

## Certificado de Lote

### Batch Certificate

<b>Nome do produto</b> <i>Name of product</i>	REMEXIAN 27/1 T8C
<b>País de destino</b> <i>Destination country</i>	Alemanha Germany
<b>Nº de autorização de AIM</b> <i>Marketing authorisation number</i>	NA
<b>Concentração da substância ativa</b> <i>Strength/potency</i>	27 ± 10% [24.3%-29.7%]
<b>Forma farmacêutica</b> <i>Dosage form</i>	Flor Seca Dry Flower
<b>Quantidade embalada e tipo de embalagem</b> <i>Package size and type</i>	113 sacos de 250g 113 250g bags
<b>Nº de Lote do produto acabado</b> <i>Batch Number of the finished product</i>	M243510119NSC
<b>Data de fabrico</b> <i>Date of manufacture</i>	03/2025
<b>Prazo de Validade</b> <i>Expiry Date</i>	09/2025

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> <i>Analysis Results</i>	Macroscopy 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" Ph. Eur. 11.6 [2.8.23]	Complies with the monograph description	Complies
HPTLC Identification (Identity test, Method C)		Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.25]	Complies with the monograph description	Complies
Foreign Matter		Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.2]	≤2% (w/w)	0% (w/w)
Loss on Drying		Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.32]	≤12%	7%
Assay		Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]		
THC	Informative		1.0%	
THCA <sup>(1)</sup>	Informative		25.2%	
CBD	Informative		< 0.05% (LOQ)	
CBDa <sup>(2)</sup>	Informative		0.06 %	
Total THC	According to label ± 10% (as is)		26.1% (as is)	
Total CBD	≤1.0% (as is)		0.06 % (as is)	

Related Substances Total CBN+CBNA	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]	≤1.0% (as is)	0.1% (as is)
Aflatoxins	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.18]	≤ 2 µg/Kg Aflatoxin B1 ≤ 4 µg/Kg Aflatoxin B1,B2,G1,G2	< 0.25 µg/Kg (LOD) < 0.25 µg/Kg (LOD)
Ochratoxin A	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.22]	≤ 20 µg/Kg	< 2 µg/Kg (LOD)
Pesticides	Ph. Eur. 11.6 [2.8.13]	Not more than the limits specified in Ph. Eur. 2.8.13	Complies
Heavy Metals			
Cd	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.4.27]	Cd ≤ 0.3 ppm	0.007 ppm)
Pb		Pb ≤ 0.5 ppm	< 0.020 ppm (LOQ)
Hg		Hg ≤ 0.1 ppm	< 0.050 ppm (LOQ)
As		As ≤ 0.2 ppm	< 0.020 ppm (LOQ)
<b>Microbiological Control</b>	Ph. Eur. 11.6 [2.6.12;2.6.13;5.1.4;5.1.8.C]		
Total aerobic microbial count (TAMC)		< 5 x 10 <sup>5</sup> CFU/g	< 100 CFU/g
Total yeast and mold count (TYMC)		<5 x 10 <sup>4</sup> CFU/g	< 100 CFU/g
Test for bile-tolerant Gram-negative bacteria		<10 <sup>4</sup> CFU/g	< 10 CFU/g
Test for <i>E. coli</i>		Absent/g	Absent/g
Test for <i>Salmonella</i>		Absent/ 25g	Absent/25g
Test for <i>S. aureus</i>		Absent/g	Absent/g
Test for <i>P. aeruginosa</i>	Absent/g	Absent/g	

### Comentários

*Comments*

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

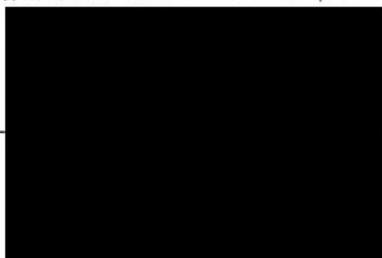
Fernando Águas/Qualified Person

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

24/03/2025

### 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.*



24/03/2025

Data *Date*

<b>Título</b> <i>Title</i>	<b>CERTIFICADO DE ANÁLISE</b> <b>CERTIFICATE OF ANALYSIS</b>		<b>Pag. 1 of 3</b>
<b>Código</b> <i>Code</i>	<b>FR.QC.023</b>	<b>Version</b>	<b>01</b>

