

CoA-079-00 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, Therismos, Pink Kush, 10g jars		
Código do produto: Product code:	1174870		
Estirpe: Strain:	Pink Kush		
Forma farmacêutica: Pharmaceutical form:	Cannabis flos		
Dosagem (Nota: alegação de rótulo): Strenght (Note: label claim):	25:1 (THC/CBD)		
N.º Lote: Batch number:	1174870001		
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-065		
Data de reteste/ validade: Retest/ expiry date:	05/2025		
Nome do cliente: Client name:	Therismos Limited		
Rótulo: Label:	THC 25 : CBD 01 : PIK		

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⁾
TLC -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 CBD A and THC A.	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	Maximum 12%	9% ³⁾
Total Ash	EP 2.4.16	≤20%	10% ⁴⁾
Assay* THC Total ¹⁾ CBD Total ²⁾	EP 2.2.29	Minimum 5,0 % (Dried Drug) Maximum 1,0% (Dried Drug) (Label Claim +/- 10%)	23,40% ³⁾ 0,06% ³⁾
Related Substances: Cannabinol (CBN)*	EP 2.2.29	Maximum 1,0%	0,02% ³⁾
Heavy Metals	EP 2.4.27	Cd ≤ 0,3 ppm Pb ≤ 0,5 ppm Hg ≤ 0,1 ppm As ≤ 0,2 ppm	Cd=0,020 ppm ³⁾ Pb<0,020 ppm (LOQ) ³⁾ Hg<0,050 ppm (LOQ) ³⁾ As<0,035 ppm ³⁾
Pesticides	EP 2.8.13	Complies	Complies ³⁾

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Microbiology:			
TAMC	Ph. Eur 2.6.12 & 5.1.8B	≤10 ⁴ CFU/g Maximum acceptable count: 50 000 CFU/g	7,00 x 10 ¹ CFU/g ⁴⁾
TYMC		≤10 ² CFU/g Maximum acceptable count: 500 CFU/g	<10 CFU/g ⁴⁾
Bile-tolerant gram (-) bacteria /Enterobacteriaceae	Ph. Eur 2.6.31 & 5.1.8B	≤10 ² CFU/g	<10 CFU/g ⁴⁾
Escherichia coli		Absent/g	Absent/g ⁴⁾
Salmonella		Absent/25g	Absent/25g ⁴⁾
Pseudomonas Aeruginosa	Ph. Eur. 2.6.13 & 5.1.4	Absent/g	Absent/g ⁴⁾
Staphylococcus aureus		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 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		Observações/ Observations: 3) The results correspond to raw material (CoA No. 24/2305); 4) The results correspond to finished product (CoA No. 24/4569) 5) Subcontracted tests	
		Informação de suporte/ Support Information: CoA do fornecedor (data de análise): CoA from the supplier (date of analysis): [CoA No. 24/2305 (29/04/2024 to 29/05/2024) CoA No. 24/4569 (12/08/2024 to 30/08/2024)] 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/ Authorized Person Data, Nome e Assinatura: <i>Date, Name and Signature</i>		 Assinado de forma digital por José Alves DN: cn=José Alves, o=Blossom Genetics, ou=Qualified Person - Quality Assurance, email=jalves@blossompharma.com, c=PT Dados: 2024.09.05 18:59:12 +01'00'	

DOCUMENT END

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