CoA-161-02 Certificado de Análise

Source Document: ***CoA-YYY Certificate of Analysis***

Informação do Produto *Product Information*			
Descrição do produto: *Product description:*	Cannabis Dry Flower, Therismos, Legendary Bozy, 15g jars		
Código do produto: *Product code:*	11711071		
Estirpe: *Strain:*	Legendary Bozy		
Forma farmacêutica: *Pharmaceutical form:*	Cannabis flos		
Dosagem (Nota: alegação de rótulo): *Strenght (Note: label claim):*	32/1 (THC/CBD)		
N.º Lote: *Batch number:*	11711071001		
N.º Lote do fornecedor (se matéria prima): *Supplier batch number (if raw material):*	NA		
Produto Irradiado *Irradiated product*	☐ **Yes**	☒ **No**	**Data de irradiação:** NA *Irradiation date*
Tamanho da embalagem: *Package size:*	15 g		
Especificação de referência: *Specification reference:*	SPEC-052		
Data de reteste/ validade: *Retest/ expiry date:*	11/2025		
Nome do cliente: *Client name:*	Therismos GmbH		
Rótulo: *Label:*	WELLFORD AQUAPONIC 32/1 LBO CANNABISBLÜTEN		

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

Testes *Tests*	**Métodos de Referência** *Reference Methods*	**Critérios de Aceitação** *Acceptance Criteria*	
		Especificações *Specifications*	**Resultados** *Results*
Macroscopic Characterization -Identity A-	EP Identification A	Dark green to pale yellow or from light brown to reddish-brown with an aromatic odour.	Complies[4)]
Microscopic Examination -Identity B-	EP 2.8.23 Identification B	Diagnostic characters of numerous glandular or covering trichomes, free or attached to epidermis can be observed under microscope.	Complies[4)]
HPTLC -Identity C-	EP 2.8.25	Characteristics of intense /faint reddish-violet zones are detected in the chromatogram of the test solution, with Rf values corresponding to Rf values of the reddish-violet zones in the chromatogram of standard solutions of THC dominant type.	Complies[4)]
Foreign Matter	EP 2.8.2	Maximum 2,0% w/w Absence of seed and any leaves with more than 1,0 cm in length	0%[4)]
Loss on Drying	EP 2.2.32	Max. 12%	10%[4)]
Assay*: THC Total [1)] CBD Total [2)]	EP 2.2.29	Minimum 5,0 % (Label Claim +/- 10%) Maximum 1,0%	29,52%[4)] 0,17%[4)]
Related Substances: Cannabinol (CBN)*	EP 2.2.29	Maximum 1,0%	<0,05% (LOQ)[4)]
Heavy Metals	EP 2.4.27	Cd ≤ 0,3 ppm Pb ≤ 0,5 ppm Hg ≤ 0,1 ppm As ≤ 0,2 ppm	<0,1004 ppm (LOQ)[3)] <0,0998 ppm (LOQ)[3)] <0,0500 ppm (LOQ)[3)] <0,1004 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	4,00 x 10^1 CFU/g[4)]
TYMC		≤ 10^4 CFU/g Maximum acceptable count: 50 000 CFU/g	1,00 x 10^1 CFU/g[4)]
Bile-tolerant gram (-) bacteria /Enterobacteriaceae	Ph. Eur 2.6.31 & 5.1.8C	≤ 10^4 CFU/g	<10 CFU/g[4)]
Escherichia coli	Ph. Eur. 2.6.13 & 5.1.4	Absent/g	Absent/g[4)]
Salmonella		Absent/25g	Absent/25g[4)]
Mycotoxins:			
Aflatoxin B1	EP 2.8.18 & 2.8.22	≤ 2 µg/kg	< 0,25 μ g/kg (LOD)[4)]
Aflatoxins B1+B2+G1+G2		≤ 4 µg/kg	< 0,5 μ g/kg (LOQ)[4)]
Ochratoxin		≤ 20 µg/kg	< 2 μ g/kg (LOD)[4)]

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
CoA-161-02 is issued to reference the assay of the final product.

Observações/ ***Observations:***
[3)] The results correspond to supplier raw material (**CoA No. ABM18500**);
[4)] The results correspond to finished product (**CoA No. 25/1563**);
[5)] Subcontracted tests.

Informação de suporte/ ***Support Information:***

CoA do fornecedor (data de análise)/: *CoA from the supplier (date of analysis):*
CoA No. ABM18500 (14/08/2024 to 16/08/2024)
[**CoA No. 25/1563** (11/02/2025 to 28/02/2025)][5]

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*

☒ **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, Nome e Assinatura:
Date, Name and Signature

[redacted]

DOCUMENT END

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 [redacted]		
Quality Compliance Manager	Quality Assurance Manager	Quality Assurance Director

