

CoA-036-02 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, 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>Strenght (Note: label claim):</i>	30/01 (THC/CBD)		
N.º Lote: <i>Batch number:</i>	1252070001		
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>	10g		
Especificação de referência: <i>Specification reference:</i>	SPEC-078		
Data de reteste/ validade: <i>Retest/ expiry date:</i>	01/2025		
Nome do cliente: <i>Client name:</i>	Nimbus Health GmbH		
Rótulo: <i>Label:</i>	Medizinische Cannabisblüten DAB GROW 30 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

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

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	Conform
Microscopic Characterization -Identity B Identification B	Identification B German Pharmacopoeia (DAB Monograph "Cannabis Flower")	Presence of glandular trichomes	Conform
Organoleptic Characteristics	Flower Properties	Brown green clustered flowers with characteristic smell of cannabis flowers	Conform
TLC -Identity C Identification C	Identification C German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.27	In accordance with the reference standards	Conform
Foreign Matter	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.8.2	≤ 2% w/w Absence of molds, insects, and other animal contamination	0%
Loss on Drying	EP 2.2.32	8 - 10%	8% ⁵⁾
Assay* THC Total ¹⁾ CBD Total ²⁾	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	27 – 33% ≤ 1%	27,1% ⁵⁾ 0,07% ⁵⁾
Related Substances: Cannabinol (CBN)*	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	≤ 1%	< 0,02% ⁵⁾
Heavy Metals	EP 2.4.27	Cd ≤ 1,0 ppm Pb ≤ 5,0 ppm Hg ≤ 0,1 ppm As ≤ 3,0 ppm	Cd=0,005 ppm (LOQ) ⁴⁾ Pb<0,020 ppm (LOQ) ⁴⁾ Hg<0,050 ppm (LOQ) ⁴⁾ As< 0,020 ppm (LOQ) ⁴⁾
Pesticides	EP 2.8.13	Complies with Eur. Ph. requirements	Conform ⁴⁾

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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	1,5 x 10 ³ CFU/g
TYMC		≤10 ⁴ CFU/g Maximum acceptable count: 50 000 CFU/g	1,6 x 10 ³ CFU/g
<i>Bile-tolerant gram (-) bacteria /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)
<p>Notes:</p> <p>* Expressed on dried basis</p> <p>1) Total THC = THC + THCA (expressed as THC) As per German Monograph: THCA (expressed as THC) = THCA x 0.877</p> <p>2) Total CBD = CBD + CBDA (expressed as CBD) As per German Monograph: CBDA (expressed as CBD) = CBDA x 0.877</p> <p>CFU: Colony Forming Units TAMC - Total Aerobic Microbial Count TYMC - Total Yeast and Mold Count</p>			
<p>Observações/Observations:</p> <p>4) The results correspond to API product (CoA No. 069/2024, rev 03);</p> <p>5) The results correspond to intermediate product (CoA No. 24/1613);</p> <p>6) Subcontracted tests CoA No. 069/2024, rev 03 21/02/2024 to 22/03/2024; 26/02/2024 to 06/03/2024 CoA No. 24/1613 27/03/2024 to 01/04/2024 CoA No. 24/2153 15/04/2024 to 06/05/2024</p> <p>CoA-036-02 issued to align the THC Label Claim spec.</p>		<p>Informação de suporte/Support</p> <p>Information: Certificado de Análise do fornecedor/ Certificate of Analysis from the supplier/:</p> <p>CoA No. 069/2024 rev 03, CoA No. 24/1613, CoA No. 24/2153</p> <p>Data de Análise/ Date of Analysis: (21/02/2024 to 22/03/2024; 26/02/2024 to 06/03/2024; 27/03/2024 to 01/04/2024; 15/04/2024 to 06/05/2024)⁶</p>	
<p>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.</p>			

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Aprovação <i>Approval</i>	
<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>	
Data, Nome e Assinatura <i>Date, Name and Signature</i>	

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