

Freigabezertifikat/ Release certificate

Produkt Product	Khiron SCD 25/1	
Stärke Strength	THC: 25 %	CBD: < 1 %
Darreichungsform Dosage form	ganze Blüte (fest) whole flower (solid)	
Charge Batch	202425CF701001	
Verfalldatum Expiry date	30.04.2025	
Packungsgröße Packaging size	10 g	

Rezepturarzneimittel zur Abgabe an Apotheken

Prescription drugs for dispensing to pharmacies

Analysenergebnisse

Analytical results

Analyses according to DAB 2023, Cannabis flow/Ph.Eur. 11.5

Test Item	Method	Specified reference value	Result
1.0 Identification			
Identity A (macroscopic)	Test according DAB	complies to requirements	compliant
Identity B (microscopic)	Test according DAB	complies to requirements	compliant
Identity C (TLC)	Test according DAB / Ph.Eur. 2.2.27	complies to requirements	compliant
Foreign matter	Test according DAB / Ph.Eur. 2.8.2	max. 2 %	< 2 %
Loss on Drying (LOD)	Test according DAB / Ph.Eur. 2.2.32	max. 12.0 % (w/w) ¹	6.7 %
2.0 Purity			
Cannabinol (CBN)	Test according DAB / Ph.Eur. 2.2.29	max. 1.0 %	< 0.1 %
3.0 Content			
Assay Δ^9-Tetrahydrocannabinol (THC)	Test according DAB / Ph.Eur. 2.2.29	25 % (22.5 – 27.5 %)	25.7 %
Assay Cannabidiol (CBD)	Test according DAB / Ph.Eur. 2.2.29	max. 1.0 %	< 0.1 %
4.0 Heavy metals			
Arsenic (As)	Ph.Eur. 2.4.27	max. 0.2 ppm ¹	n.n.
Cadmium (Cd)	Ph.Eur. 2.4.27	max. 0.3 ppm ¹	n.n.
Lead (Pb)	Ph.Eur. 2.4.27	max. 0.5 ppm ¹	n.n.
Mercury (Hg)	Ph.Eur. 2.4.27	max. 0.1 ppm ¹	n.n.

5.0 Microbiology Ph.Eur. 5.1.8 cat. C			
TAMC (Total Aerobic microbial count)	Ph.Eur. 2.6.12	max. 500.000 cfu/g ²	< 10.000 cfu/g
TYMC (Total Yeast & Molds count)	Ph.Eur. 2.6.12	max. 50.000 cfu/g ²	< 1.000 cfu/g
E.Coli	Ph.Eur. 2.6.31	absent/g	negative
Salmonella spp.	Ph.Eur. 2.6.31	absent/25g	negative
Bile tolerant Gram-Negative Bacteria	Ph.Eur. 2.6.31	max. 10 ⁴ cfu/g	< 100 cfu/g
6.0 Toxins			
Alfatoxin B1	Ph.Eur. 2.8.18	max. 2.0 ppb	n.n.
Sum of Alfatoxin B1, B2, G1, G2	Ph.Eur. 2.8.18	max. 4.0 ppb	n.n.
Ochratoxin A	Ph.Eur. 2.8.22	max. 2.0 ppb	n.n.
Pesticides incl. Dithiocarbamates	Ph.Eur. 2.8.13	absent	n.n.

n.n. = below limit of quantification

¹ acc. to Cannabis flower monography Ph. Eur. 11.5 Monography 07/2024:3028

² Maximum acceptable count (acceptance criteria TAMC: 10⁵ CFU, TYMC: 10⁴ CFU)

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 Annekathrin Danz gem. Art. 48 und 51 der RL 2001/83 am 18.09.2024 zertifiziert.

The batch was certified by the qualified person Annekathrin Danz according to §48/51 Directive 2001/83 on 18.09.2024.

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.