

CoA-048-01 Certificado de Análise



Source Document: CoA-YYY Certificate of Analysis

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Informação do Produto			
Product Information			
Descrição do produto: <i>Product description:</i>	Cannabis Dry Flower, Therismos, Atlantic Glue, 15g jars		
Código do produto: <i>Product code:</i>	1171171		
Estirpe: <i>Strain:</i>	Atlantic Glue		
Forma farmacêutica: <i>Pharmaceutical form:</i>	Cannabis flos		
Dosagem (Nota: alegação de rótulo): <i>Strenght (Note: label claim):</i>	30/01 (THC/CBD)		
N.º Lote: <i>Batch number:</i>	1171171002		
N.º Lote do fornecedor (se matéria prima): <i>Supplier batch number (if raw material):</i>	NA		
Produto Irrradiado <i>Irradiated product</i>	<input type="checkbox"/> Yes	<input checked="" type="checkbox"/> No	Data de irradiação: NA <i>Irradiation date</i>
Tamanho da embalagem: <i>Package size:</i>	15g		
Especificação de referência: <i>Specification reference:</i>	SPEC-052		
Data de reteste/ validade: <i>Retest/ expiry date:</i>	02/2025		
Nome do cliente: <i>Client name:</i>	Therismos GmbH		
Rótulo: <i>Label:</i>	30/1 Cannabisblüten Therismos ATG		

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			
Date of this document	Docum	Content of this document	Qual
27-05-2024	27/05/2024	27-05-2024	27-05-2024
Manager	Manager	Manager	Director

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Testes <i>Tests</i>	Métodos de Referência <i>Reference Methods</i>	Critérios de Aceitação <i>Acceptance Criteria</i>	
		Especificações <i>Specifications</i>	Resultados <i>Results</i>
Macroscopic Characterization -Identity A Identification A	Identification A German Pharmacopoeia (DAB Monograph "Cannabis Flower")	Pistils: Light Brown to Brown Sepals and Bracts: Dark Green to Bright Green covered with yellowish white hairs. Without grey/dark spots	Complies ⁶⁾
Microscopic Characterization -Identity B Identification B	Identification B German Pharmacopoeia (DAB Monograph "Cannabis Flower")	Presence of glandular trichomes	Complies ⁶⁾
Organoleptic Characteristics	Flower Properties	Brown green clustered flowers with characteristic smell of cannabis flowers	Complies ⁶⁾
TLC -Identity C Identification C	Identification C German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.27	In accordance with the reference standards	Complies ⁶⁾
Foreign Matter	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.8.2	≤ 2% w/w Absence of molds, insects, and other animal contamination	0% ⁶⁾
Loss on Drying	EP 2.2.32	≤ 10%	10% ⁵⁾
Assay* THC Total1) CBD Total2)	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	90 - 110 % label claim (27,0% – 33,0%) ≤ 1%	96,1% 28,83% ⁵⁾ 0,07% ⁵⁾
Related Substances: Cannabinol (CBN)*	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	≤ 1%	< 0,01% ⁵⁾
Heavy Metals	EP 2.4.27	Cd ≤ 1,0 ppm Pb ≤ 5,0 ppm Hg ≤ 0,1 ppm	Cd < 0,100 ppm (<LOQ) Pb < 0,010 ppm (<LOQ) Hg < 0,050 ppm (<LOQ) ⁴⁾
Pesticides	EP 2.8.13	Complies with Eur. Ph. requirements	Complies ⁴⁾

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27-05-2024	[Redacted]	Manager	27/05/2024	[Redacted]	Director

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Microbiology:			
TAMC	Ph. Eur 2.6.12 & 5.1.8C	≤10 ⁵ CFU/g Maximum acceptable count: 500 000 CFU/g	3,00 x 10 ¹ CFU/g ⁶⁾
TYMC		≤10 ⁴ CFU/g Maximum acceptable count: 50 000 CFU/g	<10 CFU/g ⁶⁾
<i>Bile-tolerant gram (-) bacteria</i> <i>/Enterobacteriaceae</i>	Ph. Eur 2.6.31 & 5.1.8C	≤10 ⁴ CFU/g	>10 ² and <10 ³ CFU/g ⁶⁾
<i>Escherichia coli</i>		Absent/g	Absent/g ⁶⁾
<i>Salmonella</i>		Absent/25g	Absent/25g ⁶⁾
Mycotoxins:			
Aflatoxin B1	EP 2.8.18 & 2.8.22	≤ 2 μ g/kg	< 0,25 μ g/kg (LOD) ⁶⁾
Aflatoxins B1+B2+G1+G2		≤ 4 μ g/kg	< 0,5 μ g/kg (LOQ) ⁶⁾
Ochratoxin		< 20 μ g/kg	< 2 μ g/kg (LOD) ⁶⁾
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: 4) The results correspond to raw material (CoA No. ABJ23848); 5) The results correspond to intermediate product (CoA No. 24/2306); 6) The results correspond to FP product (CoA No. 24/2864); 7) Subcontracted tests Version CoA-048-01 issued to correct a typo on TAMC and TYMC lines spec		Informação de suporte/ Support Information: CoA do fornecedor (data de análise): CoA from the supplier (date of analysis): CoA No. ABJ23848 (13/03/2024 to 18/03/2024), CoA No. 24/2306 (29/04/2024 to 22/05/2024), CoA No. 24/2864 (27/05/2024 to 07/06/2024) ⁷⁾	
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>			

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Date	Document	Author	Reviewer
27-05-2024	[Redacted]	[Redacted]	[Redacted]
27/05/2024	[Redacted]	[Redacted]	[Redacted]
27-05-2024	[Redacted]	[Redacted]	[Redacted]

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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

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: 2024.06.20 20:09:06 +01'00'

Data, Nome e Assinatura

Date, Name and Signature

DOCUMENT END

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Date	Name of this document	Docum	Content of this document	Qual	with the Quality System
27-05-2024	[Redacted]	27/05/2024	[Redacted]	27-05-2024	[Redacted]
	Quality compliance manager		ger		ector

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