

neuraxpharm Arzneimittel GmbH

Certificate of Analysis and Release

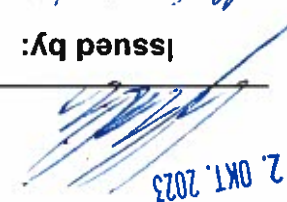
Name, Strength/ Potency	NAXIVA-PANAXOL CBD 250 /32 ml Cann. Ext.
Dosage Form	standardized Cannabis extract (CBD 25% w/w; 243 mg/ml and THC 1.5% w/w; 15 mg/ml) in MCT
Batch Number	23/202-MT
Manufacturing Date	19.01.2023
Expiry Date	12/2024

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	95 - 105 % of CBD label claim	97.60% (24.40% (w/w))
Δ^9 THC	95 - 105 % of THC label claim	96.67% (1.45% (w/w))
Vitamin E (HPLC)	$\geq 0.4\%$ (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 μ g/kg ≤ 4 μ g/kg ≤ 181 μ g/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 <i>Escherichia coli</i> <i>Salmonella</i>	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 absent absent n.d.	Residual Solvents Ethanol (GC) Water content (EP* 2.5.12) 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.

12. OKT. 2023

M. Skwinski
Quality Assurance
Issued by:

13. OKT. 2023

Dr. Martin Schroers
Head of Quality Control
Approved by: