

# CoA-031-00 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>	
<b>Descrição do produto:</b> <i>Product description:</i>	Cannabis Dry Flower, Therismos, Bruce Banner, 50g jars
<b>Código do produto:</b> <i>Product code:</i>	1170975
<b>Estirpe:</b> <i>Strain:</i>	Bruce Banner
<b>Forma farmacêutica:</b> <i>Pharmaceutical form:</i>	Cannabis flos
<b>N.º Lote:</b> <i>Batch number:</i>	1170975001
<b>N.º Lote do fornecedor:</b> <i>Supplier batch number:</i>	NA
<b>Produto Irradiado</b> <i>Irradiated product</i>	Yes <input type="checkbox"/> No X <b>Data de irradiação NA</b> <i>irradiation date</i>
<b>Tamanho da embalagem:</b> <i>Package size:</i>	50g
<b>Especificação de referência:</b> <i>Specification reference:</i>	SPEC-053
<b>Data de reteste/validade:</b> <i>Retest/expiry date:</i>	09/2024
<b>Nome do cliente:</b> <i>Client name:</i>	Therismos GmbH
<b>Nome do produto do cliente:</b> <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 <sup>4)</sup>
Microscopic Characterization -Identity B-	Identification B German Pharmacopoeia (DAB Monograph "Cannabis Flower")	Presence of glandular trichomes	Conform <sup>4)</sup>
Organoleptic Characteristics	Flower Properties	Brown green clustered flowers with characteristic smell of cannabis flowers	Conform <sup>4)</sup>
TLC -Identity C –	Identification C German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.27	In accordance with the reference standards	Conform <sup>4)</sup>
Foreign Matter	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.8.2	≤ 2% w/w Absence of molds, insects, and other animal contamination	0% <sup>4)</sup>
Loss on Drying	EP 2.2.32	≤ 10%	8,0% <sup>5)</sup>
Assay <sup>1)</sup> THC Total <sup>2)</sup>	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	90 - 110 % label claim (22,5% – 27,5%)	100,0% 25,0% <sup>5)</sup>
CBD Total <sup>3)</sup>		≤ 1%	0,06% <sup>5)</sup>
Related Substances: Cannabinol (CBN) <sup>1)</sup>	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	≤ 1,0%	0,05% <sup>5)</sup>

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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 <sup>4)</sup> Pb < 0,020 ppm (LOQ) <sup>4)</sup> Hg < 0,050 ppm (LOQ) <sup>4)</sup>
[Pesticides]	EP 2.8.13	Complies with Eur. Ph. requirements	Complies <sup>4)</sup>
<b>Microbiology:</b>			
[TAMC]	Ph. Eur 2.6.12 & 5.1.8C	≤ 10 <sup>5</sup> CFU/g Maximum acceptable count: 500 000 CFU/g	9,0x10 <sup>2</sup> CFU/g
[TYMC]		≤ 10 <sup>4</sup> CFU/g Maximum acceptable count: 50 000 CFU/g	1,0x10 <sup>1</sup> CFU/g
[Bile-tolerant gram (-) bacteria /Enterobacteriaceae]	Ph. Eur 2.6.31 & 5.1.8C	≤ 10 <sup>4</sup> CFU/g	<10 <sup>1</sup> CFU/g
[Escherichia coli]		Absent/g	Absent/g
[Salmonella]		Absent/25g	Absent/25g
<b>Mycotoxins:</b>			
[Aflatoxin B1]	EP 2.8.18 & 2.8.22	≤ 2 μ g/kg	< 1 μ g/kg (LOD) <sup>4)</sup>
[Aflatoxins B1+B2+G1+G2]		≤ 4 μ g/kg	< 2 μ g/kg (LOD) <sup>4)</sup>
[Ochratoxin]		< 20 μ g/kg	< 5 μ g/kg (LOD) <sup>4)</sup>
<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><b>Observações/Observations:</b></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><b>CoA No. 046/2024 rev01</b> 02/01/2024 to 11/01/2024; 08/01/2024 to 02/02/2024</p> <p><b>CoA No. 24/0959</b> 21/02/2024 to 26/02/2024</p> <p><b>CoA No. 24/1248</b> 21/02/2024 to 13/03/2024</p>		<p><b>Informação de suporte/Support Information:</b></p> <p>[Certificado de Análise do fornecedor/ Certificate of Analysis from the supplier]: <b>CoA No. 046/2024 rev01; CoA No. 24/0959</b></p> <p>Data de Análise/ Date of Analysis: [ 02/01/2024 to 11/01/2024; 08/01/2024 to 02/02/2024; 21/02/2024 to 26/02/2024<sup>6)</sup> ]</p>	

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**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*

**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
<b>Effective Date</b>	15-02-2024	<b>Review Date</b>	15-02-2024

# FRM-053-02 Libertação de Lote

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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).

<b>Nº Lote/ Batch number: 1170975001</b>			
<b>Descrição/nome /Description/name: Cannabis Dry Flower, Therismos, Bruce Banner, 50g jars/ 25/1 Cannabisblüten Therismos BRB</b>			
<b>Dosagem/ Strength: 25/1 (THC/CBD)</b>			
<b>Forma farmacêutica/ Pharmaceutical form: Cannabis flos</b>			
<b>Dosagem (análise de produto acabado) / Strength (finished product analysis): 25,0% THC/ 0,06% CBD</b>			
<b>Tamanho da embalagem /Package size: 50g</b>			
<b>Data de fabrico /Manufacturing date: 01-03-2024</b>			
<b>Data de validade/ Expiry date: 09/2024</b>			
<b>Nome do Cliente/ Client name or Quality Agreement: THERISMOS GmbH</b>			
<b>Referência da especificação de libertação /Release Specification Reference: SPEC-053</b>			
<b>País Importador/ Importing Country: Germany</b>			
<b>Número de Autorização de Marketing/ Marketing Authorisation Number: PZN - 19175529</b>			
<b>Fabricante/ Manufacturing Site: Blossom Genetics, Estrada do Contador, 23 2130-017 Benavente, Portugal</b> <b>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</b>			
<b>Controlo Analítico/ Analytical Control</b>	<b>Documentação/ Documentation</b>	<b>Responsabilidade/ Responsibility</b>	<b>Verif por/ Data/ Verified by/ Date</b>
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.: <b>CoA-031-00</b>	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. <b>NA</b>	QC/ QA	 08-04-2024


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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	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><b>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.</b></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.*

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Datum, Name und

Unterschrift

*Date, name, and signature*

*/Sachkundige Person/*

*Qualified Person*