FRM-053-02 Libertação de Lote

FRM-053-02 Batch Release

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

N.º Lote/ *Batch Number*: 11711071001			
Descrição do Produto/ *Product Description*: Cannabis Dry Flower, Therismos, Legendary Bozy, 15g jars			
Nome do Produto/ *Product Name*: WELLFORD AQUAPONIC 32/1 LBO; CANNABISBLÜTEN			
Alegação no Rótulo/ *Label Claim*: 32/1 (THC/CBD)	**Dosagem (análise de produto acabado)/** *Strength (finished product analysis):* 29,52% THC/0,17% CBD		
Referência da especificação de libertação/ *Release Specification Reference*: SPEC-052			
Forma farmacêutica/ *Pharmaceutical form*: Cannabis flos	**Produto Irradiado/** *Irradiated product*:	☐ Sim/*Yes* *(Ver CoA/ See CoA)*	☑ Não/*No*
Tamanho da embalagem/ *Package size*: 15 g	**Unidades de produto libertas/** *Product units released*: 638 jars		
Data de fabrico/ *Manufacturing date*: 07/02/2025	**Data de validade/** *Expiry date*: 11/2025		
Nome do Cliente/ *Client name* or ***Quality Agreement***: Therismos GmbH	**País Importador/** *Importing Country*: Germany		
Certificado Importação/ *Importing Certificate*: E 05991/2025	**Certificado Exportação/** *Exporting Certificate*: N.º 2020 / 25		
Número de Autorização de Marketing (se aplicável)/ *Marketing Authorisation Number (if applicable)*: PZN-19781069			
Condições de conservação/ *Storage conditions:* Manter a embalagem fechada, ao abrigo da luz e em ambiente seco. Conservar a temperatura inferior a 25ºC. / *Keep the package closed, away from light and in a dry environment. Keep in conditions below 25 ºC.*			
Fabricante/ *Manufacturing Site:* Blossom Genetics, Estrada do Contador 23, 2130-017 Benavente, Portugal (GMP Certificate Number: F084/S1/MH/001/2023, F084/S1/SA/001/2023). **Laboratório de Análise/** *Testing Site:* Qplab Pharma Services, Tec Labs - Centro de Inovação da FCUL, 1749-016 Lisboa, Portugal (GMP Certificate Number: F067/S1/MG/001/2022); LEF - Rua das Ferrarias del Rei, n.º 6, 2730-269 Barcarena, Portugal (GMP Certificate Number: F032/S1/MH/001/2022).			

Controlo Analítico/ *Analytical Control*	**Documentação/** *Documentation*	**Responsabilidade/** *Responsability*	**Revisto/** *Revised*
Os resultados analíticos (*Raw data*) estão disponíveis e foram revistos pelo Controlo de 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.*	***Resultados de Controlo Qualidade**/ Quality Control Results*	OP/QC/QA	☑
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.*	N.º Certificado de Análise Blossom/ *Blossom Certificate Analysis No.:* CoA-161-02	QA/QP	☑
Desvios revistos pela Garantia da Qualidade, se aplicável./ *Deviations associated reviewed by Quality Assurance, if applicable.*	Desvio(s) N.º/ *Deviation(s) Nr.* NA	QA	☑
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	☑

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, data e assinatura/ *Name, date and signature*	[redacted]

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

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).

DOCUMENT END

R05

R00(Jan23) Creation; **R01(Feb24)** Document translation.Inclusion of the fields: Strength, Manufacturing date, Expiry date, Importing country, Marketing Authorization number, Manufacturing Site and Testing Site. **R02(Feb24)** Inclusion of the "Approved/Rejected" decision; **R03(Jul24)** Inclusion of the "Product name", "Product units released", "Label". Inclusion of "Documents Approvals".Inclusion of LEF as an Analysis Laboratory. Remove point 1 from the notes. **R04(Aug24)** inclusion GMP certificates of Blossom and external qualified laboratories. **R05(Jan25)** inclusion Import and Export certificates: General Layout revision to 1 page document;

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
[redacted] 2024		
Quality Assurance Manager	Quality Compliance Manager	Quality Assurance Director

BLOSSOM

Betreff:
Subject
WELLFORD AQUAPONIC 32/1 LBO Cannabisblüten – 15g, Ch.-B.: 11711071001
WELLFORD AQUAPONIC 23/1 GTH Cannabisblüten – 50g, Ch.-B.: 11712675001
WELLFORD AQUAPONIC 32/1 LBO Cannabisblüten – 50g, Ch.-B.: 11711075001
WELLFORD PEAK 28/1 CA PKM Cannabisblüten – 50g, Ch.-B.: 11710475002
WELLFORD PEAK 28/1 CA PKM Cannabisblüten – 15g, Ch.-B.: 11710471002
WELLFORD PEAK 30/1 CA T95 Cannabisblüten – 15g, Ch.-B.: 11712771001
WELLFORD PEAK 30/1 CA T95 Cannabisblüten – 50g, Ch.-B.: 11712775001
30/1 Cannabisblüten Therismos CJU – 15g, Ch.-B.: 11710571001
33/1 Cannabisblüten Therismos PKM – 15g, Ch.-B.: 11710471001

Vertriebsland: Deutschland
Destination country: Germany

Sehr geehrte Damen und Herren,
To whom it may concern

Hiermit zertifiziere ich, dass alle Herstellungsstufen dieser Fertigproduktchargen in vo ller 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.

[redacted]

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