

Certificado de Lote

Batch Certificate

Nome do produto <i>Name of product</i>	REMEXIAN 24/1 TEN
País de destino <i>Destination country</i>	Alemanha Germany
Nº de autorização de AIM <i>Marketing authorisation number</i>	NA
Concentração da substância ativa <i>Strength/potency</i>	24 ± 10% [21.6%-26.4%]
Forma farmacêutica <i>Dosage form</i>	Flor Seca Dry Flower
Quantidade embalada e tipo de embalagem <i>Package size and type</i>	144 sacos de 250g 144 250g bags
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	M243450102NSC
Data de fabrico <i>Date of manufacture</i>	02/2025
Prazo de Validade <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

Resultados da Análise <i>Analysis Results</i>	Tests	Methods Specification	Specification	Results
	Macroscopy observation (Identity test, Method A)	Monograph Ph. Eur. "Cannabis Flower"	Complies with the monograph description	Complies
	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%	8%
	Assay	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]		
	THC		Informative	4.8%
	THCA ⁽¹⁾		Informative	18.85%
	CBD		Informative	< 0.05% (LOQ)
	CBDA ⁽²⁾		Informative	0.05 %
	Total THC		According to label ± 10% (as is)	23.7% (as is)
	Total CBD		≤1.0% (as is)	0.05 % (as is)

Related Substances Total CBN+CBNA	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]	≤1.0% (as is)	0.3% (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	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.4.27]		
Cd		Cd ≤ 0.3 ppm	0.008 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)
Microbiological Control	Ph. Eur. 11.6 [2.6.12;2.6.13;5.1.4;5.1.8.C]		
Total aerobic microbial count (TAMC)		< 5 × 10 ⁵ CFU/g	< 100 CFU/g
Total yeast and mold count (TYMC)		< 5 × 10 ⁴ CFU/g	< 100 CFU/g
Test for bile-tolerant Gram-negative bacteria		<10 ⁴ 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

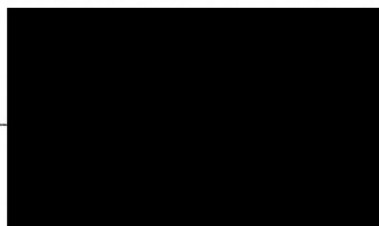
Data de Libertação do Produto
Product Release Date

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

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

Número CoA:	SQC-FB25/00191	Local:	Manufacturing Site
CoA number:		Local:	
Produto:	Cannabis sativa L.	Variedade:	Banjo
Product:		Variety:	
Descrição do Produto:	Remexian 24/1 TEN	Potência:	THC 24 %
Product description:		Strength:	CBD < 1%
Forma Farmacêutica:	Dry flower	Acondicionamento:	250 g bags
Pharmaceutical Form:		Packaging:	
Número do Lote:	M243450102NSC	Data Validade:	08/2025
Batch Number:		Expiry Date:	
Data de Receção de Amostra:	19/12/2024	Data de Análise:	26/12/2024 até 20/03/2025
Sample reception date:		Date of Analysis:	
Tipo de Análise:	Batch Release	Código TQA:	TQA-REX-001
Type of analysis:		TQA Code:	
Cliente:	REMEXIAN PHARMA	Morada do Cliente:	Märkersteig 27, 14974
Client:	GMBH	Client Address:	Ludwigsfelde, Germany
Morada do Controlo de Qualidade:	Avenida Ville La Baule, n.º 58.		
Quality Control address:	8900-227 Vila Real de Santo António. Portugal		

