

Certificado de Lote

Batch Certificate

Nome do produto <i>Name of product</i>	Remexian 30/1 HMA
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>	30 ± 10% [27%-33%]
Forma farmacêutica <i>Dosage form</i>	Flor Seca Dry Flower
Quantidade embalada e tipo de embalagem <i>Package size and type</i>	238 sacos de 250g 238 250g bags
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	M242140045NSC
Data de fabrico <i>Date of manufacture</i>	08/2024
Prazo de Validade <i>Expiry Date</i>	02/2025

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. 11.5 [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]			
THC		Informative	3.3%	
THCA ^(a)		Informative	26.4%	
CBD		Informative	≤ 0.2 % (LOQ)	
CBDa ^(a)		Informative	≤ 0.2 % (LOQ)	
Total THC		According to label ± 10% (dried basis)	29.7% (dried basis)	

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Total CBD		≤1.0% (dried basis)	≤0.2% (LOQ) (dried basis)
Related Substances CBN		≤1.0% (dried basis)	0.2% (dried basis)
Aflatoxins	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.6.10]	≤ 2 µg/kg Aflatoxin B1 ≤ 4 µg/kg Aflatoxin B1, B2, G1, G2	< 0.25 µg/kg (LOD) < 0.25 µg/kg (LOD)
Pesticides	Ph. Eur. 11.5 [2.6.13]	Complies with the monograph description	Complies
Heavy Metals			
Cd	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.4.27]	Cd ≤ 0.3 ppm	< 0.005 ppm (LOQ)
Pb		Pb ≤ 0.5 ppm	< 0.020 ppm (LOQ)
Hg		Hg ≤ 0.3 ppm	< 0.050 ppm (LOQ)
As		As ≤ 0.2 ppm	< 0.020 ppm (LOQ)
Microbiological Control	Ph. Eur. 31.5 [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)	1.5 x 10 ⁶ CFU/g
Total yeast and mold count (TYMC)		<10 ⁴ CFU/g (Max. 50 000 CFU/g)	4.7 x 10 ⁶ 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	

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

16/10/2024

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



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

Número CoA: CoA number:	SQC-FB24/00129	Local: Local:	Manufacturing Site
Produto: Product:	Cannabis sativa L.	Variedade: Variety:	Chem-de-la-Chem
Descrição do Produto: Product description:	Remexian 30/1 HMA	Potência: Strength:	THC 30% CBD < 1%
Forma Farmacêutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	250g Bags
Número do Lote: Batch Number:	M242140045NSC	Data Validade: Expiry Date:	02/2025
Data de Receção de Amostra: Sample reception date:	09/08/2024	Data de Análise: Date of Analysis:	12/08/2024 até till 03/09/2024
Tipo de Análise: Type of analysis:	Batch Release	Código TQA: TQA Code:	TQA-REM-002
Cliente: Client:	REMEXIAN PHARMA GMBH	Morada do Cliente: Client Address:	Märkersteig 27, 14974 Ludwigsfelde, Germany
Morada do Controlo de Qualidade: Quality Control address:	Avenida Vllie La Baule, n. ° 5B, 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
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	3.3 %
THC		Informative	26.4 %
THCA ¹		Informative	≤ 0.2 % (LOQ)
CBD		Informative	≤ 0.2 % (LOQ)
CBDA ²		According to label ±10% (dried basis)	29.7 % (dried basis)
Total THC+THCA ¹		≤1.0% (dried basis)	≤ 0.2 % (LOQ) (dried basis)
Related substances	Ph. Eur. 11.5 [2.8.13]	≤1.0% (dried basis)	0.2 % (dried basis)
Total CBN			
Aflatoxins *	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.5 [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)
Pesticides*	Ph. Eur. 11.5 [2.8.13]	Complies with the monograph description	Complies

¹ Expressed in THC

² Expressed in CBD

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

Número CoA: CoA number:	SQC-FB24/00129	Local: Local:	Manufacturing Site
Produto: Product:	Cannabis sativa L.	Variedade: Variety:	Chem-de-la-Chem
Descrição do Produto: Product description:	Bemedan 30/1 HMA	Potência: Strength:	THC 30% CBD < 1%
Forma Farmacêutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	250g Bags
Número do Lote: Batch Number:	M242140045NSC	Data Validade: Expiry Date:	02/2025
Data de Receção de Amostra: Sample reception date:	09/08/2024	Data de Análise: Date of Analysis:	12/08/2024 até 03/09/2024 até 03/09/2024 at
Tipo de Análise: Type of analysis:	Batch Release	Código TQA: TQA Code:	TQA-REM-002
Cliente: Client:	REMEXIAN PHARMA GMBH	Morada do Cliente: Client Address:	Märkersteig 27, 14974 Ludwigsfelde, Germany
Morada do Controlo de Qualidade: Quality Control address:	Avenida Ville La Baule, n.º 58. 8900-227 Vila Real de Santo António, Portugal		

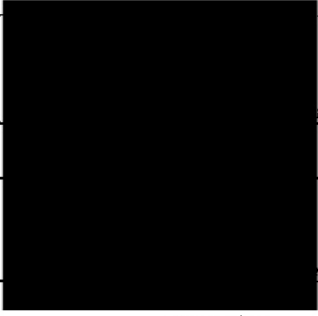
TESTES TESTS	MÉTODOS METHODS	ESPECIFICAÇÕES SPECIFICATIONS	RESULTADOS RESULTS	
Heavy Metals*	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.4.27]	Cd ≤ 0.3 ppm	< 0.005 ppm (LOQ)	
Cd		Pb ≤ 0.5 ppm	< 0.020 ppm (LOQ)	
Pb		Hg ≤ 0.1 ppm	< 0.050 ppm (LOQ)	
Hg		As ≤ 0.2 ppm	< 0.020 ppm (LOQ)	
As	Ph. Eur. 11.5 [2.6.12; 2.6.13; 5.1.4; 5.1.B.C]	Total viable aerobic count (TAMC)	1.9 x 10 ⁵ CFU/g	
Microbiological control		Total viable aerobic count (TYMC)	4.7 x 10 ⁵ CFU/g	
Total viable aerobic count (TAMC)		Bile-tolerant Gram-negative bacteria	< 10 ⁴ CFU/g	< 10 cfu/g
Total viable aerobic count (TYMC)		<i>E. coli</i>	Absent/g	Absent/g
Bile-tolerant Gram-negative bacteria		<i>Salmonella</i>	Absent/25g	Absent/25g

*Subcontracted test

COMENTÁRIOS E CONCLUSÕES:

COMMENTS AND CONCLUSIONS:

Affotoxins, pesticides and heavy metals were analyzed in the raw material, batch 094CH corresponding to the CoA: SQC-FB24/00293. The results are according to the specifications.

		16/10/2024
	(an)	Data Date
		16/10/2024
	(r)	Data Date
Approved by		