

Freigabezertifikat/ Release certificate

Produkt Product	Khiron GK 24/1	
Stärke Strength	THC: 24 %	CBD: < 1 %
Darreichungsform Dosage form	fest solid	
Charge Batch	202423CF601001	
Verfalldatum Expiry date	20.12.2024	
Packungsgröße Packaging size	100 g	

Rezepturarzneimittel zur Abgabe an Apotheken

Prescription drugs for dispensing to pharmacies

Analysenergebnisse

Analytical results

Test Item	Method	Specified reference value	Result
1.0 Identity			
1.1 Identity A - Appearance	DAB 2023	complies to the requirements	compliant
1.2 Identity B - Microscopic		complies to the requirements	compliant
1.3 Identity C	DAB 2023, Ph. Eur. 2.2.27 (11.5)	complies to the requirements	compliant
2.0 Foreign Matter	DAB 2023, Ph. Eur. 2.8.2 (11.5)	max. 2 %	< 2 %
3.0 Loss of Drying	Ph. Eur. 2.2.32 (11.5)	max. 10 %	8.9 %
4.0 Cannabinol (CBN)	DAB 2023, Ph. Eur. 2.2.29 (11.5)	max. 1.0 %	< 0.1 %
5.0 Assay Tetrahydrocannabinol (THC)	DAB 2023, Ph. Eur. 2.2.29 (11.5)	24 % (21.6 – 26.4 %)	24.1 %
6.0 Assay Cannabidiol (CBD)	DAB 2023, Ph. Eur. 2.2.29 (11.5)	≤ 1 %	< 0.1 %
7.0 Microbiology			
7.1 TAMC Total aerobic microbial count	Ph.Eur. 2.6.12 (11.5)	≤ 500.000 CFU/g	< 10.000 CFU/g
7.2 TYMC Total yeast and mold count		≤ 50.000 CFU/g	5.500 CFU/g
7.3 E. Coli	Ph.Eur. 2.6.31 (11.5)	absent/g	negative
7.4 Salmonella spp.		absent/25g	negative

Test Item	Method	Specified reference value	Result
7.5 Bite tolerant Gram-Negative Bacteria	Ph.Eur. 2.6.31 (11.5)	≤ 10.000 CFU/g	< 100 CFU/g
7.6 Aflatoxin B1	Ph. Eur. 2.8.18 (11.5)	< 2 ppb	n.n.
7.7 Aflatoxin B2		< 2 ppb	n.n.
7.8 Aflatoxin G1		< 2 ppb	n.n.
7.8 Aflatoxin G2		< 2 ppb	n.n.
7.9 Total Aflatoxins B1, B2, G1, G2		< 4 ppb	n.n.
7.9 Ochratoxin A		max. 2.0 ppb	n.n.
8.0 Heavy Metals			
8.1 Lead (PB)	Ph. Eur. 2.4.27 (11.5)	< 5 ppm	n.n.
8.2 Cadmium (CD)		< 1 ppm	n.n.
8.3 Mercury (Hg)		< 0.1 ppm	0.05 ppm
8.4 Arsenic (As)		< 1 ppm	n.n.
9.0 Pesticides incl. Dithiocarbamates	Ph. Eur. 2.8.13 (11.5)	Limits acc. Ph.Eur. 11.5	n.n.

n.n. = below 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 gem. Art. 48 und 51 der RL 2001/83 am 27.08.2024 zertifiziert.

The batch was certified by the qualified person according to §48/51 Directive 2001/83 on 27.08.2024.

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.