

**Freigabezertifikat/ Release certificate**

|                                        |                                                                                               |
|----------------------------------------|-----------------------------------------------------------------------------------------------|
| <b>Produkt</b><br>Product              | Khiron G23/1<br>Khiron G19/1                                                                  |
| <b>Stärke</b><br>Strength              | THC: 23 %                      CBD: <1 %                                                      |
| <b>Darreichungsform</b><br>Dosage form | fest, Cannabis sativa L. medizinisches Cannabis<br>solid, Cannabis sativa L. medical cannabis |
| <b>Charge</b><br>Batch                 | C240004                                                                                       |
| <b>Verfalldatum</b><br>Expiry date     | 31.07.2024                                                                                    |
| <b>Packungsgröße</b><br>Packaging size | 10 g                                                                                          |

**Rezepturarzneimittel zur Abgabe an Apotheken**

Prescription drugs for dispensing to pharmacies

**Analysenergebnisse**

Analytical results

| Test Item                                  | Method*                 | Specified reference value                                                                                                                                                                                                                                                                  | Result   |
|--------------------------------------------|-------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------|
| <b>1.0 Identity</b>                        |                         |                                                                                                                                                                                                                                                                                            |          |
| <b>1.1 Identity A - Appearance</b>         | DAB                     | Dark/Brown green of different shades. Bract fragments of dark green to green. Peduncles of a light-green color. Flower husks of a green to light green color, covered with dense yellowy-white hairs and stuck together with resin. Absence of grey/dark spots. Absence of foreign matter. | complies |
| <b>1.2 Identity B - Microscopic</b>        | DAB                     | Glandular trichomes/ hair identified                                                                                                                                                                                                                                                       | complies |
| <b>1.3 Identity C</b>                      | DAB,<br>Ph. Eur. 2.2.29 | Reference cannabinoids RT through the standard and sample.                                                                                                                                                                                                                                 | complies |
| <b>2.0 Foreign Matter</b>                  | DAB,<br>Ph. Eur. 2.8.2  | Absence of mold, insects and other animal contamination                                                                                                                                                                                                                                    | 0 %      |
| <b>3.0 Total Ash</b>                       | Ph. Eur. 2.4.16         | ≤20 %                                                                                                                                                                                                                                                                                      | 10 %     |
| <b>4.0 Average Weight of the container</b> | Weighing                | 10.0-10.5 g                                                                                                                                                                                                                                                                                | 10.2 g   |

| Test Item                                            | Method*                          | Specified reference value                                             | Result                                                         |
|------------------------------------------------------|----------------------------------|-----------------------------------------------------------------------|----------------------------------------------------------------|
| <b>5.0 Microbiology</b>                              |                                  |                                                                       |                                                                |
| <b>5.1 TAMC</b><br>Total aerobic microbial count     | DAB,<br>Ph. Eur. 5.1.4,<br>5.1.8 | $\leq 5.0 \times 10^5$ CFU/gram                                       | $3.00 \times 10^2$ cfu/g                                       |
| <b>5.2 TYMC</b><br>Total yeast and mold count        |                                  | $\leq 5.0 \times 10^4$ CFU/gram                                       | $2.30 \times 10^1$ cfu/g                                       |
| <b>5.3 Bile salt tolerant gram-negative bacteria</b> |                                  | $\leq 10^4$ CFU/gram                                                  | <10 cfu/g                                                      |
| <b>5.4 <i>Escherichia coli</i></b>                   |                                  | Absent/gram                                                           | Absent                                                         |
| <b>5.5 <i>Salmonella</i></b>                         |                                  | Absent/25 gram                                                        | absent                                                         |
| <b>5.6 Aflatoxins</b>                                | Ph. Eur. 2.8.18                  | B1 $\leq 2\mu\text{g/kg}$<br>[SUM B1+B2+G1+G2] $\leq 4\mu\text{g/kg}$ | < 0.25 $\mu\text{g/kg}$ (LOD);<br>< 0.5 $\mu\text{g/kg}$ (LOQ) |
| <b>5.7 Ochratoxin A</b>                              | Ph. Eur. 2.8.22                  | NMT 20 $\mu\text{g/Kg}$                                               | <2 $\mu\text{g/kg}$ (LOD)                                      |
| <b>6.0 Heavy Metals</b>                              |                                  |                                                                       |                                                                |
| <b>6.1 Lead</b>                                      | Ph. Eur. 2.4.27                  | NMT 5.0 ppm                                                           | <0.020 ppm (LOQ)                                               |
| <b>6.2 Cadmium</b>                                   |                                  | NMT 1.0 ppm                                                           | 0.011 ppm                                                      |
| <b>6.3 Mercury</b>                                   |                                  | NMT 0.1 ppm                                                           | <0.050 ppm (LOQ)                                               |
| <b>6.4 Arsenic</b>                                   |                                  | informative                                                           | <0.020 ppm (LOQ)                                               |
| <b>7.0 Pesticides</b>                                | Ph. Eur. 2.8.13                  | Screening analysis to comply with 2.8.13                              | complies                                                       |
| <b>8.0 Loss on drying</b>                            | DAB,<br>Ph. Eur. 2.2.32          | NMT 10 %                                                              | 7 %                                                            |
| <b>9.0 Cannabinoids Content</b>                      |                                  |                                                                       |                                                                |
| <b>9.1 Total THC</b>                                 | DAB<br>Ph.Eur. 2.2.29            | 23 % (90-110 %)                                                       | 22.00 % (95.65 %)                                              |
| <b>9.2 Total CBD</b>                                 |                                  | <1 %                                                                  | 0.08 %                                                         |
| <b>9.3 Related Substances CBN</b>                    |                                  | NMT 1 %                                                               | 0.01 %                                                         |

\*current edition

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 01.02.2024 zertifiziert.

The batch was certified by the qualified person according to §48/51 Directive 2001/83 on 01.02.2024.

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.