

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-FB24/00148	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa L.</i>	Variedade: <i>Variety:</i>	Helios Gold
Descrição do Produto: <i>Product description:</i>	Remexian 30/1 HEG	Potência: <i>Strength:</i>	THC 30 % CBD < 1%
Forma Farmacêutica: <i>Pharmaceutical Form:</i>	Dry flower	Acondicionamento: <i>Packaging:</i>	Bags of 10 g
Número do Lote: <i>Batch Number:</i>	MF8241720026NSA	Data Validade: <i>Expiry Date:</i>	01/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	01/07/2024	Data de Análise: <i>Date of Analysis:</i>	04/07/2024 até 23/07/2024 <i>till</i>
Tipo de Análise: <i>Type of analysis:</i>	Batch Release	Código TQA: <i>TQA Code:</i>	TQA-REX-001/02
Cliente: <i>Client:</i>	Remexian	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)*	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%	10 %
Assay	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.29]	Informative	0.72 %
THC*		Informative	26.97 %
THCA ¹ *		Informative	< 0.05 % (LOQ)
CBD*		Informative	0.07 %
CBDA ² *		According to label ±10% (dried basis)	27.70 % (as is)
Total THC+THCA ¹ *		≤1.0% (dried basis)	0.07 % (as is)
Total CBD+CBDA ² *		≤1.0% (dried basis)	0.16 % (as is)
Related substances Total CBN*	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.18]	≤ 2 µg/kg Aflatoxin B1	< 0.25 µg/kg (LOD)
Aflatoxins *	Ph. Eur. 11.5 [2.8.13]	Not more than the limits specified in Ph. Eur. 2.8.13	Complies
Pesticides*			

¹ Expressed in THC

² Expressed in CBD

CANNPRISMA

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

Número CoA: CoA number:	SOQ-FB24/00148	Local: Local:	Manufacturing Site
Produto: Product:	Cannabis sativa L.	Variedade: Variety:	Helios Gold
Descrição do Produto: Product description:	Remexian 30/1 HEG	Potência: Strength:	THC 30 % CBD < 1%
Forma Farmacêutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	Bags of 10 g
Número do Lote: Batch Number:	MFB241720026NSA	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 23/07/2024 III
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 Vile La Baula, n.º 5B, 8900-227 Vila Real de Santo António, Portugal		

TESTES TESTS	MÉTODOS METHODS	ESPECIFICAÇÕES SPECIFICATIONS	RESULTADOS RESULTS
Heavy Metals Cd*	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.4.27]	Cd ≤ 0.3 ppm	0.011 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 E. coli*		Absent/25g	Absent/25g

*Subcontracted test

COMENTÁRIOS E CONCLUSÕES:

COMMENTS AND CONCLUSIONS:

The results are according to the specifications.

	19/08/2024
	Data Date
	19/08/2024
	Data Date

Certificado de Lote
Batch Certificate

Nome do produto <i>Name of product</i>	Remexian 30/1 HEG
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>	1071 sacos de 10g <i>1071 10g bags</i>
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	MFB241720026NSA
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

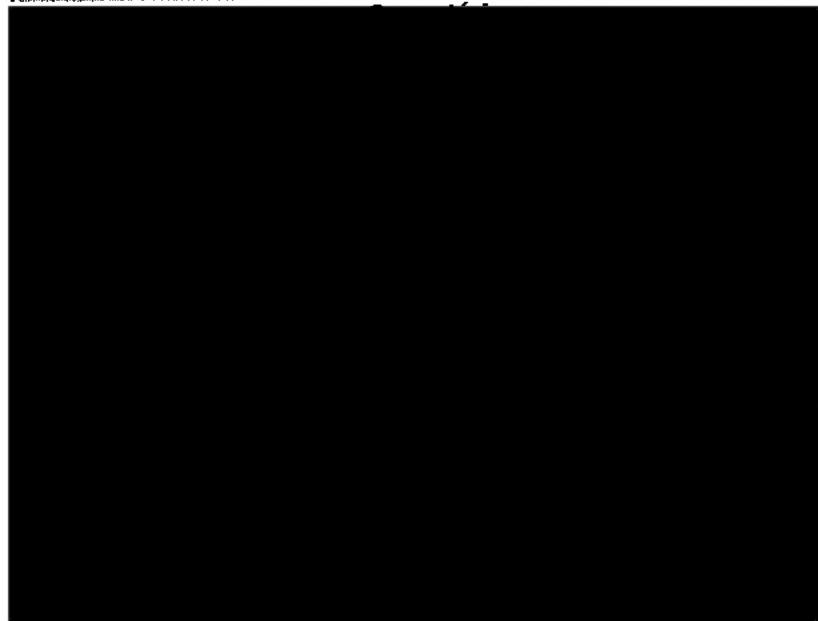
Laboratory: Cannprisma Pharma, Lda
Address: Avenida Ville La Baule nº58, 8900-227 Vila Real de Santo António, Portugal
Date: 30-07-2024
F076/S1/MH/002/2023 (FP)
F076/S1/SA/001/2023 (API)

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%	10%
	Aflatoxins	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.18]	≤2µg/kg Aflatoxin B1	<0.25 µg/Kg (LOD)
	Assay			
THC	Monograph Ph. Eur. "Cannabis Flower"	Informative	0.72%	
THCA (1)	Ph. Eur. 11.5 [2.2.29]	Informative	26.97%	
CBD		Informative	<0.05% (LOQ)	

CANNPRISMA

CBDa (%)		informative	0.07%
Total THC		According to label ± 10% (dried basis)	27.70% (as is)
Total CBD		≤1.0% (dried basis)	0.07% (as is)
Related Substances CBD		≤1.0% (dried basis)	0.16% (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	0.011 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 ⁶ CFU/g (Max. 500 000 CFU/g)	<100 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



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oram realizadas em total
manufacturing stages of this batch
 e EU.

22/08/2024
 Data Date