



CERTIFICADO DE LIBERTAÇÃO DE LOTE
BATCH RELEASE CERTIFICATE

Nome do Produto/Produç name	Somai Cannabisextrakt Hybrid 25:1 (THC:CBD)
ComposiçãoTHC:CBD/THC:CBD <i>Composition</i>	25:1 (THC:CBD)
Apresentação/Presentation	500 mL amber glass
N.º de Lote/Batch Number	C0043
Nº de CoA/ CoA Number	nº2400898
Prazo de validade ou Prazo de reteste/Expire date or Retest date	31/01/2025
Quantidade/Quantity	26 units
Fabricado por Licença nº / <i>Manufactured by authorization number</i>	INFARMED authorization N° 42/V02 from 14/09/2023 GMP Manufacture authorization number F081/001/2024 from 19/12/2023
Pais de destino/Destination country	Germany
Observações/Remarks	Not applicable

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 26/02/2024**

*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 26/02/2024*

Carregado, 11 Março 2024
Carregado, 11 th March , 2024

Dália I.R.Gonçalves

Direção Técnica/Technical Director/Qualified Person



Certificate of Analysis

Specification	ESP-131/00
Product	Somai Cannabisextrakt Hybrid 25:1 (THC:CBD)
Code	FDF0008
Batch no.	C0043
Date of Analysis	04/03/2024

CoA no.	2400898
Manufacturing date	29/01/2024
Expiry date	31/01/2025
Presentation	500 mL amber glass flasks
Bulk batch no.	C0023

TEST	Method	Acceptance Criteria	Results
Appearance	MA-008	Slightly to yellowish liquid	Complies
Identification: HPLC	MA-008	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	Positive
Identification: TLC	MA-008	The sequence of zones in the chromatograms of the reference solution and the test solution are similar	Positive
Relative density	MA-008	Informative value	0.948
Water	MA-008	≤ 0.5 %	0.06 %
Cannabinoids			
Δ⁹-THC	MA-008 / DAB	Report value	25.21 mg/mL
Δ⁹-THCA	MA-008 / DAB	Report value	< 0.003 (LOD) mg/mL
Total THC [THC+(THCAx0.877)]	MA-008 / DAB	90.0 % to 110.0 % of the label claim	100.8 % (25.21 mg/mL)
CBD	MA-008 / DAB	Report value	0.26 mg/mL
CBDA	MA-008 / DAB	Report value	< 0.003 (LOD) mg/mL
Total CBD [CBD+(CBDAx0.877)]	MA-008 / DAB	< 1.00 mg/mL	0.26 mg/mL
CBN	MA-008 / DAB	≤ 1.0 %	0.03 %
Other cannabinoid (Together with any corresponding acid)	MA-008 / DAB	≤ 2.0 %	0.13 %
Total other cannabinoids	MA-008 / DAB	Report value	0.47 %
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) *	Ph.Eur.2.4.27	≤ 1.0 ppm	< 0.020 (LOQ) ppm
Cadmium (Cd) *	Ph.Eur.2.4.27	≤ 0.5 ppm	< 0.005 (LOQ) ppm
Lead (Pb) *	Ph.Eur.2.4.27	≤ 5.0 ppm	< 0.020 (LOQ) ppm
Mercury (Hg) *	Ph.Eur.2.4.27	≤ 0.1 ppm	< 0.050 (LOQ) ppm
Nickel (Ni) *	Ph.Eur.2.4.27	Indicative	< 2.000 (LOQ) ppm
Zinc (Zn) *	Ph.Eur.2.4.27	Indicative	< 3.996 (LOQ) ppm
Pesticides			
Pesticides *	Ph.Eur.2.8.13	Complies with Ph.Eur.2.8.13	Complies



Certificate of Analysis

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Bulk batch no.	C0023

TEST	Method	Acceptance Criteria	Results
Residual solvents			
Ethanol *	Ph.Eur.5.4	< 5000 ppm	< 2228.5 (LOQ) ppm
Microbial Quality			
TAMC - Total aerobic microbial count	MA-008 / Ph.Eur.2.6.12. & Ph.Eur.5.1.4.	$\leq 10^3$ CFU/mL	< 10 CFU/mL
TYMC - Total combined yeast & mould count	MA-008 / Ph.Eur.2.6.12. & Ph.Eur.5.1.4.	$\leq 10^2$ CFU/mL	< 10 CFU/mL
Bile-tolerant gram-negative bacteria	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	$\leq 10^2$ CFU/mL	< 10 CFU/mL
Escherichia coli	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 1 mL	Absence/mL
Salmonella	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 10 mL	Absence/10mL
Staphylococcus aureus	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 1 mL	Absence/mL

Comments

Results in compliance with the specification.

Mycotoxins, Heavy Metals, Pesticides and Ethanol were performed on the purified extract batch.

(*)Result reported from LEF (CoA 23/5477)

Approved By:

Iva Vinhas

Quality Control Director

11/03/2024 14:14

Application of electronic signature