

CANNPRISMA

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

Número CoA: CoA number:	SQC-FB24/00143	Local: Local:	Manufacturing Site
Produto: Product:	Cannabis sativa L.	Variedade: Variety:	Peanut Butter Breath
Descrição do Produto: Product description:	Remexian 27/1 PBB	Potência: Strength:	THC 27 % CBD < 1%
Forma Farmacêutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	Bags of 10 g
Número do Lote: Batch Number:	MF8241720024NSA	Data Validade: Expiry Date:	01/2025
Data de Receção de Amostra: Sample reception date:	01/07/2024	Data de Analise: Date of Analysis:	04/07/2024 até 20/08/2024 till
Tipo de Analise: Type of analysis:	Batch Release	Código TQA: TQA Code:	TQA-REX-001/02
Cliente: Client:	Remexian	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)*	Monograph Ph.Eur. "Cannabis Flower"	Complies with the monograph description	Complies
Microscopy observation (Identity Test, Method B)*	Monograph Ph.Eur. "Cannabis Flower" Ph.Eur.11.5 [2.8.23]	Complies with the monograph description	Complies
TLC Identification (Identity Test, Method C)*	Monograph Ph.Eur. "Cannabis Flower" Ph.Eur.11.5 [2.8.25]	Complies with the monograph description	Complies
Foreign Matter*	Monograph Ph.Eur. "Cannabis Flower" Ph.Eur.11.5 [2.8.2]	≤ 2% (w/w)	0 % (w/w)
Loss on drying	Monograph Ph.Eur. "Cannabis Flower" Ph.Eur. 11.5 [2.2.32]	≤ 12%	8 %
Assay			
THC	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.29]	Informative	1.5 %
THCA ¹		Informative	25.3 %
CBD		Informative	≤0.2% (LOQ)
CBDA ²		Informative	≤0.2% (LOQ)
Total THC+THCA ¹		According to label ±10% (dried basis)	26.8 % (as is)
Total CBD+CBDA ²		≤1.0% (dried basis)	≤0.2% (LOQ) (as is)
Related substances Total CBN		≤1.0% (dried basis)	0.2 % (as is)
Aflatoxins *	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.18]	≤ 2 µg/kg Aflatoxin B1	< 0.25 µg/kg (LOD)
Pesticides*	Ph. Eur. 11.5 [2.8.13]	Not more than the limits specified in Ph. Eur. 2.8.13	Complies

¹ Expressed in THC

² Expressed in CBD

CANNPRISMA

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

Número CoA: CoA number:	SQC-FB24/00143	Local: Local:	Manufacturing Site
Produto: Product:	Cannabis sativa L.	Variedade: Variety:	Peanut Butter Breath
Descrição do Produto: Product description:	Remexian 27/1 PBB	Potência: Strength:	THC 27 % CBD < 1%
Forma Farmacéutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	Bags of 10 g
Número do Lote: Batch Number:	MFB241720024NSA	Data Validade: Expiry Date:	01/2025
Data de Receção de Amostra: Sample reception date:	01/07/2024	Data de Análise: Date of Analysis:	04/07/2024 até 20/08/2024 N/A
Tipo de Análise: Type of analysis:	Batch Release	Código TQA: TQA Code:	TQA-REX-001/02
Cliente: Client:	Remexian	Morada do Cliente: Client Address:	Märkersteig 27, 14974 Ludwigsfelde, Germany
Morada do Controlo de Qualidade: Quality Control adress:	Avenida Ville La Baule, n.º 5B. 8900-227 Vila Real de Santo António, Portugal		

TESTES TESTS	MÉTODOS METHODS	ESPECIFICAÇÕES SPECIFICATIONS	RESULTADOS RESULTS
Heavy Metals	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.4.27]	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. 11.5 [2.6.12; 2.6.13; 5.1.8.c]	< 10 ⁵ CFU/g (Max. 500 000 CFU/g)	< 100 CFU/g
Total viable aerobic count at 30-35 °C (TAMC)*		< 10 ⁴ CFU/g (Max. 50 000 CFU/g)	< 10 CFU/g
Total viable aerobic count at 20-25 °C (TYMC)*		< 10 ⁴ CFU/g (Max. 50 000 CFU/g)	< 10 CFU/g
Bile-tolerant Gram-negative bacteria*		Absent/g	Absent/g
Test for <i>E. coli</i> *		Absent/25g	Absent/25g

*Subcontracted test

COMENTÁRIOS E CONCLUSÕES:

COMMENTS AND CONCLUSIONS:

The results are according to the specifications.

	20/08/2024
	Data Date
	20/08/2024

Certificado de Lote Batch Certificate

Nome do produto <i>Name of product</i>	Remexian 27/1 PBB
País de destino <i>Destination country</i>	Alemanha <i>Germany</i>
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 <i>Dry Flower</i>
Quantidade embalada e tipo de embalagem <i>Package size and type</i>	816 sacos de 10g <i>816 10g bags</i>
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	MFB241720024NSA
Data de fabrico <i>Date of manufacture</i>	06/2024
Prazo de Validade <i>Expiry Date</i>	01/2025

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. 11.5 [2.8.23]	Complies with the monograph description	Complies
	TLC Identification (Identity test, Method C)	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.25]	Complies with the monograph description	Complies
	Foreign Matter	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.2]	≤2% (w/w)	0% (w/w)
	Loss on Drying	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.32]	≤12%	8%
	Aflatoxins	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.18]	≤2µg/kg Aflatoxin B1	<0.25 µg/Kg (LOD)
	Assay	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.29]		
THC	Informative		1.5%	
THCA ⁽¹⁾	Informative		25.3%	
CBD		Informative	≤0.2% (LOQ)	

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CDDA [®]		Informative	≤0.2% (LOQ)
Total THC		According to label ±10% (dried basis)	26.8% (as is)
Total CBD		≤1.0% (dried basis)	≤0.2% (LOQ) (as is)
Related Substances C9N		≤1.0% (dried basis)	0.2% (as is)
Pesticides	Ph. Eur. 11.5 [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. 11.5 [2.4.27]	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			
Total aerobic microbial count (TAMC)	Ph. Eur. 11.5 [2.6.12;2.6.13;5.1.8.C]	<10 ⁹ CFU/g (Max. 500 000 CFU/g)	<500 CFU/g
Total yeast and mold count (TYMC)		<10 ⁴ CFU/g (Max. 50 000 CFU/g)	<10 CFU/g
Test for bile-tolerant Gram-negative bacteria		<10 ⁴ CFU/g (Max. 50 000 CFU/g)	<10 CFU/g
Test for <i>E. coli</i>		Absent/g	Absent/g
Test for <i>Salmonella</i>		Absent/ 25g	Absent/ 25g

