 10 / CFU / g	ISO 16649-2	< 10 / CFU / g
	Salmonella	Negative / 25 g	ISO 6579	Negative

### Storage

- Store at room temperature
- Expiration date 36 months

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