<b>Número CoA:</b> <i>CoA number:</i>	SQC-FB25/00236	<b>Local:</b> <i>Local:</i>	Manufacturing Site
<b>Produto:</b> <i>Product:</i>	<i>Cannabis sativa L.</i>	<b>Variedade:</b> <i>Variety:</i>	Ice Cream Cake
<b>Descrição do Produto:</b> <i>Product description:</i>	Remexian 27/1 T8C	<b>Potência:</b> <i>Strength:</i>	THC 27 % CBD < 1%
<b>Forma Farmacêutica:</b> <i>Pharmaceutical Form:</i>	Dry flower	<b>Acondicionamento:</b> <i>Packaging:</i>	250 g bags
<b>Número do Lote:</b> <i>Batch Number:</i>	M243510119NSC	<b>Data Validade:</b> <i>Expiry Date:</i>	09/2025
<b>Data de Receção de Amostra:</b> <i>Sample reception date:</i>	19/12/2024	<b>Data de Análise:</b> <i>Date of Analysis:</i>	26/12/2024 até till 20/03/2025
<b>Tipo de Análise:</b> <i>Type of analysis:</i>	Batch Release	<b>Código TQA:</b> <i>TQA Code:</i>	TQA-REX-001
<b>Cliente:</b> <i>Client:</i>	REMEXIAN PHARMA GMBH	<b>Morada do Cliente:</b> <i>Client Address:</i>	Märkersteig 27, 14974 Ludwigsfelde, Germany
<b>Morada do Controlo de Qualidade:</b> <i>Quality Control adress:</i>	Avenida Ville La Baule, n. ° 58. 8900-227 Vila Real de Santo António. Portugal		

TESTES <i>TESTS</i>	MÉTODOS <i>METHODS</i>	ESPECIFICAÇÕES <i>SPECIFICATIONS</i>	RESULTADOS <i>RESULTS</i>
<b>Macroscopy observation</b> (Identity Test, Method A) <sup>(a)</sup>	Monograph Ph. Eur. "Cannabis Flower"	Complies with the monograph description	Complies
<b>Microscopy observation</b> (Identity Test, Method B) <sup>(a)</sup>	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.23]	Complies with the monograph description	Complies
<b>HPTLC Identification</b> (Identity Test, Method C) <sup>(a) *</sup>	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.25]	Complies with the monograph description	Complies
<b>Foreign Matter</b> <sup>(b) *</sup>	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.2]	≤ 2 % (w/w)	0 % (w/w)
<b>Loss on drying</b> <sup>(b)*</sup>	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.32]	≤ 12 %	7 %
<b>Assay</b> <sup>(b)*</sup> THC	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]	Informative	1.0 %
THCA <sup>1</sup>		Informative	25.2 %
CBD		Informative	< 0.05 % (LOQ)
CBDA <sup>2</sup>		Informative	0.06 %
Total THC+THCA <sup>1</sup>		According to label ±10% (as is)	26.1% (as is)
Total CBD+CBDA <sup>2</sup>		≤1 % (as is)	0.06 % (as is)
<b>Related substances</b> <sup>(b)*</sup> Total CBN		≤1 % (as is)	0.1 % (as is)
<b>Aflatoxins</b> * <sup>(b)</sup>	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.18]	≤ 2 µg/Kg Aflatoxin B1 ≤ 4 µg/Kg Aflatoxin B1, B2, G1, G2	< 0.25 µg/Kg (LOD) < 0.25 µg/Kg (LOD)
<b>Ochratoxin A</b> * <sup>(b)</sup>	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.22]	≤ 20 µg/Kg	< 2 µg/Kg (LOD)

<sup>1</sup> Expressed in THC

<sup>2</sup> Expressed in CBD

<b>Título</b> <i>Title</i>	<b>CERTIFICADO DE ANÁLISE</b> <b>CERTIFICATE OF ANALYSIS</b>		<b>Pag. 2 of 3</b>
<b>Código</b> <i>Code</i>	<b>FR.QC.023</b>	<b>Version</b>	<b>01</b>

