



## Certificate of Analysis

|                  |                                                               |
|------------------|---------------------------------------------------------------|
| Specification    | ESP-147/03                                                    |
| Product          | Oromucosal oil THC:CBD 10 mg/mL:10 mg/mL IND 30 mL CR+ UK RLF |
| Code             | FDF0047                                                       |
| Batch no.        | C0397                                                         |
| Date of Analysis | 25/09/2024                                                    |

|                    |                                                             |
|--------------------|-------------------------------------------------------------|
| CoA no.            | 2404959                                                     |
| Manufacturing date | 15/07/2024                                                  |
| Expiry date        | 15/07/2026                                                  |
| Presentation       | 30 mL amber glass vials with child resistant closure system |
| Bulk batch no.     | C0276                                                       |

| 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                                                                                                                                               | 0.948                   |
| Water                                                    | MA-008                 | $\leq 0.5$ %                                                                                                                                                    | 0.05 %                  |
| Cannabinoids                                             |                        |                                                                                                                                                                 |                         |
| $\Delta^9$ -THC                                          | MA-008 / DAB           | Report value                                                                                                                                                    | 9.99 mg/mL              |
| $\Delta^9$ -THCA                                         | MA-008 / DAB           | Report value                                                                                                                                                    | < 0.003 (LOD) mg/mL     |
| Total THC<br>[THC + (THCA x 0.877)]                      | MA-008 / DAB           | 90.0 % to 110.0 % of the label claim                                                                                                                            | 99.9 % (9.99 mg/mL)     |
| CBD                                                      | MA-008 / DAB           | Report value                                                                                                                                                    | 10.08 mg/mL             |
| CBDA                                                     | MA-008 / DAB           | Report value                                                                                                                                                    | 0.04 mg/mL              |
| Total CBD<br>[CBD + (CBDA x 0.877)]                      | MA-008 / DAB           | 90.0 % to 110.0 % of the label claim                                                                                                                            | 101.1 % (10.11 mg/mL)   |
| CBN                                                      | MA-008 / DAB           | $\leq 1.0$ %                                                                                                                                                    | 0.02 %                  |
| Other cannabinoid (Together with any corresponding acid) | MA-008 / DAB           | $\leq 2.0$ %                                                                                                                                                    | 0.11 %                  |
| Total other cannabinoids                                 | MA-008 / DAB           | Report value                                                                                                                                                    | 0.36 %                  |
| Mycotoxins                                               |                        |                                                                                                                                                                 |                         |
| Aflatoxin B1                                             | MA-008 / Ph.Eur.2.8.18 | $\leq 2$ $\mu$ g/Kg                                                                                                                                             | < 0.25 (LOD) $\mu$ g/Kg |
| Aflatoxins<br>(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    |
| 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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| Presentation       | 30 mL amber glass vials with child resistant closure system |
| Bulk batch no.     | C0276                                                       |

| 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 17:23

Application of electronic signature