TESTES TESTS	MÉTODOS METHODS	ESPECIFICAÇÕES SPECIFICATIONS	RESULTADOS RESULTS
Macroscopy observation (Identity Test, Method A) ^(a)	Monograph Ph. Eur. "Cannabis Flower"	Complies with the monograph description	Complies
Microscopy observation (Identity Test, Method B) ^(a)	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.23]	Complies with the monograph description	Complies
HPTLC Identification (Identity Test, Method C) ^{(a) *}	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.25]	Complies with the monograph description	Complies
Foreign Matter ^{(b) *}	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.2]	≤ 2 % (w/w)	0 % (w/w)
Loss on drying ^{(b)*}	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.32]	≤ 12 %	8 %
Assay ^{(b)*} THC	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]	Informative	4.8 %
THCA ¹		Informative	18.85 %
CBD		Informative	< 0.05 % (LOQ)
CBDA ²		Informative	0.05 %
Total THC+THCA ¹		According to label ±10% (as is)	23.7 % (as is)
Total CBD+CBDA ²		≤ 1 % (as is)	0.05 % (as is)
Related substances ^{(b)*} Total CBN		≤ 1 % (as is)	0.3 % (as is)
Aflatoxins * ^(b)	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 * ^(b)	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.22]	≤ 20 µg/Kg	< 2 µg/Kg (LOD)

¹ Expressed in THC² Expressed in CBD

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

Número CoA: <i>CoA number:</i>	SQC-FB25/00191	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa L.</i>	Variedade: <i>Variety:</i>	Banjo
Descrição do Produto: <i>Product description:</i>	Remexian 24/1 TEN	Potência: <i>Strength:</i>	THC 24 % CBD < 1%
Forma Farmacêutica: <i>Pharmaceutical Form:</i>	Dry flower	Acondicionamento: <i>Packaging:</i>	250 g bags
Número do Lote: <i>Batch Number:</i>	M243450102NSC	Data Validade: <i>Expiry Date:</i>	08/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	19/12/2024	Data de Análise: <i>Date of Analysis:</i>	26/12/2024 até 20/03/2025 <i>till</i>
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.º 58. 8900-227 Vila Real de Santo António, Portugal		

TESTES TESTS	MÉTODOS METHODS	ESPECIFICAÇÕES SPECIFICATIONS	RESULTADOS RESULTS
Pesticides* (b)	Ph. Eur. 11.6 [2.8.13]	Not more than the limits specified in Ph. Eur. 2.8.13	Complies
Heavy Metals*(b)	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.4.27]	Cd ≤ 0.3 ppm	0.008 ppm
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 ⁵ CFU/g	< 100 CFU/g
Total viable aerobic count (TYMC)		≤ 5 x 10 ⁴ CFU/g	< 100 CFU/g
Bile-tolerant Gram-negative bacteria		≤ 10 ⁴ 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

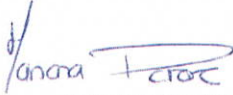
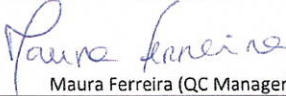
COMENTÁRIOS E CONCLUSÕES:

COMMENTS AND CONCLUSIONS:

The analyses marked ^(a) were carried out on the raw material from batch 240806 and those marked ^(b) were carried out on the API from batch M243450102.

The results are according to the specifications.

Título Title		CERTIFICADO DE ANÁLISE CERTIFICATE OF ANALYSIS		Pag. 3 of 3	
Código Code		FR.QC.023		Version 01	
Número CoA: CoA number:		SQC-FB25/00191		Local: Manufacturing Site	
Produto: Product:		Cannabis sativa L.		Variedade: Variety:	
Descrição do Produto: Product description:		Remexian 24/1 TEN		Potência: Strength:	
Forma Farmacêutica: Pharmaceutical Form:		Dry flower		Acondicionamento: Packaging:	
Número do Lote: Batch Number:		M243450102NSC		Data Validade: Expiry Date:	
Data de Receção de Amostra: Sample reception date:		19/12/2024		Data de Analise: Date of Analysis:	
Tipo de Analise: Type of analysis:		Batch Release		Código TQA: TQA Code:	
Cliente: Client:		REMEXIAN PHARMA GMBH		Morada do Cliente: Client Address:	
Morada do Controlo de Qualidade: Quality Control adress:		Avenida Ville La Baule, n. ° 58. 8900-227 Vila Real de Santo António. Portugal		Märkersteig 27, 14974 Ludwigsfelde, Germany	

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

