CB21 Pharma, s.r.o.
Studentska 812/6, Bohunice, 625 00 Brno, Czech Republic,
Company ID : 075 63 094,
info@cb21pharma.com
tel: +420 776 291 231

CERTIFICATE OF ANALYSIS

Product name:	**APOCAN 5g**
Trade name:	(–)-trans-Cannabidiol, PhG isolate
Manufacturer of API:	CB21 Pharma s.r.o., Studentská 812/6, Bohunice, 625 00 Brno, Czech Republic, +420 776 291 231
Analytical specification:	ASLL/KJ/CBD-PhG-03
Batch No. of the final product.:	LL72112021
Batch No. of the used API:	LL56092021
Mfg. Date of API:	09/2021
Mfg. Date of final product:	11/2021
Quantity:	80 x 5g
Storage Conditions (if applicable):	15 – 25 °C
Retest Date:	09/2023

Analytical specification number: **ASLL/KJ/CBD-PhG-03**

Parametr /*Parameter*	**Limit**	**Výsledek / *Result***	**Jednotka / *Unit***	**Metoda / *Method***
VLASTNOSTI / *CHARACTERS*				
Vzhled / *Appearance*	Téměř bílý až nažloutlý prášek / *Whitish to yellowish powder*	conforms	-	Visuálně / *Visual* (DAC/NRF 2020/2, C – 052)
ZKOUŠKY TOTOŽNOSTI / *IDENTIFICATION*				
Zkouška totožnosti (IČ) / *Identification IR spectrum*	Shoduje se s IČ referenčním spektrem / *Corresponds to the IR reference spectrum*	conforms	-	Ph. Eur. 2.2.24 (FTIR) DAC/NRF 2020/2, C – 052
STANOVENÍ OBSAHU / *ASSAY*				
Cannabidiol (CBD)	98.0 - 102.0	99.0	%	Ph. Eur. 2.2.29 (HPLC-DAD) DAC/NRF 2020/2, C – 052
ZKOUŠKY NA ČISTOTU / *TESTS*				
Specifická optická otáčivost / *Specific Rotation*	-129.5 to -135.0	- 131.0	°	Ph. Eur. 2.2.7 DAC/NRF 2020/2, C – 052
Síranový popel / *Sulfated Ash*	≤0.1	0.01	%	Ph. Eur. 2.4.14 DAC/NRF 2020/2, C – 052

CB21 Pharma, s.r.o.
Studentska 812/6, Bohunice, 625 00 Brno, Czech Republic,
Company ID : 075 63 094,
info@cb21pharma.com
tel: +420 776 291 231

Parametr / *Parameters*	**Limit**	**Výsledek / *Result***	**Jednotka / *Unit***	**Metoda / *Method***
Příbuzné látky / *Related Substances*				
Cannabinol (CBN)	≤0.1	<0.005	%	Ph. Eur. 2.2.29 (HPLC-MS/MS) Modified DAC/NRF 2020/2, C – 052
Δ9-tetrahydrocannabinol (Δ9-THC)	≤0.1	<0.005		
Δ8-tetrahydrocannabinol (Δ8-THC)	≤0.1	<0.005		
Další příbuzné látky / *Other Related Substances*				
Cannabidivarin (CBDV)	≤0.5	0.0386	%	Ph. Eur. 2.2.29 (HPLC-MS/MS) Modified DAC/NRF 2020/2, C – 052
Cannabidiol-C4 (CBDB)	≤0.5	0.1338		
Nespecifikované nečistoty jednotlivě / *Single unspecified impurities*	≤0.1	RRT = 0.824 0.0010 RRT = 1.257 0.0005	%	
Nečistoty celkově / *Total impurities*	≤0.5	0.0023		
ZBYTKOVÁ ROZPOUŠTĚDLA / *RESIDUAL SOLVENTS*				
Σ(Propan-2-ol, n-Heptane)	≤0.5	<0.025	%	Ph. Eur. 5.4 (2.2.32)
TĚŽKÉ KOVY / *HEAVY METALS*				
Cadmium (Cd)	<0.1	<0.1	ppm	ICP-MS
Lead (Pb)	<0.1	<0.1		
Arsen (As)	<0.1	<0.03		
Mercury (Hg)	<0.01	<0.01		AAS-AMA
MIKROBIOLOGIE/*MICROBIOLOGY*				
Celkový počet aerobních mikroorganismů / *Total aerobic microbial count (TAMC)*	NMT 2,000	0	KTJ/CFU/g	Ph. Eur. 5.1.4; (2.6.12, 2.6.13)
Celkový počet plísní a kvasinek / *Total combined yeasts/moulds count (TYMC)*	NMT 200	0	KTJ/CFU/g	
Escherichia coli	Nepřítomna / *Absent*/g	absent	-	

CB21 Pharma, s.r.o.
Studentska 812/6, Bohunice, 625 00 Brno, Czech Republic,
Company ID : 075 63 094,
info@cb21pharma.com
tel: +420 776 291 231

Výsledek - rozhodnutí pro použití/**Result - decision for use:**

The tested batch conforms to the related specification of DAC/NRF 2020/2, C-052 and of the general chapters of European Pharmacopeia (Ph. Eur.). The mentioned batch was manufactured, analysed, handled and stored in accordance with Good Manufacturing Practise (GMP) in conformance with the above regulations and as outlined in the International Conference on Harmonized „ICH Q7 guideline on Good Manufacturing Practise for Active Pharmaceutical Ingredients".

Produkt vyhovuje specifikaci ASLL/KJ/CBD-PhG-03 a byl uvolněn k distribuci pro další zpracování /The product complies with the specification ASLL/KJ/CBD-PhG-03 and has been released for distribution for further processing.

07.01.2022

…… ……

Approved by: **Antonín Malík** *Release date*:
QM Director, QP