

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>	103 sacos de 250g 103 250g bags
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	M243510117NSC
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

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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. 11.6 [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%	9%
	Assay	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]		
	THC		Informative	2.6%
	THCA ⁽¹⁾		Informative	23.8%
	CBD		Informative	< 0.05% (LOQ)
	CBDA ⁽²⁾		Informative	0.07%
	Total THC		According to label ± 10% (as is)	26.4% (as is)
	Total CBD	≤1.0% (as is)	0.07% (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	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.4.27]		
Cd		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	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	< 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*

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