

Certificado de Lote
Batch Certificate

Nome do produto <i>Name of product</i>	Remexian 30/1 PRT
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>	30 ± 10% [27%-33%]
Forma farmacêutica <i>Dosage form</i>	Flor Seca <i>Dry Flower</i>
Quantidade embalada e tipo de embalagem <i>Package size and type</i>	356 sacos de 250g <i>356 250g bags</i>
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	M242830061NSC
Data de fabrico <i>Date of manufacture</i>	10/2024
Prazo de Validade <i>Expiry Date</i>	04/2025

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>Analyse 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. 11.5 [2.8.23]	Complies with the monograph description	Complies	
HPTLC 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%	7%	
Assay	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.29]	Informative	0.8%	
THCA ^(H)		Informative	28.2%	
CBD		Informative	≤ 0.2% (LOQ)	
CBDA ^(H)		Informative	≤ 0.2% (LOQ)	
Total THC		According to label ± 10% (dried basis)	29.0% (dried basis)	
Total CBD		≤1.0% (dried basis)	≤ 0.2% (LOQ) (dried basis)	

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Related Substances CBM		≤1.0% (dried basis)	0.13% (dried basis)
Microbiological Control	Ph. Eur. 1.2.5 (2.6.12; 2.6.13; 5.1.4 5.1.8 C)		
Total aerobic microbial count (TAMC)		<10 ⁶ CFU/g (Max. 500,000 CFU/g)	4.87 x 10 ⁵ CFU/g
Total yeast and mold count (TYMC)		<10 ⁵ CFU/g (Max. 50,000 CFU/g)	1.23 x 10 ⁵ CFU/g
Test for bile-tolerant Gram-negative bacteria		<10 ⁵ CFU/g (Max. 50,000 CFU/g)	> 10 ⁵ and < 10 ⁶ CFU/g
Test for <i>E. coli</i>		Absent/g	Absent/g
Test for <i>Salmonella</i>		Absent/25g	Absent/25g

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 24/10/2024

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 steps of the batch of finished product have been carried out in full compliance with GMP requirements of the EU.*



24/10/2024
Data Date

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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-FB24/00327	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa L.</i>	Variedade: <i>Variety:</i>	Think Fast
Descrição do Produto: <i>Product description:</i>	Remexian 30/1 PRT	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>	M242830061NSC	Data Validade: <i>Expiry Date:</i>	04/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	09/10/2024	Data de Análise: <i>Date of Analysis:</i>	09/10/2024 até till 24/10/2024
Tipo de Análise: <i>Type of analysis:</i>	Batch Release	Código TQA: <i>TQA Code:</i>	TQA-REM-002
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 Vile 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. 11.5 [2.8.23]	Complies with the monograph description	Complies
HPTLC Identification (Identity Test, Method C) ^(a)	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.25]	Complies with the monograph description	Complies
Foreign Matter ^(b)	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.2]	≤ 2 % (w/w)	0 % (w/w)
Loss on drying ^(b)	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.32]	≤ 12%	7 %
Assay ^(b) THC	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.29]	Informative	0.8 %
THCA ¹		Informative	28.2 %
CBD		Informative	≤ 0.2 % (LOQ)
CBDA ²		Informative	≤ 0.2 % (LOQ)
Total THC+THCA ¹		According to label ±10% (dried basis)	29.0 % (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)

¹ Expressed in THC

² Expressed in CBD