

Freigabezertifikat/ Release certificate

Produkt Product	Khiron G19/1 Khiron G19/1
Stärke Strength	THC: 19 % CBD: <1 %
Darreichungsform Dosage form	fest, Cannabis sativa L. medizinisches Cannabis solid, Cannabis sativa L. medical cannabis
Charge Batch	C240003
Verfalldatum Expiry date	31.07.2024
Packungsgröße Packaging size	10 g

Rezepturarzneimittel zur Abgabe an Apotheken

Prescription drugs for dispensing to pharmacies

Analysenergebnisse

Analytical results

Test Item	Method*	Specified reference value	Result
1.0 Identity			
1.1 Identity A - Appearance	DAB	Dark/Brown green of different shades. Bract fragments of dark green to green. Peduncles of a light-green color. Flower husks of a green to light green color, covered with dense yellowy-white hairs and stuck together with resin. Absence of grey/dark spots. Absence of foreign matter.	complies
1.2 Identity B - Microscopic	DAB	Glandular trichomes/ hair identified	complies
1.3 Identity C	DAB, Ph. Eur. 2.2.29	Reference cannabinoids RT through the standard and sample.	complies
2.0 Foreign Matter	DAB, Ph. Eur. 2.8.2	Total NMT 2% (w/w) Absence of mold, insects and other animal contamination	0 %
3.0 Total Ash	Ph. Eur. 2.4.16	≤20 %	8 %

Test Item	Method*	Specified reference value	Result
4.0 Average Weight of the container	Weighing	10.0-10.5 g	10.2 g
5.0 Microbiology			
5.1 TAMC Total aerobic microbial count	DAB, Ph. Eur. 5.1.4, 5.1.8	$\leq 5.0 \times 10^5$ CFU/gram	<100 cfu/g
5.2 TYMC Total yeast and mold count		$\leq 5.0 \times 10^4$ CFU/gram	1.9×10^2 cfu/g
5.3 Bile salt tolerant gram-negative bacteria		$\leq 10^4$ CFU/gram	<10 cfu/g
5.4 Escherichia coli		Absent/gram	Absent
5.5 Salmonella		Absent/25 gram	absent
5.6 Aflatoxins	Ph. Eur. 2.8.18	$B1 \leq 2 \mu\text{g/kg}$ SUM $B1 + B2 + G1 + G2 - \leq 4 \mu\text{g/kg}$	< 0.25 $\mu\text{g/kg}$ (LOD); < 0.25 $\mu\text{g/kg}$ (LOD)
5.7 Ochratoxin A	Ph. Eur. 2.8.22	NMT 20 $\mu\text{g/Kg}$	<2 $\mu\text{g/kg}$ (LOD)
6.0 Heavy Metals			
6.1 Lead	Ph. Eur. 2.4.27	NMT 5.0 ppm	<0.020 ppm (LOQ)
6.2 Cadmium		NMT 1.0 ppm	0.011 ppm
6.3 Mercury		NMT 0.1 ppm	<0.050 ppm (LOQ)
6.4 Arsenic		informative	<0.020 ppm (LOQ)
7.0 Pesticides	Ph. Eur. 2.8.13	Screening analysis to comply with 2.8.13	complies
8.0 Loss on drying	DAB, Ph. Eur. 2.2.32	NMT 10 %	9 %
9.0 Cannabinoids Content			
9.1 Total THC	DAB Ph.Eur. 2.2.29	19 % (90-110 %)	18.32 % (96.42 %)
9.2 Total CBD		<1 %	0.10 %
9.3 Related Substances CBN		NMT 1 %	0.01 %

*current edition

n.n. below limit of quantification

Die Charge wurde nach den derzeit gültigen Prüfverfahren getestet und erfüllt die Spezifikation.

The batch was tested according to the currently valid testing procedure and fulfils the specification.

Die Charge wurde durch die Sachkundige Person gem. Art. 48 und 51 der RL 2001/83 am 01.02.2024 zertifiziert.

The batch was certified by the qualified person according to §48/51 Directive 2001/83 on 01.02.2024.

Dieses Zertifikat ist elektronisch erstellt worden und ohne Unterschrift gültig.

This certificate has been created electronically on the basis of the information provided by the Qualified Person according to Article 15 AMG and is valid without signature.