

Certificado de Lote
Batch Certificate

Nome do produto <i>Name of product</i>	Barongo 27/1 MAC3
País de destino <i>Destination country</i>	Alemanha <i>Germany</i>
Nº de autorização de AIM <i>Marketing authorization number</i>	NA
Concentração da substância ativa <i>Strength/potency</i>	27 ± 10% [24.3%-29.7%]
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>	M243550130NSA
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 8A, 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 [2.3.23]	Complies with the monograph description	Complies	
HPTLC Identification (Identity test, Method C)	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.3.25]	Complies with the monograph description	Complies	
Foreign Matter	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.3.2]	≤2% (w/w)	0% (w/w)	
Loss on Drying	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.32]	≤12%	5%	
Assay	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.29]	Informative	2.0%	
THC		Informative	22.7%	
THCA ^(*)		Informative	< 0.2 % (LOQ)	
CBD		Informative	< 0.2 % (LOQ)	
CBD ^(*)		According to label ± 10% (dried basis)	24.6% (as is)	
Total THC		≤1.0% (dried basis)	< 0.2 % (LOQ) (as is)	
Total CBD				

Related Substances CBN		≤1.0% (dried basis)	0.2% (as is)
Aflatoxins	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.16]	≤ 2 µg/Kg Aflatoxin B1 ≤ 4 µg/Kg Aflatoxin B1, B2, G1, G2	< 0.25 µg/Kg (LOQ) < 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 (LOQ)
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	< 0.055 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 aerobic microbial count (TAMC)	Ph. Eur. 11.5 [2.6.12; 2.6.13; 5.1.9.C]	< 5 × 10 ⁶ CFU/g	1.1 × 10 ⁴ CFU/g
Total yeast and mold count (TYMC)		< 5 × 10 ⁴ CFU/g	1.5 × 10 ³ CFU/g
Test for bile-tolerant Gram-negative bacteria		< 10 ⁴ CFU/g	> 10 and < 10 ⁵ 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 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

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-FB25/00130	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa L.</i>	Variedade: <i>Variety:</i>	MAC3
Descrição do Produto: <i>Product description:</i>	BARONGO 27/1 MAC3	Potência: <i>Strength:</i>	THC 27% CBD < 1%
Forma Farmacéutica: <i>Pharmaceutical Form:</i>	Dry flower	Acondicionamento: <i>Packaging:</i>	10g Bags
Número do Lote: <i>Batch Number:</i>	M248550130NSA	Data Validade: <i>Expiry Date:</i>	07/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	26/12/2024	Data de Análise: <i>Date of Analysis:</i>	02/01/2025 até 28/01/2025
Tipo de Análise: <i>Type of analysis:</i>	Batch Release	Código TQA: <i>TQA Code:</i>	TQA-WMG-001
Cliente: <i>Client:</i>	WMG Pharma GmbH	Morada do Cliente: <i>Client Address:</i>	Hesserring 15 C, 64546 Mörfelden-Walldorf, 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>
Macroscopy observation (Identity Test, Method A) ^(a)	Monograph Ph. Eur. "Cannabis Flower"	Complies with the monograph description	Complies
Microscopy observation (Identity Test, Method B) ^(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) * ^(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%	5 %
Assay ^(b) THC	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.5 [2.2.29]	Informative	2.0 %
THCA ¹		Informative	22.7 %
CBD		Informative	< 0.2 % (LOQ)
CBDA ²		Informative	< 0.2 % (LOQ)
Total THC+THCA ¹		According to label ±10% (as is)	24.6 % (as is)
Total CBD+CBDA ²		≤1 % (as is)	< 0.2 % (LOQ) (as is)
Related substances ^(b) Total CBN+CBNA		≤1 % (as is)	0.2 % (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 * ^(b)	Monograph Ph.Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.22]	≤ 20 µg/Kg	< 2 µg/Kg (LOD)

¹ Expressed in THC

² Expressed in CBD

CANNPRISMA

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

Número CoA: <i>CoA number:</i>	SQC-FB25/00130	Local: <i>Local:</i>	Manufacturing Site
Produto: <i>Product:</i>	<i>Cannabis sativa L.</i>	Variedade: <i>Variety:</i>	MAC3
Descrição do Produto: <i>Product description:</i>	BARONGO 27/1 MAC3	Potência: <i>Strength:</i>	THC 27% CBD < 1%
Forma Farmacêutica: <i>Pharmaceutical Form:</i>	Dry flower	Acondicionamento: <i>Packaging:</i>	10g Bags
Número do Lote: <i>Batch Number:</i>	M243550130NSA	Data Validade: <i>Expiry Date:</i>	07/2025
Data de Receção de Amostra: <i>Sample reception date:</i>	26/12/2024	Data de Análise: <i>Date of Analysis:</i>	02/01/2025 até 28/01/2025 <i>til</i>
Tipo de Análise: <i>Type of analysis:</i>	Batch Release	Código TQA: <i>TQA Code:</i>	TQA-WMG-001
Cliente: <i>Client:</i>	WMG Pharma GmbH	Morada do Cliente: <i>Client Address:</i>	Hessenering 15 C, 64546 Mörfelden-Walldorf, Germany

Morada do Controlo de Qualidade: Avenida Ville La Gaule, n.º 58.
Quality Control address: 8900-227 Vila Real de Santo António, Portugal

TESTES <i>TESTS</i>	MÉTODOS <i>METHODS</i>	ESPECIFICAÇÕES <i>SPECIFICATIONS</i>	RESULTADOS <i>RESULTS</i>
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 ≤ 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 × 10 ⁵ CFU/g 1.1 × 10 ⁴ CFU/g
Total Yeast and Mold Count (TYMC)		≤ 5.0 × 10 ⁴ CFU/g 1.5 × 10 ³ CFU/g	
Bile-tolerant Gram-negative bacteria		≤ 10 ⁴ CFU/g > 10 and < 10 ² 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 010-2024-0003 and those marked ^(b) were carried out on the API from batch M243550130.

The results are according to the specifications.

		05/02/2025
		Data <i>Date</i>
		06/02/2025
		Data <i>Date</i>