

CoA-032-01 Certificado de Análise/ Certificate of Analysis



Source Document: *CoA-YYY Certificate of Analysis*

Document Approvals

Approved by	Signature	Position	Date
Author – Confirming the technical content of this document			
Rute Coelho		Quality Assurance Manager	24/11/2023
Document Owner – Confirming the technical content of this document			
Rute Coelho		Quality Assurance Manager	24/11/2023
Quality – Confirming compliance of this document with the Quality System			
José Alves		Quality Assurance Director	24-11-2023
Effective Date	24-11-2023	Review Date	24-11-2023

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Informação do Produto <i>Product Information</i>			
Descrição do produto: <i>Product description:</i>	Cannabis Dry Flower, Therismos, Bruce Banner, 15g jars		
Código do produto: <i>Product code:</i>	1170971		
Estirpe: <i>Strain:</i>	Bruce Banner		
Forma farmacêutica: <i>Pharmaceutical form:</i>	Cannabis flos		
N.º Lote: <i>Batch number:</i>	1170971001		
N.º Lote do fornecedor: <i>Supplier batch number:</i>	NA		
Produto Irrradiado <i>Irradiated product</i>	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	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>	08/2024		
Nome do cliente: <i>Client name:</i>	Therismos GmbH		
Nome do produto do cliente: <i>Client product name:</i>	25/1 Cannabisblüten Therismos BRB		

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

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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 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 ⁴⁾
Microscopic Characterization -Identity B-	Identification B German Pharmacopoeia (DAB Monograph "Cannabis Flower")	Presence of glandular trichomes	Conform ⁴⁾
Organoleptic Characteristics	Flower Properties	Brown green clustered flowers with characteristic smell of cannabis flowers	Conform ⁴⁾
TLC -Identity C –	Identification C German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.27	In accordance with the reference standards	Conform ⁴⁾
Foreign Matter	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.8.2	≤ 2% w/w Absence of molds, insects, and other animal contamination	0% ⁴⁾
Loss on Drying	EP 2.2.32	≤ 10%	8,0% ⁵⁾
Assay ¹⁾ THC Total ²⁾	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	90 - 110 % label claim (22,5% – 27,5%)	100,0% 25,0% ⁵⁾
CBD Total ³⁾		≤ 1%	0,06% ⁵⁾
Related Substances: Cannabinol (CBN) ¹⁾	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	≤ 1,0%	0,05% ⁵⁾

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Heavy Metals	EP 2.4.27	Cd ≤ 1,0 ppm Pb ≤ 5,0 ppm Hg ≤ 0,1 ppm	Cd = 0,013 ppm ⁴⁾ Pb < 0,020 ppm (LOQ) ⁴⁾ Hg < 0,050 ppm (LOQ) ⁴⁾
Pesticides	EP 2.8.13	Complies with Eur. Ph. requirements	Complies ⁴⁾
Microbiology:			
TAMC	Ph. Eur 2.6.12 & 5.1.8C	≤ 10 ⁵ CFU/g Maximum acceptable count: 500 000 CFU/g	8,0x10 ² CFU/g
TYMC		≤ 10 ⁴ CFU/g Maximum acceptable count: 50 000 CFU/g	3,0x10 ¹ CFU/g
Bile-tolerant gram (-) bacteria /Enterobacteriaceae	Ph. Eur 2.6.31 & 5.1.8C	≤ 10 ⁴ CFU/g	<10 ¹ CFU/g
Escherichia coli		Absent/g	Absent/g
Salmonella		Absent/25g	Absent/25g
Mycotoxins:			
Aflatoxin B1	EP 2.8.18 & 2.8.22	≤ 2 μ g/kg	< 1 μ g/kg (LOD) ⁴⁾
Aflatoxins B1+B2+G1+G2		≤ 4 μ g/kg	< 2 μ g/kg (LOD) ⁴⁾
Ochratoxin		< 20 μ g/kg	< 5 μ g/kg (LOD) ⁴⁾
<p>Notes:</p> <p>1) Expressed on dried basis</p> <p>2) Total THC = THC + THCA (expressed as THC) As per German Monograph: THCA (expressed as THC) = THCA x 0.877</p> <p>3) 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. 046/2024 rev01);</p> <p>5) The results correspond to Intermediate product (CoA No. 24/0959);</p> <p>6) Subcontracted tests</p> <p>CoA No. 046/2024 rev01 02/01/2024 to 11/01/2024; 08/01/2024 to 02/02/2024 CoA No. 24/0959 21/02/2024 to 26/02/2024 CoA No. 24/1247 21/02/2024 to 13/03/2024</p>		<p>Informação de suporte/Support Information:</p> <p>Certificado de Análise do fornecedor/ <i>Certificate of Analysis from the supplier:</i> CoA No. 046/2024 rev01; CoA No. 24/0959; CoA 24/1247</p> <p>Data de Análise/ <i>Date of Analysis:</i>: 02/01/2024 to 11/01/2024; 08/01/2024 to 02/02/2024; 21/02/2024 to 26/02/2024; 21/02/2024 to 13/03/2024⁶⁾</p>	

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Issued version 01 of the CoA due to a typo in the expiration date.

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.

Aprovação

Approval

X Conforme / *Comply*

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.*

Não Conforme / *Non-compliant*

Pessoa Autorizada

Authorized Person

Data

Date

Nome e assinatura

Name and Signature

DOCUMENT END

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 Liberação de Lote



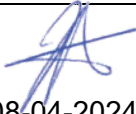
FRM-053-02 Batch Release

Source Document: SOP-053 Liberação de Lotes

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Este FRM é preenchido após verificação da documentação de lote pelo QA (FRM-053-01) para atestar a liberação 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: 1170971001			
Descrição/nome /Description/name: Cannabis Dry Flower, Therismos, Bruce Banner, 15g jars/ 25/1 Cannabisblüten Therismos BRB			
Dosagem/ Strength: 25/1 (THC/CBD)			
Forma farmacêutica/ Pharmaceutical form: Cannabis flos			
Dosagem (análise de produto acabado) / Strength (finished product analysis): 25,0% THC/ 0,06% CBD			
Tamanho da embalagem /Package size: 15g			
Data de fabrico /Manufacturing date: 29-02-2024			
Data de validade/ Expiry date: 08/2024			
Nome do Cliente/ Client name or Quality Agreement: THERISMOS GmbH			
Referência da especificação de liberação /Release Specification Reference: SPEC-052			
País Importador/ Importing Country: Germany			
Número de Autorização de Marketing/ Marketing Authorisation Number: PZN - 19175512			
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	 08-04-2024
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.: <u>CoA-032-01</u>	QA	 08-04-2024
Desvios revistos pela Garantia da Qualidade, se aplicável./ Deviations associated reviewed by Quality Assurance, if applicable.	Desvio(s) N.º/ Deviation(s) No. Dev 011/2024	QC/ QA	 08-04-2024


FRM-053-02 Liberação de Lote

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Requisitos específicos / <i>Specific Requirements</i>		
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> <i>Relevant observations:</i> Second issuance of the CoC to add the German product name; Updated the CoA nr,	QA	 08-04-2024
Libertação de lote para cliente / <i>Batch release to client</i>		
<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.

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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

25/1 Cannabisblüten Therismos BRB – 15 g, Ch.-B.: 1170971001

25/1 Cannabisblüten Therismos BRB – 50 g, Ch.-B.: 1170975001

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