

Certificado de Lote

Batch Certificate

Nome do produto <i>Name of product</i>	Buuo 15/1 SC
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>	15 ± 10% [13.5%-16.5%]
Forma farmacêutica <i>Dosage form</i>	Flor Seca Dry Flower
Quantidade embalada e tipo de embalagem <i>Package size and type</i>	250g
Nº de Lote do produto acabado <i>Batch Number of the finished product</i>	M250510043NSC
Data de fabrico <i>Date of manufacture</i>	02/2025
Prazo de Validade <i>Expiry Date</i>	08/2025

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. 11.6 [2.8.23]	Complies with the monograph description	Complies
	HPTLC Identification (Identity test, Method C)	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.25]	Complies with the monograph description	Complies
	Foreign Matter	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.8.2]	≤2% (w/w)	0% (w/w)
	Loss on Drying	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.32]	≤12%	7%
	Assay			
	THC	Monograph Ph. Eur. "Cannabis Flower" Ph. Eur. 11.6 [2.2.29]	Informative	0.4%
	THCA ⁽¹⁾		Informative	15.5%
	CBD		Informative	< 0.2 % (LOQ)
	CBDa ⁽²⁾		Informative	< 0.2 % (LOQ)
	Total THC		According to label ± 10% (as is)	16.1% (as is)
	Total CBD		≤1.0% (as is)	< 0.2 % (LOQ) (as is)

Related Substances CBN		≤1.0% (as is)	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	< 0.5 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	< 5 µg/Kg (LOQ)
Pesticides	Ph. Eur. 11.6 [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. 11.6 [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		Cd ≤ 0.2 ppm	< 0.020 ppm (LOQ)
Microbiological Control	Ph. Eur. 11.6 [2.6.12;2.6.13;5.1.8.C]		
Total aerobic microbial count (TAMC)		< 5 x 10 ⁵ CFU/g	1.1 x 10 ³ CFU/g
Total yeast and mold count (TYMC)		< 5 x 10 ⁴ CFU/g	1.5 x 10 ³ CFU/g
Test for bile-tolerant Gram-negative bacteria		<10 ⁴ CFU/g	> 10 ² and <10 ³ 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

17/03/2025

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.*

Assinado por: **Fernando Manuel Jorge Águas**

Num. de Identificação: 08493638

Data: 2025.03.17 17:32:30+00'00'

Qualified Person *QP*

17/03/2025

Data *Date*