

<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>

Número CoA: <i>CoA number:</i>	SQC-FB25/00186	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa L.</i>	Variedade: <i>Variety:</i>	Facade
Descrição do Produto: <i>Product description:</i>	Remexian 27/1 QUI	Potência: <i>Strength:</i>	THC 27 % CBD < 1%
Forma Farmacêutica: <i>Pharmaceutical Form:</i>	Dry flower	Acondicionamento: <i>Packaging:</i>	250 g bags
Número do Lote: <i>Batch Number:</i>	M243480112NSC	Data Validade: <i>Expiry Date:</i>	08/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	16/12/2024	Data de Análise: <i>Date of Analysis:</i>	26/12/2024 até <i>till</i> 05/03/2025
Tipo de Análise: <i>Type of analysis:</i>	Batch Release	Código TQA: <i>TQA Code:</i>	TQA-REX-001
Cliente: <i>Client:</i>	REMEXIAN PHARMA GMBH	Morada do Cliente: <i>Client Address:</i>	Märkersteig 27, 14974 Ludwigsfelde, Germany
Morada do Controlo de Qualidade: <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>
Macroscopy observation (Identity Test, Method A) <sup>(a)</sup>	Monograph Ph. Eur. "Cannabis Flower"	Complies with the monograph description	Complies
Microscopy observation (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
HPTLC Identification (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
Foreign Matter <sup>(b) *</sup>	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.2]	≤ 2 % (w/w)	0 % (w/w)
Loss on drying <sup>(b)*</sup>	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.32]	≤ 12 %	9 %
Assay <sup>(b)*</sup> THC	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]	Informative	2.0 %
THCA <sup>1</sup>		Informative	24.9 %
CBD		Informative	< 0.05 % (LOQ)
CBDA <sup>2</sup>		Informative	0.06 %
Total THC+THCA <sup>1</sup>		According to label ±10% (as is)	26.9 % (as is)
Total CBD+CBDA <sup>2</sup>		≤1 % (as is)	0.06 % (as is)
Related substances <sup>(b)*</sup> Total CBN		≤1 % (as is)	0.1 % (as is)
Aflatoxins * <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) < 0.5 µg/Kg (LOQ)
Ochratoxin A * <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

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

Número CoA: CoA number:	SQC-FB25/00186	Local: Local:	Manufacturing Site
Produto: Product:	Cannabis sativa L.	Variedade: Variety:	Facade
Descrição do Produto: Product description:	Remexian 27/1 QUI	Potência: Strength:	THC 27 % CBD < 1%
Forma Farmacêutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	250 g bags
Número do Lote: Batch Number:	M243480112NSC	Data Validade: Expiry Date:	08/2025
Data de Receção de Amostra: Sample reception date:	16/12/2024	Data de Análise: Date of Analysis:	26/12/2024 até till 05/03/2025
Tipo de Análise: Type of analysis:	Batch Release	Código TQA: TQA Code:	TQA-REX-001
Cliente: Client:	REMEXIAN PHARMA GMBH	Morada do Cliente: Client Address:	Märkersteig 27, 14974 Ludwigsfelde, Germany
Morada do Controlo de Qualidade: Quality Control adress:	Avenida Ville La Baule, n. ° 58. 8900-227 Vila Real de Santo António. Portugal		

TESTES TESTS	MÉTODOS METHODS	ESPECIFICAÇÕES SPECIFICATIONS	RESULTADOS RESULTS
Pesticidas* <sup>(b)</sup>	Ph. Eur. 11.6 [2.8.13]	Not more than the limits specified in Ph. Eur. 2.8.13	Complies
Heavy Metals* <sup>(b)</sup>	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.4.27]	Cd ≤ 0.3 ppm	< 0.005 ppm (LOQ)
Cd		Pb ≤ 0.5 ppm	< 0.020 ppm (LOQ)
Pb		Hg ≤ 0.1 ppm	< 0.050 ppm (LOQ)
Hg		As ≤ 0.2 ppm	< 0.020 ppm (LOQ)
As	Ph. Eur.11.6 [2.6.12;2.6.13;5.1.4;5.1.8.C]	Microbiological control	
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
E. coli		Absent/g	Absent/g
Salmonella		Absent/25g	Absent/25g
S. aureus		Absent/g	Absent/g
P. aeruginosa	Absent/g	Absent/g	

\*Subcontracted test

#### COMENTÁRIOS E CONCLUSÕES:



#### COMMENTS AND CONCLUSIONS:

The analyses marked <sup>(a)</sup> were carried out on the raw material from batch 240816 and those marked <sup>(b)</sup> were carried out on the API from batch M243480112.

The results are according to the specifications.

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Código Code	FR.QC.023	Version	01

Número CoA: CoA number:	SQC-FB25/00186	Local: Local:	Manufacturing Site
Produto: Product:	Cannabis sativa L.	Variedade: Variety:	Facade
Descrição do Produto: Product description:	Remexian 27/1 QUI	Potência: Strength:	THC 27 % CBD < 1%
Forma Farmacêutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	250 g bags
Número do Lote: Batch Number:	M243480112NSC	Data Validade: Expiry Date:	08/2025
Data de Receção de Amostra: Sample reception date:	16/12/2024	Data de Análise: Date of Analysis:	26/12/2024 até till 05/03/2025
Tipo de Análise: Type of analysis:	Batch Release	Código TQA: TQA Code:	TQA-REX-001
Cliente: Client:	REMEXIAN PHARMA GMBH	Morada do Cliente: Client Address:	Märkersteig 27, 14974 Ludwigsfelde, Germany
Morada do Controlo de Qualidade: Quality Control adress:	Avenida Ville La Baule, n. ° 58. 8900-227 Vila Real de Santo António, Portugal		

 Mariana Pereira (QC Technician)	31/03/2025
Preparado por	Data Date
 Maura Ferreira (QC Manager)	31/03/2025
Aprovado por Approved by	Data Date

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) < 0.5 µg/Kg (LOQ)
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			
<i>Cd</i>	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.4.27]	<i>Cd</i> ≤ 0.3 ppm	< 0.005 ppm (LOQ)
<i>Pb</i>		<i>Pb</i> ≤ 0.5 ppm	< 0.020 ppm (LOQ)
<i>Hg</i>		<i>Hg</i> ≤ 0.1 ppm	< 0.050 ppm (LOQ)
<i>As</i>		<i>As</i> ≤ 0.2 ppm	< 0.020 ppm (LOQ)
<b>Microbiological Control</b>			
Total aerobic microbial count (TAMC)	Ph. Eur. 11.6 [2.6.12;2.6.13;5.1.4;5.1.8.C]	< 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*

31/03/2025

## 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.*



Qualified Person *QP*

31/03/2025

Data *Date*

## Certificado de Lote

### Batch Certificate

<b>Nome do produto</b> <i>Name of product</i>	REMEXIAN 27/1 QUI
<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>	100 sacos de 250g 100 250g bags
<b>Nº de Lote do produto acabado</b> <i>Batch Number of the finished product</i>	M243480112NSC
<b>Data de fabrico</b> <i>Date of manufacture</i>	02/2025
<b>Prazo de Validade</b> <i>Expiry Date</i>	08/2025

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%	9%
<b>Assay</b>				
	THC	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]	Informative	2.0%
	THCA <sup>(1)</sup>		Informative	24.9%
	CBD		Informative	< 0.05% (LOQ)
	CBDA <sup>(2)</sup>		Informative	0.06%
	Total THC		According to label ± 10% (as is)	26.9% (as is)
	Total CBD		≤1.0% (as is)	0.06% (as is)