

CoA-054-00 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, Therismos, Bruce Banner, 50g jars		
Código do produto: <i>Product code:</i>	1170975		
Estirpe: <i>Strain:</i>	Bruce Banner		
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>	1170975002		
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>	50g		
Especificação de referência: <i>Specification reference:</i>	SPEC-053		
Data de reteste/ validade: <i>Retest/ expiry date:</i>	03/2025		
Nome do cliente: <i>Client name:</i>	Therismos GmbH		
Rótulo: <i>Label:</i>	30/1 Cannabisblüten Therismos BRB		

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 <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	≤10%	9% ⁴⁾
Assay* THC Total ¹⁾ CBD Total ²⁾	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	90 - 110 % label claim (27% – 33%) ≤ 1%	97,0% 29,10% ⁴⁾ 0,08% 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	Cd<0,104 ppm (<LOQ) ³⁾ Pb<0,0998 ppm (<LOQ) ³⁾ Hg<0,050 ppm (<LOQ) 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	≤10 ⁵ CFU/g Maximum acceptable count: 500 000 CFU/g	1,00X10 ¹ CFU/g ⁵⁾
TYMC		≤10 ⁴ CFU/g Maximum acceptable count: 50 000 CFU/g	1,00X10 ¹ CFU/g ⁵⁾
<i>Bile-tolerant gram (-) bacteria</i> <i>/Enterobacteriaceae</i>	Ph. Eur 2.6.13 & 5.1.8C	≤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⁾
Mycotoxins:			
Aflatoxin B1	EP 2.8.18 & 2.8.22	≤ 2 μ g/kg	< 0,25 μ g/kg (LOD) ⁵⁾
Aflatoxins B1+B2+G1+G2		≤ 4 μ g/kg	< 0,25 μ g/kg (LOD) ⁵⁾
Ochratoxin		< 20 μ g/kg	< 2 μ 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 raw material (CoA No. ABJ11877); ⁴⁾ The results correspond to intermediate product (CoA No. 24/2308); ⁵⁾ The results correspond to FP product (CoA No. 24/3257); ⁶⁾ Subcontracted tests		CoA do fornecedor (data de análise): <i>CoA from the supplier (date of analysis):</i> [CoA No. ABJ11877 (12/03/2024 to 18/03/2024), CoA No. 24/2308 (29/04/2024 to 29/05/2024), CoA No. 24/3257 (11/06/2024 to 24/06/2024)] ⁶⁾	
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>			

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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	

DOCUMENT END

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FRM-053-02 Liberação de Lote



FRM-053-02 Batch Release

Source Document: *SOP-053 Liberação de Lotes*

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Document Approvals

Approved by	Signature	Position	Date
Author – Confirming the technical content of this document			
Rute Coelho		Quality Assurance Manager	15/02/2024
Document Owner – Confirming the technical content of this document			
Rute Coelho		Quality Assurance Manager	15/02/2024
Quality – Confirming compliance of this document with the Quality System			
José Alves		Quality Assurance Director	15-02-2024
Effective Date	15-02-2024	Review Date	15-02-2024

FRM-053-02 Libertação de Lote

FRM-053-02 Batch Release

Source Document: SOP-053 Libertação de Lotes

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Este FRM é preenchido após verificação da documentação de lote pelo QA (FRM-053-01) para atestar a libertação de lote para um cliente específico (confirmando que os requisitos acordados com cliente foram cumpridos)./ This FRM is completed after checking the batch documentation by QA (FRM-053-01) to certify the batch release for a specific customer (confirming that the requirements agreed with the customer have been met).

