

Certificate of Analysis No. 210-1082314

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 CZECH REPUBLIC

Date: 23-Mar-2023

Customer No.:	23203	Sample No.:	457339
Product:	Medizinalcannabis / Medical Ca		
Label: Naxiva Panaxol THC50mg/ml CBD10mg/ml, batch 31821KT02A; Expiry date 10/2023; Solvent – ethanol, MCT oil; Excipients – tocoferol alfa 0,5% MCT oil 78-86%			
Arrival Date:	24-Feb-2023	Start / End of Analysis:	24-Feb-2023 / 09-Mar-2023
Kind/Origin:	Cannabis sativae extract, full spectrum, liquid	Packaging:	Glas / glass
Seal:	unverletzt/intact	Temp.:	store tightly closed, protected from light in original container at 15 – 25°C

VA349 (2020-06) Analysis of cannabis extracts, Appearance, DAB monograph Cannabis extractum normatum -GMP-

Parameter	Method	Unit	Specification	Result
Appearance	DAB Property		greenish or yellow to brown liquid	compliant
Version DAB				2022

Conclusion:

The test was carried out in accordance with recognised pharmaceutical regulations and agreed specifications. Within the scope of the tests carried out, the present batch complies with the DAB specification. The test was carried out in a company with a permit in accordance with § 13 AMG.

VA784 (2023-03) Acid-Value, titrimetric -GMP-

Parameter	Method	Result
Acid value	Ph. Eur. 2.5.1	2,7
Version Ph. Eur.		10.7

Ph. Eur. 2.5.5 VA801 Peroxide Value, iodometric titration - GMP -

Parameter	Method	Result
Peroxide value	Ph. Eur. 2.5.5	1,8
Version Ph. Eur.		10.7

VA14280 (2021-01) Identity of Cannabis (extracts) according to customer specifications by (U)HPLC -GMP-

Parameter	Method	Specification	Result
Identity (retention time/match factor), Chromatogram	Ph. Eur. 2.2.29	*	compliant

* according to valid product specifications

VA15005 (2021-03) Analysis of cannabis extracts, Pesticide-Residues, LC-MS/MS and GC-MS/MS, Ph.Eur. 2.8.13 -GMP-

Parameter in [mg/kg]	Method	Limit	LOQ*	Result
Acephate	LC-MS/MS	0,1	0,05	n.n.
Alachlor	LC-MS/MS	0,05	0,1	n.n.
Sum Aldrin+Dieldrin	GC-MS/MS	0,05	0,1	n.n.
Azinphos-ethyl	LC-MS/MS	0,1	0,05	n.n.
Azinphos-methyl	LC-MS/MS	1	0,05	n.n.
Bromophos-ethyl	GC-MS/MS	0,05	0,05	n.n.
Bromophos-methyl	GC-MS/MS	0,05	0,025	n.n.
Bromopropylate	GC-MS/MS	3	1	n.n.
Chinalphos (=Quinalphos)	LC-MS/MS	0,05	0,025	n.n.
Chlordane (Sum of cis-, trans- and Oxy-)	GC-MS/MS	0,05	0,5/0,1	n.n.
Chlorfenvinphos	GC-MS/MS	0,5	0,2	n.n.
Chlorpyrifos-ethyl	GC-MS/MS	0,2	0,1	n.n.
Chlorpyrifos-methyl	GC-MS/MS	0,1	0,05	n.n.
Chlorthal-dimethyl	GC-MS/MS	0,01	0,01	n.n.
Cyfluthrine (Sum)	GC-MS/MS	0,1	0,1	n.n.
Cyhalothrine-lambda	GC-MS/MS	1	0,5	n.n.
Cypermethrine and Isomers (Sum)	GC-MS/MS	1	0,5	n.n.
DDT (Sum of o.p'-DDE, p.p'-DDE, o.p'-DDT, p.p'-DDT, o.p'-TDE und p.p'-TDE)	GC-MS/MS	1	0,1	n.n.
Deltamethrine	GC-MS/MS	0,5	0,25	n.n.
Diazinon	GC-MS/MS	0,5	0,25	n.n.
Dichlofluanid	LC-MS/MS	0,1	0,05	n.n.
Dichlorvos (DDVP)	LC-MS/MS	1	0,5	n.n.
Dicofol	GC-MS/MS	0,5	0,2	n.n.
Dimethoate und Omethoate (Summe)	LC-MS/MS	0,1	0,05	n.n.
Endosulfan (Sum of Isomers und Endosulfan sulfate)	GC-MS/MS	3	0,5	n.n.
Endrin	GC-MS/MS	0,05	0,1	n.n.
Ethion	LC-MS/MS	2	1	n.n.
Etrimphos	LC-MS/MS	0,05	0,02	n.n.
Fenchlorphos (Sum of Fenchlorphos und Fenchlorphos-oxon)	GC-MS/MS	0,1	0,05	n.n.
Fenitrothion	GC-MS/MS	0,5	0,25	n.n.
Fenpropathrin	LC-MS/MS	0,03	0,5	n.n.
Fensulfothion (Sum of Fensulfothion, Fensulfothion-oxon, Fensulfothion-oxon-sulfone and Fensulfothion-sulfone)	LC-MS/MS	0,05	0,02	n.n.

