

## Freigabezertifikat/ Release certificate

|                                 |                                            |            |
|---------------------------------|--------------------------------------------|------------|
| Produkt<br>Product              | <b>Khiron LBO 24/1</b>                     |            |
| Stärke<br>Strength              | THC: 24 %                                  | CBD: < 1 % |
| Darreichungsform<br>Dosage form | ganze Blüte (fest)<br>whole flower (solid) |            |
| Charge<br>Batch                 | 2025CF2601001                              |            |
| Verfalldatum<br>Expiry date     | 31.01.2026                                 |            |
| Packungsgröße<br>Packaging size | 10 g                                       |            |

## Rezepturarzneimittel zur Abgabe an Apotheken

Prescription drugs for dispensing to pharmacies

## Analysenergebnisse

Analytical results

### Analyses according to Ph.Eur. 11.7, Monograph 3028

| Test Item                                                             | Method                            | Specified reference value                                                                                                      | Result             |
|-----------------------------------------------------------------------|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------|--------------------|
| <b>Identification</b>                                                 |                                   |                                                                                                                                |                    |
| <b>Identity A<br/>(macroscopic)</b>                                   | Test according Ph. Eur.           | complies to the requirements<br>of Ph. Eur. Monograph 3028                                                                     | compliant          |
| <b>Identity B<br/>(microscopic)</b>                                   | Test according Ph. Eur.<br>2.8.23 | complies to the requirements<br>of Ph. Eur. Monograph 3028                                                                     | compliant          |
| <b>Identity C<br/>(HPTLC)</b>                                         | Test according Ph. Eur.<br>2.8.25 | complies to the requirements<br>of Ph. Eur. Monograph 3028                                                                     | compliant          |
| <b>Foreign matter</b>                                                 | Test according Ph.Eur.<br>2.8.2   | max. 2 %<br>does not contain any seeds or any leaves<br>more than 1.0 cm length                                                | < 2 %<br>compliant |
| <b>Loss of drying<br/>(LOD)</b>                                       | Test according Ph. Eur.<br>2.2.32 | max. 12.0 % (w/w)                                                                                                              | 9.8 %              |
| <b>Purity</b>                                                         |                                   |                                                                                                                                |                    |
| <b>Cannabinol<br/>(CBN)</b>                                           | Test according Ph. Eur.<br>2.2.29 | max. 1.0 %                                                                                                                     | < 0.1 %            |
| <b>Content</b>                                                        |                                   |                                                                                                                                |                    |
| <b>Assay<br/><math>\Delta^9</math>-Tetrahydrocannabinol<br/>(THC)</b> | Test according Ph. Eur.<br>2.2.29 | not less than 90.0 % and not<br>more than 110.0 % of the<br>strength declared <sup>1)</sup><br>24 % $\pm$ 10 % (21.6 – 26.4 %) | 23.1 %             |
| <b>Assay Cannabidiol<br/>(CBD)</b>                                    | Test according Ph. Eur.<br>2.2.29 | max. 1.0 %                                                                                                                     | < 0.1 %            |

| Heavy metals                                                                       |                 |                            |              |
|------------------------------------------------------------------------------------|-----------------|----------------------------|--------------|
| <b>Arsenic (As)</b>                                                                | Ph. Eur. 2.4.27 | max. 0.2 ppm               | n.n.         |
| <b>Cadmium (Cd)</b>                                                                | Ph. Eur. 2.4.27 | max. 0.3 ppm               | n.n.         |
| <b>Lead (Pb)</b>                                                                   | Ph. Eur. 2.4.27 | max. 0.5 ppm               | n.n.         |
| <b>Mercury (Hg)</b>                                                                | Ph. Eur. 2.4.27 | max. 0.1 ppm               | n.n.         |
| Microbiology Ph. Eur. 5.1.8 cat. C                                                 |                 |                            |              |
| <b>TAMC</b><br>(Total Aerobic microbial count)                                     | Ph. Eur. 2.6.12 | max. 500.000 CFU/g         | 10.000 CFU/g |
| <b>TYMC</b><br>(Total Yeast & Molds count)                                         | Ph. Eur. 2.6.12 | max. 50.000 CFU/g          | 5.500 CFU/g  |
| <b><i>E. coli</i></b>                                                              | Ph. Eur. 2.6.31 | absent/g                   | negative     |
| <b><i>Salmonella spp.</i></b>                                                      | Ph. Eur. 2.6.31 | absent/25 g                | negative     |
| <b>Bile tolerant Gram-Negative Bacteria</b>                                        | Ph. Eur. 2.6.31 | max. 10 <sup>4</sup> CFU/g | < 100 CFU/g  |
| Toxins                                                                             |                 |                            |              |
| <b>Aflatoxin B<sub>1</sub></b>                                                     | Ph. Eur. 2.8.18 | max. 2 ppb (2 µg/kg)       | n.n.         |
| <b>Sum of Aflatoxin B<sub>1</sub>, B<sub>2</sub>, G<sub>1</sub>, G<sub>2</sub></b> | Ph. Eur. 2.8.18 | max. 4 ppb (4 µg/kg)       | n.n.         |
| <b>Ochratoxin A</b>                                                                | Ph. Eur. 2.8.22 | max. 2 ppb (2 µg/kg)       | n.n.         |
| <b>Pesticides incl. Dithiocarbamates</b>                                           | 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 [REDACTED] gem. Art. 48 und 51 der RL 2001/83 am 13.06.2025 zertifiziert.

The batch was certified by the qualified person Annekathrin Danz according to §48/51 Directive 2001/83 on 13.06.2025.

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.