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

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

Informação do Produto *Product Information*			
Descrição do produto: *Product description:*	Cannabis Dry Flower, Therismos, Dr Lime, 15g jars		
Código do produto: *Product code:*	1170871		
Estirpe: *Strain:*	Dr Lime		
Forma farmacêutica: *Pharmaceutical form:*	Cannabis flos		
N.º Lote: *Batch number:*	1170871001		
N.º Lote do fornecedor: *Supplier batch number:*	NA		
Produto Irradiado *Irradiated product*	**Yes** ☐	**No** X	**Data de irradiação** NA *Irradiation date*
Tamanho da embalagem: *Package size:*	15g		
Especificação de referência: *Specification reference:*	SPEC-052		
Data de reteste/validade: *Retest/expiry date:*	07/2024		
Nome do cliente: *Client name:*	Therismos GmbH		
Nome do produto do cliente: *Client product name:*	24/1 Cannabisblüten Therismos DRL		

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

Testes *Tests*	**Métodos de Referência** *Reference Methods*	**Critérios de Aceitação** *Acceptance Criteria*	
		Especificações *Specifications*	**Resultados** *Results*
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
Microscopic Characterization -Identity B-	Identification B German Pharmacopoeia (DAB Monograph "Cannabis Flower")	Presence of glandular trichomes	Conform
Organoleptic Characteristics	Flower Properties	Brown green clustered flowers with characteristic smell of cannabis flowers	Conform
TLC -Identity C –	Identification C German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.27	In accordance with the reference standards	Conform
Foreign Matter	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.8.2	≤ 2% w/w Absence of molds, insects, and other animal contamination	0%
Loss on Drying	EP 2.2.32	≤10%	9,2%
Assay[1)] THC Total[2)] CBD Total[3)]	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	90 - 110 % label claim (21,6% – 26,4%) ≤ 1%	101,3% 24,3%[4)] <0,15% (LOQ)
Related Substances: Cannabinol (CBN) [1)]	German Pharmacopoeia (DAB Monograph "Cannabis Flower") EP 2.2.29	≤ 1,0%	< 0,05% (LOD)

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Heavy Metals	EP 2.4.27	Cd ≤ 1,0 ppm Pb ≤ 5,0 ppm Hg ≤ 0,1 ppm	Cd = 0,008 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	1,1x10^3 CFU/g
TYMC		≤ 10^4 CFU/g Maximum acceptable count: 50 000 CFU/g	1,0x10^1 CFU/g
Bile-tolerant gram (-) bacteria /Enterobacteriaceae	Ph. Eur 2.6.31 & 5.1.8C	≤ 10^4 CFU/g	< 10 CFU/g
Escherichia coli		Absent/g	Absent/g
Salmonella		Absent/25g	Absent/25g
Mycotoxins:			
Aflatoxin B1	EP 2.8.18 & 2.8.22	≤ 2 μg/kg	< 1 μg/kg (LOD) [4)]
Aflatoxins B1+B2+G1+G2		≤ 4 μg/kg	< 2 μg/kg (LOD) [4)]
Ochratoxin		< 20 μg/kg	< 5 μg/kg (LOD) [4)]

Notes:
[1)] Expressed on dried basis
[2)] Total THC = THC + THCA (expressed as THC)
As per German Monograph: THCA (expressed as THC) = THCA x 0.877
[3)] 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:*

[4)] The results correspond to API product (**CoA No. 045/2024rev02)**;

[5)] Subcontracted tests
CoA No. 045/2024 rev02
22/01/2024 to 08/02/2024; 24/01/2024 to 14/02/2024

CoA No. 047/2024, rev01
02/01/2024 to 11/01/2024; 08/01/2024 to 02/02/2024

Informação de suporte/*Support Information:*

Certificado de Análise do fornecedor/

Certificate of Analysis from the supplier/: **CoA No. 045/2024 rev02**; **CoA No. 047/2024, rev01**

Data de Análise/ *Date of Analysis:*: 22/01/2024 to 08/02/2024; 24/01/2024 to 14/02/2024; 02/01/2024 to 11/01/2024; 08/01/2024 to 02/02/2024[5)]

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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 ºC.

