

Certificado de Lote

Batch Certificate

Nome do produto <i>Name of product</i>	WTF 24/1 MIC
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>	24 ± 10% [21.6%-26.4%]
Forma farmacêutica <i>Dosage form</i>	Flor Seca Dry Flower
Quantidade embalada e tipo de embalagem <i>Package size and type</i>	757 sacos de 250g 757 250g bags
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	M251120136NSC
Data de fabrico <i>Date of manufacture</i>	05/2025
Prazo de Validade <i>Expiry Date</i>	11/2025

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 <i>Analysis Results</i>	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. 11.7 [2.8.23]	Complies with the monograph description	Complies
	HPTLC Identification (Identity test, Method C)	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.7 [2.8.25]	Complies with the monograph description	Complies
	Foreign Matter	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.7 [2.8.2]	≤2% (w/w)	0% (w/w)
	Loss on Drying	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.7 [2.2.32]	≤12%	7%
	Assay			
	THC	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.7 [2.2.29]	Informative	0.4%
	THCA ⁽¹⁾		Informative	22.9%
	CBD		Informative	< 0.2 % (LOQ)
	CBDA ⁽²⁾		Informative	< 0.2 % (LOQ)
	Total THC		According to label ± 10% (dried basis)	23.3% (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. 11.7 [2.2.29]	≤1.0% (dried basis)	0.2% (dried basis)
Aflatoxins	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.7 [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. 11.7 [2.8.22]	≤ 20 µg/Kg	< 5 µg/Kg (LOQ)
Pesticides	Ph. Eur. 11.7 [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. 11.7 [2.4.27]		
Cd		Cd ≤ 0.3 ppm	0.021 ppm
Pb		Pb ≤ 0.5 ppm	0.025 ppm
Hg		Hg ≤ 0.1 ppm	< 0.050 ppm (LOQ)
As		As ≤ 0.2 ppm	< 0.020 ppm (LOQ)
Microbiological Control	Ph. Eur. 11.7 [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

12/06/2025

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*

comply with GMP requirements of the EU.

12/06/2025
Data Date

CANNPRISMA

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-FB25/00899	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa</i> L.	Variedade: <i>Variety:</i>	Sugar Cookies
Descrição do Produto: <i>Product description:</i>	WTF 24/1 MIC	Potência: <i>Strength:</i>	THC 24 % CBD < 1%
Forma Farmacêutica: <i>Pharmaceutical Form:</i>	Dry flower	Acondicionamento: <i>Packaging:</i>	250 g bags
Número do Lote: <i>Batch Number:</i>	M251120136NSC	Data Validade: <i>Expiry Date:</i>	11/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	24/04/2025	Data de Análise: <i>Date of Analysis:</i>	06/05/2025 até till 04/06/2025
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 address:</i>	Avenida Ville La Baule, n.º 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. 11.7 [2.8.23]	Complies with the monograph description	Complies
HPTLC Identification (Identity Test, Method C) ^{(a) *}	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.7 [2.8.25]	Complies with the monograph description	Complies
Foreign Matter ^(b)	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.7 [2.8.2]	≤ 2 % (w/w)	0 % (w/w)
Loss on drying ^(b)	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.7 [2.2.32]	≤ 12 %	7 %
Assay ^(b) THC	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.7 [2.2.29]	Informative	0.4 %
THCA ¹		Informative	22.9 %
CBD		Informative	< 0.2 % (LOQ)
CBDA ²		Informative	< 0.2 % (LOQ)
Total THC+THCA ¹		According to label ±10% (dried basis)	23.3 % (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)
Aflatoxins ^{*(a)}	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.7 [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 ^{*(a)}	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.7 [2.8.22]	≤ 20 µg/Kg	< 5 µg/Kg (LOQ)

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:	SQC-FB25/00899	Local:	Manufacturing Site	
CoA number:		Local:		
Produto:	Cannabis sativa L.	Variedade:	Sugar Cookies	
Product:		Variety:		
Descrição do Produto:	WTF 24/1 MIC	Potência:	THC 24 %	
Product description:		Strength:	CBD < 1%	
Forma Farmacêutica:	Dry flower	Acondicionamento:	250 g bags	
Pharmaceutical Form:		Packaging:		
Número do Lote:	M251120136NSC	Data Validade:	11/2025	
Batch Number:		Expiry Date:		
Data de Receção de Amostra:	24/04/2025	Data de Análise:	06/05/2025	até 04/06/2025
Sample reception date:		Date of Analysis:	till	
Tipo de Análise:	Batch Release	Código TQA:	TQA-REX-001	
Type of analysis:		TQA Code:		
Cliente:	REMEXIAN PHARMA	Morada do Cliente:	Märkersteig 27, 14974	
Client:	GMBH	Client Address:	Ludwigsfelde, Germany	
Morada do Controlo de Qualidade:	Avenida Ville La Baule, n. ° 58.			
Quality Control adress:	8900-227 Vila Real de Santo António, Portugal			

TESTES TESTS	MÉTODOS METHODS	ESPECIFICAÇÕES SPECIFICATIONS	RESULTADOS RESULTS
Pesticides* (a)	Ph. Eur. 11.7 [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. 11.7 [2.4.27]	Cd ≤ 0.3 ppm	0.021 ppm
Cd		Pb ≤ 0.5 ppm	0.025 ppm
Pb		Hg ≤ 0.1 ppm	< 0.050 ppm (LOQ)
Hg		As ≤ 0.2 ppm	< 0.020 ppm (LOQ)
As	Ph. Eur.11.7 [2.6.12;2.6.13;5.1.4;5.1.8.C]		
Microbiological control			
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
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 CO-BC-002 and those marked (b) were carried out on the API from batch M251120136.

The results are according to the specifications.

