

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

Número CoA: CoA number:	SQC-FB25/00243	Local: Local:	Manufacturing Site
Produto: Product:	Cannabis sativa L.	Variedade: Variety:	Future Island
Descrição do Produto: Product description:	Remexian 24/1 CBM	Potência: Strength:	THC 24 % CBD < 1%
Forma Farmacêutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	250 g bags
Número do Lote: Batch Number:	M243480114NSC	Data Validade: Expiry Date:	09/2025
Data de Receção de Amostra: Sample reception date:	16/12/2024	Data de Análise: Date of Analysis:	26/12/2024 até till 19/03/2025
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
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 %	6 %
Assay ^(b) THC	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]	Informative	0.6 %
THCA ¹		Informative	23.4 %
CBD		Informative	< 0.2 % (LOQ)
CBDA ²		Informative	< 0.2 % (LOQ)
Total THC+THCA ¹		According to label ±10% (dried basis)	24.0 % (dried basis)
Total CBD+CBDA ²		≤1 % (dried basis)	< 0.2 % (LOQ) (dried basis)
Related substances ^(b) Total CBN		≤1 % (dried basis)	0.1 % (dried basis)
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 THC

² 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-FB25/00243	Local: Local:	Manufacturing Site		
Produto: Product:	Cannabis sativa L.	Variedade: Variety:	Future Island		
Descrição do Produto: Product description:	Remexian 24/1 CBM	Potência: Strength:	THC 24 % CBD < 1%		
Forma Farmacêutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	250 g bags		
Número do Lote: Batch Number:	M243480114NSC	Data Validade: Expiry Date:	09/2025		
Data de Receção de Amostra: Sample reception date:	16/12/2024	Data de Análise: Date of Analysis:	26/12/2024	até till	19/03/2025
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
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	0.069 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			
Microbiological control	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 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
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 ^(a) were carried out on the raw material from batch 240925 and those marked ^(b) were carried out on the API from batch M243480114.

The results are according to the specifications.

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Código Code		FR.QC.023		Version 01	
Número CoA: CoA number:		SQC-FB25/00243		Local: Local:	
Produto: Product:		Cannabis sativa L.		Varietade: Variety:	
Descrição do Produto: Product description:		Remexian 24/1 CBM		Potência: Strength:	
Forma Farmacêutica: Pharmaceutical Form:		Dry flower		Acondicionamento: Packaging:	
Número do Lote: Batch Number:		M243480114NSC		Data Validade: Expiry Date:	
Data de Receção de Amostra: Sample reception date:		16/12/2024		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.º 58. 8900-227 Vila Real de Santo António, Portugal		Märkersteig 27, 14974 Ludwigsfelde, Germany	

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

Certificado de Lote

Batch Certificate

Nome do produto Name of product	REMEXIAN 24/1 CBM
País de destino Destination country	Alemanha Germany
Nº de autorização de AIM Marketing authorisation number	NA
Concentração da substância ativa Strength/potency	24 ± 10% [21.6%-26.4%]
Forma farmacêutica Dosage form	Flor Seca Dry Flower
Quantidade embalada e tipo de embalagem Package size and type	112 sacos de 250g 112 250g bags
Nº de Lote do produto acabado Batch Number of the finished product	M243480114NSC
Data de fabrico Date of manufacture	03/2025
Prazo de Validade Expiry Date	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

Resultados da Análise Analysis Results	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%	6%
	Assay	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]		
	THC		Informative	0.6%
	THCA ⁽¹⁾		Informative	23.4%
	CBD		Informative	< 0.2% (LOQ)
	CBDA ⁽²⁾		Informative	< 0.2% (LOQ)
	Total THC		According to label ± 10% (dried basis)	24.0% (dried basis)
	Total CBD		≤1.0% (dried basis)	< 0.2% (LOQ) (dried basis)

Related Substances Total CBN+CBNA	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]	≤1.0% (dried basis)	0.1% (dried basis)
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	0.069 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 x 10 ⁵ CFU/g	< 100 CFU/g
Total yeast and mold count (TYMC)		< 5 x 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

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.*

[Redacted Signature]

Qualified Person *QP*

31/03/2025

Date