

Freigabezertifikat/ Release certificate

Produkt Product	Khiron G 19/1	
Stärke Strength	THC: 19 %	CBD: < 1 %
Darreichungsform Dosage form	ganze Blüte (fest) whole flower (solid)	
Charge Batch	2400551	
Verfalldatum Expiry date	31.05.2025	
Packungsgröße Packaging size	10 g	

Rezepturarzneimittel zur Abgabe an Apotheken

Prescription drugs for dispensing to pharmacies

Analysenergebnisse

Analytical results

Analyses according to Ph.Eur. 11.5, Monograph 3028

Test Item	Method	Specified reference value	Result
1.0 Identification			
Identity A (macroscopic)	Test according Ph.Eur.	complies to requirements	compliant
		Ph.Eur. Monograph 3028	
Identity B (microscopic)	Test according Ph.Eur.	complies to requirements	compliant
	2.8.23	Ph.Eur. Monograph 3028	
Identity C (HPTLC)	Test according Ph.Eur.	complies to requirements	compliant
	2.8.25	Ph.Eur. Monograph 3028	
Foreign matter	Test according Ph.Eur.	max. 2 %	0 %
	2.8.2		
Loss on Drying (LOD)	Test according Ph.Eur.	max. 12.0 % (w/w)	9.3 %
	2.2.32		
2.0 Content			
Assay Δ^9-Tetrahydrocannabinol (THC)	Test according Ph.Eur.	19 % $\pm$ 10 %	18.6 %
	2.2.29	(17.1 – 20.9 %)	
Assay Cannabidiol (CBD)	Test according Ph.Eur.	max. 1.0 %	< LOQ (0.05 %)
	2.2.29		
Cannabinol (CBN)	Test according Ph.Eur.	max. 1.0 %	0.1 %
	2.2.29		
4.0 Heavy Metals			
Arsenic (As)	Ph.Eur. 2.4.27	max. 0.2 ppm	0.0 ppm
Cadmium (Cd)	Ph.Eur. 2.4.27	max. 0.3 ppm	< LOQ (0.005 ppm)
Lead (Pb)	Ph.Eur. 2.4.27	max. 0.5 ppm	< LOQ (0.020 ppm)
Mercury (Hg)	Ph.Eur. 2.4.27	max. 0.1 ppm	< LOQ (0.050 ppm)

5.0 Microbiology Ph.Eur. 5.1.8 cat. C			
TAMC (Total Aerobic microbial count)	Ph.Eur. 2.6.12	$\leq 10^5$ cfu/g (max. 500.000 cfu/g)	2.40×10^3 cfu/g
TYMC (Total Yeast & Molds count)	Ph.Eur. 2.6.12	$\leq 10^4$ cfu/g (max. 50.000 cfu/g)	1.00×10^3 cfu/g
E.Coli	Ph.Eur. 2.6.31	absent/g	absent/g
Salmonella spp.	Ph.Eur. 2.6.31	absent/25g	absent/25g
Bile tolerant Gram-Negative Bacteria	Ph.Eur. 2.6.31	max. 10^4 cfu/g	< 10 cfu/g
6.0 Toxins			
Alfatoxin B1	Ph.Eur. 2.8.18	max. 2.0 ppb (2 μ g/kg)	< LOD (0.25 μ g/kg)
Sum of Alfatoxin B1, B2, G1, G2	Ph.Eur. 2.8.18	max. 4.0 ppb (4 μ g/kg)	< LOD (0.25 μ g/kg)
Ochratoxin A	Ph.Eur. 2.8.22	max. 20 ppb (20 μ g/kg)	< LOD (2 μ g/kg)
Pesticides	Ph.Eur. 2.8.13	must comply with requirements of monograph	complies

LOQ = Limit of Quantitation
LOD = Limit of Detection

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 Catarina Paixão gem. Art. 48 und 51 der RL 2001/83 am 04.12.2024 zertifiziert.
The batch was certified by the qualified person Catarina Paixão according to 548/51 Directive 2001/83 on 04.12.2024.

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.