Fenthion (Sum of Fenthion, Fenthion-oxon, Fenthion-oxon-sulfone, Fenthion-oxon-sulfoxide, Fenthion-sulfone und Fenthion-sulfoxide)	LC-MS/MS	0,05	0,02	n.n.
Fenvalerat	GC-MS/MS	1,5	1	n.n.
Flucythrinate	LC-MS/MS	0,05	0,5	n.n.
Fluvalinate-tau	LC-MS/MS	0,05	1	n.n.
Fonofos	GC-MS/MS	0,05	0,02	n.n.
Heptachlor (Sum of Heptachlor, cis-Heptachlorepoxide und trans-Heptachloepoxide)	GC-MS/MS	0,05	0,1	n.n.
Hexachlorobenzene	GC-MS/MS	0,1	0,05	n.n.
Hexachlorocyclohexane (Sum of a-, b-, d- and e-Isomere)	GC-MS/MS	0,3	0,05	n.n.
Lindane (g-Hexachlorocyclohexane)	GC-MS/MS	0,6	0,05	n.n.
Malathion und Malaoxon (Summe)	LC-MS/MS	1	0,1	n.n.
Mecarbam	LC-MS/MS	0,05	0,02	n.n.
Methacriphos	GC-MS/MS	0,05	0,02	n.n.
Methamidophos	LC-MS/MS	0,05	0,02	n.n.
Methidathion	LC-MS/MS	0,2	0,1	n.n.
Methoxychlor	GC-MS/MS	0,05	1	n.n.
Mirex	GC-MS/MS	0,01	1	n.n.
Monocrotophos	LC-MS/MS	0,1	0,05	n.n.
Parathion-ethyl und Paraoxon-ethyl (Sum)	LC-MS/MS	0,5	0,25	n.n.
Parathion-methyl und Paraoxon-methyl (Sum)	LC-MS/MS	0,2	0,2	n.n.
Pendimethalin	LC-MS/MS	0,5	0,1	n.n.
Pentachloroanisole	GC-MS/MS	0,01	0,05	n.n.
Permethrin and Isomers (Sum)	LC-MS/MS	1	1	n.n.
Phosalone	LC-MS/MS	0,1	0,05	n.n.
Phosmet	LC-MS/MS	0,05	0,02	n.n.
Piperonyl butoxide	LC-MS/MS	3	0,1	n.n.
Pirimiphos-ethyl	LC-MS/MS	0,05	0,02	n.n.
Pirimiphos-methyl (Sum of Pirimiphos-methyl und N-Desethyl-pirimiphos-methyl)	LC-MS/MS	4	1	n.n.
Procymidon	GC-MS/MS	0,1	0,05	n.n.
Profenophos	LC-MS/MS	0,1	0,05	n.n.
Prothiophos	LC-MS/MS	0,05	0,5	n.n.
Pyrethrum (Sum of Cinerin I, Cinerin II, Jasmolin I, Jasmolin II, Pyrethrin I and Pyrethrin II)	LC-MS/MS	3	1	n.n.
Quintozen (Sum of Quintozen, Pentachloranilin and Methylpentachlorphenylsulfide)	GC-MS/MS	1	0,2	n.n.
S-421 (Octachlorodipropyl ether or N-Desethyl-pirimiphos-methyl)	GC-MS/MS	0,02	0,05	n.n.
Tecnazene	GC-MS/MS	0,05	0,02	n.n.
Tetradifon	GC-MS/MS	0,3	0,15	n.n.
Vinclozolin	GC-MS/MS	0,4	0,2	n.n.
>>> Further risk-based pesticides				

