

CoA-125-02 Certificado de Análise



Source Document: CoA-YYY Certificate of Analysis

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Informação do Produto Product Information			
Descrição do produto: Product description:	Cannabis Dry Flower, Nedcann, Amnesia, 10g Jars		
Código do produto: Product code:	13807870		
Estirpe: Strain:	Amnesia		
Forma farmacêutica: Pharmaceutical form:	Cannabis flos		
Dosagem (Nota: alegação de rótulo): Strenght (Note: label claim):	22:01 (THC/CBD)		
N.º Lote: Batch number:	13807870002		
N.º Lote do fornecedor (se matéria prima): Supplier batch number (if raw material):	NA		
Produto Irrradiado Irradiated product	☐ Yes	☒ No	Data de irradiação: NA Irradiation date
Tamanho da embalagem: Package size:	10 g		
Especificação de referência: Specification reference:	SPEC-107		
Data de reteste/ validade: Retest/ expiry date:	22/08/2025		
Nome do cliente: Client name:	California´s Medical GmbH		
Rótulo: Label:	NEDCANN AH 22/01		

Fabricante/ Manufacturing Site:

Blossom Genetics Lda, Estrada do Contador, 23 2130-017 Benavente, Portugal

Laboratório de Análise/ Testing Site:

Qplab Pharma Services, Tec Labs – Centro de Inovação da FCUL, 1749-016 Lisboa, Portugal

LEF – Laboratório de Estudos Farmacêuticos – Rua das Ferrarias del Rei 6A, Urbanização da Fábrica da Pólvora 2730-269 Barcarena, Portugal

R02		
R00 – Creation; R01 – Product info update; R02 – General layout update.		
DOCUMENT APPROVALS		
Author – Confirming the technical content of this document	Document Owner – Confirming the technical content of this document	Quality – Confirming compliance of this document with the Quality System
27-05-2024	27/05/2024	27-05-2024
Quality Compliance Manager	Quality Assurance Manager	Quality Assurance Director
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Testes Tests	Métodos de Referência Reference Methods	Critérios de Aceitação Acceptance Criteria	
		Especificações Specifications	Resultados Results
Macroscopic Characterization -Identity A -	EP Identification A	Dark green to pale yellow or from light brown to reddishbrown with an aromatic odour.	Complies ⁴⁾
Microscopic Characterization -Identity B-	EP 2.8.23 Identification B	Diagnostic characters of numerous glandular or covering trichomes, free or attached to epidermis can be observed under microscope.	Complies ⁴⁾
HTLC -Identity C-	EP 2.8.25	Characteristics of intense /faint reddish-violet zones are detected in the chromatogram of the test solution, with Rf values corresponding to Rf values of the reddish-violet zones in the chromatogram of standard solutions of THC dominant type.	Complies ⁴⁾
Foreign Matter	EP 2.8.2	Maximum 2,0% w/w Absence of seed and any leaves with more than 1,0 cm in length	0% ⁴⁾
Loss on Drying	EP 2.2.32	≤ 10%	8,1 % ³⁾
Total Ash	EP 2.4.16	≤ 20%	11% ²⁾
Assay* THC Total CBD Total	EP 2.2.29	Minimum 5,0 % (Dried Drug) (Label Claim +/- 10%) Maximum 1,0% (Dried Drug)	21,6% ³⁾ <0,2% (LOQ) ³⁾
Related Substances: Cannabinol (CBN)*	EP 2.2.29	Maximum 1,0%	0,28% ⁵⁾
Heavy Metals	EP 2.4.27	Cd ≤ 0,3 ppm Pb ≤ 0,5 ppm Hg ≤ 0,1 ppm As ≤ 0,2 ppm	<0,14171 ppm (LOQ) ¹⁾ <0,004127 ppm (LOQ) ¹⁾ <0,000212 ppm (LOQ) ¹⁾ <0,020 ppm (LOQ) ¹⁾
Pesticides	EP 2.8.13	Complies with Eur. Ph. requirements	Complies ¹⁾

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Microbiology:			
TAMC		10 ⁵ CFU/g Maximum acceptable count: 500 000 CFU/g	1,00 X 10 ¹ CFU/g ⁴⁾
TYMC	EP 2.6.12 & 2.6.31 & 5.1.8C	≤ 10 ⁴ CFU/g Maximum acceptable count: 50 000 CFU/g	<10 CFU/g ⁴⁾
<i>Bile-tolerant gram (-) bacteria</i> <i>/Enterobacteriaceae</i>		≤ 10 ⁴ CFU/g	<10 CFU/g ⁴⁾
<i>Escherichia coli</i>		Absent/g	Absent/g ⁴⁾
<i>Salmonella</i>		Absent/25g	Absent/25g ⁴⁾
<i>P. aeruginosa</i>		Absent/g	Absent/g ⁴⁾
<i>S. aureus</i>	EP 2.6.13 & 5.1.4	Absent/g	Absent/g ⁴⁾
Mycotoxins:			
Aflatoxin B1	EP 2.8.18 & 2.8.22	≤ 2 µ g/kg	< 0,25 µ g/kg (LOD) ⁴⁾
Aflatoxins B1+B2+G1+G2		≤ 4 µ g/kg	< 0,25 µ g/kg (LOD) ⁴⁾
Ochratoxin A		≤ 20 µ g/kg	< 2 µ g/kg (LOD) ⁴⁾
Notes: * Expressed as THC CFU: Colony Forming Units TAMC - Total Aerobic Microbial Count TYMC - Total Yeast and Mold Count CoA-125-02 issued to reflect the CoA nr of the intermediate QC result		Observações/ Observations: 1) The results correspond to supplier raw material product (CoA No. CoAFP_240603_8057_006); 2) The results correspond to raw material product (CoA No.24/4561); 3) The results correspond to intermediate product (CoA No. 591/2024); 4) The results correspond to FP product (CoA No. 24/7297); 5) Subcontracted tests.	
		Informação de suporte/ Support Information: CoA do fornecedor (data de análise): CoA from the supplier (date of analysis): CoA No. CoAFP_240603_8057_006 (02/01/2024) [CoA No. 24/4561 (12/08/2024 to 03/09/2024) CoA No. 591/2024 (06/11/2024 to 12/11/2024) CoA No. 24/7297 (02/12/2024 to 10/12/2024)] ⁵⁾	
Condições de conservação: Manter a embalagem fechada, ao abrigo da luz e em ambiente seco. Manter em condições abaixo de 25 °C. <i>Storage conditions: Keep the package closed, away from light and in a dry environment. Keep in conditions below 25 °C.</i>			
Aprovação/ Approval			
☒ Conforme/ Comply Certifico que as informações acima são autênticas e corretas. Este lote de produto foi fabricado, embalado/rotulado e o controlo de qualidade, na(s) instalação(ões) acima referida(s), em total conformidade com os requisitos de BPF da autoridade reguladora local e com as especificações aprovadas. / I hereby certify that the above information is authentic and accurate. This batch of product has been manufactured, including packaging/labelling and quality control at the above mentioned site(s) in full compliance with the GMP requirements of the local Regulatory Authority and with the approved specifications.			
☐ Não Conforme/ Non-compliant			
Pessoa Autorizada/ <i>Authorized Person</i> Data, Nome e Assinatura: <i>Date, Name and Signature</i>		Digitally signed by ou=Quality Assurance - Qualified Person, @blossompharma.com, c=PT Date: 2025.02.11 15:46:13 Z	

DOCUMENT END

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