

CERTIFICADO DE LIBERTAÇÃO DE LOTE
BATCH RELEASE CERTIFICATE

Nome do Produto <i>Product name</i>	Cannabisdestillat Hybrid THC 72- 88%
Composição THC: CBD <i>THC: CBD Composition</i>	THC 72- 88%
Apresentação <i>Presentation</i>	500 mL amber glass flasks
N.º de Lote <i>Batch Number</i>	D0315
Prazo de validade ou Prazo de reteste <i>Expire date or Retest date</i>	30/04/2027
Quantidade <i>Quantity</i>	1 unit
Fabricado por Licença nº <i>Manufactured by authorization number</i>	INFARMED authorization Nº 42/V04 from 12/10/2024 GMP Manufacture authorization number F081/001/2025 from 09/06/2025
País de destino <i>Destination country</i>	Germany
Controlo de Mudança <i>Change Control</i>	Not Applicable
Desvios <i>Deviations</i>	Not Applicable
OOS/OOT <i>OOS/OOT</i>	Not Applicable
Observações <i>Remarks</i>	CoA nº 2503986

DECLARAÇÃO DE CERTIFICAÇÃO DE LIBERTAÇÃO
RELEASE CERTIFICATION STATEMENT

Certifico que a informação acima e anexa (CoA) é autêntica e correta.
Este lote foi fabricado, embalado e testado localmente em total cumprimento das Boas Práticas de Fabrico (BPFs) e dos requisitos da Autoridade Reguladora Local e de acordo com os termos descritos com Canymed GmbH em acordo técnico de Qualidade de 01/07/2024

*I certify that the enclosed and attached (CoA) information is authentic and correct.
This batch has been manufactured, packaged, and tested locally in full compliance with Good Manufacturing Practices (GMP's) and requirements of the Local Regulatory Authority and with the terms described in the Quality technical agreement with Canymed GmbH of 01/07/2024*

Carregado, 28 de Julho 2025 / Carregado, 28th July 2025

SOMAI PHARMACEUTICALS LDA.

NIPC: 516 217 127

Lugar de Casal Pinheiro - Urb. Pinheiros Park II

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2580-507 Carregado

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Direção Técnica/Technical Director/Qualified Person

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Mod.025/02

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Certificate of Analysis

Specification	ESP-007/12
Product	Cannabisdestilat Hybrid THC 72-88%
Code	FDF0105
Batch no.	D0315
Date of Analysis	28/07/2025

CoA no.	2503986
Manufacturing date	30/04/2025
Expiry date	30/04/2027
Presentation	500 g amber glass flasks
Bulk batch no.	D0160

TEST	Method	Acceptance Criteria	Results
Appearance	MA-008	Yellow to amber, solid at room temperature	Complies
Identification: HPLC	MA-008 / DAB	The chromatograms of the sample solution obtained in the assay test must show the main peaks with a retention time similar to the chromatograms of the standard solution	Positive
Identification: TLC	MA-008	The sequence of zones in the chromatograms of the reference solution and the test solution are similar	Positive
Water	MA-008	≤ 0.5 %	0.05 %
Cannabinoids			
Δ ⁹ -THC	MA-008 / DAB	Report value	83.4 %
Δ ⁹ -THCA	MA-008 / DAB	Report value	< 0.03 (LOD) %
Total THC [THC + (THCA x 0.877)]	MA-008 / DAB	90.0 % to 110.0 % of the label content	104.2 % (83.4 % w/w)
CBD	MA-008 / DAB	Report value	0.60 %
CBDA	MA-008 / DAB	Report value	< 0.03 (LOD) %
Total CBD [CBD + (CBDA x 0.877)]	MA-008 / DAB	≤ 2.0 %	0.60 %
CBN	MA-008 / DAB	≤ 2.5 %	0.44 %
Other cannabinoid (Together with any corresponding acid)	MA-008 / DAB	Report value	3.8 %
Total other cannabinoids	MA-008 / DAB	Report value	12.1 %
Mycotoxins			
Aflatoxin B1	MA-008 / Ph.Eur.2.8.18	≤ 2 µg/Kg	< 0.25 (LOD) µg/Kg
Aflatoxins (B1+B2+G1+G2)	MA-008 / Ph.Eur.2.8.18	≤ 4 µg/Kg	< 0.25 (LOD) µg/Kg
Ochratoxin A	MA-008 / Ph.Eur.2.8.22	≤ 20 µg/Kg	< 2 (LOD) µg/Kg
Heavy Metals			
Arsenic (As) *	MA-008 / Ph.Eur.2.4.27	≤ 0.2 ppm	< 0.020 (LOQ) ppm
Cadmium (Cd) *	MA-008 / Ph.Eur.2.4.27	≤ 0.3 ppm	< 0.005 (LOQ) ppm
Lead (Pb) *	MA-008 / Ph.Eur.2.4.27	≤ 0.5 ppm	< 0.020 (LOQ) ppm
Mercury (Hg) *	MA-008 / Ph.Eur.2.4.27	≤ 0.1 ppm	< 0.050 (LOQ) ppm
Nickel (Ni) *	MA-008 / Ph.Eur.2.4.27	Indicative	< 2.000 (LOQ) ppm
Zinc (Zn) *	MA-008 / Ph.Eur.2.4.27	Indicative	< 3.996 (LOQ) ppm
Pesticides			
Pesticides *	MA-008 / Ph.Eur.2.8.13	Complies with Ph.Eur.2.8.13	Complies
Residual solvents			
Ethanol	MA-008 / Ph.Eur.5.4.	< 5000 ppm	< 312.5 (LOD) ppm



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CoA no.	2503986
Manufacturing date	30/04/2025
Expiry date	30/04/2027
Presentation	500 g amber glass flasks
Bulk batch no.	D0160

TEST	Method	Acceptance Criteria	Results
Microbial Quality			
TAMC - Total aerobic microbial count	MA-008 / Ph.Eur.2.6.12. & Ph.Eur.5.1.4.	$\leq 10^3$ CFU/g	$< 10^3$ CFU/g
TYMC - Total combined yeast & mould count	MA-008 / Ph.Eur.2.6.12. & Ph.Eur.5.1.4.	$\leq 10^2$ CFU/g	$< 10^2$ CFU/g
Bile-tolerant gram-negative bacteria	MA-008 / Ph.Eur.2.6.13 & Ph.Eur. 5.1.4.	$\leq 10^2$ CFU/g	< 10 CFU/g
<i>Escherichia coli</i>	MA-008 / Ph.Eur.2.6.13 & Ph.Eur. 5.1.4.	Absence in 1 g	Absence /g
<i>Salmonella</i>	MA-008 / Ph.Eur.2.6.13 & Ph.Eur. 5.1.4.	Absence in 25 g	Absence /25g

Comments

Results in compliance with the specification.

(*)Result reported from LEF (CoA 25/3301)

Status:
Approved

Signed by:
Sofia Crispim
Quality Control Supervisor
28/07/2025 18:54

Application of electronic signature