

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

Número CoA: <i>CoA number:</i>	SQC-FB25/000283	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa L.</i>	Variedade: <i>Variety:</i>	Think Fast
Descrição do Produto: <i>Product description:</i>	Remexian 30/1 PRT	Potência: <i>Strength:</i>	THC 30 % CBD < 1%
Forma Farmacêutica: <i>Pharmaceutical Form:</i>	Dry flower	Acondicionamento: <i>Packaging:</i>	10 g bags
Número do Lote: <i>Batch Number:</i>	M243520122NSA	Data Validade: <i>Expiry Date:</i>	08/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	20/12/2024	Data de Análise: <i>Date of Analysis:</i>	23/12/2024 até till 06/03/2025
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) ^(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	1.2 %
THCA ¹		Informative	29.3 %
CBD		Informative	< 0.2 % (LOQ)
CBDA ²		Informative	< 0.2 % (LOQ)
Total THC+THCA ¹		According to label ±10% (dried basis)	30.5 % (dried basis)
Total CBD+CBDA ²		≤ 1 % (dried basis)	< 0.2 % (LOQ) (dried basis)
Related substances ^(b) Total CBN		≤ 1 % (dried basis)	0.2 % (dried basis)

¹ Expressed in THC

² Expressed in CBD

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

Número CoA: CoA number:	SQC-FB25/000283	Local: Local:	Manufacturing Site
Produto: Product:	Cannabis sativa L.	Varietade: Variety:	Think Fast
Descrição do Produto: Product description:	Remexian 30/1 PRT	Potência: Strength:	THC 30 % CBD < 1%
Forma Farmacêutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	10 g bags
Número do Lote: Batch Number:	M243520122NSA	Data Validade: Expiry Date:	08/2025
Data de Receção de Amostra: Sample reception date:	20/12/2024	Data de Análise: Date of Analysis:	23/12/2024 até till 06/03/2025
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
Microbiological control	Ph. Eur.11.6 [2.6.12;2.6.13;5.1.4;5.1.8.C]		
Total viable aerobic count (TAMC)		$\leq 5 \times 10^5$ CFU/g	4.4×10^3 CFU/g
Total viable aerobic count (TYMC)		$\leq 5 \times 10^4$ CFU/g	5.8×10^3 CFU/g
Bile-tolerant Gram-negative bacteria		$\leq 10^4$ CFU/g	$> 10^2$ and $< 10^3$ 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 CPL241010014 and those marked ^(b) were carried out on the API from batch M243520122.

The tests for pesticides, heavy metals, aflatoxins, and ochratoxin are not included in the analyses performed due to being supported by a risk assessment, which can be requested whenever necessary.

The results are according to the specifications.

	12/03/2025
	Data Date
	12/03/2025
	Data Date

Certificado de Lote

Batch Certificate

Nome do produto <i>Name of product</i>	REMEXIAN 30/1 PRT
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>	30 ± 10% [27%-33%]
Forma farmacêutica <i>Dosage form</i>	Flor Seca Dry Flower
Quantidade embalada e tipo de embalagem <i>Package size and type</i>	1000 sacos de 10g 1000 10g bags
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	M243520122NSA
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

	Tests	Methods Specification	Specification	Results
	Resultados da Análise <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%	6%
Assay		Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]		
THC	Informative		1.2%	
THCA ⁽¹⁾	Informative		29.3%	
CBD	Informative		< 0.2 % (LOQ)	
CBDA ⁽²⁾	Informative		< 0.2 % (LOQ)	
Total THC	According to label ± 10% (dried basis)		30.5% (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)	0.2% (dried basis)
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	4.4 x 10 ⁵ CFU/g
Total yeast and mold count (TYMC)		<5 x 10 ⁴ CFU/g	5.8 x 10 ³ CFU/g
Test for bile-tolerant Gram-negative bacteria		<10 ⁴ CFU/g	> 10 ² and < 10 ³ 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

13/03/2025

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.*



13/03/2025

Data *Date*