

CoA-060-00 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, Pink Lilac, 10g jars	
Código do produto: <i>Product code:</i>	1252270	
Estirpe: <i>Strain:</i>	Pink Lilac	
Forma farmacêutica: <i>Pharmaceutical form:</i>	Cannabis flos	
Dosagem (Nota: alegação de rótulo): <i>Strength (Note: label claim):</i>	27/01 (THC/CBD)	
N.º Lote: <i>Batch number:</i>	1252270001	
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>	03/2025	
Nome do cliente: <i>Client name:</i>	Nimbus Health GmbH	
Rótulo: <i>Label:</i>	Medizinische Cannabisblüten DAB GROW 27 PL Kultivar Pink Lilac 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 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 <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 ⁵⁾
Microscopic Characterization Identity B Identification B	Identification B German Pharmacopoeia (DAB Monograph "Cannabis Flower")	Presence of glandular trichomes	Complies ⁵⁾
Organoleptic Characteristics	Flower Properties	Brown green clustered flowers with characteristic smell of cannabis flowers	Complies ⁵⁾
TLC Identity C Identification C	Identification C German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.27	In accordance with the reference standards	Complies ⁵⁾
Foreign Matter	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.8.2	≤ 2% w/w Absence of molds, insects, and other animal contamination	0% ⁵⁾
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	24.3 – 29,7% ≤ 1%	25,70% ⁴⁾ 0,06% ⁴⁾
Related Substances: Cannabinol (CBN)*	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	≤ 1%	0,02% ⁴⁾
Heavy Metals	EP 2.4.27	Cd ≤ 1,0 ppm Pb ≤ 5,0 ppm Hg ≤ 0,1 ppm As ≤ 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⁾

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Microbiology:			
TAMC	Ph. Eur 2.6.12 & 5.1.8C	$\leq 10^5$ CFU/g Maximum acceptable count: 50 000 CFU/g	$7,00 \times 10^1$ CFU/g ⁵⁾
TYMC		$\leq 10^4$ CFU/g Maximum acceptable count: 500 CFU/g	$7,00 \times 10^1$ CFU/g ⁵⁾
<i>Bile-tolerant gram (-) bacteria /Enterobacteriaceae</i>	Ph. Eur 2.6.31 & 5.1.8C	$\leq 10^4$ CFU/g	<10 CFU/g ⁵⁾
<i>Escherichia coli</i>		Absent/g	Absent/g ⁵⁾
<i>Salmonella</i>		Absent/25g	Absent/25g ⁵⁾
<i>Staphylococcus aureus</i>	Ph. Eur 2.6.13 & 5.1.4	Absent/g	Absent/g ⁵⁾
<i>Pseudomonas aeruginosa</i>		Absent/g	Absent/g ⁵⁾
Mycotoxins:			
Aflatoxin B1	EP 2.8.18 & 2.8.22	$\leq 2 \mu\text{g/kg}$	< 0,25 $\mu\text{g/kg}$ (LOD) ⁵⁾
Aflatoxins B1+B2+G1+G2		$\leq 4 \mu\text{g/kg}$	< 0,5 $\mu\text{g/kg}$ (LOD) ⁵⁾
Ochratoxin		$\leq 20 \mu\text{g/kg}$	< 2 $\mu\text{g/kg}$ (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			
Observações/Observations:		Informação de suporte/ Support Information:	
3) The results correspond to API product (CoA No. 1706655890);		CoA do fornecedor (data de análise): CoA from the supplier (date of analysis):	
4) The results correspond to intermediate product (CoA No. 24/2565);		CoA No. 1706655890 (24-01-2024 to 30-01-2024)	
5) The results correspond to finish product (CoA No. 24/3525);		CoA No. 24/2565 (07/05/2024 to 08/05/2024) ⁶⁾	
6) Subcontracted tests		CoA No. 24/3525 (25/06/2024 to 16/07/2024) ⁶⁾	
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.			

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Aprovação Approval	
<input checked="" type="checkbox"/> Conforme/ Comply	<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/ Non-compliant	
Pessoa Autorizada Authorized Person	
Data, Nome e Assinatura Date, Name and Signature	

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