

CoA-047-02 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, Therismos, Sensi Double Kush, 15g jars		
Código do produto: <i>Product code:</i>	1170771		
Estirpe: <i>Strain:</i>	Sensi Double Kush		
Forma farmacêutica: <i>Pharmaceutical form:</i>	Cannabis flos		
Dosagem (Nota: alegação de rótulo): <i>Strenght (Note: label claim):</i>	24/01 (THC/CBD)		
N.º Lote: <i>Batch number:</i>	1170771002		
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>	24/1 Cannabisblüten Therismos SDK		

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 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 (21,6% – 26,4%) ≤ 1%	107,2% 25,72% 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	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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Microbiology:			
TAMC	Ph. Eur 2.6.12 & 5.1.8C	≤10 ⁵ CFU/g Maximum acceptable count: 500 000 CFU/g	3,10 x 10 ³ CFU/g ⁶⁾
TYMC		≤10 ⁴ CFU/g Maximum acceptable count: 50 000 CFU/g	3,60 x 10 ³ 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 ¹ and <10 ² 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⁾
<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 raw material (CoA No. ABJ33222);</p> <p>5) The results correspond to intermediate product (CoA No. 24/2307);</p> <p>6) The results correspond to FP product (CoA No. 24/2812);</p> <p>7) Subcontracted tests</p> <p>Version CoA-047-02 issued to correct a typo on TAMC and TYMC lines spec</p>		<p>Informação de suporte/ Support Information:</p> <p>CoA do fornecedor (data de análise): <i>CoA from the supplier (date of analysis):</i> CoA No. ABJ33222 (13/03/2024 to 18/03/2024), CoA No. 24/2307 (29/04/2024 to 07/05/2024), CoA No. 24/2812 (21/05/2024 to 27/05/2024)⁷⁾</p>	
<p>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></p>			

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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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