

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

Número CoA: CoA number:	SQC-FB25/00540	Local: Local:	Manufacturing Site
Produto: Product:	Cannabis sativa L.	Variedade: Variety:	Booberry Cookies
Descrição do Produto: Product description:	Remexían 30/1 CIV	Potência: Strength:	THC 30% CBD < 1%
Forma Farmacêutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	250 g bags
Número do Lote: Batch Number:	M250500042NSC	Data Validade: Expiry Date:	09/2025
Data de Receção de Amostra: Sample reception date:	20/02/2025	Data de Análise: Date of Analysis:	26/02/2025 até till 10/04/2025
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 %	7 %
Assay ^(b) THC	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]	Informative	0.3 %
THCA ¹		Informative	28.9 %
CBD		Informative	< 0.2 % (LOQ)
CBDA ²		Informative	< 0.2 % (LOQ)
Total THC+THCA ¹		According to label ±10% (dried basis)	29.2 % (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 ^{*(a)}	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 ^{*(a)}	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-FB25/00540	Local: Local:	Manufacturing Site
Produto: Product:	Cannabis sativa L.	Variedade: Variety:	Booberry Cookies
Descrição do Produto: Product description:	Remexian 30/1 CIV	Potência: Strength:	THC 30% CBD < 1%
Forma Farmacêutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	250 g bags
Número do Lote: Batch Number:	M250500042NSC	Data Validade: Expiry Date:	09/2025
Data de Receção de Amostra: Sample reception date:	20/02/2025	Data de Análise: Date of Analysis:	26/02/2025 até till 10/04/2025
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* (a)	Ph. Eur. 11.6 [2.8.13]	Not more than the limits specified in Ph. Eur. 2.8.13	Complies
Heavy Metals* (a)	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 ⁵ CFU/g	1.5 x 10 ³ CFU/g
Total viable aerobic count (TYMC)		≤ 5 x 10 ⁴ CFU/g	1.0 x 10 ² 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 10289 and those marked (b) were carried out on the API from batch M250500042.

The results are according to the specifications.

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

Número CoA: <i>CoA number:</i>	SQC-FB25/00540	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa L.</i>	Variedade: <i>Variety:</i>	Booberry Cookies
Descrição do Produto: <i>Product description:</i>	Remexian 30/1 CIV	Potência: <i>Strength:</i>	THC 30% CBD < 1%
Forma Farmacêutica: <i>Pharmaceutical Form:</i>	Dry flower	Acondicionamento: <i>Packaging:</i>	250 g bags
Número do Lote: <i>Batch Number:</i>	M250500042NSC	Data Validade: <i>Expiry Date:</i>	09/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	20/02/2025	Data de Análise: <i>Date of Analysis:</i>	26/02/2025 até 10/04/2025 till
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		

	14/09/2025
	Data Date
	14/04/2025
	Data Date

Certificado de Lote

Batch Certificate

Nome do produto <i>Name of product</i>	Remexian 30/1 CIV
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>	122 sacos de 250g 122 250g bags
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	M250500042NSC
Data de fabrico <i>Date of manufacture</i>	03/2025
Prazo de Validade <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
Resultados da Análise <i>Analysis Results</i>	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%	7%
	Assay	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]		
	THC		Informative	0.3%
	THCA ⁽¹⁾		Informative	28.9%
	CBD		Informative	< 0.2 % (LOQ)
	CBDA ⁽²⁾		Informative	< 0.2 % (LOQ)
	Total THC		According to label ± 10% (dried basis)	29.2% (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			
<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)
Microbiological Control			
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 ⁵ CFU/g	1.5 x 10 ³ CFU/g
Total yeast and mold count (TYMC)		<5 x 10 ⁴ CFU/g	1.0 x 10 ² 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*

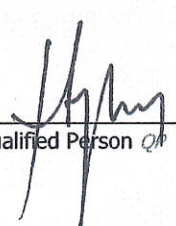
Fernando Águas/Qualified Person

Data de Libertação do Produto
Product Release Date

14/04/2025

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*

14/04/2025

Data *Date*