

## Certificado de Lote

### Batch Certificate

|   |                                  |
|---|----------------------------------|
| <b>Nome do produto</b><br><i>Name of product</i>                                    | Remexian 30/1 SCK                |
| <b>País de destino</b><br><i>Destination country</i>                                | Alemanha<br>Germany              |
| <b>Nº de autorização de AIM</b><br><i>Marketing authorisation number</i>            | NA                               |
| <b>Concentração da substância ativa</b><br><i>Strength/potency</i>                  | 30 ± 10% [27%-30%]               |
| <b>Forma farmacêutica</b><br><i>Dosage form</i>                                     | Flor Seca<br>Dry Flower          |
| <b>Quantidade embalada e tipo de embalagem</b><br><i>Package size and type</i>      | 86 sacos de 250g<br>86 250g bags |
| <b>Nº de Lote do produto acabado</b><br><i>Batch Number of the finished product</i> | M241980043NSC                    |
| <b>Data de fabrico</b><br><i>Date of manufacture</i>                                | 09/2024                          |
| <b>Prazo de Validade</b><br><i>Expiry Date</i>                                      | 03/2025                          |

**Manufacturer:** Cannprisma Pharma, Lda  
**Address:** Avenida Ville La Baule nº58, 8900-227 Vila Real de Santo António, Portugal  
**Date:** 30-07-2024  
**F076/S1/MH/002/2023 (FP)**  
**F076/S1/SA/001/2023 (API)**

**Nome, endereço e número de autorização de todos os locais de fabrico e locais de controlo de qualidade**  
*Name, address and authorisation number of all manufacturing sites and quality control sites*

**Laboratory:** Cannprisma Pharma, Lda  
**Address:** Avenida Ville La Baule nº 58, 8900-227 Vila Real de Santo António, Portugal  
**Date:** 30-07-2024  
**F076/S1/MH/002/2023 (FP)**  
**F076/S1/SA/001/2023 (API)**

**Laboratory:** LEF - Laboratório de Estudos Farmacêuticos  
**Address:** R. Ferrarias Del Rei 6A, 2730-036, Barcarena, Portugal  
**F032/003/2021**  
**F032/S1/ME/003/2021**  
**F032/S1/SA/001/2021**

|  | Tests   | Methods Specification  | Specification                           | Results                                 |
|--|---|--|---|---|
|  | <b>Resultados da Análise</b><br><i>Analysis Results</i> | Microscopy observation (Identity test, Method A)               | Monograph Ph. Eur. "Cannabis Flower"    | Complies with the monograph description |
| Microscopy observation (Identity test, Method B) |   | Monograph Ph. Eur. "Cannabis Flower"<br>Ph. Eur. 11.5 [2.8.23] | Complies with the monograph description | Complies                                |
| HPTLC Identification (Identity test, Method C)   |   | Monograph Ph. Eur. "Cannabis Flower"<br>Ph. Eur. 11.5 [2.8.25] | Complies with the monograph description | Complies                                |
| Foreign Matter                                   |   | Monograph Ph. Eur. "Cannabis Flower"<br>Ph. Eur. 11.5 [2.8.2]  | ≤2% (w/w)                               | 0% (w/w)                                |
| Loss on Drying                                   |   | Monograph Ph. Eur. "Cannabis Flower"<br>Ph. Eur. 11.5 [2.2.32] | ≤12%                                    | 8%                                      |
| Assay  |   | Monograph Ph. Eur. "Cannabis Flower"<br>Ph. Eur. 11.5 [2.2.29] |   |   |
| THC  | Informative   |  | 1.1%                                    |   |
| THCA <sup>(1)</sup>                              | Informative   |  | 27.4%                                   |   |
| CBD  | Informative   |  | ≤ 0.2% (LOQ)                            |   |
| CBDA <sup>(2)</sup>                              | Informative   |  | ≤ 0.2% (LOQ)                            |   |
| Total THC  |   | According to label ± 10% (dried basis)                         | 28.5% (dried basis)                     |   |
| Total CBD  |   | ≤1.0% (dried basis)  | ≤ 0.2% (LOQ) (dried basis)              |   |

