

Freigabezertifikat/ Release certificate

Produkt Product	Khiron SLH 24/1	
Stärke Strength	THC: 24 %	CBD: <1 %
Darreichungsform Dosage form	fest, Cannabis sativa L. medizinisches Cannabis solid, Cannabis sativa L. medical cannabis	
Charge Batch	2400721	
Verfalldatum Expiry date	30.06.2025	
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	Specification	Result
1.0 Identification		
1.1 Identity A – Macroscopic	Complies with requirements of Monograph	complies
1.2 Identity B - Microscopic	Complies with requirements of Monograph	complies
1.2 Identity C – HPTLC	Complies with requirements of Monograph	complies
2.0 Foreign Matter	≤ 2% (w/w)	0 %
3.0 Loss on Drying	≤ 12.0 % (w/w)	8.6 %
4.0 Assay		
4.1 Total THC	24 % ± 10 % (21.6 % - 26.4 %)	23.1 %
4.2 Total CBD	≤ 1.0 % (w/w)	< LOQ (0.2 %)
5.0 Total CBN	≤ 1.0 % (w/w)	0.2 %

Test Item	Specification	Result
6.0 Heavy Metals		
6.1 Cadmium	≤ 0.3 ppm	< LOQ (0.005 ppm)
6.2 Lead	≤ 0.5 ppm	< LOQ (0.020 ppm)
6.3 Mercury	≤ 0.1 ppm	< LOQ (0.050 ppm)
6.4 Arsenic	≤ 0.2 ppm	< LOQ (0.020 ppm)
7.0 Microbiology		
7.1 Total Aerobic Microbial Count (TAMC)	$\leq 10^5$ CFU/g (max. 500.000 CFU/g)	1.00×10^2 CFU/g
7.2 Total Yeast and Mold Count (TYMC)	$\leq 10^4$ CFU/g (max. 50.000 CFU/g)	< 100 CFU/g
7.3 Bile-tolerant gram-negative bacteria	$\leq 10^4$ CFU/g	< 10 CFU/g
7.4 Escherichia coli	Absence in 1 g	Absent/g
7.5 Salmonella	Absence in 25 g	Absent/25g
8. Aflatoxins		
8.1 B1	≤ 2 µg/kg	< LOD (0.25 µg/kg)
8.2 Sum of B1, B2, G1, G2	≤ 4 µg/kg	< LOQ (0.25 µg/kg)
9. Ochratoxin A	≤ 20 µg/kg	< LOD (2 µg/kg)
10. Pesticides	Must comply with requirements of Monograph	complies

LOD = Limit of Detection

LOQ = Limit of Quantification

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 16.01.2025 zertifiziert.

The batch was certified by the qualified person Valdemar Raposo according to §48/51 Directive 2001/83 on 15.10.2024.

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.