<b>Número CoA:</b> <i>CoA number:</i>	SQC-FB25/00236	<b>Local:</b> <i>Local:</i>	Manufacturing Site
<b>Produto:</b> <i>Product:</i>	<i>Cannabis sativa L.</i>	<b>Variedade:</b> <i>Variety:</i>	Ice Cream Cake
<b>Descrição do Produto:</b> <i>Product description:</i>	Remexian 27/1 T8C	<b>Potência:</b> <i>Strength:</i>	THC 27 % CBD < 1%
<b>Forma Farmacêutica:</b> <i>Pharmaceutical Form:</i>	Dry flower	<b>Acondicionamento:</b> <i>Packaging:</i>	250 g bags
<b>Número do Lote:</b> <i>Batch Number:</i>	M243510119NSC	<b>Data Validade:</b> <i>Expiry Date:</i>	09/2025
<b>Data de Receção de Amostra:</b> <i>Sample reception date:</i>	19/12/2024	<b>Data de Análise:</b> <i>Date of Analysis:</i>	26/12/2024 até 20/03/2025 <i>till</i>
<b>Tipo de Análise:</b> <i>Type of analysis:</i>	Batch Release	<b>Código TQA:</b> <i>TQA Code:</i>	TQA-REX-001
<b>Cliente:</b> <i>Client:</i>	REMEXIAN PHARMA GMBH	<b>Morada do Cliente:</b> <i>Client Address:</i>	Märkersteig 27, 14974 Ludwigsfelde, Germany
<b>Morada do Controlo de Qualidade:</b> <i>Quality Control adress:</i>	Avenida Ville La Baule, n. ° 58. 8900-227 Vila Real de Santo António. Portugal		

TESTES <i>TESTS</i>	MÉTODOS <i>METHODS</i>	ESPECIFICAÇÕES <i>SPECIFICATIONS</i>	RESULTADOS <i>RESULTS</i>
<b>Pesticides*<sup>(b)</sup></b>	Ph. Eur. 11.6 [2.8.13]	Not more than the limits specified in Ph. Eur. 2.8.13	Complies
<b>Heavy Metals*<sup>(b)</sup></b>	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.4.27]	Cd ≤ 0.3 ppm	0.007 ppm
<i>Cd</i>		Pb ≤ 0.5 ppm	< 0.020 ppm (LOQ)
<i>Pb</i>		Hg ≤ 0.1 ppm	< 0.050 ppm (LOQ)
<i>Hg</i>		As ≤ 0.2 ppm	< 0.020 ppm (LOQ)
<i>As</i>			
<b>Microbiological control</b>	Ph. Eur.11.6 [2.6.12;2.6.13;5.1.4;5.1.8.C]	Total viable aerobic count (TAMC)	≤ 5 x 10 <sup>5</sup> CFU/g < 100 CFU/g
Total viable aerobic count (TYMC)		≤ 5 x 10 <sup>4</sup> CFU/g < 100 CFU/g	
Bile-tolerant Gram-negative bacteria		≤ 10 <sup>4</sup> CFU/g < 10 CFU/g	
<i>E. coli</i>		Absent/g Absent/g	
<i>Salmonella</i>		Absent/25g Absent/25g	
<i>S. aureus</i>		Absent/g Absent/g	
<i>P. aeruginosa</i>		Absent/g Absent/g	

\*Subcontracted test

## COMENTÁRIOS E CONCLUSÕES:

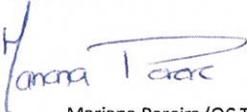
### COMMENTS AND CONCLUSIONS:

The analyses marked <sup>(b)</sup> were carried out on the raw material from batch 241018 and those marked <sup>(b)</sup> were carried out on the API from batch M243510119.

The results are according to the specifications.

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<b>Código</b> <i>Code</i>	<b>FR.QC.023</b>	<b>Version</b>	<b>01</b>

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<b>Forma Farmacêutica:</b> <i>Pharmaceutical Form:</i>	Dry flower	<b>Acondicionamento:</b> <i>Packaging:</i>	250 g bags
<b>Número do Lote:</b> <i>Batch Number:</i>	M243510119NSC	<b>Data Validade:</b> <i>Expiry Date:</i>	09/2025
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<b>Cliente:</b> <i>Client:</i>	REMEXIAN PHARMA GMBH	<b>Morada do Cliente:</b> <i>Client Address:</i>	Märkersteig 27, 14974 Ludwigsfelde, Germany
<b>Morada do Controlo de Qualidade:</b> <i>Quality Control adress:</i>	Avenida Ville La Baule, n.º 58. 8900-227 Vila Real de Santo António, Portugal		

 Mariana Pereira (QC Technician)	24/03/2025
Preparado por <i>Prepared by</i>	Data <i>Date</i>
 Maura Ferreira (QC Manager)	24/03/2025
Aprovado por <i>Approved by</i>	Data <i>Date</i>