Nº Lote/ Batch number: 1170975002			
Descrição/nome /Description/name: Cannabis Dry Flower, Therismos, Bruce Banner 50g jars 30/1 Cannabisblüten Therismos BRB			
Dosagem/ Strength: 30/1 (THC/CBD)			
Forma farmacêutica/ Pharmaceutical form: Cannabis flos			
Dosagem (análise de produto acabado) / Strength (finished product analysis): 29,1% THC / 0,08% CBD			
Tamanho da embalagem /Package size: 50g			
Data de fabrico /Manufacturing date: 06-06-2024			
Data de validade/ Expiry date: 03/2025			
Nome do Cliente/ Client name or Quality Agreement: THERISMOS GmbH			
Referência da especificação de libertação /Release Specification Reference: SPEC-053			
País Importador/ Importing Country: Germany			
Número de Autorização de Marketing/ Marketing Authorisation Number: PZN - 19175541			
Fabricante/ Manufacturing Site: Blossom Genetics, 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 - Rua das Ferrarias del Rei, n.º 6, 2730-269 Barcarena, Portugal			
Controlo Analítico/ Analytical Control	Documentação/ Documentation	Responsabilidade/ Responsibility	Verif por/ Data/ Verified by/ Date
Os resultados analíticos (Raw data) estão disponíveis e foram revistos pelo Controlo da Qualidade/ Garantia da Qualidade confirmando que os resultados obtidos estão de acordo com limites definidos na especificação./ The analytical results (Raw data) are available and have been reviewed by Quality Control/Quality Assurance confirming that the results obtained are in accordance with the limits defined in the specification.	Raw data	QC/QA	 08-07-2024
O Certificado de Análise foi revisto pelo Quality Assurance Manager e encontra-se conforme a especificação./ The Certificate of Analysis was reviewed by the Quality Assurance Manager and is in accordance with specification.	Nº Certificado de Análise/ Certificate Analysis No.: CoA-054-00	QA	 08-07-2024
Desvios revistos pela Garantia da Qualidade, se aplicável./ Deviations associated reviewed by Quality Assurance, if applicable.	Desvio(s) N.º/ Deviation(s) No.	QC/ QA	 08-07-2024


FRM-053-02 Liberação de Lote

FRM-053-02 Batch Release

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DEV-023/24		
Requisitos específicos / Specific Requirements		
Verificação de requisitos específicos do cliente e do <i>Quality Agreement</i> <i>Observações relevantes/ Verification of customer-specific requirements and the Quality Agreement</i> Relevant observations: NA	QA	 08-07-2024
Libertação de lote para cliente / Batch release to client		
<input checked="" type="checkbox"/> Aprovado/ <i>Approved</i> <input type="checkbox"/> Rejeitado/ <i>Rejected</i>		
<p>Certifico que as informações acima são autênticas e precisas. Este lote de produto foi fabricado, incluindo embalagem/rotulagem e controlo de qualidade no(s) local(is) acima mencionado(s) em total conformidade com os requisitos das BPF da Autoridade Reguladora Portuguesa (INFARMED) e com os requisitos da Autorização de Introdução no Mercado/ Registo do país importador. Os registos do processamento, embalagem e análise do lote foram revistos e considerados conformes com as BPF.</p> <p><i>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 Portuguese Regulatory Authority (INFARMED) and with the definitions in the Marketing Authorisation/ Registry of the importing country. The batch documentation regarding processing, packaging and quality control analysis records were reviewed and found to be in compliance with GMP.</i></p>		
Qualified Person _____ Nome a Assinatura / <i>Name and Signature</i>	Data/ <i>Date</i> _____	

1. Uma cópia deste documento, depois de assinado deve ser enviado para a Supply Chain, confirmando a libertação do lote / A copy of this document, once signed, must be sent to Supply Chain, confirming the release of the batch.

2. Este documento deverá ficar arquivado junto do Master Batch Record do lote / This document must be filed with the batch's Master Batch Record.

FRM-053-02 Liberação de Lote

FRM-053-02 Batch Release

Source Document: *SOP-053 Liberação de Lotes*

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Change History

Version Number	Date	Change Number	Description of Changes
02	Fevereiro/ February 2024	N/AP	Inclusion of the "Approved/Rejected" decision.
01	Fevereiro/ February 2024	N/AP	Document translation. Inclusion of the fields: Strength, Manufacturing date, Expiry date, Importing country, Marketing Authorization number, Manufacturing Site and Testing Site.
00	Janeiro 2023	N/AP	Initial version

Template reference: *TMP-001-04_Form Template (Portrait)_r01*

DOCUMENT END

Betreff:*Subject*

30/1 Cannabisblüten Therismos BRB – 15g, Ch.-B.: 1170971002

30/1 Cannabisblüten Therismos BRB – 50g, Ch.-B.: 1170975002

Vertriebsland: Deutschland

*Destination country***Sehr geehrte Damen und Herren,***To whom it may concern*

Hiermit zertifiziere ich, dass alle Herstellungsstufen dieser Fertigproduktchargen in voller Übereinstimmung mit den Anforderungen der Guten Herstellungspraxis der EU und mit den Anforderungen der Genehmigung(en) für das Inverkehrbringen im Zielland durchgeführt wurden.

I hereby certify that all the manufacturing stages of this batches of finished products have been carried out in full compliance with the GMP requirements of the EU and with the requirements of the Marketing Authorisation(s) of the destination country.

Datum, Name und**Unterschrift***Date, name, and signature***/Sachkundige Person/***Qualified Person*