

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	2025CF2801001	
Verfalldatum Expiry date	17.11.2025	
Packungsgröße Packaging size	10 g	

Rezepturarzneimittel zur Abgabe an Apotheken

Prescription drugs for dispensing to pharmacies

Analysenergebnisse

Analytical results

Analyses according to Ph.Eur. 11.6, Monograph 3028

Test Item	Method	Specified reference value	Result*
Identification			
Identity A (macroscopic)	Test according Ph. Eur.	complies to the requirements of Ph. Eur. Monograph 3028	compliant
Identity B (microscopic)	Test according Ph. Eur. 2.8.23	complies to the requirements of Ph. Eur. Monograph 3028	compliant
Identity C (HPTLC)	Test according Ph. Eur. 2.8.25	complies to the requirements of Ph. Eur. Monograph 3028	compliant
Foreign matter	Test according / Ph.Eur. 2.8.2	max. 2 %	< 2 % compliant
Loss of drying (LOD)	Test according Ph. Eur. 2.2.32	max. 12.0 % (w/w)	8.1 %
Purity			
Cannabinol (CBN)	Test according Ph. Eur. 2.2.29	max. 1.0 %	<0.1 %
Content			
Assay Δ^9- Tetrahydrocannabinol (THC)	Test according Ph. Eur. 2.2.29	not less than 90.0 % and not more than 110.0 % of the strength declared ¹⁾ 25 % $\pm$ 10 % (22.5 – 27.5 %)	26.6 %
Assay Cannabidiol (CBD)	Test according Ph. Eur. 2.2.29	max. 1.0 %	<0.1 %

Heavy metals			
Arsenic (As)	Ph. Eur. 2.4.27	max. 0.2 ppm	n.n.
Cadmium (Cd)	Ph. Eur. 2.4.27	max. 0.3 ppm	n.n.
Lead (Pb)	Ph. Eur. 2.4.27	max. 0.5 ppm	n.n.
Mercury (Hg)	Ph. Eur. 2.4.27	max. 0.1 ppm	n.n.
Microbiology Ph. Eur. 5.1.8 cat. C			
TAMC (Total Aerobic microbial count)	Ph. Eur. 2.6.12	max. 500.000 CFU/g	20.000 CFU/g
TYMC (Total Yeast & Molds count)	Ph. Eur. 2.6.12	max. 50.000 CFU/g	9.000 CFU/g
<i>E. coli</i>	Ph. Eur. 2.6.31	absent/g	negative
<i>Salmonella spp.</i>	Ph. Eur. 2.6.31	absent/25 g	negative
Bile tolerant Gram-Negative Bacteria	Ph. Eur. 2.6.31	max. 10 ⁴ CFU/g	<100 CFU/g
Toxins			
Aflatoxin B₁	Ph. Eur. 2.8.18	max. 2 ppb (2 µg/kg)	n.n.
Sum of Aflatoxin B₁, B₂, G₁, G₂	Ph. Eur. 2.8.18	max. 4 ppb (4 µg/kg)	n.n.
Ochratoxin A	Ph. Eur. 2.8.22	max. 2 ppb (2 µg/kg)	n.n.
Pesticides incl. Dithiocarbamates	Ph. Eur. 2.8.13	absent	n.n.

n.n. = below limit of quantitation

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 21.03.2025 zertifiziert.

The batch was certified by the qualified person Annekathrin Danz according to §48/51 Directive 2001/83 on 21.03.2025.

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.