

Freigabezertifikat/ Release certificate
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Produkt Product	Khiron ELG 33/1		
Stärke Strength	THC: 33 %	CBD: < 1 %	
Darreichungsform Dosage form	ganze Blüte (fest) whole flower (solid)		
Charge Batch	2025CF5302001		
Verfalldatum Expiry date	29.09.2026		
Packungsgröße Packaging size	100 g		

Rezepturarzneimittel zur Abgabe an Apotheken

Prescription drugs for dispensing to pharmacies

Analysenergebnisse

Analytical results

Analyses according to Ph.Eur. 11.8, Monograph 07:2024/3028

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 % does not contain any seeds or leaves more than 1.0 cm length	< 2 % compliant
Loss of drying (LOD)	Test according Ph. Eur. 2.2.32	max. 12.0 % (w/w)	8.5 %
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⁾ 33 % \pm 10 % (29.7 – 36.3 %)	31.5 %

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	< 10.000 CFU/g
TYMC (Total Yeast & Molds count)	Ph. Eur. 2.6.12	max. 50.000 CFU/g	<1.000 CFU/g
<i>E. coli</i>	Ph. Eur. 2.6.31	absent/g	absent/g
<i>Salmonella spp.</i>	Ph. Eur. 2.6.31	absent/25 g	absent/25g
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

Hiermit wird bestätigt, dass alle Herstellungsschritte dieser Charge vollständig in Übereinstimmung mit den EU-GMP-Anforderungen durchgeführt wurden.

This is to confirm that all manufacturing steps for this batch were carried out in full compliance with EU GMP requirements.

Die Herstellungs-, Verpackungs- und Prüfdokumentation ist vollständig, wurde überprüft und ordnungsgemäß von den jeweiligen Verantwortlichen unterzeichnet.

The manufacturing, packaging and testing documentation is complete, has been reviewed and has been fully signed by the responsible persons

Die Charge wurde durch die Sachkundige Person [REDACTED] z gem. Art. 48 und 51 der RL 2001/83 am 05.01.2026 zertifiziert.

The batch was certified by the qualified person [REDACTED] according to §48/51 Directive 2001/83 on 06.01.2026.

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.