Acetamiprid	LC-MS/MS	8,4**	1	n.n.
Aldicarb	LC-MS/MS	0,6**	0,3	n.n.
Azadirachtin	LC-MS/MS	12**	1	n.n.
Azoxystrobin	LC-MS/MS	24**	1	n.n.
Bifenazate	LC-MS/MS	1,2**	1	n.n.
Bifenthrin	LC-MS/MS	1,8**	1	n.n.
Boscalide	LC-MS/MS	4,8**	1	n.n.
Carbaryl	LC-MS/MS	0,9**	0,5	n.n.
Carbofuran (incl. Carbosulfan)	LC-MS/MS	0,24**	0,1	n.n.
Chlorantraniliprole (Rynaxapyr)	LC-MS/MS	187,2**	0,1	n.n.
Chlorfenapyr	GC-MS/MS	1,8**	1	n.n.
Coumaphos	LC-MS/MS	0,06**	0,05	n.n.
Daminozide	LC-MS/MS	54**	1	n.n.
Dimethomorph	LC-MS/MS	6**	1	n.n.
Ethoprophos	LC-MS/MS	0,048**	0,02	n.n.
Étofenprox	LC-MS/MS	3,6**	1	n.n.
Etoxazol	LC-MS/MS	4,8**	1	n.n.
Fenhexamide	LC-MS/MS	24**	1	n.n.
Fenoxycarb	LC-MS/MS	6,36**	1	n.n.
Fenpyroximate	LC-MS/MS	1,2**	0,5	n.n.
Fipronil	LC-MS/MS	0,024**	0,01	n.n.
Flonicamid	LC-MS/MS	3**	1	n.n.
Fludioxonil	LC-MS/MS	44,4**	1	n.n.
Hexythiazox	LC-MS/MS	3,6**	1	n.n.
Imazalil	LC-MS/MS	3**	1	n.n.
Imidacloprid	LC-MS/MS	7,2**	1	n.n.
Kresoxim-methyl	LC-MS/MS	48**	1	n.n.
Metalaxyl	LC-MS/MS	9,6**	1	n.n.
Methiocarb (Mercaptodimethur)	LC-MS/MS	1,56**	1	n.n.
Methomyl	LC-MS/MS	0,3**	0,1	n.n.
Mevinphos	LC-MS/MS	0,096**	0,05	n.n.
MGK 264 (N-octyl bicycloheptene dicarboximide)	LC-MS/MS	8,4**	0,2	n.n.
Myclobutanil	LC-MS/MS	3**	1	n.n.
Naled	GC-MS/MS	0,01***	0,5	n.n.
Oxamyl	LC-MS/MS	0,12**	0,05	n.n.
Paclobutrazol	LC-MS/MS	2,64**	1	n.n.
Prallethrin	LC-MS/MS	2,4**	0,5	n.n.
Propiconazol	LC-MS/MS	4,8**	1	n.n.
Propoxur	LC-MS/MS	2,4**	1	n.n.
Pyridaben	LC-MS/MS	1,2**	0,5	n.n.
Spinetoram (J+L)	LC-MS/MS	3**	1	n.n.
Spinosad (Spinosyn A+D)	LC-MS/MS	2,88**	1	n.n.
Spiromesifen	LC-MS/MS	3,6**	1	n.n.
Spirotetramat	LC-MS/MS	6**	1	n.n.
Spiroxamin	LC-MS/MS	3**	1	n.n.
Tebuconazole	LC-MS/MS	3,6**	1	n.n.
Thiacloprid	LC-MS/MS	1,2**	1	n.n.

