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	22/178-MT
Manufacturing Date	19.01.2023
Expiry Date	12/2023

Test	Specification	Results
Organoleptic properties (visual Inspection)	Homogenous greenish or yellow to brown liquid, no significant precipitate observed	complies
Relative density (EP* 2.2.5)	Indicative for individual product	0.99 g/ml
Identification (TLC; DAB*)	Zonal pattern of test solution conforms to the zonal pattern of reference solution	complies
Assay – Cannabinoids concentration (HPLC; DAB*) CBD Δ^9 THC	 95 - 105 % of CBD label claim 95 - 105 % of THC label claim	 97.60% (24.40% (w/w)) 96.67% (1.45% (w/w))
Vitamin E (HPLC)	≥ 0.4%(w/w)	0.4%(w/w)
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; 2.8.22) Aflatoxin B1 Total Aflatoxins (B1, B2, G1, G2) Ochratoxin A	 ≤ 2 µg/kg ≤ 4 µg/kg ≤ 181 µg/kg	 n.d. n.d. n.d.
Purity test (HPLC; DAB 2020) Cannabinol (CBN)	 ≤ 2.5 %(w/w)	 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 CFU/g < 10 CFU/g < 10 CFU/g absent absent
Residual Solvents Ethanol (GC)	 ≤ 5000 ppm	 n.d.
Water content (EP* 2.5.12)	≤ 0.5 %	< 0.2%
Pesticides (EP*2.8.13)	Complies with limits indicated in EP*2.8.13	complies

*current edition
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

I hereby confirm the release of the batch by a Qualified Person of a contract manufacturer located in EU. The batch was produced and released in compliance to GMP-Guidelines and complies with the specifications.

17. JULI 2023

Issued by:
M. Sliwinski
Quality Assurance

25. JULI 2023

Approved by:
Dr. M. Schroers
Head of QC