

Freigabezertifikat/ Release certificate
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Produkt <small>Product</small>	Khiron G23/1 <small>Khiron G19/1</small>
Stärke <small>Strength</small>	THC: 23 % CBD: <1 %
Darreichungsform <small>Dosage form</small>	fest, Cannabis sativa L. medizinisches Cannabis <small>solid, Cannabis sativa L. medical cannabis</small>
Charge <small>Batch</small>	C240004
Verfalldatum <small>Expiry date</small>	31.07.2024
Packungsgröße <small>Packaging size</small>	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	Absence of mold, insects and other animal contamination	0 %
3.0 Total Ash			
	Ph. Eur. 2.4.16	≤20 %	10 %
4.0 Average Weight of the container			
	Weighing	10.0-10.5 g	10.2 g

Test Item	Method*	Specified reference value	Result
5.0 Microbiology			
5.1 TAMC Total aerobic microbial count		$\leq 5.0 \times 10^5$ CFU/gram	3.00×10^2 cfu/g
5.2 TYMC Total yeast and mold count		$\leq 5.0 \times 10^4$ CFU/gram	2.30×10^1 cfu/g
5.3 Bile salt tolerant gram-negative bacteria	DAB, Ph. Eur. 5.1.4, 5.1.8	$\leq 10^4$ 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); < 0.5 $\mu\text{g/kg}$ (LOQ)
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		NMT 5.0 ppm	<0.020 ppm (LOQ)
6.2 Cadmium	Ph. Eur. 2.4.27	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 %	7 %
9.0 Cannabinoids Content			
9.1 Total THC		23 % (90-110 %)	22.00 % (95.65 %)
9.2 Total CBD	DAB Ph.Eur. 2.2.29	<1 %	0.08 %
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.