

Certificado de Lote

Batch Certificate

Nome do produto <i>Name of product</i>	Remexian 24/1 VLI
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>	24 ± 10% [21.6%-26.4%]
Forma farmacêutica <i>Dosage form</i>	Flor Seca <i>Dry Flower</i>
Quantidade embalada e tipo de embalagem <i>Package size and type</i>	495 sacos de 10g <i>495 10g bags</i>
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	MFB241790028NSA
Data de fabrico <i>Date of manufacture</i>	07/2024
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)

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)

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: 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%	7%
	Aflatoxins	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.18]	≤2µg/kg Aflatoxin B1	<0.25 µg/Kg (LOD)
	Ochratoxins	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.22]	≤ 20 µg/kg	< 2 µg/kg (LOD)
	Assay THC	Monograph Ph. Eur. "Cannabis Flower"	Informative	0.5%

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THCA ⁽¹⁾	Ph. Eur. 11.5 [2.2.29]	Informative	22.0%
CBD		Informative	≤0.2% (LOQ)
CBDA ⁽²⁾		Informative	≤0.2% (LOQ)
Total THC		According to label ± 10% (dried basis)	22.5%
Total CBD		≤1.0% (dried basis)	≤0.2% (LOQ) (as is)
Related Substances CBN		≤1.0% (dried basis)	0.2% (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	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [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)
Mikrobiological Control	Ph. Eur. 11.5 [2.6.12; 2.6.13; 5.1.8.C]		
Total aerobic microbial count (TAMC)		<10 ⁶ CFU/g (Max. 500 000 CFU/g)	1.00 x 10 ⁵ CFU/g
Total yeast and mold count (TYMC)		<10 ⁴ CFU/g (Max. 50 000 CFU/g)	3.70 x 10 ² 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 liberação do produto
Name and position/title of person authorising the batch release

Fernando Águas/Qualified Person

Data de Libertação do Produto
Product Release Date

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.*



5/09/2024

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-FB24/00202_Recitification	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	Cannabis sativa L.	Variedade: <i>Variety:</i>	Vanilla Ice
Descrição do Produto: <i>Product description:</i>	REMEXIAN 24/1 VLI	Potência: <i>Strength:</i>	THC 24% 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>	MF8241790028NSA	Data Validade: <i>Expiry Date:</i>	01/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	08/07/2024	Data de Análise: <i>Date of Analysis:</i>	08/07/2024 até 28/08/2024 <i>till</i>
Tipo de Análise: <i>Type of analysis:</i>	Batch Release	Código TQA: <i>TQA Code:</i>	TQA-REX-002
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)*	German Monograph (DAB) "Cannabis Flower"	Complies with the monograph description	Complies
Microscopy observation (Identity Test, Method B)*	German Monograph (DAB) "Cannabis Flower" Ph.Eur.11.5 [2.8.23]	Complies with the monograph description	Complies
TLC Identification (Identity Test, Method C)*	German Monograph (DAB) "Cannabis Flower"	Complies with the monograph description	Complies
Foreign Matter*	German Monograph (DAB) "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	0.5%
THC		Informative	22.0 %
THCA ¹		Informative	≤ 0.2 % (LOQ)
CBD		Informative	≤ 0.2 % (LOQ)
CBDA ²		According to label ±10% (dried basis)	22.5 %
Total THC+THCA ¹		≤1.0% (dried basis)	≤ 0.2 % (LOQ) (as is)
Total CBD+CBDA ²		≤1.0% (dried basis)	0.2 % (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 *	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.22]	≤ 20 µg/kg	< 2 µg/kg (LOD)
Ochratoxins*			

¹ Expressed in THC

² Expressed in CBD

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

Número CoA: CoA number:	SQC-FB24/00202_Recitification	Local: Local:	Manufacturing Site
Produto: Product:	Cannabis sativa L.	Variedade: Variety:	Vanilla Ice
Descrição do Produto: Product description:	REMEXIAN 24/1 VLI	Potência: Strength:	THC 24% CBD < 1%
Forma Farmacêutica: Pharmaceutical Form:	Dry flower	Acondicionamento: Packaging:	Bags of 10 g
Número do Lote: Batch Number:	MF8241790028NSA	Data Validade: Expiry Date:	01/2025
Data de Receção de Amostra: Sample reception date:	08/07/2024	Data de Análise: Date of Analysis:	08/07/2024 até 28/08/2024 #/##
Tipo de Análise: Type of analysis:	Batch Release	Código TQA: TQA Code:	TQA-REX-002
Cliente: Client:	Remexian	Morada do Cliente: Client Address:	Märkersteig 27, 14974 Ludwigsfelde, Germany
Morada do Controlo de Qualidade: Quality Control adress:	Avenida Ville La Baule, n.º 58. 8900-227 Vila Real de Santo António, Portugal		

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	< 0.005 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			
Total viable aerobic count at 30-35 °C (TAMC)*	Ph. Eur. 11.5 [2.6.12; 2.6.13; 5.1.8.C]	< 10 ⁵ CFU/g (Max. 500 000 CFU/g)	1.00 x 10 ⁵ cfu/g
Total viable aerobic count at 20-25 °C (TYMC)*		< 10 ⁴ CFU/g (Max. 50 000 CFU/g)	3.70 x 10 ² cfu/g
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

*Subcontracted test

COMENTÁRIOS E CONCLUSÕES:

COMMENTS AND CONCLUSIONS:

The results are according to the specifications.

This certificate of analysis replaces the previously one issued on 29-08-2024.

		12/09/2024
Preparado por Prepared by		Data Date
		12/09/2024
Aprovado por Approved by		Data Date