

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

Número CoA: <i>CoA number:</i>	SQC-FB25/00238	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa L.</i>	Variedade: <i>Variety:</i>	Frosted Cookies
Descrição do Produto: <i>Product description:</i>	Remexian 27/1 ADV	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>	M243510118NSC	Data Validade: <i>Expiry Date:</i>	09/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	18/12/2024	Data de Análise: <i>Date of Analysis:</i>	26/12/2024 até 19/03/2025 <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. ° 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 %	8 %
Assay ^{(b)*} THC	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]	Informative	2.7 %
THCA ¹		Informative	23.6 %
CBD		Informative	< 0.05 % (LOQ)
CBDA ²		Informative	0.06 %
Total THC+THCA ¹		According to label ±10% (as is)	26.3 % (as is)
Total CBD+CBDA ²		≤ 1 % (as is)	0.06 % (as is)
Related substances ^{(b)*} Total CBN		≤ 1 % (as is)	0.2 % (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) < 0.25 µg/Kg (LOD)
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

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Número CoA: <i>CoA number:</i>	SQC-FB25/00238	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa L.</i>	Variedade: <i>Variety:</i>	Frosted Cookies
Descrição do Produto: <i>Product description:</i>	Remexian 27/1 ADV	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>	M243510118NSC	Data Validade: <i>Expiry Date:</i>	09/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	18/12/2024	Data de Análise: <i>Date of Analysis:</i>	26/12/2024 até 19/03/2025 <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 address:</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>
Pesticidas*^(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	< 0.005 ppm (LOQ)
<i>Cd</i>		Pb ≤ 0.5 ppm	< 0.020 ppm (LOQ)
<i>Pb</i>		Hg ≤ 0.1 ppm	< 0.050 ppm (LOQ)
<i>Hg</i>		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 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:


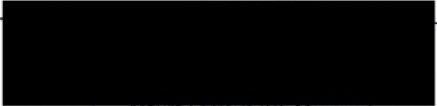
COMMENTS AND CONCLUSIONS:

The analyses marked ^(a) were carried out on the raw material from batch 240920 and those marked ^(b) were carried out on the API from batch M243510118.

The results are according to the specifications.

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Número CoA: <i>CoA number:</i>	SQC-FB25/00238	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa L.</i>	Variedade: <i>Variety:</i>	Frosted Cookies
Descrição do Produto: <i>Product description:</i>	Remexian 27/1 ADV	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>	M243510118NSC	Data Validade: <i>Expiry Date:</i>	09/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	18/12/2024	Data de Análise: <i>Date of Analysis:</i>	26/12/2024 até 19/03/2025 <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. ° 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

Certificado de Lote

Batch Certificate

Nome do produto <i>Name of product</i>	REMEXIAN 27/1 ADV
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>	27 ± 10% [24.3%-29.7%]
Forma farmacêutica <i>Dosage form</i>	Flor Seca Dry Flower
Quantidade embalada e tipo de embalagem <i>Package size and type</i>	111 sacos de 250g 111 250g bags
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	M243510118NSC
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
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	2.7%
	THCA ⁽¹⁾		Informative	23.6%
	CBD		Informative	< 0.05% (LOQ)
	CBDA ⁽²⁾		Informative	0.06%
	Total THC		According to label ± 10% (as is)	26.3% (as is)
	Total CBD		≤1.0% (as is)	0.06% (as is)

Related Substances Total CBN+CBNA	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]	≤1.0% (as is)	0.2% (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) < 0.25 µg/Kg (LOD)
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			
Cd	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.4.27]	Cd ≤ 0.3 ppm	< 0.005 ppm (LOQ)
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			
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	< 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.*

Qualified Person *QP*

31/03/2025

Data *Date*