

CoA-134-01 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, Karoo, Mimosa, 10g jars		
Código do produto: Product code:	11608270		
Estirpe: Strain:	Mimosa		
Forma farmacêutica: Pharmaceutical form:	Cannabis flos		
Dosagem (Nota: alegação de rótulo): Strength (Note: label claim):	19:01 (THC/CBD)		
N.º Lote: Batch number:	11608270001		
N.º Lote do fornecedor (se matéria prima): Supplier batch number (if raw material):	NA		
Produto Irradiado Irradiated product	☒ Yes	☐ No	Data de irradiação: 25/06/2024 Irradiation date
Tamanho da embalagem: Package size:	10 g		
Especificação de referência: Specification reference:	SPEC-154		
Data de reteste/ validade: Retest/ expiry date:	09/2025		
Nome do cliente: Client name:	Therismos Limited		
Rótulo: Label:	THC 19 : CBD 01 : MIM		

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

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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	Pistils: Light Brown to Brown Sepals and Bracts: Dark Green to Bright Green covered with yellowish white hairs. Without grey/dark spots	Complies ⁵⁾
Microscopic Characterization -Identity B-	EP 2.8.23 Identification B	Presence of glandular trichomes	Complies ⁵⁾
HTLC -Identity C-	EP 2.8.25	Characteristics 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 ⁵⁾
Foreign Matter	EP 2.8.2	≤ 2% w/w Absence of seed and any leaves with more than 1,0cm in length.	0% ⁵⁾
Loss on Drying	EP 2.2.32	≤10%	9% ⁴⁾
Total Ash	EP 2.4.16	≤20%	10% ³⁾
Assay* THC Total ¹⁾ CBD Total ²⁾	EP 2.2.29	Minimum 5,0 % (Dried Drug) (Label Claim +/- 10%) Maximum 1,0% (Dried Drug)	18,7% ⁴⁾ <0,2% (LOQ) ⁴⁾
Related Substances: Cannabinol (CBN)*	EP 2.2.29	≤1,0%	0,4% ⁴⁾
Heavy Metals	EP 2.4.27	Cd ≤ 0,3 ppm Pb ≤ 0,5 ppm Hg ≤ 0,1 ppm As ≤ 0,2 ppm	<0,01 ppm ³⁾ <0,05 ppm ³⁾ <0,05 ppm ³⁾ <0,01 ppm ³⁾
Pesticides	EP 2.8.13	Complies with Eur. Ph. requirements	Complies ³⁾

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Microbiology:			
TAMC	Ph. Eur 2.6.12 & 5.1.4	≤10 ² CFU/g Maximum acceptable count: 200 CFU/g	<10 CFU/g ⁵⁾
TYMC		≤10 ¹ CFU/g Maximum acceptable count: 20 CFU/g	<10 CFU/g ⁵⁾
Bile-tolerant gram (-) bacteria /Enterobacteriaceae	Ph. Eur 2.6.31 & 5.1.4	Absent/g	Absent/g ⁵⁾
Escherichia coli		Absent/g	Absent/g ⁵⁾
Salmonella		Absent/25g	Absent/25g ⁵⁾
Pseudomonas Aeruginosa	Ph. Eur. 2.6.13 & 5.1.4	Absent/g	Absent/g ⁵⁾
Staphylococcus aureus		Absent/g	Absent/g ⁵⁾
Mycotoxins:			
Aflatoxin B1	EP 2.8.18 & 2.8.22	≤ 2 µ g/kg	< 0,25 µ g/kg (LOD) ⁵⁾
Aflatoxins B1+B2+G1+G2		≤ 4 µ g/kg	< 0,5 µ g/kg (LOQ) ⁵⁾
Ochratoxin A		≤ 20 µ g/kg	< 2 µ g/kg (LOD) ⁵⁾
Notes: * Expressed on dried basis 1) Total THC = THC+THCA (expressed as THC) As per German Monograph: THCA (expressed as THC) = THCA x 0.877 2) Total CBD = CBD + CBDA (expressed as CBD) As per German Monograph: CBDA (expressed as CBD) = CBDA x 0.877 CFU: Colony Forming Units TAMC - Total Aerobic Microbial Count TYMC - Total Yeast and Mold Count CoA-134-01 was issued to correct a typo in the micro spec.		Observações/ Observations: 3) The results correspond to supplier raw material (CoA No. 986 - 001); 4) The results correspond to intermediate (CoA No. 550/2024); 5) The results correspond to finished product (CoA No. 25/0454) 6) Subcontracted tests	
		Informação de suporte/ Support Information: CoA do fornecedor (data de análise): CoA from the supplier (date of analysis): [CoA No. 986 - 001 (15/04/2024) CoA No. 550/2024 (22/10/2024 to 28/10/2024) CoA No. 25/0454 (17/12/2024 to 06/01/2025)] ⁶⁾	
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/ Authorized Person Data, Nome e Assinatura: <i>Date, Name and Signature</i>		 Digitally signed by José Alves DN: cn=José Alves, o=Blossom Genetics, Lda, ou=Quality Assurance - Qualified Person, email=jalves@blossompharma.com, c=PT Date: 2025.02.19 17:52:50 Z	

DOCUMENT END

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