# CANNPRISMA

| Related Substances CBN                        |   | ≤1.0% (dried basis)                            | 0.2 %<br>(dried basis)           |
|---|---|--|----------------------------------|
| <b>Microbiological Control</b>                |   |  |                                  |
| Total aerobic microbial count (TAMC)          | Ph. Eur. 11.5<br>(2.6.12;2.6.13;5.1.4<br>5.1.8.C) | <10 <sup>6</sup> CFU/g<br>(Max. 500 000 CFU/g) | 4.0 x 10 <sup>6</sup> CFU/g      |
| Total yeast and mold count (TYMC)             |   | <10 <sup>4</sup> CFU/g<br>(Max. 50 000 CFU/g)  | 4.0 x 10 <sup>6</sup> CFU/g      |
| Test for bile-tolerant Gram-negative bacteria |   | <10 <sup>4</sup> CFU/g<br>(Max. 50 000 CFU/g)  | > 10 and < 10 <sup>2</sup> CFU/g |
| Test for <i>E. coli</i>                       |   | Absent/g                                       | Absent/g                         |
| Test for <i>Salmonella</i>                    |   | Absent/25g                                     | Absent/25g                       |

### Comentários

#### Comments

**Nome e posição/título da pessoa autorizada para a libertação do produto**  
*Name and position/title of person authorising the batch release*

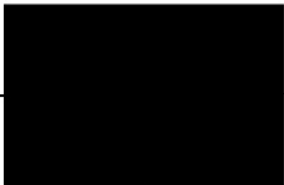
Fernando Águas/Qualified Person

**Data de Libertação do Produto**  
*Product Release Date*

30/10/2024

### Declaração de Certificação *Certification Statement*

Certifico que todas as etapas de fabrico deste lote de produto acabado foram realizadas em total conformidade com os requisitos das GMP da EU. *I hereby certify that all the manufacturing stages of this batch of finished product have been carried out in full compliance with GMP requirements of the EU.*



30/10/2024

Data Date

# CANNPRISMA

|                               |   |                |                    |
|-------------------------------|---|----------------|--------------------|
| <b>Título</b><br><i>Title</i> | <b>CERTIFICADO DE ANÁLISE</b><br><b>CERTIFICATE OF ANALYSIS</b> |                | <b>Pag. 1 of 2</b> |
| <b>Código</b><br><i>Code</i>  | <b>FR.QC.023</b>  | <b>Version</b> | <b>01</b>          |

|   |   |   |  |
|---|---|---|--|
| <b>Número CoA:</b><br><i>CoA number:</i>                                  | SQC-FB24/00335  | <b>Local:</b><br><i>Local:</i>                      | Manufacturing Site                             |
| <b>Produto:</b><br><i>Product:</i>  | <i>Cannabis sativa L.</i>   | <b>Variedade:</b><br><i>Variety:</i>                | Strawberry Cookies                             |
| <b>Descrição do Produto:</b><br><i>Product description:</i>               | Remexian 30/1 SCK   | <b>Potência:</b><br><i>Strength:</i>                | THC 30%<br>CBD < 1%                            |
| <b>Forma Farmacêutica:</b><br><i>Pharmaceutical Form:</i>                 | Dry flower  | <b>Acondicionamento:</b><br><i>Packaging:</i>       | 250 g bags                                     |
| <b>Número do Lote:</b><br><i>Batch Number:</i>                            | M241980043NSC   | <b>Data Validade:</b><br><i>Expiry Date:</i>        | 03/2025  |
| <b>Data de Receção de Amostra:</b><br><i>Sample reception date:</i>       | 07/08/2024  | <b>Data de Análise:</b><br><i>Date of Analysis:</i> | 12/08/2024 até 30/09/2024<br><i>till</i>       |
| <b>Tipo de Análise:</b><br><i>Type of analysis:</i>                       | Batch Release   | <b>Código TQA:</b><br><i>TQA Code:</i>              | TQA-REX-001                                    |
| <b>Cliente:</b><br><i>Client:</i>   | Remexian  | <b>Morada do Cliente:</b><br><i>Client Address:</i> | Märkersteig 27, 14974<br>Ludwigsfelde, Germany |
| <b>Morada do Controlo de Qualidade:</b><br><i>Quality Control adress:</i> | Avenida Vilje La Baule, n. ° 58.<br>8900-227 Vila Real de Santo António, Portugal |   |  |

