

# CoA-153-01 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, GroVida, Runtz, 10g jars	
Código do produto: <i>Product code:</i>	12609370	
Estirpe: <i>Strain:</i>	Runtz	
Forma farmacêutica: <i>Pharmaceutical form:</i>	Cannabis flos	
Dosagem (Nota: alegação de rótulo): <i>Strenght (Note: label claim):</i>	22/1 (THC/CBD)	
N.º Lote: <i>Batch number:</i>	12609370001	
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>	10 g	
Especificação de referência: <i>Specification reference:</i>	SPEC-054	
Data de reteste/ validade: <i>Retest/ expiry date:</i>	09/2025	
Nome do cliente: <i>Client name:</i>	BALANCIAL GmbH	
Rótulo: <i>Label:</i>	BALANCIAL 22/1 PT RUNTZ	

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

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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 <sup>4)</sup>
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 <sup>4)</sup>
HPTLC -Identity C-	EP 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 THC dominant type.	Complies <sup>4)</sup>
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% <sup>4)</sup>
Loss on Drying	EP 2.2.32	≤12%	9,3% <sup>3)</sup>
Total Ashes	EP 2.4.16	≤20%	9% <sup>2)</sup>
Assay <sup>a)</sup> THC Total CBD Total	EP 2.2.29	≥ 5,0% (Nominal content +/- 10%) ≤ 1%	22,6% <sup>3)</sup> <0,2% (LOQ) <sup>3)</sup>
Related Substances: Cannabinol (CBN) <sup>a)</sup>	EP 2.2.29	≤ 1,0%	0,15% <sup>3)</sup>
Heavy Metals	EP 2.4.27	Cd ≤ 0,3 ppm Pb ≤ 0,5 ppm Hg ≤ 0,1 ppm As ≤ 0,2 ppm	0,007 ppm <sup>1)</sup> <0,020 ppm (LOQ) <sup>1)</sup> <0,050 ppm (LOQ) <sup>1)</sup> <0,020 ppm (LOQ) <sup>1)</sup>
Pesticides	EP 2.8.13	Complies	Complies <sup>1)</sup>

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Microbiology:			
TAMC		≤10 <sup>5</sup> CFU/g Maximum acceptable count: 500 000 CFU/g	1,10 X10 <sup>2</sup> CFU/g <sup>4</sup>
TYMC		≤10 <sup>4</sup> CFU/g Maximum acceptable count: 50 000 CFU/g	6,00 X10 <sup>1</sup> CFU/g <sup>4</sup>
<i>Bile-tolerant gram (-) bacteria</i> <i>/Enterobacteriaceae</i>	Ph. Eur 2.6.12 & 5.1.8C	≤10 <sup>4</sup> CFU/g	Initial Sampling: >10 <sup>4</sup> CFU/g <sup>4</sup> New Sampling (1): <10 CFU/g <sup>4</sup> >10 <sup>2</sup> and <10 <sup>3</sup> CFU/g <sup>4</sup> <10 CFU/g <sup>4</sup> New Sampling (2): >10 <sup>1</sup> and <10 <sup>2</sup> CFU/g <sup>4</sup> <10 CFU/g <sup>4</sup> <10 CFU/g <sup>4</sup> <sup>b</sup>
<i>Escherichia coli</i>		Absent/g	Absent/g <sup>4</sup>
<i>Salmonella</i>		Absent/25g	Absent/25g <sup>4</sup>
<i>P. aeruginosa</i>	Ph. Eur 2.6.13 & 5.1.4	Absent/g	Absent/g <sup>4</sup>
<i>Staphylococcus aureus</i>		Absent/g	Absent/g <sup>4</sup>
Mycotoxins:			
Aflatoxin B1		≤ 2 μ g/kg	< 0,25 μ g/kg (LOD) <sup>4</sup>
Aflatoxins B1+B2+G1+G2	EP 2.8.18 & 2.8.22	≤ 4 μ g/kg	< 0,5 μ g/kg (LOQ) <sup>4</sup>
Ochratoxin A		≤ 20 μ g/kg	< 2 μ g/kg (LOD) <sup>4</sup>
<b>Notes:</b> a) Expressed as THC/CBD b) OOS2025/01393; CFU: Colony Forming Units TAMC - Total Aerobic Microbial Count TYMC - Total Yeast and Mold Count Rev01 issued to correct a typo in reference methods for Identity B and Identity C.		<b>Observações/ Observations:</b> 1) The results correspond to supplier raw material (GV240016); 2) The results correspond to raw material (CoA No. 24/5031); 3) The results correspond intermediate product (CoA No. 594/2024) 4) The results correspond to the finished product (CoA No. 25/0141) 5) Subcontracted tests	
		<b>Informação de suporte/ Support Information:</b> CoA do fornecedor (data de análise): CoA from the supplier (date of analysis): CoA No. GV240016 (19/08/2024) [CoA No. 25/5031 (02/09/2024 to 24/09/2024) CoA No. 594/2024 (06/11/2024 to 12/11/2024) CoA No. 25/0141 (19/12/2024 to 14/02/2025)] <sup>5</sup>	
<b>Condições de conservação: Manter a embalagem fechada, ao abrigo da luz e em ambiente seco. Manter em condições abaixo de 25 °C.</b> Storage conditions: Keep the package closed, away from light and in a dry environment. Keep in conditions below 25 °C.			
Aprovação/ Approval			
<input checked="" type="checkbox"/> <b>Conforme/ Comply</b> 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.			
<input type="checkbox"/> <b>Não Conforme/ Non-compliant</b>			
<b>Pessoa Autorizada/ Authorized Person</b>  Data, Nome e Assinatura: Date, Name and Signature			

DOCUMENT END

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