NEURAXPHARM®

neuraxpharm Arzneimittel GmbH

Certificate of Analysis and Release

Name, Strength/ Potency	NAXIVA-PANAXOL CBD 250 /32 ml Cann. Ext.
Dosage Form	standardized Cannabis extract (CBD 25% w/w; 243 mg/ml and THC 1.5 % w/w; 15 mg/ml) in MCT
Batch Number	24322KT01-1
Manufacturing Date	30.08.2022
Expiry Date	07/2024

Test	Specification	Results
Organoleptic properties (visual inspection, DAB 2022)	Homogenous greenish or yellow to brown liquid	complies
Relative density (EP* 2.2.5)	Indicative for individual product	0.978
Identification (TLC, EP* 2.2.27; DAB 2022)	Zonal pattern of test solution conforms to the zonal pattern of reference solution	complies
Assay – Cannabinoids concentration (HPLC; EP* 2.2.29; DAB 2021) CBD Δ^9 THC	 95 - 110 % of CBD label claim 95 - 110 % of THC label claim	 101% (25.22% (w/w)) 100% (1.50% (w/w))
Vitamin E (HPLC, EP* 2.2.29)	≥ 0.4%	0.63%
Heavy metals (EP* 2.4.27) Cadmium Lead Mercury	 ≤ 1.0 ppm ≤ 5.0 ppm ≤ 0.1 ppm	 < 0.05 ppm < 0.1 ppm < 0.05 ppm
Toxins-Mycotoxins (EP* 2.8.18) Aflatoxin B1 Total Aflatoxins (B1, B2, G1, G2) Ochratoxin A	 ≤ 2µg/Kg ≤ 4µg/Kg Negative	 n.d. n.d. n.d.
Purity test (HPLC; EP* 2.2.29; DAB 2021) Cannabinol (CBN)	≤ 2.5%	< 0.1% (w/w)

Microbiological quality (EP* 2.6.12; 2.6.31) TAMC TYMC *Bile-tolerant gram-negative bacteria* *Escherichia coli* Salmonella	 10^4 CFU/g (max. acceptable count: 50000 CFU/g) 10^2 CFU/g (max. acceptable count: 500 CFU/g) <10^2 (CFU/g) Absence (1 g) Absence (25 g)	 < 100 < 10 < 10 negative negative
Residual Solvents Ethanol (GC) Water content (EP* 2.5.12; DAB 2022)	 ≤ 5000 ppm ≤ 0.5%	 n.d. 0.23% (w/w)

*edition 10.6

Abbreviations: n.d.: not detectable; ppm: parts per million; EP: european pharmacopoeia; TLC: thin layer chromatography; TAMC: total aerobic microbial count; TYMC: total combined yeasts and molds count; CFU: colony-forming unit; HPLC: High performance liquid chromatography

This batch of product has been manufactured and tested in full compliance with the EU-GMP requirements. The tested batch complies with the specification and can be released.

22. MRZ. 2023

Issued by:
M. Sliwinski
QA Specialist

22. MRZ. 2023

Approved by:
Dr. M. Schroers
Head of QC

28. MRZ. 2023

Released by:
Dr. Jean-Paul M. Makosi
Qualified Person