



Certificate of Analysis

Specification	ESP-053/05
Product	Oral Solution 25:<1 mg/mL IND 30 mL TE DE CNFY
Code	FDF0014
Batch no.	C0181
Date of Analysis	07/06/2024

CoA no.	2402685
Manufacturing date	08/04/2024
Expiry date	31/10/2025
Presentation	30 mL amber glass vials with screw cap
Bulk batch no.	C0075

TEST	Method	Acceptance Criteria	Results
Appearance	MA-008	Slightly to 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 %
Cannabinoids			
Δ^9 -THC	MA-008 / DAB	Report value	24.99 mg/mL
Δ^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	100.0 % (24.99 mg/mL)
CBD	MA-008 / DAB	Report value	0.23 mg/mL
CBDA	MA-008 / DAB	Report value	0.004 mg/mL
Total CBD [CBD + (CBDA x 0.877)]	MA-008 / DAB	< 1.00 mg/mL	0.24 mg/mL
CBN	MA-008 / DAB	\leq 1.0 %	0.03 %
Other cannabinoid (Together with any corresponding acid)	MA-008 / DAB	\leq 2.0 %	0.06 %
Total other cannabinoids	MA-008 / DAB	Report value	0.39 %
Mycotoxins			
Aflatoxin B1	MA-008 / Ph.Eur.2.8.18	\leq 2 μ g/Kg	< 0.25 (LOD) μ g/Kg
Aflatoxins (B1+B2+G1+G2)	MA-008 / Ph.Eur.2.8.18	\leq 4 μ g/Kg	< 0.25 (LOD) μ g/Kg
Ochratoxin A	MA-008 / Ph.Eur.2.8.22	\leq 20 μ g/Kg	< 2 (LOD) μ g/Kg
Heavy Metals			
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
Pesticides			
Pesticides *	Ph.Eur.2.8.13	Complies with Ph.Eur.2.8.13	Complies



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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.	≤ 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.	≤ 10 ² CFU/mL	< 10 CFU/mL
Bile-tolerant gram-negative bacteria	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	≤ 10 ² CFU/mL	< 10 CFU/mL
<i>Escherichia coli</i>	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 1 mL	Absence/mL
<i>Salmonella</i>	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 10 mL	Absence/10mL
<i>Staphylococcus aureus</i>	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 23/3746)

Status:

Approved

Signed by:

Iva Vinhas

Quality Control Director

07/06/2024 17:46

Application of electronic signature