| TESTES<br><i>TESTS</i>  | MÉTODOS<br><i>METHODS</i>   | ESPECIFICAÇÕES<br><i>SPECIFICATIONS</i>    | RESULTADOS<br><i>RESULTS</i>   |
|---|---|--|--------------------------------|
| <b>Macroscopy observation</b> <sup>(a)</sup> *<br>(Identity Test, Method A) | Monograph Ph. Eur.<br>"Cannabis Flower"                           | Complies with the monograph<br>description | Complies                       |
| <b>Microscopy observation</b> <sup>(a)</sup> *<br>(Identity Test, Method B) | Monograph Ph. Eur.<br>"Cannabis Flower"<br>Ph. Eur. 11.5 [2.8.23] | Complies with the monograph<br>description | Complies                       |
| <b>HPTLC Identification</b> <sup>(a)</sup> *<br>(Identity Test, Method C)   | Monograph Ph. Eur.<br>"Cannabis Flower"<br>Ph. Eur. 11.5 [2.8.25] | Complies with the monograph<br>description | Complies                       |
| <b>Foreign Matter</b> <sup>(b)</sup> *                                      | Monograph Ph. Eur.<br>"Cannabis Flower"<br>Ph. Eur. 11.5 [2.8.2]  | ≤ 2 % (w/w)                                | 0 % (w/w)                      |
| <b>Loss on drying</b> <sup>(b)</sup>  | Monograph Ph. Eur.<br>"Cannabis Flower"<br>Ph. Eur. 11.5 [2.2.32] | ≤ 12 %                                     | 8 %                            |
| <b>Assay</b> <sup>(b)</sup><br>THC  | Monograph Ph.Eur.<br>"Cannabis Flower"<br>Ph. Eur. 11.5 [2.2.29]  | Informative                                | 1.1 %                          |
| THCA <sup>1</sup>   |   | Informative                                | 27.4 %                         |
| CBD   |   | Informative                                | ≤ 0.2 % (LOQ)                  |
| CBDA <sup>2</sup>   |   | Informative                                | ≤ 0.2 % (LOQ)                  |
| Total THC+THCA <sup>1</sup>   |   | According to label ±10%<br>(dried basis)   | 28.5 %<br>(dried basis)        |
| Total CBD+CBDA <sup>2</sup>   |   | ≤ 1 % (dried basis)                        | ≤ 0.2 % (LOQ)<br>(dried basis) |
| <b>Related substances</b> <sup>(b)</sup><br>Total CBN                       |   | ≤ 1 % (dried basis)                        | 0.2 %<br>(dried basis)         |