Storage conditions: Keep the package closed, away from light and in a dry environment. Keep in conditions below 25 ºC.

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* Nome e assinatura *Name and Signature*		Assinado de forma digital por José Alves DN: cn=José Alves, o=Blossom Genetics, ou=Qualified Person - Quality Assurance, email=jalves@blossompharma.com, c=PT Dados: 2024.03.01 20:14:44 Z
		Data *Date*

DOCUMENT END

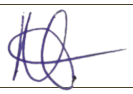
Blossom Genetics
Estrada do Contador, 23 2130-017 Benavente, Portugal

FRM-053-02 Libertação de Lote

FRM-053-02 Batch Release

Source Document: ***SOP-053 Libertação de Lotes***

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***

Este FRM é preenchido após verificação da documentação de lote pelo QA (FRM-053-01) para atestar a libertação de lote para um cliente especifico (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*****: 1170871001**
Descrição/nome /*Description/name*: Cannabis Dry Flower, Therismos, Dr Lime, 15g jars
Dosagem/ ***Strenght*****: 24/1 (THC/CBD)**
Forma farmacêutica/ ***Pharmaceutical form*****: Cannabis flos**
Dosagem (análise de produto acabado) / ***Strength (finished product analysis):*** **24,3% THC/ <0,15% CBD**
Tamanho da embalagem /*Package size*: 15g
Data de fabrico ***/Manufacturing date:*** ***15-01-2024***
Data de validade/ ***Expiry date:*** **07-2024**
Nome do Cliente/ ***Client*** **name or *Quality Agreement*: THERISMOS GmbH**
Referência da especificação de libertação /*Release Specification Reference*: SPEC-052
País Importador/ ***Importing Country*****: Germany**
Número de Autorização de Marketing/ ***Marketing Authorisation Number*****: PZN - 19175475**
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/** ***Responsability***	**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	04-03-2024
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-028-00	QA	04-03-2024
Desvios revistos pela Garantia da Qualidade, se aplicável./ *Deviations associated reviewed by Quality Assurance, if applicable.*	Desvio(s) N.º/ *Deviation(s) No.* **NA**	QC/ QA	04-03-2024

	_____		
Requisitos específicos / *Specific Requirements*			
Verificação de requisitos específicos do cliente e do *Quality Agreement* *Observações relevantes/ Verification of customer-specific requirements and the Quality Agreement* *Relevant observations:* ***NA***		QA	 04-03-2024
Libertação de lote para cliente / *Batch release to client*			

☑ Aprovado/ *Approved*

☐ Rejeitado/ *Rejected*

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.

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.

Qualified Person _____ Nome a Assinatura /*Name and Signature*	 Assinado de forma digital por José Alves DN: cn=José Alves, o=Blossom Genetics, ou=Qualified Person - Quality Assurance, email=jalves@blossompharma.com, c=PT Dados: 2024.03.04 12:51:40 Z	Data/ *Date* _____

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.

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
24/1 Cannabisblüten Therismos DRL – 15 g, Ch.-B.: 1170871001
24/1 Cannabisblüten Therismos DRL – 50 g, Ch.-B.: 1170875001
28/1 Cannabisblüten Therismos SDK – 15 g, Ch.-B.: 1170771001
28/1 Cannabisblüten Therismos SDK – 50 g, Ch.-B.: 1170775001
30/1 Cannabisblüten Therismos ATG – 15 g, Ch.-B.: 1171171001

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.

Assinado de forma digital por José Alves
DN: cn=José Alves, o=Blossom Genetics, ou=Qualified Person - Quality Assurance, email=jalves@blossompharma.com, c=PT
Dados: 2024.03.04 15:19:12 Z

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