Thiametoxam	LC-MS/MS	3,12**	1	n.n.
Trifloxystrobin	LC-MS/MS	4,8**	1	n.n.
Version Ph.Eur.				Version 10.7

*LOQ = limit of quantitation (Reporting Limit), n.n. = below loq; ** risk-based pesticide, limit according to Ph.Eur. calculated by ADI (assumption daily dose of 5 g)

*** risk-based pesticide, no ADI determinable, limit value 0.01 mg/kg (non-approved pesticide 396/2005)

Please note the additional information in the appendix on pesticides whose LOQ is above the limit set according to Ph.Eur. .
For the individual limit, the drug-extract ratio according to Ph.Eur. 2.8.13 for preparations is to be considered.

The expanded relative measurement uncertainty is 50 % (coverage factor k=2.58; confidence interval 99 %) without taking the sampling into account.

Conclusion:

The test was carried out in accordance with recognised pharmaceutical regulations and agreed specifications. Within the scope of the tests carried out, the present batch complies with the Ph.Eur specification. The test was carried out in a company with a permit in accordance with §13 AMG.

VA15010 (2022-08) Analysis of cannabis flowers/extract, Pesticide-Residues

Dithiocarbamates, Headspace-GC/MS, Ph.Eur. 2.8.13 -GMP-

Parameter in mg/kg=ppm	permitted level**	loq*	Result
Dithiocarbamates as CS2	2,0	0,5	n.n.
Version Ph.Eur.			Version 10.7

* loq = limit of quantitation, n.n. = below loq, < = lower than

** for herbal drugs according to Ph. Eur., 2.8.13

The expanded relative measurement uncertainty is 50 % (coverage factor k=2.58; confidence interval 99 %) without taking the sampling into account.

Conclusion:

The test was carried out in accordance with recognised pharmaceutical regulations and agreed specifications. Within the scope of the tests carried out, the present batch complies with the Ph.Eur specification. The test was carried out in a company with a permit in accordance with §13 AMG.

VA31975 (2022-02) Analysis of cannabis extract, Cannabinoids (Content determination),

DAB monograph Cannabis extractum normatum -GMP-

Parameter	Method	Unit	Specification	Result
d9-Tetrahydrocannabinol (d9-THC, Dronabinol)	HPLC-UV/Ph.Eur. 2.2.29	g/100g	1 - 25, next line	5,0
Specification d9-THC (Dronabinol)	HPLC-UV/Ph.Eur. 2.2.29	g/100g		4 - 7
d9-Tetrahydrocannabinolic acid (THCA)	HPLC-UV/Ph.Eur. 2.2.29	g/100g	-	<0,1
Total d9-THC (Dronabinol) calculated as d9-THC*	HPLC-UV/Ph.Eur. 2.2.29	g/100g	-	5,0
Cannabidiol (CBD)	HPLC-UV/Ph.Eur. 2.2.29	g/100g	next line	1,0
Specification CBD	HPLC-UV/Ph.Eur. 2.2.29	g/100g		1 - 5
Cannabidiolic acid (CBDA)	HPLC-UV/Ph.Eur. 2.2.29	g/100g	-	<0,1
Total CBD calculated as CBD*	HPLC-UV/Ph.Eur. 2.2.29	g/100g	-	1,0
Cannabinol (CBN)	HPLC-UV/Ph.Eur. 2.2.29	g/100g	max. 2,5 %	<0,1
Version Ph.Eur.				10.7
Version DAB				2022/2

* To calculate the sum, the acid is multiplied by the factor 0.877.

