

CANNPRISMA

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

Número CoA:	SQC-FR25/00128	Local:	Manufacturing Site
CoA number:		Local:	
Produto:	Cannabis sativa L.	Variedade:	Banjo
Product:		Variety:	
Descrição do Produto:	BARONGO.24/1 BANJO	Potência:	THC 24%
Product description:		Strength:	CBD < 1%
Forma Farmacêutica:	Dry flower	Acondicionamento:	10g Bags
Pharmaceutical Form:		Packaging:	
Número do Lote:	M243530126NSA	Data Validade:	07/2025
Batch Number:		Expiry Date:	
Data de Receção de Amostra:	20/12/2024	Data de Análise:	02/01/2025 até 28/01/2025
Sample reception date:		Date of Analysis:	
Tipo de Análise:	Batch Release	Código TQA:	TOA-WMG-001
Type of analysis:		TQA Code:	
Cliente:	WMG Pharma GmbH	Morada do Cliente:	Hessenring 15 C,
Client:		Client Address:	64548 Mörfelden-Walldorf, Germany
Morada do Controlo de Qualidade:	Avenida Ville La Baule, n.º 58,		
Quality Control address:	8900-227 Vila Real de Santo António, Portugal		

TESTES TESTS	MÉTODOS METHODS	ESPECIFICAÇÕES SPECIFICATIONS	RESULTADOS RESULTS
Pesticidas* ^(a)	Ph. Eur. 11.5 [2.8.13]	Not more than the limits specified in Ph. Eur. 2.8.13	Complies
Heavy Metals* ^(a)	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)
Microbiological control	Ph. Eur. 11.5 [2.6.12; 2.6.13; 5.1.8.C]		
Total Aerobic Microbial Count (TAMC)		≤ 5.0 x 10 ⁵ CFU/g	3.2 x 10 ⁵ CFU/g
Total Yeast and Mold Count (TYMC)		≤ 5.0 x 10 ⁴ CFU/g	8.4 x 10 ³ CFU/g
Bile-tolerant Gram-negative bacteria		≤ 10 ⁶ CFU/g	> 10 ⁶ and < 10 ⁴ CFU/g
E. coli		Absent/g	Absent/g
Salmonella		Absent/25g	Absent/25g

*Subcontracted test

COMENTÁRIOS E CONCLUSÕES:

COMMENTS AND CONCLUSIONS:

The analyses marked ^(a) were carried out on the raw material from batch 001-2024-0010 and those marked ^(b) were carried out on the API from batch M243530126.

The results are according to the specifications.

		05/02/2025
		Data Date
		06/02/2025
		Data Date

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

Número CoA:	SQC-F825/00128	Local:	Manufacturing Site	
CoA number:		Local:		
Produto:	Cannabis sativa L.	Variedade:	Banjo	
Product:		Variety:		
Descrição do Produto:	BARONGO 24/1 BANJO	Potência:	THC 24%	
Product description:		Strength:	CBD < 1%	
Forma Farmacêutica:	Dry flower	Acondicionamento:	10g Bags	
Pharmaceutical Form:		Packaging:		
Número do Lote:	M243530126NSA	Data Validade:	07/2025	
Batch Number:		Expiry Date:		
Data de Receção de Amostra:	20/12/2024	Data de Análise:	02/01/2025	até 28/01/2025
Sample reception date:		Date of Analysis:		
Tipo de Análise:	Batch Release	Código TQA:	TQA-WMG-001	
Type of analysis:		TQA Code:		
Cliente:	WMG Pharma GmbH	Morada do Cliente:	Hessenring 15 C,	
Client:		Client Address:	64546 Mörfelden-Walldorf,	
			Germany	
Morada do Controlo de Qualidade:	Avenida Villa La Baule, n.º 58.			
Quality Control address:	8900-227 Vila Real de Santo António, Portugal			

TESTES TESTS	MÉTODOS METHODS	ESPECIFICAÇÕES SPECIFICATIONS	RESULTADOS RESULTS
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. 11.6 [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%	8 %
Assay ^(b) THC	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.29]	Informative	2.8 %
THCA ¹		Informative	20.9 %
CBD		Informative	< 0.2 % (LOQ)
CBDA ²		Informative	< 0.2 % (LOQ)
Total THC+THCA ¹		According to label ±10% (as is)	23.6 % (as is)
Total CBD+CBDA ²		≤ 1 % (as is)	< 0.2 % (LOQ) (as is)
Related substances ^(b) Total CBN+CBNA		≤ 1 % (as is)	0.1 % (as is)
Aflatoxins * ^(a)	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.18]	≤ 2 µg/Kg Aflatoxin B1 ≤ 4 µg/Kg Aflatoxin B1, B2, G1, G2	< 0.25 µg/Kg (LOD) < 0.5 µg/Kg (LOQ)
Ochratoxin A * ^(a)	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.22]	≤ 20 µg/Kg	< 2 µg/Kg (LOD)

¹ Expressed in THC² Expressed in CBD

Related Substances CBN		≤1.0% (dried basis)	0.1% (as is)
Aflatoxins	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.18]	≤ 2 µg/Kg Aflatoxin B1 ≤ 4 µg/Kg Aflatoxin B1, B2, G1, G2	< 0.25 µg/Kg (LOD) < 0.5 µg/Kg (LOQ)
Ochratoxin A	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.22]	≤ 20 µg/Kg	< 2 µg/Kg (LOD)
Pesticides	Ph. Eur. 11.5 [2.8.13]	Not more than the limits specified in the 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	Ph. Eur. 11.5 [2.6.12; 2.6.13; 5.1.8.C]		
Total aerobic microbial count (TAMC)		< 5 x 10 ⁵ CFU/g	3.2 x 10 ⁵ CFU/g
Total yeast and mold count (TYMC)		< 5 x 10 ³ CFU/g	8.4 x 10 ³ CFU/g
Test for bile-tolerant Gram-negative bacteria		< 10 ⁴ CFU/g	> 10 ⁵ and < 10 ⁶ CFU/g
Test for E. coli		Absent/g	Absent/g
Test for Salmonella		Absent/25g	Absent/25g

Comentários

Comments

Nome e posição/título da pessoa autorizada para a libertação do produto

Name and position/title of person authorizing the batch release

Fernando Águas/Qualified Person

Data de Libertação do Produto

Product Release Date

06/02/2025

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.



6/2/2025

Data Date

Certificado de Lote

Batch Certificate

Nome do produto <i>Name of product</i>	Barongo 24/1 Banjo
País de destino <i>Destination country</i>	Alemanha <i>Germany</i>
Nº de autorização da AIM <i>Marketing authorization 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>	
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	M243530126NSA
Data de fabrico <i>Date of manufacture</i>	01/2025
Prazo de Validade <i>Expiry Date</i>	07/2025

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 authorization 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%	8%
	Assay	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.29]	Informative	2.8%
	THC		Informative	20.9%
	THCA ^(a)		Informative	< 0.2 % (LOQ)
	CBD		Informative	< 0.2 % (LOQ)
	CBDA ^(a)		According to label ± 10% (dried basis)	23.6% (as is)
	Total THC		≤1.0% (dried basis)	< 0.2 % (LOQ) (as is)
	Total CBD			