



Certificate of Analysis

Specification	ESP-149/02
Product	Oromucosal oil THC:CBD 25 mg/mL:25 mg/mL IND 30 mL CR+ UK RLF
Code	FDF0049
Batch no.	C0399
Date of Analysis	26/09/2024

CoA no.	2405004
Manufacturing date	11/07/2024
Expiry date	11/07/2026
Presentation	30 mL amber glass vials with child resistant closure system
Bulk batch no.	C0274

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	0.953
Water	MA-008	$\leq$ 0.5 %	0.05 %
Cannabinoids			
Δ^9 -THC	MA-008 / DAB	Report value	25.65 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	102.6 % (25.65 mg/mL)
CBD	MA-008 / DAB	Report value	25.54 mg/mL
CBDA	MA-008 / DAB	Report value	0.08 mg/mL
Total CBD [CBD + (CBDA x 0.877)]	MA-008 / DAB	90.0 % to 110.0 % of the label claim	102.5 % (25.62 mg/mL)
CBN	MA-008 / DAB	$\leq$ 1.0 %	0.03 %
Other cannabinoid (Together with any corresponding acid)	MA-008 / DAB	$\leq$ 2.0 %	0.28 %
Total other cannabinoids	MA-008 / DAB	Report value	0.81 %
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	$\leq$ 0.2 ppm	< 0.020 (LOQ) ppm
Cadmium (Cd) *	Ph.Eur.2.4.27	$\leq$ 0.3 ppm	< 0.005 (LOQ) ppm
Lead (Pb) *	Ph.Eur.2.4.27	$\leq$ 0.5 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	MA-008 / Ph.Eur.5.4.	< 5000 ppm	< 1250 (LOQ) ppm
Microbial Quality			
<i>Pseudomonas aeruginosa</i>	MA-008 / Ph.Eur.2.6.13 & Ph. Eur. 5.1.4.	Absence in 1 mL	Absence/mL
TAMC - Total aerobic microbial count	MA-008 / Ph.Eur.2.6.12. & Ph.Eur.5.1.4.	$\leq 10^2$ CFU/mL	< 10 CFU/mL
TYMC - Total combined yeast & mould count	MA-008 / Ph.Eur.2.6.12. & Ph.Eur.5.1.4.	$\leq 10^1$ 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
<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 LEF CoA no 24/3469)

Status:

Approved

Signed by:

Iva Vinhas

Quality Control Director

27/09/2024 15:33

Application of electronic signature