<sup>1</sup> Expressed in THC

<sup>2</sup> Expressed in CBD

# CANNPRISMA

|                               |   |                |                    |
|-------------------------------|---|----------------|--------------------|
| <b>Título</b><br><i>Title</i> | <b>CERTIFICADO DE ANÁLISE</b><br><b>CERTIFICATE OF ANALYSIS</b> |                | <b>Pag. 2 of 2</b> |
| <b>Código</b><br><i>Code</i>  | <b>FR.QC.023</b>  | <b>Version</b> | <b>01</b>          |

|   |   |   |  |
|---|---|---|--|
| <b>Número CoA:</b><br><i>CoA number:</i>                                  | SQC-FB24/00335  | <b>Local:</b><br><i>Local:</i>                      | Manufacturing Site                             |
| <b>Produto:</b><br><i>Product:</i>  | <i>Cannabis sativa L.</i>   | <b>Variedade:</b><br><i>Variety:</i>                | Strawberry Cookies                             |
| <b>Descrição do Produto:</b><br><i>Product description:</i>               | Remexían 30/1 SCK   | <b>Potência:</b><br><i>Strength:</i>                | THC 30%<br>CBD < 1%                            |
| <b>Forma Farmacêutica:</b><br><i>Pharmaceutical Form:</i>                 | Dry flower  | <b>Acondicionamento:</b><br><i>Packaging:</i>       | 250 g bags                                     |
| <b>Número do Lote:</b><br><i>Batch Number:</i>                            | M241980043NSC   | <b>Data Validade:</b><br><i>Expiry Date:</i>        | 03/2025  |
| <b>Data de Receção de Amostra:</b><br><i>Sample reception date:</i>       | 07/08/2024  | <b>Data de Análise:</b><br><i>Date of Analysis:</i> | 12/08/2024 até<br>till 30/09/2024              |
| <b>Tipo de Análise:</b><br><i>Type of analysis:</i>                       | Batch Release   | <b>Código TQA:</b><br><i>TQA Code:</i>              | TQA-REX-001                                    |
| <b>Cliente:</b><br><i>Client:</i>   | Remexían  | <b>Morada do Cliente:</b><br><i>Client Address:</i> | Märkersteig 27, 14974<br>Ludwigsfelde, Germany |
| <b>Morada do Controlo de Qualidade:</b><br><i>Quality Control adress:</i> | Avenida Ville La Baule, n. ° 58.<br>8900-227 Vila Real de Santo António, Portugal |   |  |

| TESTES<br><i>TESTS</i>                  | MÉTODOS<br><i>METHODS</i>                | ESPECIFICAÇÕES<br><i>SPECIFICATIONS</i> | RESULTADOS<br><i>RESULTS</i>     |
|---|--|---|----------------------------------|
| <b>Microbiological control</b>          | Ph. Eur. 11.5<br>[2.6.12;2.6.13;5.1.8.C] |   |                                  |
| Total viable aerobic count<br>(TAMC)    |  | < 10 <sup>5</sup> CFU/g                 | 4.0 × 10 <sup>3</sup> CFU/g      |
| Total viable aerobic count<br>(TYMC)    |  | < 10 <sup>4</sup> CFU/g                 | 4.0 × 10 <sup>3</sup> CFU/g      |
| Bile-tolerant Gram-negative<br>bacteria |  | < 10 <sup>4</sup> CFU/g                 | > 10 and < 10 <sup>2</sup> CFU/g |
| <i>E. coli</i>                          |  | Absent/g                                | Absent/g                         |
| <i>Salmonella</i>                       |  | Absent/25g                              | Absent/25g                       |

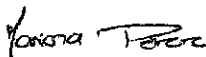
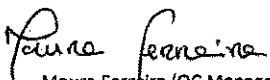
\*Subcontracted test

## COMENTÁRIOS E CONCLUSÕES:

### COMMENTS AND CONCLUSIONS:

The analyses marked <sup>(a)</sup> were carried out on the raw material from batch CPL232860198 and those marked <sup>(b)</sup> were carried out on the API from batch M241980043.

The results are according to the specifications.

|  |                     |
|--|---------------------|
| <br>Marlana Pereira (QC Technician) | 30/10/2024          |
| Preparado por<br><i>Prepared by</i>  | Data<br><i>Date</i> |
| <br>Maura Ferreira (QC Manager)     | 30/10/2024          |
| Aprovado por<br><i>Approved by</i>   | Data<br><i>Date</i> |