

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-FB24/00135	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa L.</i>	Variedade: <i>Variety:</i>	Black Kyber Crystal
Descrição do Produto: <i>Product description:</i>	Remexian 30/1 BKC	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>	MF8241720021NSA	Data Validade: <i>Expiry Date:</i>	01/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	01/07/2024	Data de Analise: <i>Date of Analysis:</i>	04/07/2024 até 23/07/2024 <i>till</i>
Tipo de Analise: <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			
THC*	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.29]	Informative	0.71%
THCA ¹ *		Informative	28.25%
CBD*		Informative	< 0.05% (LOQ)
CBDA ² *		Informative	0.07%
Total THC+THCA ¹ *		According to label ±10% (dried basis)	28.98% (as is)
Total CBD+CBDA ² *		≤1.0% (dried basis)	0.07% (as is)
Related substances Total CBN*		≤1.0% (dried basis)	0.12% (as is)
Aflatoxins *	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.18]	≤ 2 µg/kg Aflatoxin B1	< 0.25 µg/kg (LOD)
Pesticides*	Ph. Eur. 11.5 [2.8.13]	Not more than the limits specified in Ph. Eur. 2.8.13	Complies

¹ Expressed in THC

² Expressed in CBD

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Código <i>Code</i>	FR.QC.023	Version	01

Número CoA: <i>CoA number:</i>	SQC-FB24/00135	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	Cannabis sativa L.	Varietade: <i>Variety:</i>	Black Kyber Crystal
Descrição do Produto: <i>Product description:</i>	Remexjan 30/1 BKÇ	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>	MFB241720021NSA	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 till
Tipo de Análise: <i>Type of analysis:</i>	Batch Release	Código TQA: <i>TQA Code:</i>	TQA-REX-001/02
Cliente: <i>Client:</i>	Remexjan	Morada do Cliente: <i>Client Address:</i>	Märkersteig 27, 14974 Ludwigsfelde, Germany
Morada do Controlo de Qualidade: <i>Quality Control address:</i>	Avenida Ville 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>
Heavy Metals <i>Cd*</i>	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.4.27]	Cd ≤ 0.3 ppm	< 0.005 ppm (LOQ)
<i>Pb*</i>		Pb ≤ 0.5 ppm	< 0.020 ppm (LOQ)
<i>Hg*</i>		Hg ≤ 0.1 ppm	< 0.050 ppm (LOQ)
<i>As*</i>		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)	2.00 × 10 ¹ 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 <i>E. coli</i> *		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 BKC
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>	796 sacos de 10g 796 10g bags
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	MFB241720021NSA
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)

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%	10%
	Aflatoxins	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.8.18]	≤2µg/kg Aflatoxin B1	<0.25 µg/Kg (LOD)
	Assay	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.29]		
THC	informative		0.71%	
THCA ⁽¹⁾	Informative		28.25%	
CBD	Informative		<0.05%(LOQ)	

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	CBDA (2)		Informative	0.07%
	Total THC		According to label \pm 10% (dried basis)	28.98% (as is)
	Total CBD		\leq 1.0% (dried basis)	0.07% (as is)
	Related Substances CBN		\leq 1.0% (dried basis)	0.12% (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 \leq 0.3 ppm	< 0.005 ppm (LOQ)
	Pb		Pb \leq 0.5 ppm	< 0.020 ppm (LOQ)
	Hg		Hg \leq 0.1 ppm	< 0.050 ppm (LOQ)
	As		As \leq 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 ⁵ 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)	2.00 x 10 ¹ 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

22/08/2024

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.*

Assinado por: **Fernando Manuel Jorge Águas**
 Num. de identificação: 08493638
 Data: 2024.08.22 19:06:36+01'00'

Qualified Person *QP*

22/08/2024
 Data *Date*