



## Certificate of Analysis

Specification	ESP-046/02
Product	Oral Solution THC:CBD 5:20 mg/mL IND 30 mL TE DE CNFY
Code	FDF0013
Batch no.	C0179
Date of Analysis	06/06/2024

CoA no.	2402679
Manufacturing date	08/04/2024
Expiry date	31/10/2025
Presentation	30 mL amber glass vials with screw cap
Bulk batch no.	C0074

TEST	Method	Acceptance Criteria	Results
Appearance	MA-008	Colourless to slightly yellowish liquid	Complies
Deliverable Volume	MA-008	Mean volume $\geq$ 30 mL; Individual volume $\geq$ 28.5 mL	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	0.949
Water	MA-008	$\leq$ 0.5 %	0.03 %
<b>Cannabinoids</b>			
$\Delta^9$ -THC	MA-008 / DAB	Report value	5.07 mg/mL
$\Delta^9$ -THCA	MA-008 / DAB	Report value	< 0.003 (LOD) mg/mL
Total THC [THC + (THCA x 0.877)]	MA-008 / DAB	90.0 % to 110.0 % of the label claim	101.5 % (5.07 mg/mL)
CBD	MA-008 / DAB	Report value	19.80 mg/mL
CBDA	MA-008 / DAB	Report value	0.02 mg/mL
Total CBD [CBD + (CBDA x 0.877)]	MA-008 / DAB	90.0 % to 110.0 % of the label claim	99.1 % (19.82 mg/mL)
CBN	MA-008 / DAB	$\leq$ 1.0 %	0.01 %
Other cannabinoid (Together with any corresponding acid)	MA-008 / DAB	$\leq$ 2.0 %	0.15 %
Total other cannabinoids	MA-008 / DAB	Report value	0.35 %
<b>Mycotoxins</b>			
Aflatoxin B1	MA-008 / Ph.Eur.2.8.18	$\leq$ 2 $\mu$ g/Kg	< 0.25 (LOD) $\mu$ g/Kg
Aflatoxins (B1+B2+G1+G2)	MA-008 / Ph.Eur.2.8.18	$\leq$ 4 $\mu$ g/Kg	< 0.25 (LOD) $\mu$ g/Kg
Ochratoxin A	MA-008 / Ph.Eur.2.8.22	$\leq$ 20 $\mu$ g/Kg	< 2 (LOD) $\mu$ g/Kg
<b>Heavy Metals</b>			
Arsenic (As) *	Ph.Eur.2.4.27	$\leq$ 1.0 ppm	< 0.020 (LOQ) ppm
Cadmium (Cd) *	Ph.Eur.2.4.27	$\leq$ 0.5 ppm	< 0.005 (LOQ) ppm
Lead (Pb) *	Ph.Eur.2.4.27	$\leq$ 5.0 ppm	< 0.020 (LOQ) ppm
Mercury (Hg) *	Ph.Eur.2.4.27	$\leq$ 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
<b>Pesticides</b>			
Pesticides *	Ph.Eur.2.8.13	Complies with Ph.Eur.2.8.13	Complies



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

(\*)Result reported from LEF (CoA 24/1091)

**Status:**

Approved

**Signed by:**

Iva Vinhas

Quality Control Director

07/06/2024 08:32

*Application of electronic signature*