

CoA-049-00 Certificado de Análise



Source Document: CoA-YYY Certificate of Analysis

Document source: Blossom Genetics Unipessoal Lda

Informação do Produto	
Descrição do produto: <i>Product description:</i>	Cannabis Dry Flower, Grow, Gelato Sherbert, 10g jars
Código do produto: <i>Product code:</i>	1252070
Estirpe: <i>Strain:</i>	Gelato Sherbert
Forma farmacêutica: <i>Pharmaceutical form:</i>	Cannabis flos
Dosagem (Nota: alegação de rótulo): <i>Strength (Note: label claim):</i>	30/01 (THC/CBD)
N.º Lote: <i>Batch number:</i>	1252070002
N.º Lote do fornecedor (se matéria prima): <i>Supplier batch number (if raw material):</i>	NA
Produto Irradiado <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>	10g
Especificação de referência: <i>Specification reference:</i>	SPEC-078
Data de reteste/ validade: <i>Retest/ expiry date:</i>	02/2025
Nome do cliente: <i>Client name:</i>	Nimbus Health GmbH
Rótulo: <i>Label:</i>	Medizinische Cannabisblüten DAB GROW 30 GS Kultivar Gelato Sherbert 10g

Fabricante/ Manufacturing Site:

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

Laboratório de Análise/ Testing Site:

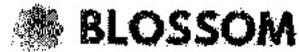
Qplab Pharma Services, Tec Labs – Centro de Inovação da FCUL, 1749-016 Lisboa, Portugal

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

FIM	
DOCUMENT APPROVALS	
27-05-2024	27-05-2024

BLOSSOM GENETICS
Estrada do Contador, 23 | 2130-017 Benavente | Portugal

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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
Microscopic Characterization -Identity B Identification B	Identification B German Pharmacopoeia (DAB Monograph "Cannabis Flower")	Presence of glandular trichomes	Complies
Organoleptic Characteristics	Flower Properties	Brown green clustered flowers with characteristic smell of cannabis flowers	Complies
TLC -Identity C Identification C	Identification C German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.27	In accordance with the reference standards	Complies
Foreign Matter	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.8.2	$\leq 2\%$ w/w Absence of molds, insects, and other animal contamination	0%
Loss on Drying	EP 2.2.32	8 - 10%	9% ⁴⁾
Assay* THC Total ¹⁾ CBD Total ²⁾	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	10 - 30% $\leq 1\%$	28,00% ⁴⁾ 0,07% ⁴⁾
Related Substances: Cannabinol (CBN)*	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	$\leq 1\%$	< 0,02% ⁴⁾
Heavy Metals	EP 2.4.27	Cd $\leq 1,0$ ppm Pb $\leq 5,0$ ppm Hg $\leq 0,1$ ppm As $\leq 3,0$ ppm	Not detected ³⁾ Not detected ³⁾ Not detected ³⁾ Not detected ³⁾
Pesticides	EP 2.8.13	Complies with Eur. Ph. requirements	Complies ³⁾

RFB

Fato - Caudam, PDI - Produto em estado: FMC - General layout: aplicable

RECEBIMOS O SEU PEDIDO DE ANÁLISE

27-04-2024	27-04-2024	27-04-2024
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Microbiology:			
TAMC	Ph. Eur 2.6.12 & 5.1.8C	≤10 ⁶ CFU/g Maximum acceptable count: 50.000 CFU/g	4,00 x 10 ³ CFU/g
TYMC		≤10 ⁴ CFU/g Maximum acceptable count: 500 CFU/g	1,10 x 10 ⁴ CFU/g
<i>Bile-tolerant gram (-) bacteria</i> <i>/Enterobacteriaceae</i>	Ph. Eur 2.6.31 & 5.1.8C	<10 ⁴ CFU/g	<10 CFU/g
<i>Escherichia coli</i>		Absent/g	Absent/g
<i>Salmonella</i>		Absent/25g	Absent/25g
<i>Staphylococcus aureus</i>	Ph. Eur 2.6.13 & 5.1.4	Absent/g	Absent/g
<i>Pseudomonas aeruginosa</i>		Absent/g	Absent/g
Mycotoxins:			
Aflatoxin B1	EP 2.8.18 & 2.8.22	≤ 2 μ g/kg	< 0,25 μ g/kg (LOD)
Aflatoxins B1+B2+G1+G2		≤ 4 μ g/kg	< 0,25 μ g/kg (LOD)
Ochratoxin		< 20 μ g/kg	< 2 μ g/kg (LOD)
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:		Informação de suporte/ Support information:	
3) The results correspond to API product (CoA No. 1702681141);		CoA do fornecedor (data de análise): CoA from the supplier (date of analysis):	
4) The results correspond to intermediate product (CoA No. 24/2155);		[CoA No. 1702681141 (06/12/2023 to 15/12/2023), CoA No. 24/2155 (15/04/2024 to 03/05/2024), CoA No. 24/2835 (27/05/2024 to 04/06/2024)] ⁵	
5) Subcontracted tests			
CoA No. 24/1675 (18/03/2024 to 09/04/2024), CoA No. 24/2155 (15/04/2024 to 03/05/2024), CoA No. 24/2835 (27/05/2024 to 04/06/2024)			
Condições de conservação:			
Manter a embalagem fechada, ao abrigo da luz e em ambiente seco. Manter em condições abaixo de 25 °C.			
Storage conditions: Keep the package closed, away from light and in a dry environment. Keep in conditions below 25 °C.			

F02			
PDA - Cannabis: Aze - Produto para consumo: BHC - Branco branco tratado			
LABORATORIO	DATA	LAB	QND
27-05-2024	27/05/2024		27-05-2024
Blossom Genetics			
Rua do Contador, 25 2103-317 Benavente (Portugal)			

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Aprovação Approval	
<input checked="" type="checkbox"/> Conforme! <i>Comply</i>	
<p>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.</p>	
<input type="checkbox"/> Não Conforme! <i>Non-compliant</i>	
Pessoa Autorizada <i>Authorized Person</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: 2024.07.05 16:00:43 +01'00'
Data, Nome e Assinatura <i>Date, Name and Signature</i>	

DOCUMENT END

R02			
BSC - Creation, R01 - Prepared into system, R02 - Approved for use			
DOCUMENT APPROVALS			
Request	User	Requester	Date
27-06-2024	[Redacted]	2024/07/05	27-06-2024

Blossom Genetics, 22 | 2500-017 | Barcelona | Portugal