The expanded relative measurement uncertainty is 5 % (coverage factor k=2.58; confidence interval 99 %) without taking the sampling into account.

Conclusion:

The test was carried out in accordance with recognised pharmaceutical regulations and agreed specifications. Within the scope of the tests carried out, the present batch complies with the DAB/Ph.Eur specifications. The test was carried out in a company with a permit in accordance with § 13 AMG.

VA45110 (2021-10) Analysis of cannabis flowers/extract, aflatoxins, Ph.Eur. 2.8.18 for cannabis validated method -GMP-

Parameter	Method	Unit	Specification	Result**
Aflatoxin B1	Ph.Eur. 2.8.18*	µg/kg	max. 2µg/kg	n.n.
Aflatoxin B2	Ph.Eur. 2.8.18*	µg/kg	-	n.n.
Aflatoxin G1	Ph.Eur. 2.8.18*	µg/kg	-	n.n.
Aflatoxin G2	Ph.Eur. 2.8.18*	µg/kg	-	n.n.
Total content aflatoxines	Ph.Eur. 2.8.18*	µg/kg	max. 4µg/kg	n.n.
Version Ph.Eur.				10.7

*analysis via LC-MS/MS

**n.n. = below limit of quantitation (LOQ); LOQ Aflatoxin B1, B2, G1: 0,5 µg/kg; LOQ Aflatoxin G2: 1,0 µg/kg

Conclusion:

The test was carried out in accordance with recognised pharmaceutical regulations and agreed specifications. Within the scope of the tests carried out, the present batch complies with the Ph.Eur specification. The test was carried out in a company with a permit in accordance with §13 AMG.

VA52077 (2023-02) Analysis of cannabis flowers and cannabis extracts, microbiology* according to customer specification, Ph.Eur. -GMP-

Parameter	Method	Unit	Specification	Result
TAMC/g	Ph.Eur. 2.6.12	CFU	max.200**	< 10
TYMC/g	Ph.Eur. 2.6.12	CFU	max.20**	< 10
Bile salt tolerant gram-negative bacteria/1g	Ph. Eur. 2.6.13	-	absent in 1 g	negative
Escherichia coli/1g	Ph. Eur. 2.6.31	-	absent in 1 g	negative
Pseudomonas aeruginosa/1g	Ph. Eur. 2.6.13	-	absent in 1 g	negative
Staphylococcus aureus/1g	Ph. Eur. 2.6.13	-	absent in 1 g	negative
Salmonella/10g	Ph. Eur. 2.6.13	-	absent in 10 g	negative
Version Ph.Eur.				10.7

*subcontracting to qualified laboratory BAV Institute GmbH

**maximum acceptable count (acceptance criteria TAMC: 100 CFU, TYMC: 10 CFU)

Conclusion:

The test was carried out in accordance with recognised pharmaceutical regulations and agreed specifications. Within the scope of the tests carried out, the present batch complies with the Ph.Eur specification. The test was carried out in a company with a permit in accordance with §13 AMG.

VA77400 (2022-01) Analysis of cannabis flowers/extract, heavy metals*, Pb, Cd, Hg, ICP-MS, Ph.Eur. -GMP-

Parameter	Method	Unit	Specification	Result
Lead (Pb)	Ph.Eur. 2.4.27	mg/kg	max. 5 mg/kg	<0,1
Cadmium (Cd)	Ph.Eur. 2.4.27	mg/kg	max. 1 mg/kg	<0,05
Mercury (Hg)	Ph.Eur. 2.4.27	mg/kg	max. 0,1 mg/kg	<0,05
Version Ph.Eur.				10.7

*subcontracting to qualified laboratory Indikator GmbH

Conclusion:

The test was carried out in accordance with recognised pharmaceutical regulations and agreed specifications. Within the scope of the tests carried out, the present batch complies with the Ph.Eur specification. The test was carried out in a company with a permit in accordance with §13 AMG.

Quality Services International GmbH

Version 2 replacing Version 1


Svenja Dohrmann
Deputy Head of Laboratory
Deputy Head of Quality Control



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