

Freigabezertifikat/ Release certificate

Produkt Product	Khiron G 19/1	
Stärke Strength	THC: 19 %	CBD: <1 %
Darreichungsform Dosage form	fest, Cannabis sativa L. medizinisches Cannabis solid, Cannabis sativa L. medical cannabis	
Charge Batch	C240049	
Verfalldatum Expiry date	31.03.2025	
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	Ph.Eur. Monograph	Dark/Brown green of different shades. Bract fragments of dark green to green. Peduncles of a light-green colour. Flower husks of a green to light green colour, 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	Ph.Eur. Monograph	Glandular trichomes/ hair identified	complies
1.3 Identity C (HPTLC)	Ph. Eur. 2.8.25	Comply with monograph	complies
2.0 Foreign Matter	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 %	0 %
4.0 Average Weight of the container	Weighing	10.0 - 10.5 g	10.3 g

Test Item	Method	Specified reference value	Result
5.0 Microbiology			
5.1 TAMC Total aerobic microbial count	Ph. Eur. 2.6.12 Ph.Eur. 2.6.13 Ph.Eur. 2.6.31	$\leq 10^4$ CFU/gram	< 100 CFU/g
5.2 TYMC Total yeast and mold count		$\leq 10^2$ CFU/gram	10 CFU/g
5.3 Bile salt tolerant gram-negative bacteria		$\leq 10^2$ CFU/gram	absent/g
5.4 Escherichia coli		absent/gram	absent/g
5.5 Salmonella		absent/25 gram	absent/25g
5.6 Aflatoxins	Ph. Eur. 2.8.18	B1 ≤ 2 µg/kg SUM B1 + B2 + G1 + G2 - ≤ 4 µg/kg	< 0.25 µg/kg (LOD); < 0.5 µg/kg (LOQ)
5.7 Ochratoxin A	Ph. Eur. 2.8.22	NMT 20 µg/Kg	< 5 µg/kg (LOD)
6.0 Heavy Metals			
6.1 Lead	Ph. Eur. 2.4.27	NMT 0.5 ppm	0.022 ppm
6.2 Cadmium		NMT 0.3 ppm	0.011 ppm
6.3 Mercury		NMT 0.1 ppm	< 0.050 ppm (LOQ)
6.4 Arsenic		NMT 0.2 ppm	< 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	Ph. Eur. 2.2.32	NMT 12 %	9 %
9.0 Cannabinoids Content			
9.1 Total THC	Ph.Eur. 2.2.29	19 % (17.1 % - 20.9 %) (90 - 110 %)	19.38 % (102 %)
9.2 Total CBD		< 1 %	0.17 %
9.3 Related Substances CBN		NMT 1 %	0.15 %

Analytische Monografie Cannabisblüten der Europäischen Pharmakopöe ab dem 01.07.2024
Analytical monograph on Cannabis Flowers by European Pharmacopoeia from 01/07/2024

LOD = Limit of Detection LOQ = Limit of Quantification
n.n. = below limit of quantification NMT = not more than

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 Valdemar Raposo gem. Art. 48 und 51 der RL 2001/83 am 17.09.2024 zertifiziert.
The batch was certified by the qualified person Valdemar Raposo according to §48/51 Directive 2001/83 on 17.09.2024.

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.